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Bescripten Notes	There are two versions of the supporting statement included. Eighteen numbered attachments include; Report reviewing OMB's review of CDC studies, NIOSH Occupational Health Study questionnaires, participation consent forms, Prototype Introduction to Worker, Introduction script, NIOSH Occupational Health Study Fact Sheet (two copies), second USPHS-NIOSH Health Study Fact Sheet, Letter and script for wives in study, NIOSH Occupational Health Study Exam Forms, Manual for Electrophysiological and Quantitative Sensory Testing Procedures, Optacon Tactile Tester- Operating Manual and Testing documents

#### PHASE II

#### Supporting Statement

NIOSH Study of Morbidity in Workers Exposed to Chemical-Herbicide Production and Community Residents of Unknown Exposure Status

#### A. Justification

#### 1. Background

The extreme toxicity of 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) has been recognized for several decades. An unwanted contaminant of several chemical processes, TCDD causes death and diverse morbidity in multiple animal species. In humans, occupational exposures to TCDD-contaminated production processes cause chloracne and are suspected of causing liver and lipid metabolism dysfunction, neurologic, endocrine, immunologic, and hematopoetic dysfunction, as well as psychological and reproductive dysfunction, and cancer.

TCDD was a contaminant of Agent Orange, a defoliant used in Vietnam, a fact which has generated intense interest among veterans and which has resulted in the federal government undertaking several major epidemiologic studies of veterans. In addition to the concern felt by Vietnam veterans over the health effects of exposure to Agent Orange, workers and residents in the community at large have expressed increasing worry about their health with the discovery of widespread environmental contamination with TCDD in Missouri, and worksite and neighborhood contamination in New Jersey. Workers from two plants in particular--one in Missouri, whose wastes were responsible for the environmental contamination in the state, and one in New Jersey, whose processes were presumed responsible for some of the worksite and neighborhood TCDD contamination--have sought assistance from the CDC and NIOSH in evaluating their health status. In response to this public health concern, and in view of the opportunity to provide answers to questions of major scientific importance, NIOSH has proposed to conduct of an epidemiologic medical study of these Missouri and New Jersey workers and a suitable comparison group.

Research in occupational health is authorized by Section 20 (a) (1) of the Occupational Safety and Health Act of 1970 (attachment #1). Under the Act, the National Institute for Occupational Safety and Health (NIOSH) has been given the authority to conduct and to publish epidemiologic studies of the medical effects of exposure to toxic occupational exposures.

# 2. Use of Data

Because TCDD is a toxic substance suspected of affecting multiple organ systems--including the soft tissues (soft tissue sarcoma), the nervous system, the cardiovascular system, skin, and human psychological response--the proposed study will involve research into five of NIOSH's Top Ten work-related diseases. Although occupational groups have been studied to determine both the prevalence and persistence of morbidity in workers exposed to TCDD-contaminated processes, every existing study to date has been plagued by problems which impair the validity of the results. Convincing answers to

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questions about the persistence of morbidity associated with exposure to TCDD have not been forthcoming. Without a careful epidemiological study in which health outcomes are related to exposure, there is little hope of answering the existing questions about the health effects of dioxins in humans.

In addition to workers, Vietnam veterans and community residents in contaminated areas are suspected of having some exposure to dioxins. However, since production workers as a group have almost certainly had the highest exposures to TCDD, important health effects would be more likely to show up in such a group than in any other. Because the exposure information on industrial workers is far better and more detailed than, for example, can be obtained from Vietnam veterans, this piece of research will provide a major resource in the federal decision-making process with respect to recommendations regarding the dioxin problem. Thus, the results of this study will be valuable to both OSHA and the EPA for future judgements regarding exposures to workers and the community. The study results will also assist with developing intervention strategies for workers and community residents exposed to TCDD-contaminated materials, and prevention strategies for the ten leading work-related diseases and injuries, specifically occupational cancers, neurotoxic disorders, dermatologic disorders, psychological disorders, and reproductive disorders.

Since March 5, 1987, NIOSH has been conducting a study of a sample of 80 workers (and their referents and wives) who were employed in the production of chemicals contaminated with 2,3,7,8-TCDD (Phase I of the study, approved on January 7, 1986 by OMB).

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NIOSH proposes to conduct Phase II of the study to investigate the health status of the remaining surviving and locatable workers from the New Jersey plant and all of the workers from the Missouri plant, and to study the health status of individuals who are similar to the living workers (with respect to age, sex, and race) and who live in the same neighborhood as the workers. In addition, next-of-kin of deceased workers will be interviewed for health and exposure information, and the wives of the workers will be interviewed to obtain reproductive history information.

Since there are 448 living workers total in the two cohorts, 358 from the New Jersey facility and 90 from the Missouri facility, and since 80 of the New Jersey group were included in Phase I of this study, Phase II will be composed of 278 New Jersey workers and 90 Missouri workers (368), as well as their referents and wives. Detailed information about occupational exposures to dioxin-contaminated processes will be constructed from plant records and from the detailed interviews with workers.

Workers and neighborhood comparisons (who will be referred to as referents in the remainder of this document) will be interviewed in their homes by trained interviewers. The estimated response time for the in-home occupational interview will be one and one-half hour. An additional one-half hour will be utilized for a medical history interview at the examination site. Wives will be interviewed by telephone, and the estimated duration of the interview will be average forty five minutes. After the in-home interview, workers and their matched neighborhood referents will be scheduled for a medical examination at the Lovelace Medical Foundation in Albuquerque, New Mexico. The examination requires one and one-half days. Subjects will incur no expense, since travel, lodging, and subsistence will be paid for by NIOSH.

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#### 3. Information Technology

The use of the "computer assisted personal interview" (CAPI) system for the wives' reproductive interviews is being considered. The quality control advantages of CAPI are those of any computerized, electronic system. However, the final decision about the telephone interviews will be determined by the Phase II contract award. The longer interview being administered to the worker subjects and their referents warrants a face-to-face interview technique.

#### 4. Identification of Duplication

Although there have been a number of published papers describing health effects in occupational groups exposed to TCDD-contaminated materials, none of them has been a study of an entire cohort of workers, none has had a convincing comparison population (most have been case series and have had no real comparison group), and none has had adequate characterization of exposure to TCDD-contaminated materials. This study will remedy all of those deficiencies and will thus provide a uniquely valid study design. As already noted, no existing or planned study has information which adequately characterizes the level of occupational exposure to TCDD-contaminated materials. Industrial cohorts are certainly the most heavily exposed of all groups, and it is possible to recreate a detailed work history for each worker, using plant records and interview data. Recent information about a few of the workers from the Missouri plant indicates that although the workers were exposed to TCDD-contaminated materials for less than two years, their TCDD body burden exceeded the background levels by several orders of magnitude. Additional information from serum TCDD levels will validate the

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predictive exposure estimates obtained from historical records and interview information. There has been no comparable work in the field of occupational dioxin research. The Centers for Disease Control (CDC) and the Air Force are currently conducting studies to analyze levels of TCDD in the bodies of veterans. Our study results of TCDD levels in workers will provide a context for interpreting levels of exposure in Vietnam veterans.

#### 5. Use of Existing Data

Existing data are insufficient to address the question of whether workers occupationally exposed in the past to TCDD-contaminated processes have more health problems than persons who are similar to them but who have not worked with TCDD-contaminated marterials. Nor do existing data fully define the nature of those health problems. The Czechoslovakian work by Jirasek (1974) and Pazderova-Vijlupkova (1981), and the American work by Suskind, Moses, and Bond provide suggestions, but the results require validation (Moses 1984, Suskind 1984, Bond 1983).

Jirasek 1, Kalensky K, et al.: Chronic poisoning by 2,3,7,8-tetrachlorodibenzo -p-dioxin. Cesk Dermatol 1974;49:145 - 157.

Pazderova-Vijlupkova J, Nemcova M, et al.: The development and prognosis of chronic intoxication by tetrachlorodibenzo-p-dioxin in men. Arch Environ Health 1981;36:5 - 11.

Bond GG, Ott MG, Brenner FE, Cook RR: Medical and morbidity surveillance findings among employees exposed to TCDD. Br J Ind Med 1983;40:318 - 324.

Moses M, Lilis R, Crow KD, Thornton J, Fischbein A, Anderson HA, Selikoff IJ: Health status of workers with past exposure to 2,3,7,8-Tetrachlorodibenzo-p -dioxin in the manufacture of 2,4,5-Trichlorophenoxyacetic acid. Am J Ind Med 1984;5:161 - 182.

Suskind RR, Hertzberg VS: Human health effects of 2,4,5-T and its toxic contaminants. JAMA 1984;251:2372 - 2380.

Similarly, existing data have been insufficiently valid or powerful to assess reproductive outcomes such as spontaneous abortion in TCDD-exposed production workers. Vietnam veterans, if exposed to dioxins in Agent Orange, are likely to have had much lower exposures than the production workers. Thus the studies of Vietnam veterans, such as the Ranch Hand study and the Vietnam Experience Study, involve inadequately detailed exposure characterization as well as probably low level exposures. Similarly, although the Centers for Disease Control has just completed a case-control birth defects study examining risk associated with Vietnam veteran status and Agent Orange exposure, the population is too different and the exposure information too imprecise to serve as an adequate substitute for the reproductive effects portion of the present study.

#### 6. Small Business

The data collection effort will not involve small businesses or similar entities.

# 7. Consequences of a Less-Prequent Collection

The data collection will be one time only. No other studies are planned at this time.

# 8. <u>5 CFR 1320.6</u>

Compensation will be provided to the participants undergoing the medical examinations, since the examination will require one and one-half days, with travel on the preceding and succeeding days of the examination.

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Participation rates have been shown to increase with compensation, and a high rate of participation is essential for a valid study. The Air Force Ranch Hand Study recompensed its subjects at the rate of \$100/day, and the Centers for Disease Control provides \$300 per day. The Ranch Hand study achieved an excellent participation rate for the medical examination portion of the study (average 82%), which was necessary for its fixed cohort size. The CDC also achieved a high rate of participation in their examination phase of the study (approximately 70%). To avoid problems of participation bias or low participation rates, NIOSH is compensating each participant who completes the examination \$300.00.

# 9. Consultation

In developing this project, NIOSH has had a great number of consultations with various experts within and outside of the government. These have included principally scientific reviews. The NIOSH "blue ribbon" Dioxin Peer Review Panel met in November 1983 in its first review of the project, and has reviewed subsequent changes in study design in 1984 and 1985. The Science Panel of the White House Agent Orange Working Group also reviewed the protocol in August, 1984 and in May, 1987.

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There were no major problems that could not be resolved during the consultation and review process.

All NIOSH Dioxin peer review meetings were open to the public for attendance, discussion, and comment. No other public meetings devoted specifically to the proposed project are planned.

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# 10. Confidentiality Assurance

The information collected will be protected by the Privacy Act of 1974. The final disposition of the data will be all questionnaire data in its original form, all laboratory results in their original form, and unedited and edited computer tapes maintained in accordance with regular NIOSH policies of handling sensitive data. The method of handling the data complies with the Freedom of Information Act and the Privacy Act of 1974.

# 11. Sensitive Data

Much of the data to be collected in this study can be considered sensitive. Questions will be asked regarding race, income, alcohol and drug use, social security number, religion, and fertility problems. Race is a matching factor, but race must in addition be identified since certain factors under study (cancer, pulmonary function) are not distributed randomly in the population. Income must be considered because it is a corollary of socioeconomic status, which is itself a determinant of disease prevalence. Thus income must be analyzed to assess whether the socioeconomic status of workers and referents is comparable. Alcohol and drugs are important confounders of a number of the conditions under consideration (liver disease, neurological impairment,

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neuropsychological status), and so information must be collected for epidemiological analysis. NIOSH already has social security numbers for most of the workers, and numbers will be requested from the remaining workers in order to provide complete identifying data to the NIOSH Dioxin Registry, of which these two plants are a part, and upon which a mortality study is being conducted. Mortality studies require social security numbers for complete follow-up of vital status. Social security numbers are not required of the referents. Religion is asked because certain religions (e.g. Seventh Day Adventist) have restrictions on dietary and alcohol consumption. This information will be utilized in analyzing for confounding exposures. Finally, information about fertility is central to the reproductive portion of the study.

#### 12. Cost of the Study

Conduct of Phase II will involve both "in-house" and contract expenses slightly in excess of \$4,607,666 over a period of three years. Costs will be borne by the Environmental Protection Agency Superfund. a.) Cost to the Federal Government

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	FY'87	FY'88	FY'89
	(3 months)	(12 months)	(12 months)
In-house			
(travel, statistical			
services, data			
analysis, consultants,			
equipment & supplies)	\$212,950	\$533,050	\$64,000
Contract			
(Interviews,			
medical exami-			
nations)	\$2,972,228	\$100,000	\$ -0
Administrative			
Cost to CDC	\$163,459	\$ 42,678	\$ 14,776
Personnel	\$ <u>52,500</u>	<u>\$220,500</u>	\$231,525
TOTAL	\$3,401,137	\$896,228	\$310,301

No direct costs will accrue to the study participants. Interviews will be scheduled at times that do not conflict with the particular respondent's work, and participants in the medical examination component of the study will have no out-of-pocket expenses for travel, lodging, subsistnce, or incidentals associated with the examination. The examination itself will, of course, be free to participants. Cost burden is estimated to the general public at the rate of \$10.00 per hour. It is estimated based on calculations of burden hours (see section A.13.) that the cost to the public assuming a \$10 per hour rate will be the following:

b.) Cost to the Public

1987	1988		
(3 months)	(10 months)		
\$3680	\$12,265		

The above cost to the public was calculated using a total of 1553.6 burden hours from successful interviews, 40.9 burden hours from refusals, multiplying the sum by \$10, and dividing this between the two years in which interviewing will be accomplished. (Interviews are not conducted during the third year of the study, which is devoted to analysis.)

# 13. Respondent Burden

The proposed Phase II NIOSH study will involve an anticipated maximum of 1362 persons: 736 workers and referents, and 85% of the surviving wives of the male workers and referents (626). These estimates are based on the probable maximum number of participants, using information presently available about the

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location of cohort members. The burden is calculated based on an 80% response rate and an average interview time of 2 hours for workers and referents (1 1/2 hour in-home interview and 1/2 hour interview at examination site); 0.75 hours for the wives reproductive interview, and .15 hours for administering the refusants questionnaire. The interview times are based on use of the questionnaires used during Phase I of the study. The majority of the cohort members are male, and based on our Phase I experience, it is expected that the number of current and former wives of male workers will be approximately one wife or former wife for each male worker and referent. Current and former wives will be interviewed concerning their reproductive outcomes, if they can be located and are willing to participate.

<u>Questionnaire</u>	No. of	No. of	Hrs. per	Total		
	Respondents	Responses	Response	Burden		
Health and exposure quest	ion-					
naire of chemical-herbicid	le					
workers and community res-						
idents (Attachment 2)	589 (80%)	1	2	1178		
	(workers &					
	referents					
Refusant Questionnaire	147 (20%)	1	.15	22.1		
(Attachment 7)	(workers &	referents)				
Reproductive Questionnaire						
(Attachment 3)	501 (80%)	1	. 75	375.6		
	(wives)					
Refusant Questionnaire	125 (20%)	1	.15	18.8		
	(wives)					

# Total Burden

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1,594.5

The annualized burden is estimated to be 368 hours during FY'87 and 1226 hours during FY'88, when interviewing may take place.

# 14. Changes in Burden

At this time there is no cause to expect changes in the estimate of respondent burden.

#### 15. Project Schedule

Phase II of the NIOSH study will begin as soon as OMB approval has been received. The following time table is proposed, assuming that OMB approval is received by June 21, 1987. If a two month downtime is necessary, the schedule will be delayed by a similar amount of time at the cost of \$100,000 per month delay.

June,	1987-August	1988	Location	and	inter	view:	ing	of	Phase	II
			workers,	refe	rents	and	wive	s		

Medical examination of Phase II workers and referents

September, 1988-December, 1988

January, 1989-January, 1990

Data analysis; preparation of reports and publications

Outstanding data to NIOSH

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B. Collection of Information Employing Statistical Methods

#### 1. Respondent Universe

The potential respondent universe for Phase II of the NIOSH study is the population of two plants totaling 368 workers (90 from the Missouri plant and 278 remaining workers from the New Jersey plant). The potential universe of referents is not readily calculable, since it is the population of individuals of similar age, race, and sex currently living in the neighborhood or community of surviving workers. In addition, based on the results of our experience in Phase I, we estimate that each participant will have approximately one current or former wife.

#### 2. Data Collection Procedures

NIOSH has already conducted extensive follow-up on the members of the two worker cohorts. The vital status and whereabouts of 100% of the Missouri group and 95% of the New Jersey cohort are known. In addition to vital status and address, NIOSH has some work history information on cohort members from the NIOSH Dioxin Registry. More complete job history information will be collected during the interview portion of the study, from both workers and referents. Information collected during the interview portion of the study and information from plant records will be used to evaluate exposure within the worker cohort. Questionnaire information will be used assess exposures of the referents.

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Data collection in general will proceed as follows: The contractor who is conducting the interview portion of the study will receive from NIOSH the "content" questionnaire (Attachments 2 & 3: worker/referent/next-of-kin questionnaire, and wives questionnaire). NIOSH will provide the contractor with a list of names and addresses and phone numbers for the study participants. When the interview instrument is ready, the contractor will begin contacting workers. Each surviving worker will be contacted in person by a field representative of the contractor (Attachment 5: Introduction script for exposed persons). If the cohort member agrees to participate in the study, the contractor representative will then seek a matched referent for that worker in the same neighborhood. The interviewer identifies 6 referents matched for age ( $\pm$  5 years), race and sex, and living in the same census block of the worker. The 6 persons are randomly assigned numbers from 1 to 6 by the home office, and the interviewer approaches the potential referents beginning with the first number in the random sequence, until one person agrees to participate. Like the exposed workers, referents will be contacted in person at home and approached for participation in the study (Attachment #6: introduction script for comparison persons.) Eligible subjects in both the worker and referent group who decline to participate will be asked to complete a brief questionnaire asking for limited demographic, health, and occupational information and the reason for refusal (Attachment #7: Refusant questionnaire). If a worker is deceased or incapacitated, a proxy interview will be administered to the next-of-kin of the worker. If a worker refuses to participate in the study or if the worker is deceased or incapacitated, no neighborhood referent will be sought. The contractor representative will explain the extent of the study, the risks and the benefits, and will arrange a convenient time for the interview during the initial visit, and will also confirm the current telephone number, or will attempt to obtain a telephone

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number at which the participant can be reached (Attachment #8 is Study Information---an explanation of the study to be used as information guidance for the contract interviewer--, and Attachment #9 is the Fact Sheet--to be left with the study subject after the introductory visit).

At the time of the actual interview, the contractor will ascertain when the study subject will be able to undergo the medical examination (Attachment #2--worker/referent/next-of-kin questionnaire). During the interview, the contractor will also arrange for the future administration of the current wife's telephone interview, and will obtain as much locating information as possible in preparation for the telephone interview of any former wives (Attachment #10 --Introductory letter and telephone script for wives; Attachment #3--Wives Reproductive Questionnaire).

When the worker or referent interview is complete, the subject can then be scheduled for his (her) examination, which will be done at the subject's convenience, during the examination period. This scheduling will obviously not apply to proxy respondents. The contractor will make all arrangements for travel, lodging, and subsistence required during the examination.

The medical examination, as noted, will involve a general physical examination (Attachment #11), a special skin examination (Attachment #12), a special neurological examination (Attachment #13), nerve conduction testing (Attachment #14), quantitative sensory testing (Attachments #15 and 16), and the collection of blood and urine samples (Attachment #17). In addition,

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pulmonary function testing will be done (this is a very standard procedure, and the contractor will provide the protocol for approval during contract negotiations) and neurobehavioural and psychological testing (Attachment #18).

# 3. Sample Size Considerations

Power calculations for this study were conducted for outcomes which imply major morbidity, and which have been suggested in other studies of occupational groups, notably those by Moses, and by Suskind, both of which were performed on chemical workers from a production plant in Nitro, West Virginia. Both the Suskind and Moses studies were too epidemiologically flawed to consider them valid, but the outcomes noted by them are the best available for use in sample size calculations.

The conditions for which power calculations were performed (see Table I) include 1) ulcer disease, 2) abnormal pulmonary function (PFT) in exposed workers who are current smokers, 3) heart disease, 4) neuropathy, and 5) decreased libido. Chloracne was so frequently found in exposed workers, and its association with TCDD exposure is so well established, that no attempt was made to calculate the power of the NIOSH study to detect chloracne. In addition, in the Moses and Suskind studies, chloracne was often used as a surrogate for exposure.

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The power calculations were made using both the Missouri and New Jersey plant populations for Phases I and II. We assumed that 80% of the group (N = 716, workers and referents) will participate, that 35% of the group is a current smoker (N = 251) and that 20% of the group is under 50 years old (N = 143). When the background prevalence of a condition appeared to be 0%, 1% was substituted to allow utilization of the Rothman-Boice program for the Hewlett Packard calculator. The alpha level chosen is .05 (one tail test).

7

Power

<u>Outcome</u>	<u>Prevalence</u>	PRR*	_ <u>N**</u> _	<u>Power</u>		
in "unexposed"						
Ulcer	5.5%	4	716	99%		
Abnormal						
PFT in curr	ent					
smokers	6.7%	4	251	96%		
Heart disea	se					
(angina,						
age less t	han					
50 years)	1.0%	6	143	28%		
Decreased						
libido						
(age less						
than 50 ye	ars) 5.0%	4	143	67%		
Neuropathy	0%	18	716	100%		

\*PRR=prevalence rate ratio; \*\*N=the number of workers and referents for Phases
I and II.

5511U/5026U

It can be seen from the previous table that the study overall has excellent power to detect ulcer disease, abnormal pulmonary function, diminished libido, and sensory neuropathy, if approximately the same conditions prevail in this group as in the Nitro, West Virginia group. However, in contrast to the Nitro studies, which used self-reporting of illness, the NIOSH study will use medical record verification of major illnesses. Thus we may find that the actual prevalence of disease as confirmed by medical records is lower in our group, since self-reporting may overestimate disease.

It should be added that the power of this study will also be excellent for detecting differences between the exposed and unexposed groups with respect to most so-called <u>continuous</u> outcomes (e.g., liver function tests, nerve conduction tests, immunologic assays, etc.).

## 4. Participation Rates

We expect overall participation to be at least 75% - 80%. The participants who will undergo the medical exam will be offered compensation for their travel, their lodging and meals, and their time, an arrangement which will increase response rates. Based on our experience in Phase I, we may obtain participation rates as high as 95% in the in-home interview and 85% in the medical examination. However, we have based our calculations in this document on a participation rate of 80%.

# 5. Pretests and Pilots

The questionnaires for the workers, referents, and wives have just been pretested by use in Phase I of this study (OMB Clearance 0920-0183). The information has been used in estimating response burden for Phase II.

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#### 5511U/5026U

# 6. <u>Statistical Analysis</u>

Because of the nature of this study, the statistical analyses will be complex. We will examine crude associations, conduct stratified analyses on major confounding variables, conduct tests for dose response, and can also anticipate using multivariate analyses including both general linear regression and multiple logistic regression.

NIOSH's statistical consultant is Richard Hornung, a member of the NIOSH Statistical Peer Review Group (telephone 513-684-4211).

## Supporting Statement

Dioxin Morbidity and Reproductive Study

of U.S. Chemical Workers

# A. Justification

1. Background

The extreme toxicity of 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) has been recognized for several decades. An unwanted contaminant of several chemical processes, TCDD causes death and diverse morbidity in multiple animal In humans, occupational exposures to TCDD-contaminated production, species. processes cause chloracne and are suspected of causing derangements in liver function and lipid metabolism, endocrine and hematopoetic function, in neurologic, psychological, and reproductive function, and cancer. TCDD was also a contaminant of Agent Orange, a defoliant used in Vietnam, a fact which has generated intense interest among veterans and which has resulted in the federal government undertaking several major epidemiologic studies of veterans. In addition to the concern felt by Vietnam veterans over the health effects of exposure to Agent Orange, workers and residents in the community at large have expressed increasing worry about their health with the discovery of widespread environmental contamination with TCDD in Missouri, and worksite and neighborhood contamination in New Jersey. Workers from two plants in particular-one in Missouri whose wastes were responsible for the environmental contamination in the state, and one in New Jersey whose processes were presumed responsible for some of the worksite and neighborhood TCDD contamination--have sought assistance from the CDC and NIOSH in evaluating their health status. In response to this public health concern, and in view of the opportunity to provide answers to questions of major

scientific importance, NIOSH and the CDC have proposed the conduct of an epidemiological medical study of these Missouri and New Jersey workers and a suitable comparison group.

Research in occupational health is authorized by Section 20 (a) (1) of the Occupational Safety and Health Act of 1970 (attachment #1). Under the Act, the National Institute for Occupational Safety and Health (NIOSH) has been given the authority to conduct and to publish epidemiologic studies of the medical effects of exposure to toxic occupational exposures.

# 2. Use of Data

Because TCDD is a toxic substance suspected of affecting multiple organ systems--including the soft tissues (soft tissue sarcoma), the nervous system, the cardiovascular system, skin, and human psychological response--theproposed study will involve research into five of NIOSH's Top Ten work-related diseases. Although occupational groups have been frequently studied in an effort to determine both the prevalence and persistence of morbidity in workers exposed to TCDD-contaminated processes, every existing study to date has been plagued by problems which impair the validity of the results. (Mathematical contexpendence)

Convincing answers to questions about the persistence of morbidity associated with exposure to TCDD have not been forthcoming. Without a careful epidemiological study in which health outcomes are related to exposure, there is little hope of answering the existing questions about the health effects of dioxins in humans. In addition to workers, Viet Nam veterans and various

-2-

community residents in contaminated areas are suspected of having some exposure to dioxins. However, since production workers as a group have almost certainly had the bighest exposures to TCDD, important health effects would be more likely to show up in such a group than in any other. Because the exposure information on industrial workers is far better and more detailed than, for example, can be obtained from Viet Nam veterans, this plece of research will provide a major resource in the federal decision-making process with respect to recommendations regarding the dioxin problem. Thus, the results of this study will be valuable to both OSHA and the EPA for future decisions regarding exposures to workers and the community. The study results will also assist with developing intervention strategies for workers and community residents exposed to TCDD and prevention strategies for the ten leading work-related diseases and injuries, specifically occupational cancers, neurotoxic disorders, dermatologic disorders, psychological disorders, and reproductive disorders.

NIOSH proposes to study the health status of surviving workers from the two plants mentioned above, and to study the health status of individuals who are similar to the living workers (with respect to age, sex, and race) and who live in the same neighborhood as the workers. In addition, the current and former wives of the workers will be interviewed to obtain reproductive history information. There are 576 workers total in the two cohorts, of whom 85 are currently known to be deceased. Detailed information about exposures will be constructed from existing plant records by NIOSH staff and from the detailed interviews.

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Workers, and the neighborhood comparison population (which will be referred to as referents in the remainder of this document) will be interviewed whenever possible in their homes by trained interviewers. The estimated response time for the interview will be one and one-half hours. Wives will be interviewed by telephone, and the estimated duration of the interview will be forty five minutes. At a later time, workers and neighborhood referents will be scheduled for a medical examination. Medical examination subjects will be brought to a medical center. The examination is expected to require one and one-half days. Subjects will incur no expense, since travel, lodging, and subsistence will be paid for.

# 3. Information Technology

The use of the "computer assisted telephone interview" (CATI) system for the wives' reproductive interviews is being considered. The quality control advantages of CATI are those of any computerized, electronic system. However, we will make the final decision about the telephone interviews in consultation with the contractor. The longer interview being administered to the worker subjects and their referents warrants a face-to-face interview technique.

# 4. Identification of Duplication

Although there have been a number of published papers describing health effects in occupational groups exposed to <u>TGDD-contaminated materials</u>, none of them has been a study of an entire cohort of workers, none has had a convincing comparison population (most have been case series and have had no

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real comparison group), and none has had adequate characterization of exposure. This study will remedy all of those deficiencies and will thus provide a uniquely valid study design. To our knowledge, no existing or planned study has adequate exposure information. Industrial cohorts are certainly the most heavily exposed of all groups, and it is furthermore possible to recreate a detailed work history for each worker, using existing plant records and interview data. There has been no comparable work in the field of occupational dioxin research.

# 5. Use of Existing Data

Existing data is not adequate to address the question of whether workers occupationally exposed in the past to TCDD-contaminated processes have more health problems than persons who are similar to them but who have not worked with TCDD-contaminated materials. Nor does existing data define adequately what the nature of those health problems might be (the Czechoslovakian work by Jirasek and Pazderova-Vijlupkova, and the American work by Suskind and by Moses provide suggestions but they require validation). Similarly, existing data (Moses 1984, Suskind 1984) have been insufficiently valid or powerful to assess reproductive outcomes such as spontaneous abortion in TCDD-exposed production workers. Vietnam veterans, if exposed to dioxins in Agent Orange, are likely to have had much lower exposures than the production-workers. Thus the Ranch Hand study involved inadequately detailed exposure characterization and as well as probably low level exposures. Similarly, although the Centers for Disease Control has just completed a case-control birth defects study examining risk associated with Vietnam veteran status and Agent Orange

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exposure, the population is too different and the exposure information too imprecise to serve as an adequate substitute for the reproductive effects portion of the present study.

6. Small Business

The data collection effort will not involve small businesses or similar entities.

7. Consequences of a Less-Frequent Collection

The data collection will be one time only. No other studies are planned at this time.

8. 5 CFR 1320.6

Compensation will be provided to the participants undergoing the medical examinations, since the examination will require one and one-half days, with travel on the preceding day and during the afternoon after the examination is completed.

The time involved makes it infeasible to attempt to conduct all examinations on weekends, and many subjects will have work which will not provide them with paid "time off" for purposes such as these. The only reasonable option which prevents participation in the study from becoming financially prohibitive (especially to the less affluent members of the group, which would itself

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almost certainly produce a biased sample) is to provide adequate compensation for each medical examination participant.

In addition, participation rates have been shown to increase with compensation, and a high rate of participation is essential for a valid study. The <u>Air Force Ranch Hand Study recompensed its subjects at the rate of \$100/day, and the Centers for Disease Control will provide the same level of compensation. The Ranch Hand study achieved an excellent participation rate for the medical examination portion of the study (average 82%), which was necessary for its fixed cohort size. If NIOSH hopes to avoid problems of participation bias or low participation rates, a similar plan of compensation would seem advisable.</u>

9. Consultation

In developing this project, NIOSH has had a number of "outside" consultations with various experts. These have included principally scientific reviews. The NIOSH "blue ribbon" Dioxin Peer Review Panel met in November 1983 in its first review of the project, and has reviewed subsequent changes in study design in 1984 and 1985. The Science Panel of the White House Agent Orange Working Group also reviewed the protocol in August 1984.

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The following is a list of scientific advisors with whom NIOSH has worked:

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There were no major problems that could not be resolved during the consultation and review process.

The NIOSH Dioxin peer review meeting in November 1983 was open to the public for attendance, discussion, and comment. No other public meetings devoted specifically to the proposed project are planned.

# 10. Confidentiality Assurance

The information collected will be protected by the Privacy Act of 1974. The final disposition of the data will be all questionnaire data in its original form, all laboratory results in their original form, and unedited and edited computer tapes maintained in accordance with regular NIOSH policies of handling sensitive data. The method of handling the data complies with the Freedom of Information Act and the Privacy Act of 1974.

11. Sensitive Data

Much of the data to be collected in this study can be considered sensitive. Questions will be asked regarding race, income, alcohol and drug use, social security number, and fertility problems. Race is a matching factor, but race must in addition be identified since certain factors under study (cancer, pulmonary function) are not distributed randomly in the population. Income must be considered because it is a corollary of socioeconomic status, which is itself a determinant of disease prevalence. Thus income must be analyzed to assess whether the socioeconomic status of workers and referents is comparable. Alcohol and drugs are important confounders of a number of the conditions under consideration (liver disease, neurological impairment, neuropsychological status), and so information must be collected for

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epidemiological analysis. NIOSH already has social security numbers for most of the workers, and numbers will be requested from the remaining workers in order to provide complete identifying data to the NIOSH Dioxin Registry, of which these two plants are a part, and upon which a mortality study is being conducted. Mortality studies require social security numbers for complete follow-up of vital status. Social security numbers are not required of the referents. Finally, information about fertility is central to the reproductive portion of the study. Questions on religion are included as part of the reproductive questionnaire (Attachment 3) because of the relationship between religious preference and reproductive practices.

# 12. Cost of the Study

Conduct of this study will involve both "in-house" and contract expenses horne by the Environmental Protection Agency-Superfund.

a.) Cost to the Federal Government - N/A

No direct costs will accrue to the study participants. Interviews will be scheduled at times that do not conflict with the particular respondent's work, and participants in the medical examination component of the study will have no out-of-pocket expenses for travel, lodging, subsistance, or incidentals associated with the examination. The examination itself will, of course, be free to participants. Cost burden for respondents is estimated at the rate of \$10.00 per hour. It is estimated based on calculations of burden hours (see

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section A.13.) that the cost to respondents assuming a \$10 per hour rate will

be the following:

b.) Cost to Respondents

1985	1986	1987	
	-		
\$4,913	\$4,913	\$4,913	

The above cost to respondents was calculated by multiplying the annual burden of 491.3 hours by \$10.

#### 13. Respondent Burden

The proposed NIOSH studies will involve an anticipated maximum of 1584 persons: 442 workers, 350 referents, and 792 wives of the male workers and referents. These estimates are based on the probable maximum number of participants using information presently available about the location of cohort members. There are 576 workers in the cohort, 85 are verified deceased and for 49 the vital status is unknown. The burden is calculated based on an 80% response rate; an average interview time of 1.5 hours for workers and referents; 0.75 hours for the wives reproduction section, and .15 hours for refusants. The interview times are based on informal administration with 9 people of the current questionnaires. The majority of the cohort members are male and based on the Ranch Hand Study experience it is expected that the number of current and former wives will be the same as the live cohort members

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and referents. Current and former wives will be interviewed if they can be

Questionnaire	No. of Respondents	No. of <u>Responses</u>	Hrs. per <u>Response</u>	Total <u>Burden</u>
Health and exposure question- naire of chemical-herbicide workers and community resider (Attachment 2)	(workers & refer	l rents)	1.5	951
Refusant Questionnaire (Attachment 7) (wo	158 (20%) prkers & referent	1 ts)	.15	23.7
Reproductive Questionnaire (Attachment 3)	634 (80%) (wives)	1	.75	475.5
Refusant Questionnaire (Attachment 7)	158 (20%) - (wives)	1	.15	23.7

Total Burden 1,473.9 The annualized burden is estimated to be 491.3 hours per year over the three years that the interviews will take place.

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14. Changes in Burden

This study is in the FY 1985 ICB at 3200 hours. However, the annualized burden is considerably less. At this time there is no cause to expect changes in this estimate of respondent burden.

15. Project Schedule

The study will begin only after OMB approval and award of contract. At present, the following timetable is proposed for the three study phases:

# September 1985-January 1986

Contract awarded Finalize and test questionnaire format, Missouri subject contact, referent selection, interview all Missouri related individuals, perform medical examinations on all participating Missouri subjects Begin wife interviews

New Jersey subject contact, referent selection, interviews of all New Jersey-related individuals, perform medical examinations on all participating New Jersey subjects. Complete wife interviews from Missouri and N.J.

Outstanding data delivered to NIOSH.

Data analysis conducted and reports and publications prepared

February 1986-December 1986

January 1987-April 1987

May 1987-April 1988

B. Collection of Information Employing Statistical Methods

# 1. Respondent Universe

The potential respondent universe for the proposed NIOSH study is the population of two plants totalling 576 workers. The potential universe of referents is not readily calculable, since it is the population of individuals of similar age, race, and sex currently living in the neighborhood or community of surviving workers. In addition, based on a maximum anticipated participation of 792 workers and referents, and on the results of the Air Force Ranch Hand study, we estimate that the male members of this group will have an approximately equal number of current and former wives, or 792 wives.

#### 2. Data Collection Procedures.

NIOSH has already conducted extensive follow-up on the members of the two worker cohorts. The vital status and whereabouts of 100% of the Missouri group and 90% of the New Jersey cohort are known. In addition to vital status and address, NIOSH has some work history information from existing company records on cohort members. More complete job history information will be collected during the interview portion of the study, from both workers and referents. Information collected during the interview portion of the study and information from plant records will be used to evaluate exposure within the worker cohort. Questionnaire information alone will be used to assess exposures of the referents. Data collection in general will proceed as follows: The contractor who is conducting the interview portion of the study will receive from NIOSH "content" questionnaire (Attachment 2: worker/referent questionnaire, wives questionnaire, Attachment 3 and Consent form for workers and referents. Attachment 4) which the contractor will then finalize, format, and field test on 9 or lass volunteers. Although the questions will remain the same, the contractor may reformate for consistency and logic. NIOSH will provide the contractor with a list of names and addresses and phone numbers for the cohorts. The two companies involved have allowed NIOSH access to existing company records to extract the necessary locating information. The workers will not be sent a letter or phoned for an interview appointment because the referents can not be determined until the cohort member is interviewed. It is important for comparability to contact the cohort members and referents in the same manner. When the interview instrument is ready, the contractor will begin contacting workers. Each surviving worker will be contacted in person by a field representative of the contractor (Attachment 5: Introduction script for exposed persons). If the cohort member agrees to participate in the study, the contractor representative will then seek a matched referent for that worker in the same neighborhood, using an algorithm (to be determined by contractor and reviewed by NIOSH for soundness) which is appropriate for the population density in that area and matched by age, sex, and race. Like the exposed workers, referents will be contacted in person at home and approached for participation in the study (Attachment #6: introduction script for comparison persons.) Eligible refusants in both the worker and referent group will be asked to complete a brief questionnaire asking for limited demographic, health, and occupational information and the reason for refusal

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(Attachment 47: Refusant questionnaire). If a worker refuses to participate in the study, no neighborhood referent will be sought. The contractor representative will explain the extent of the study, the risks and the benefits, and will arrange a convenient time for the interview during the initial visit, and will also confirm the current telephone number or will attempt to obtain a telephone number at which the participant can be reached (Attachment #8 is Study Information--an explanation of the study to be used as information guidance for the contract interviewer--, and Attachment #9 is the Fact Sheet--to be left with the study subject after the introductory visit).

At the time of the actual interview, the contractor will ascertain when the study subject will be able to undergo the medical examination (Attachment #2--worker/referent questionnaire). During the interview, the contractor will also arrange to conduct the current wife's telephone interview, and will obtain as much locating information as possible in preparation for the telephone interview of any former wives (Attachment #10 --Letter, Consent Form, and Introductory Telephone Script for Wives; Attachment #3--wives reproductive interview). The consent form contains a medical records release form so the information provided on the questionnaire can be verified.

When the worker or referent interview is complete, the subject can then be scheduled for his (her) examination, which will be done at his convenience but as soon after the interview as is feasible. The contractor will make all arrangements for travel, lodging, and subsistence required during the examination. After the interviews are complete or scheduled for the workers and their referents still living in the state or immediate geographic area,

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- the contractor will then make contact with workers living outside the state. The current plan is to interview and bring in to the examination site those workers living out of state.

Interview and examination procedures for Missouri and New Jersey will be essentially the same, although medical examinations will be conducted at different fixed sites.

The medical examination, as noted, will involve a general physical examination (Attachment #11), a special skin examination (Attachment #12), a special neurological examination (Attachment #13), nerve conduction testing (Attachment #14), quantitative sensory testing (Attachments #15 and 16), and the collection of blood and urine samples (Attachment #17). In addition, pulmonary function testing will be done (this is a very standard procedure, and the contractor will provide the protocol for approval during contract negotiations) and neurobehavioural and psychological testing (Attachment #18).

3. Sample Size Considerations

Power calculations for this study were conducted for outcomes which imply major morbidity, and which have been suggested in other studies of occupational groups, notably those by Moses, and by Suskind, both of which were performed on chemical workers from a production plant in Nitro, West Virginia. Both the Suskind and Moses studies were too epidemiologically flawed to consider them valid, but the outcomes noted by them are the best available for use in sample size calculations.

-23-

The conditions for which power calculations were performed (see Table I) include 1) ulcer disease, 2) abnormal pulmonary function (PFT) in exposed workers who are current smokers, 3) heart disease, 4) neuropathy, and 5) decreased libido. Chloracne was so frequently found in exposed workers, and its association with TCDD exposure is so well established, that no attempt was made to calculate the power of the NIOSH study to detect chloracne. In addition, in the Moses and Suskind studies, chloracne was often used as a surrogate for exposure.

The power calculations were made using only the New Jersey cohort. We assumed that 50% of the New Jersey plant is alive and still living in New Jersey, and that 80% of that group will participate (overall n=190). When the background prevalence of a condition appeared to be 0%, 1% was substituted to allow utilization of the Rothman-Boice program for the Hewlett Packard calculator. The alpha level chosen is -.05 (one tail test).

# Power

Outcome Pres	Prevalence	Prevalence	PRR*	<u>N**</u>	Power
-	in "unexposed"	in exposed		- · _	• • •
•. •.				·	
Vlcer	6%	18%	3-	<b>19</b> 0	99%
- ·			· .		· · ·
Abnormal			-	•	
PFT in curr	ent				-
smokers	6.7%	26%	3.9	65	96%
			. <u>.</u> .	-	-
Heart disea	se			-	
(angina,	· ·	- · · · · ·			
age less t	han				-
50 years)	1%	67	6	60	40%
- ·					• •
Decreased					
libido		· .			·
(age less		-			
than 50 ye	ars) 2%	. 8%	4	60	83%
Neuropathy	0%	18%	18	190	100% .

\*PRR=prevalence rate ratio; \*\*N=the number available in this cohort

It can be seen from the previous table that the study overall has excellent power to detect ulcer disease, abnormal pulmonary function, diminished libido, and sensory neuropathy, if approximately the same conditions prevail in this group as in the Nitro. West Virginia group. However, in contrast to the Nitro studies, which used self-reporting of illness, the NIOSH study will use medical record verification of major illnesses. Thus we may find that the actual prevalence of disease as confirmed by medical records is lower in our group, since self-reporting may overestimate disease.

It should be added that the power of this study will also be excellent for detecting differences between the exposed and unexposed groups with respect to most so-called <u>continuous</u> outcomes (e.g., liver function tests, nerve conduction tests, immunologic assays, etc.).

# 4. Participation Rates

We expect participation to range between 75% and 80%. The participants who will be undergoing the medical exam will be offered compensation for their travel and lodging, and time, etc., which will increase response rates based on the experience of the Air Force Ranch Hand Study.

#### 5. Pretests and Pilots

The questionnaire for the cohort and referents, will be pretested with 9 or fewer persons by the contractor. The reproductive questionnaire (Attachment 3) for the wives has been used in other NIOSH studies (OMB#092-0037).

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Because of the nature of this study, the statistical analyses will be complex. We will examine crude associations, conduct stratified analyses on major confounding variables, conduct tests for dose response, and can also anticipate using multivariate analyses including both multiple linear regression and multiple logistic regression.

NIOSH's statistical consultant is Richard Hornung, a member of the NIOSH Statistical Peer Review Group (telephone 513-684-4211).

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In 1980. Congress enacted the Paperwork Reduction Act with the intended goal of reducing the burden of government paperwork on the general public. For the purpose of implementing the Act, review of all government information collection was consolidated into the Office of Information and Regulatory Affairs (OIRA) within the President's Office of Management and Budget (OMB). At the time of passage of the Act, Congress expressed concern that this consolidation of review power within OMB might be subject to abuse. Because of this concern, language was included in the Act specifically stating that the OMB review was not to interfere with the substantive programs and policies of agencies.

OMB is required by the Act to clear all information collection requests by Federal agencies. This requirement includes the power to review scientific and medical information collection by agencies such as the Centers for Disease Control (CDC). OMB's review is for paperwork reduction purposes only. This review should be distinguished from the extensive scientific peer review which involves numerous experts in the evaluation of CDC studies.

Given the initial legislative concern about the potential for OMB abuse of its Paperwork Reduction Act authorities, we reviewed the OMB clearance process as it has actually affected CDC studies during the period from January. 1984, to March, 1986. During this period, six major peer review studies from CDC were either significantly delayed, seriously altered in scientific design, or disapproved entirely by OMB.

We evaluated the six studies systematically; all had received a thorough and appropriate review from panels of nationally recognized experts, and all were approved by the respective peer review group.

The OMB review. which was superimposed on the peer review process, generally relied on single consultants rather than a panel of experts. The process was poorly documented and often demonstrated a dismaying ignorance of the fundamentals of science and public decisionmaking.

Three major studies (on the health effects of dioxin, video display terminals, and MBOCA) were initially disapproved and then subsequently approved by OMB following Congressional inquiries. We present a summary of each of these cases here:

(1) <u>Dioxin</u> - Concern about dioxin is broad-based with the public and relevant to several Federal agencies. Human exposures have occurred at work sites in various communities and among Vietnam veterans exposed to Agent Orange. Those concerned with government policy decisions on ~2-

dioxin exposure have argued that a clear study relating human doses to clinical outcomes is needed to evaluate the relationship of dioxin exposure and outcomes, such as birth defects, metabolic disorders, and cancer.

The White House Agent Orange Working Group and a panel of NIOSH peer reviewers agreed that the NIOSH study of dioxin-exposed workers in Newark, New Jersey and Verona, Missouri, would provide this important exposureeffect data. Notwithstanding the impressive array of scientific panels that articulated the importance of this study and who approved its design, OMB disapproved the study. Following a Senate directive that the study should go forward, OMB approved a pretest of the study methodology; the full study has not yet been approved.

Conditions imposed by OMB during its paperwork review of the dioxin study have delayed the initiation of the study substantially, have increased contracting costs by at least \$270,000, and may even totally block the completion of this important study.

- (2) <u>Video Display Terminals</u> Twelve reported clusters of abnormal birth outcomes in women working with video display terminals have caused considerable public alarm. Industry, labor, and public health professionals all agreed on the need for a definitive study on this issue by the National Institute for Occupational Safety and Health. OMB initially disapproved the study. Following two Congressional hearings which addressed the specific need for this particular study, OMB finally gave the study partial approval, but required the removal of important questions related to fertility and stress. Numerous experts agree that OMB's tampering with the study design has significantly weakened the study to the extent that the results will be less credible.
- (3) <u>MBQCA</u> A CDC study of 500 workers in Adrian, Michigan, exposed to this carcinogenic chemical, was initially disapproved by OMB. A more limited study was finally allowed to go forward following an inquiry from the office of Congressman John D. Dingell. OMB's paperwork review resulted in a 6-month delay in undertaking important cancer screening in a large population at risk and may have weakened the proposed study design.

Three other studies, relating to ladder falls, hazards of information processing, and reproductive outcomes of CDC workers, were totally blocked by OMB. The alteration or cancellation by OMB of approved peer reviewed CDC research is of concern. A redirection of research by an agency without public health competence has occurred in each of these six cases.

Because of our concern, we reviewed all fifty-one research projects submitted by CDC to OMB from January, 1984

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to March, 1986. We assessed whether OMB's rejections fell differentially on certain types of studies. Statistically reviewing the pattern of OMB rejections, we found that OMB was seven times more likely to reject studies with an environmental or occupational health focus than to reject studies that focused on issues such as infectious diseases or other conventional diseases. Studies with a reproductive focus, such as birth defects or venereal disease, also were more likely to be rejected by OMB.

Our analysis indicated a demonstrable bias in the application of the Paperwork Reduction Act clearance process as administered by OMB's Office of Information and Regulatory Affairs. The health policy implications are serious; OMB is clearly interfering with the substance of CDC research. OMB has delayed, impeded, and thwarted governmental research efforts designed to answer public demands for information on serious public health questions. Rather than minimizing the costs of information collection, the paperwork review process has resulted in a diversion of tax dollars from productive health research into paperwork clearance activities and unnecessary contracting costs.

Reviewing the actual functioning of the Paperwork Reduction Act as administered by OMB, we find evidence that the initial legislative concern, that the administration of the Act might be subject to abuse, was indeed warranted.

## INTRODUCTION

When government agencies are mandated to engage in scientific research, questions arise concerning the scientific review process. How is the quality and the appropriateness of a study to be assessed? Who should review and monitor the study? Are those who are reviewing trained and capable of understanding the product they are reviewing? Is their review one that is constructive, improves the projected research, and assures that it is carried out in the most beneficial way?

These issues have become particularly salient as we have seen the delay. alteration, or cancellation of various research projects by the President's Office of Management and Budget (OMB). While OMB is not a scientific agency, it does have certain powers of review provided under the Paperwork Reduction Act of 1980. Recently, critics of OMB have argued that the agency has been using its role as a paperwork reviewer to interfere with research proposals initiated by the Centers for Disease Control (CDC). OMB's role in such review may have gone beyond the role mandated by the Paperwork Reduction Act. Critics have claimed that it has used its power of review to redirect the focus of CDC's scientific research.

A White House office with the effective power to review, alter, approve, or disapprove research by another agency is in a strong position to determine the direction that research will take. Such a process of review could affect health policy significantly. If research on particular topics is blocked, information is unavailable for informed decisionmaking in the public health sector. The regulatory process is thwarted because there is no data to justify regulation. Thus, the blockage of research can prevent informed action to protect the public health.

We have analyzed the process by which CDC studies are reviewed by OMB under the Paperwork Reduction Act. Our goal was to evaluate how the review was affecting the research process and to assess whether the benefits of the review justify the financial and public health costs.

There are four sections of analysis:

- A summary of the Paperwork Reduction Act, focusing on the provisions for review of scientific research under the Act.
- 2. A review of the traditional scientific peer review process as it occurs at CDC and a comparison with the mandated OMB review process.
- 3. Case histories of CDC studies disapproved or conditionally approved by OMB to determine whether the OMB review process was appropriate and beneficial.

4. Statistical analysis to evaluate whether the patterns of OMB disapproval are systematic and imply an imposed health policy bias.

#### THE OMB REVIEW PROCESS UNDER THE PAPERWORK REDUCTION ACT

Under the Paperwork Reduction Act, OMB has broad authority to control the collection of information by Federal agencies. The Act applies to any "collection of information," which is defined as "the obtaining or soliciting of facts or opinions by an agency through the use of written report forms, application forms, schedules, questionnaires, reporting or recordkeeping requirements, or other similar methods...."1

The Act requires agencies to obtain approval of all information collection requests from OMB's Office of Information and Regulatory Affairs (OIRA). The Act imposes a duty on OMB to "determine whether the collection of information by an agency is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility."<sup>2</sup>

OMB regulations implementing the Act essentially require each agency to demonstrate to OMB that its proposed information collection requests are: (a) "the least burdensome necessary for the proper performance of the agency's functions to comply with legal requirements and achieve program objectives;" (b) "not duplicative of information otherwise accessible to the agency;" and (c) of "practical utility." As defined in the Act, the term "practical utility" means "the ability of an agency to use information it collects, particularly the capability to process such information in a timely and useful fashion."<sup>3</sup> If OMB does not approve, the agency may not collect the requested information.

Under the provisions of the Act, OMB must either deny or approve an agency's information collection request within 90 days. However, OMB's regulations do provide for reconsideration of a disapproval if the agency provides "significant new or additional information relevant to the original decision."<sup>4</sup>

From the legislative history of the Paperwork Reduction Act, it is clear that Congress intended that information collection requests included in epidemiological studies would be subject to OMB review.<sup>5</sup> However. it is equally clear from the Act itself and its legislative history that Congress did not intend to increase OMB's power over the substantive policies and programs of the agencies. In fact, the Act contains a provision which states:

Nothing in this chapter shall be interpreted as

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increasing or decreasing the authority of the President, the Office of Management and Budget or the Director thereof. under the laws of the United States, with respect to the substantive policies and programs of departments, agencies and offices....6

The late Senator Jacob Javits of New York elaborated on the distinction between OMB's paperwork review authorities and the substantive policies and programs of the agencies during the Senate debate on the Act, as follows:

I have been concerned that the method used to accomplish this worthwhile goal -- particularly the provision that all agency recordkeeping requirements be cleared by OMB -- could be used to undermine substantive programs. For without adequate information on which to base its decisions, an agency cannot function. The sponsors of this legislation have made very clear that nothing in the bill in any way affects ome's authority over substantive policies and programs.... However, the line between substance and procedure is not always entirely clear. While I do not believe OMB's authority over any program, whether it is worker safety or pure food and drugs, should be, or is, increased by this legislation .... I will be watching its implementation very carefully.7

Finally, section 3504(a) of the Act specifies that the authority of OMB must be exercised in ways that are consistent with applicable law. However, the Senate Committee acknowledged that these protections might not be adequate stating:

These provisions will hopefully provide adequate protection from potential abuse or political interference. But this situation merits close attention in the future.<sup>8</sup>

#### THE PEER REVIEW PROCESS

The review of scientific studies done by OMB for the purposes of the Paperwork Reduction Act differs from the extensive internal "peer review" to which CDC subjects its major studies. The tradition of scientific peer review is well established in scientific circles. This process involves trained scientists from related fields in the assessment of scientific research projects. Such a review is a prerequisite for funding of research in scademic institutions and for publication in major scientific and medical journals. A peer review panel will be convened for a and to improve the research design. At CDC this scientific tradition of peer review is long-standing. For major studies, peer review panels include independent experts from various fields of science related to the study at hand; panel members evaluate each study proposal. and the proposal is then reworked by the CDC scientists based on the comments of the reviewers.

For example, a proposed study to evaluate the possibility of birth defects resulting from a given toxic exposure could be reviewed by a panel of experts from several areas. The panel might include an epidemiologist with expertise in reproductive outcomes, a toxicologist, a pathologist with expertise in the area of laboratory tests that are proposed for medical evaluation, and a statistician. If the study were controversial. more than one expert per area of study might be called. Copies of the study proposal would be sent to all team members. They would review the proposal and then meet with the researchers for a full discussion of possible changes in study design. Written comments would be sent to the CDC investigators.

The peer review process is not rigidly defined nor does it guarantee a perfect outcome but it does have a structure that has traditionally provided for better science for the following reasons:

- 1. There are several independent reviewers. This means that the individual prejudices of a single scientist cannot govern the approval or disapproval of a study. The scientific tradition of finding a better truth out of free debate is maintained.
- 2. The reviewers come from several different areas of expertise. Thus, different aspects of the study will be reviewed by experts from that particular area.
- 3. The team that reviews a study functions independently and without conflicts of interest.

Four broad criteria have been proposed for evaluating peer review: adequacy, value, effectiveness, and legitimacy.<sup>9</sup> The criteria of adequacy involves the reliability of the data, the study design, and statistical methods. Value relates to the importance of the problem addressed; in other words, low marks would be given for a patently trivial proposal. Effectiveness suggests that a study will move scientific research forward by providing needed answers in a current area of controversy. Legitimacy means that the study design is consistent with recognized traditions of scientific thought.

The traditional scientific peer review process that is used at CDC thus involves a team of independent experts from various fields related to a particular study who evaluate that study for its adequacy, value, effectiveness, and legitimacy. While scientific consensus is hardly guaranteed by the peer review process, this process enhances the likelihood that the research product that emerges will be consistent with current scientific standards.

The traditional scientific peer review is a thorough review involving various experts who focus their discussions on the quality of the science presented. This review contrasts with the review that is mandated under the Paperwork Reduction Act, which is intended to focus on paperwork burden and practical utility rather than on scientific substance.

#### CASE REVIEWS

The Paperwork Reduction Act was passed in 1980; the final rule governing its implementation has been in place more than three years. There is now a body of information available to evaluate whether the OMB clearance process has functioned in a manner that is consistent with Congressional intent.

In our analysis, we conducted an in-depth evaluation of the OMB review process as it applied to six CDC studies that were either disapproved or only conditionally approved by OMB following endorsement by scientific peer review panels. These six studies comprised all of the peer reviewed research projects rejected by OMB since January, 1984 on which we had full documentation of the peer review process. Three of these studies were major studies that received only conditional acceptance. Three were fully rejected by OMB notwithstanding acceptance by the peer review panel. The review process was examined to determine whether it interfered with the substantive programs and policies of the scientific research agencies. We have focused on four areas of interest:

- What were the issues raised in the initial CDC <u>study</u> <u>design</u>? What was the nature of the public health issue addressed?
- What <u>peer review</u> occurred? Was it adequate and appropriate?
- 3. What was the nature of the <u>OMB</u> <u>review</u>? What was the final outcome?
- 4. What was the <u>effect of the OMB review</u> on the timing, quality, and costs of the final product?

Analysis of each of the studies involved a review of a substantial body of agency documents. We traced each CDC study from the primary proposal through the various stages of peer review. The issues raised during the peer review were scrutinized, and the subsequent proposals were reviewed to totes ted

determine whether these issues were addressed adequately in the final product.

Then, we evaluated the OMB review and compared OMB's review process and findings with those of the scientific peer review panel. Finally, we reviewed the end product to assess the impact of the superimposed OMB review on the CDC study.

The analysis for each study is rather lengthy so for the purposes of this report, a summary of the six studies is included in Table 1. The full discussion of each case is included in the sppendix.

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#### TABLE 1

	Dìoxin	VDTs	MBOCA	Ladder Falis	Information Processing	CDC Reproductive Outcomes
PURIFOSE	Study intended to provide dose related data on morbidity & re- productive ef- fects not pre- viously re- searched in humans	Study would provide defini~ tive data on the reproduc- tive hazards of video dis- play terminals	Study was de- signed to screen 500 workers expos- ed to potent animal car- cinogen for bladder cancer	Study was first scienti- fic project to provide con- trolled data on this major occupational safety problem & was designed to assist regu- latory & non- regulatory safety initi- atives	Study designed as initial information- gathering step to assess rela- tionship between repetitive men- tal tasks and physiologic changes	Study intended to provide impor- tant baseline data for numerous epidemiological reproductive studies
ISSURS	*Hajor animal toxin causing tumors & birth defects *Public health issues, inclu- ding exposures at work sites, Superfund sites, Vietnam veterans *Lack of dose related data on morbidity & birth defects	*12 reported clusters of abnormal re- productive outcomes *Serious pub- lic concern for large num- ber of women exposed *No existing controls	*Potent animal carcinogen *Exposure of 500 workers in Adrian, MI *Serious com- munity concern *No existing regulatory controls	*Persistent 4 severe indus- trial accident *No scientific data with con- trol popula- tion *Some current OSHA regula- tions under revision	*Initial inves- tigation of relationship be- tween the stress of repetitive men- tal tasks 6 phy- siologic changes	*Cluster of ab- normal birth outcomes in lab- oratory workers at CDC *Chance for ideal reproductive survey data in an informed population *Important base- line data for many other re- productive studies

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# Summary of Case Reviews

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	Dioxin	VdTs	HBOCA	Ladder Falls	Information Processing	CDC Reproductive Outcomes
STUDY DESIGN	*Interviews & medical screwn- ing of 460 dioxin exposed workers at two sites and com- munity controls	<pre>finterview data    survey of    medical records    collecting re-    trospective data    on 2000 female    VDT users &amp;    2000 controls</pre>	<pre>*Interviews &amp;   medical screen-   ing of 500   workers</pre>	*Interview data from cases & matched con- trols	*Interview data \$ physiologic measures	*Surveillance of CDC employees
и <b>г</b> ат <b>ем</b> Ъргон	*NICSH 12- member panel Approved *White House Agent Orange Working Group Science Panel Approved	*5-member panel Approved	*4-member panel Approved	*18 consul- tants Approved	*7 peer reviewers Approved	*Broad committee of all sections of CDC Approved
onb UKA 15M	<ul> <li>Disupproved (11/85) (enough stud- ies on dioxin)</li> <li>Approved with conditions fol- lowing appeal</li> <li>Senate direc- tive (3/86)</li> <li>APretest of methodology approved tuli study not yet approved</li> </ul>	<pre>*Disapproved    (12/85)    ("design flaws") *Approved with    conditions fol-    lowing Congres-    sional inquiry    (6/86) *Removal of    questions    related to    stress and    fertility</pre>	*Disapproved (5/85) ("design flaws") *Approved with condition fol- lowing Congres- sional inguiry (8/85)	<pre>*Disapproved    (9/84)  ("no practical    utility")</pre>	<pre>*Disapproved   (2/85)   (insufficient   evidence of   health &amp; safety   problem)</pre>	<pre>*Disapproved   (3/86) Appealed by CDC   *Disapproved   (6/86)</pre>

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P ONB have been have been jor industrial related disease would provide		Dioxin	VDTS	MBOCA	, Ladder Falls	Information Processing	CDC Reproductive Outcomes
	EPPECTS OP ONB REVIEW	have been blocked *No full study yet approved *If study does go forward, costs will be increased	have been blocked *Many experts feel study is significantly weakened by removal of stress 4 ferti- lity questions *Costs increased	have been blocked *Delay of can- cer screening for six months *Weakening of	jor İndustrial safety issue	related disease	would provide important repro- ductive base- line data in an ideal population

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н' , Our review of six studies which were rejected by OMB reveals several significant patterns. All six studies were designed to address legitimate scientific and public health questions. At least three of the studies (relating to dioxin, the reproductive hazards of video display terminals, and the carcinogenic potential of MBOCA) addressed major public health issues about which citizens had expressed profound concern.

All six studies were subjected to extensive peer review. Protocol revisions based on the peer reviewers comments ranged from minor adjustments to substantial changes in study design but all study protocols eventually were redesigned and approved by the peer review panels.

The results of the OMB review fell into two general categories. OMB initially disapproved all six studies but the stated reasons for disapproval varied. In the case of the dioxin, VDT, and MBOCA studies, OMB's initial rejection was based on the budget office's assessment of the scientific value or quality of each study. The disapprovals were not based on a finding of burdensome or duplicative paperwork. For example, OMB rejected the dioxin study on the grounds that it was "unnecessary" in view of previous dioxin research. OMB vetoed the initial information collection requests for the VDT and MBOCA studies based on its assessment that these studies had major design flaws.

In all three of these cases, OMB relied heavily on outside consultants, who were either unprepared or were unfavorably disposed to the study they were to evaluate and who raised questions which already had been discussed by the agency peer review panels. In all of these cases, a critique requested by OMB from a single consultant or provided to OMB from industry consultants overrode the scientific judgment of a multi-discipline peer review panel, which had approved the study.

The inappropriate scientific nature of OMB's review is a pattern that is confirmed in further review of these three studies. In all of these studies, following agency appeals and expressions of Congressional and public concern, OMB conditioned its ultimate approval on the redesign of the scientific protocol. In addition, in all three cases, the redesign that occurred appears to have weakened the studies.

In the other three cases, the OMB disapproval was premised on the conclusion that the studies lacked "practical utility." OMB disapproved the epidemiologic study of ladder falls on the grounds that OSHA had initiated rulemaking in this area and therefore new information was not needed. Yet, OME's conclusion disregarded the assertions of both OSHA and NIOSH that the proposed study would not only benefit efforts to revise or eliminate OSHA's regulations but also would greatly assist voluntary safety efforts.

The studies on the health hazards of information

processing and reproductive outcomes of CDC employees were disapproved because OMB concluded that there was insufficient evidence of existing health problems. Both of these studies were designed to investigate possible public health risks in areas that had not been previously evaluated epidemiologically. The reasoning applied by OMB is only justified if the hazard is already understood. Thus, if OMB's reasoning were consistently applied, research into any new area would be blocked.

Reviewing the effect of OMB's paperwork review, we find that OMB, an agency without public health expertise, has used its authority under the Paperwork Reduction Act to alter the direction of public health research proposed by public health OMB's review in these cases had several effects, agencies. all of which were deleterious. Studies were delayed, weakened, increased in cost, or blocked altogether. When studies are blocked or diminished in quality, certain research findings will be unavailable for informed decisionmaking on public health issues. In these cases, the quality of public health information and the public health decisions based on that information will be undercut. In addition, productive research resources have been diverted into nonproductive paperwork review activities and unnecessary contracting costs.

## OMB PATTERNS OF APPROVAL AND DISAPPROVAL

Our review of the six cases demonstrated a pattern of rejection that might be interpreted as interference with the substance of CDC research. It was possible that the patterns seen in our review of the cases were simply an example of poor bureaucratic management, rather than systematic bias. If this were so, it would have been likely that disapprovals would have occurred randomly across all types of studies done at CDC. In order to determine whether the Office of Information and Regulatory Affairs was conducting its reviews in a manner that fell selectively on certain types of studies, we made a statistical evaluation of the patterns of OME acceptances and rejections of CDC research studies.

#### Methods and Data

Our methodology involved a review of all CDC submissions made to OMB for clearance during the period January 1984 to March 1986. CDC submissions were selected as the sample for review because CDC is an agency that does a large segment of Federally funded epidemiologic research and because CDC is not a regulatory agency (and thus the submissions are of a purely research nature).

We chose to review submissions starting in 1984 because

OMB's final rules on paperwork management reduction became effective during 1983. During the time period reviewed, there were 61 submissions to OMB from CDC; of these submissions, 51 involved the collection of information from individuals for the purpose of scientific research. Ten submissions were non-research in nature (<u>i.e.</u>, routine approval forms) and were excluded from the analysis.

Research submissions were categorized by content area, into three categories:

<u>Environmental or occupational studies</u> were those that involved work-related diseases or exposure to environmental pollutants. These studies came from the offices of NIOSH or the Center for Environmental Health. Of the case studies we reviewed, the projects on MBOCA, VDTs, dioxin, ladder falls, and health risks of information processing would all fall into this category.

<u>Reproductive</u> <u>studies</u> involved questions of reproductive bealth as their primary focus. Study topics in this category ranged from venereal disease studies to birth defect analysis. The study on reproductive outcomes of CDC employees from the CDC Birth Defects Section was included in this grouping because the focus of the study was to provide baseline reproductive statistics.

Studies that related to all <u>other disease processes</u> constituted the final category. A broad range of topics were involved, including studies on childhood immunization, hepatitis in renal dialysis patients, malaria in foreign travelers, sudden infant death syndrome, lower respiratory disease in day care centers, and Reye's Syndrome.

The outcome measure was the final result of OMB classification that was known to have occurred during the study period (i.e., acceptance, rejection, conditional acceptance). It was determined that conditional acceptances would be analyzed in the same category as rejections. We adopted this approach for two reasons. First, case review indicated that significant efforts had to be made by parties outside OMB (usually Congress) to overturn an initial OMB rejection of a study and to obtain a conditional acceptance. It was doubtful that the upgrade would have occurred under routime circumstances. Second, our review indicated that implementation of the study had been delayed or the substance of the study had been altered in the cases involving conditional acceptances.

We considered whether our categorization might be a measure that was confounded by other issues. Two possible confounders were considered and rejected. First, it was

considered that our categorization by topic might actually be a measure of studies coming from one particular office. Thus, it might be argued that a high rejection rate was occurring because one particular office produced particularly poor research proposals. Reviewing our categories, we found that the environmental/occupational category included studies from two NIOSH offices in Morgantown, West Virginia, one NIOSH office in Cincinnati, Ohio, and from the Center for Environmental Health in Atlanta. Reproductive studies also came from several different offices within CDC. Thus, the single office theory was rejected. Second, we considered the possibility that studies were rejected on the basis of undue cost. Cost data were unavailable for all of the studies but an analysis of the rejected studies showed a wide range of projected costs, making this confounding explanation less likelv.

# Statistical Evaluation

To analyze the pattern of OME rejections, we performed a statistical analysis measuring whether the pattern of rejection occurred randomly across the different content categories. A Fisher's Exact Test was used to measure statistical significance.

When we compared the environmental/occupational category with the other (non-reproductive) category, we found that there was a strong pattern of OMB rejection of these studies (see, table 2). OMB's Office of Information and Regulatory Affairs was found to be seven times more likely to reject an environmental or occupational study than to reject a CDC study on other topics, which were less likely to have potential regulatory significance. The strength of this association was highly significant, with the likelihood of these results occurring by chance of 2 in 1000.

The pattern of rejection of reproductive studies was analyzed in a similar fashion. The numbers involved in this analysis were extremely small. With such small numbers, effective measurement of statistically significant findings is difficult. Nevertheless, the pattern of rejection of these studies suggests that reproductive studies also were rejected more frequently than other studies of a non-environmental/non-occupational nature.

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# TABLE 2

	<u>jection of Cl</u> <u>Comparison</u>	-17- TABLE 2 <u>OC Submissions</u> <u>of Environment</u> <u>VS</u> productive) Stu	<u>a1</u>	- AMALINE SHUMAN
Study Type	Conditiona Reject	l/ Accept	% Reject	- Pr cori
Environmental/ Occupational	7	14	33.0%	
Other/ Nonreproductive	1	21	4.52	
		p≃.002 odds rati	o 10.4	

TABLE	3
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Rejection of CDC Submissions to OMB Reproductive Submissions VB Other (Non-environmental) Studies

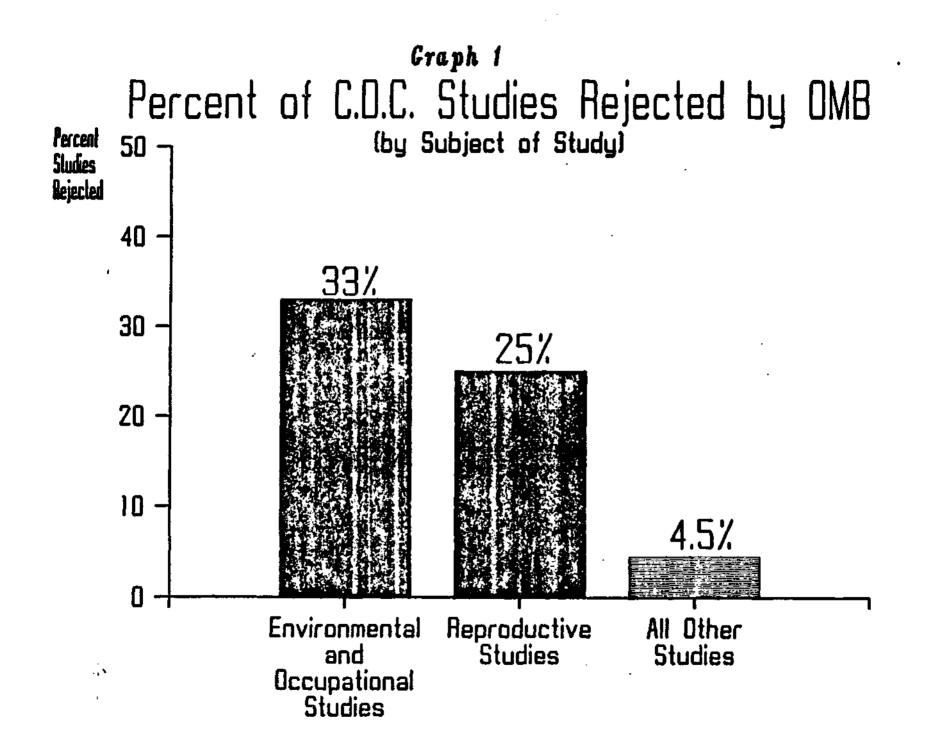
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Study Type	Conditional/ Reject	Accept	% Reject
Reproductive	2	6	25.07
Other	1	21	4.5%

# Findings

The patterns show, in our evaluation, that environmental and occupational studies were particularly subject to rejection during the OMB review procedure and that reproductive studies may have a comparable vulnerability. The rejection rates for both of these types of studies are markedly higher than the rejection rate for other studies.

[INSERT GRAPH 1]



While the intent of the OMB reviewers cannot be inferred from statistical measures, the differing pattern of review among studies that should presumably receive similar treatment raises serious concerns.

We previously have discussed two possible confounders which might have accounted for our findings; office of origin of the study and cost of the study. However, we have concluded that both of these confounders are unlikely to explain the analytical results, for reasons previously cited.

Therefore, we have considered three other possible explanations of the selective rejection rate. First, it is possible that OMB found that CDC's peer review process for environmental, occupational, or reproductive studies contained flaws which were not apparent in other types of studies. Thus, OMB may be especially likely to reject studies on these topics, because the peer review was particularly flawed.

In our view, this explanation is unlikely. The peer review of all the studies rejected by OMB involved a competent, thorough examination of the study design by a group of recognized experts in the appropriate field.

Second, it is possible that the etiology of the OMB bias against environmental, occupational, and reproductive studies related to the complexity of these studies. It is generally conceded that studies relating to environmental and occupational health or reproductive outcome involve difficult issues of study design when compared to more conventional epidemiologic studies. It is possible that OMB reviewers were more likely to reject a study where the design was controversial, hence increasing the rejection rate in thoseareas.

While we find this explanation plausible, it raises serious public health concerns. The science involved in addressing environmental and occupational health effects and reproductive outcomes is difficult but this does not mean that they should not be studied. Decisions on the commitment of resources to public health research should involve a considered weighing of the importance of the public health issue as well as the quality of the information to be obtained. It is inappropriate to block research in important because the study design is not simple areas and ' straightforward. This is particularly true in epidemiological research where scientists must rely on conditions of human exposure as they find them in the real world. Difficult areas of research often require new and controversial approaches but minor imperfections perceived in the study design are no reason to abandon the research if the issue is an important public health problem.

OMB reviewers, unlike CDC reviewers, are not public health professionals. Thus, they are less likely to value the public health importance of information as highly as public health workers. Failure to appreciate the public health importance of environmental, occupational, and reproductive problems may have contributed to OMB's finding of "no practical utility" in some of the rejected cases.

Third, it is possible that OMB's bias represents an intentional effort to block occupational, environmental, or reproductive studies that ultimately might lead to additional Federal regulation. Although the Paperwork Reduction Act does not vest OMB with the authority to interfere with proposed research on policy grounds, the increased rejection rates for occupational, environmental, and reproductive studies raises the possibility that such political interference has occurred. APPENDIX OF CASE STUDIES

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# Study of Dioxin Worker's Morbidity and Reproductive Effects

The extreme toxicity of 2,3,7,8 tetrachlorodibenzo-pdioxin (TCDD) has been recognized for several decades. effects (morbidity). Diverse adverse health including tumorogenic and teratogenic effects have been shown in multiple animal studies. In humans, occupational exposure to TCDD-contaminated production is known to cause a skin disorder called chloracne. Ruman exposure also has been associated with derangements in liver metabolism, in endocrine and hematopoietic function, and in neurologic, psychological, and reproductive function.

Human exposure to dioxin has occurred in a variety of circumstances, including worksite and environmental contamination. Questions of contamination have been raised with reference to certain Superfund sites and with reference to by-products from incineration. TCDD was a contaminant of Agent Orange, a defoliant used in Vietnam, a fact which has generated interest among veterans. The concern about dioxin is broad-based with the public and is relevant to multiple Federal agencies. The White House Agent Orange Working Group (AOWG) currently functions to coordinate efforts on these issues.

Though the scientific literature contains many publications related to dioxin, the literature leaves major gaps in knowledge that limit our ability to assess its effect in significant clinical situations. Human studies related to many of the systemic effects are considered to be suggestive but not definitive. The literature is particularly lacking in data that relates human doses to clinical outcome. Data that relates human exposure to the more serious types of morbidity outcomes, such as birth defects and cancer, is considered by some to be insufficient to justify regulation or compensation. Dose-related information on morbidity incidence would be the basis of informed regulation, clinical assessment, and protective policy. Multiple Federal agencies (i.e., OSHA, EPA, the Veteran's Administration) would use this type of information in developing dioxin-related policies.

To establish and evaluate dose-related morbidity incidence in a human study, it is necessary to evaluate a well delineated population with quantifiable exposures. Exposure data in most of the exposed populations, such as agricultural workers and Vietnam veterans, is extremely imprecise. Worker populations have high, long-term exposure, and exposure information on these groups is far better and more detailed.

In response to the need for dose-related morbidity data, NIOSH proposed to evaluate two groups of workers exposed to chemicals contaminated with 2,3,7,8-TCDD. The proposal involved the evaluation of 360 individuals employed at the Diamond Shamrock Plant in Newark, New Jersey and 80 individuals employed at the NEPACCO, Hoffman Taff/Syntex plant in Verona, Missouri. Interviews and medical testing were proposed. There were to be matched controls from the surrounding neighborhoods. Because this study would address the important question of dioxin dose-related morbidity, the White House Agent Orange Working Group determined that this study was one of 11 essential studies to be completed by 1990.

The peer review to which this study was subjected must be described as extensive. Outside review started in 1983 with scrutiny by a 12-person dioxin peer review panel. There were subsequent panel reviews in 1984 and 1985. Additionally, the protocol was reviewed by the AOWG Science Panel in 1984. The AOWG panel meeting of September 25, 1984 reported:

The Science Panel finds that both...the Morbidity Study [and a related Mortality Study] are well designed and carefully considered and should provide useful information on the possible long term health effects of industrial exposure to dioxin contaminated products. The Science Panel recommends that both studies procede [sic] as soon as appropriate resources can be allocated.<sup>10</sup>

With regard to the adequacy of peer review of this study, the situation was well summarized in December 1984 by one of the NIOSH peer reviewers who stated:

This study is in danger of being reviewed to death -- if in fact that has not already occurred. Surely, review by both the peer review panel of NIOSH and the Science Panel of AOWG -- not once, but several times -- is superfluous and inefficient. The money spent would be better put into the conduct of the study itself.<sup>11</sup>

The study was submitted to OMB pursuant to the Paperwork Reduction Act in July 1985. OMB responded to the proposal by raising extensive questions about the utility of the study and the study design, including the choice of the control population, the methods of quantifying exposure, and the power of the study to measure exposure effects. All of these questions about study design had been previously discussed in great detail by the various peer review panels, and the panels had concluded that these issues had been addressed adequately. Nevertheless, OMB raised these questions again, and NIOSH provided the requested information.

Notwithstanding NIOSH's attempts to satisfy OMB's concerns, OMB disapproved the study on November 17, 1985,

stating:

... [t]his study is unnecessary in view of the fact that workers proposed for examination are already included in NIOSH's dioxin registry study of dioxinexposed chemical workers, and since numerous dioxin exposure in the workplace studies have been conducted, to which the proposed study would add little if any, further intelligence.12

The OMB conclusions run counter to the findings of the various expert panels in several significant ways. First. ONE's conclusions show little awareness of the nature of the scientific literature on dioxin and specifically of the need for the exposure-related data that would be provided by this study. Second, OMB's assertion that the dioxin registry data should be adequate indicates a failure to understand the difference between morbidity (disease-related) and mortality (death-related). The dioxin registry information is limited to mortality data and simply could not answer questions about the incidence of non-fatal diseases in the population nor the occurrence of birth defects in offspring of exposed These gross misconstructions of the basic individuals. science involved in the study suggest serious deficiencies in the OMB review process.

NIOSH internal documents indicate that OMB had discussions prior to the disapproval with Colonel Alvin Young, Ph.D., Senior Policy Analyst for the White House Office of Science and Technology Policy (OSTP). NIOSH documents state that Colonel Young "indicated his view that the Dow and Monsanto studies might have been enough. He said that he had not been able to justify the expenditure when compared with the need to fund radon studies."<sup>13</sup> These opinions clearly run counter to the approval expressed by the NIOSH review panel and by the Science Panel of AOWG of which Colonel Young is a member. OMB gave great weight to the opinions of a dissenting member of the Science Panel rather than following the recommendations of the full group.

Both NIOSH and the involved communities elected to appeal the disapproval and presented their appeals to OMB for reconsideration through several channels. On December 6, 1985, at the behest of Senator Frank R. Lautenberg of New Jersey, the Senate Committee on Appropriations included language in its continuing appropriations measure expressing strong concern about OMB interference in the dioxin study. The report emphasized:

The Committee is most concerned about a recent action by the Office of Management and Budget blocking further gathering of statistics on the Morbidity Study of Persistent Health Effects in Chemical Herbicide Workers and Community Residents being conducted by the National Institute of Occupational Safety and Health (NIOSH). The Committee believes that the study should go forward without further interference from OMB.14

On December 11, 1985, the Department of Health and Human Services (HHS) submitted an appeal of OMB's disapproval to Dr. Wendy Lee Gramm, Administrator of OHB's Office of Information and Regulatory Affairs. The appeal emphasized the importance of the study to the Public Health Service "as well as to other Federal agencies (<u>e.g.</u>, Science Panel, a subgroup of the White House Agent Orange Working Group; the Environmental Protection Agency, which is providing funds for this project; the Veterans Administration, etc.)." The HHS appeal also included letters of support from the New Jersey Department of Health.

On December 16, NIOSH officials met with Alvin Young of OSTP and with Mark Winer of the Statistical Policy Branch of OIRA. This meeting had been arranged at the suggestion of Colonel Young shortly after the Senate report directed that the dioxin study should go forward. Dr. Fingerhut, the NIOSE Project Officer, and Colonel Young had further discussions the following day. From these discussions emerged Colonel Young's suggestion for a two-phase approach to the study, which would allow the termination of the project after the first phase.<sup>15</sup>

On January 7, 1986, Robert Bedell, Deputy Administrator of OMB's Office of Information and Regulatory Affairs, wrote to John J. O'Shaughnessy of the Department of Health and Human Services and agreed "to approve a portion" of the dioxin study. According to this letter, this partial study was to include a sample size which "shall not exceed 80 and shall be drawn exclusively from the New Jersey site." The partial study only would evaluate the methodology proposed for the full study. The sample size of this pretest is far too small to provide useful information about dioxin.

Moreover, Mr. Bedell's letter underscored the conditional nature of OMB's approval. He stressed that:

we continue to have reservations regarding the degree to which there will be adequate variation in exposure levels, appropriate selection of the control cases and the practical utility of study results.... Future consideration of the remainder of the study will be dependent on the demonstration that the objectives of the full study can be reasonably met.... Once the technical concerns are resolved, the practical utility of the study must be demonstrated.<sup>16</sup>

Notwithstanding OMB's approval of a portion of the dioxin study on January 7, 1986, further delays ensued. NIOSH did not receive official notice of OMB's approval of the pilot study until March 24, 1986. At this point, the pretest has not yet started. OMB will not make a determination on the full study until the pretest is complete.

The history of the dioxin study is highly instructive in evaluating the effects of the paperwork review process in the research arena. In this case, the impact of OMB's interference has been substantial. OMB's activities have not only delayed the development of important public health information; they also have diverted Federal dollars from productive research. According to official estimates, the two-stage study methodology imposed by OMB will increase contracting costs for the dioxin study by at least \$270,000. 17

In addition, concerns have been raised that the conditions imposed by OMB may in fact weaken the study design. Pretesting among part of a population may confound results from the study of the whole group.

The public health implications of the OMB review process should be considered. Under the Paperwork Reduction Act, OMB is supposed to assess whether data has practical utility to the agency requesting the collection. In the case of the dioxin study, OMB did not find utility where numerous other scientists did. OMB's analysis ran counter to the findings of the NIOSH peer review panel and the Science Panel of the White House Agent Orange Working Group. Under the current version of the Act, the OMB determination takes precedence and the study is blocked, notwithstanding strong indications of the public health value of this study.

More than nine months after the Senate Appropriations Committee directed OMB to cease its interference in the NIOSE dioxin study, approval has been given only for a pretest. OMB's letter of January 7, 1986, makes clear that final approval is by no means assured. It is still possible that OMB will thwart the scientific recommendations of the professional staff of NIOSH, of the agency's peer review panel, the White House Agent Orange Working Group, and the Congress itself.

# <u>NIOSH Reproductive Study of Female Video Display Terminal</u> Operators

A study of reproductive outcome in video display terminal (VDT) operators was initially proposed by NIOSH because various user groups were concerned about widely publicized reports that clusters of women VDT operators suffered high rates of spontaneous abortion, birth defects among their children, and other reproductive problems of pregnancy. Because these clusters of affected users were too small and the reproductive problems too varied, it was not possible to draw any scientifically valid conclusions.

NIOSH estimates that there are currently 7 million VDT

users in the United States. The agency was concerned that given the large number of women users of reproductive age, even a small increase in birth defects or spontaneous abortion rates caused by VDTs would mean a large increase in the absolute number of those suffering these effects.

There are 12 widely reported clusters of abnormal birth outcomes related to VDT use. Interpretation of these clusters is a matter of epidemiologic controversy. There is a strong likelihood of such clusters occurring by chance alone, in a large population. Nevertheless, there is serious concern among VDT users, and industry, labor, and public health officials all agree on the need for a strong definitive study that would give a solid assessment of this problem.

In general, reproductive studies are more difficult to design than other epidemiologic studies because medical records on miscarriages and birth defects are not as reliable or consistent as those related to death or disease. Often these records are not included in company personnel records. Because of these factors, NIOSH chose to design a study based on worker interviews rather than on medical record surveys. For this design to be effective, it was necessary for NIOSH to find a group of VDT-exposed workers and a group of nonexposed controls for comparison.

The proposed study was designed to take advantage of a "natural experiment," a situation where two very similar groups of women at Bell South Corporation had very similar jobs with the exception that only one group was using VDTs. According to its proposal, NIOSH planned to compare pregnancy outcomes of women workers using VDTs (directory assistance operators) and those who were not (long distance operators) at the Bell South Corporation.

Peer review of this study involved three reproductive epidemiologists, as well as an expert in stress and ergonomics, and a statistical reviewer. The questions raised were those that are usually controversial in retrospective reproductive studies. The most important of these concerned the issues of recall bias and measurement of pregnancy outcome. "Recall bias" raises the issue that women who know they are exposed to possible hazards may be more likely to report a bad birth outcome, thus biasing results. Measurement problems involve difficulties in establishing specific definitions of birth defects or spontaneous abortions.

Multiple recommendations were made by the peer reviewers to improve the methodology. These recommendations were incorporated into the revised proposal. The general assessment of the final proposal by the peer review panel was that the study was well designed, was necessary, and should be done.<sup>18</sup>

The study was submitted to OMB in September, 1985. In

November, 1985, representatives of the Bell South Corporation wrote directly to Wendy L. Gremm, the Administrator of OMB's Office of Information and Regulatory Affairs, stating that:

We share the goal of resolving scientifically whether video display terminals cause adverse pregnancy outcomes. We are concerned, however, that the proposed study as currently designed will not provide reliable and useful scientific information.<sup>19</sup>

The Bell South representatives noted that their concerns already had been expressed to the scientific staff at NIOSH. Bell South also notified OMB that two academic epidemiologists had been retained to review the study protocol for Bell South. This review was subsequently mailed to OMB.

In December, OMB disapproved the VDT study citing major design flaws and a large number of irrelevant questions as reasons for its action.<sup>20</sup> The criticisms that OMB used in its disapproval notice to NIOSH represent an abbreviated version of the critique commissioned by Bell South.

Questions similar to those raised by the Bell South report were discussed by NIOSH peer reviewers though the solutions raised were different. The nature of academic differences over study design is not the issue. The process is the focus of concern. The review by Bell South's consultants is presented directly to OMB. OMB then uses this particular consultants' report to disapprove the study.

Disapproval of the study was of significant concern to NIOSH and to representatives of VDT users. NIOSH appealed OMB's decision in March, 1986. Congressional hearings on April 14, 1986 and June 4, 1986, addressed OMB's interference in the proposed research effort. On June 6, 1986, OMB finally approved the VDT study.

However, OME's June 6 approval involved several major conditions, including a requirement to substantiate miscarriages by examining medical records and the elimination of questions related to stress and fertility because they are "intrusive" and "irrelevant."

Removal of the questions relating to stress and fertility involved a rather subtle, but extremely important, controversy. In all epidemiologic studies, the issue of "confounding variables" arises. Confounding occurs when something that is not the primary issue in a study is related to outcome. For example, stress may be associated with poor pregnancy outcome. If the study group (those who used VDTs) also faced more stress than the control group (those who did not use VDTs), it could be possible that any bad pregnancy outcomes found in the study group would be due to stress, not VDTs. Similarly, if the group using VDTs simply through random selection included more women who had impaired fertility (for example due to use of birth control or previous hysterectomy), abnormal study results would occur unless these were corrected. The need to measure confounders is an important one but it must be weighed against the detrimental effects of measuring too much and measuring imprecisely. In the VDT study, OMB and Bell South's consultants argued against measuring too many variables and against measuring variables that were subject to bias because of imprecise "recall" by patients. Based on these arguments, questions focusing on fertility-related issues, such as use of contraception, previous hysterectomy, alcohol and tobacco use, and stress were removed.

Removal of these questions sparked debate. Many felt that collection of the data on fertility and stress was necessary to establish the presence or absence of important confounders in the study. It was believed that these questions were necessary to maintain a highly credible study. Teresa Schnorr, the NIOSH VDT project director, has stated: "My feeling is that those questions (on stress and fertility) were important to the study. Without them the study will be less credible."<sup>21</sup>

At the request of Congressman Ted Weiss, Chairman of the Subcommittee on Intergovernmental Relations and Human Resources of the House Committee on Government Operations, the staff of the Office of Technology Assessment (OTA) and a highly regarded group of scientists reviewed the fertility and stress questions deleted by OMB from the VDT study. The scientific reviewers included Zena Stein, M.D., Richard Neave, M.D., Donald Mattison, M.D., Irving Selikoff, M.D., and William Butler, Ph.D. The overwhelming majority concluded that the deletion of the fertility questions weakened the proposed study significantly.

The OTA staff analysis concluded that:

The OMB excluded questions would have provided valuable information for a study of the possible adverse reproductive effects of radiation exposure from work.... Due to the high visibility of this study and the likely use of the conclusions by a wide variety of individuals, it is important that its conclusions be as clear as possible. The questions deleted by OMB were intended to provide important and useful information that would reduce the potential for alternative explanations of the study results. While the wording of specific questions and the order of the questionnaire might be reexamined and improved, complete deletion of questions on fertility and stress will limit the conclusions that can be drawn from this study.<sup>22</sup>

The comments of William J. Butler, Ph.D., illustrate the concern of various academic experts about OMB's deletion of the stress and fertility questions. In a July 16, 1986 letter to Congressman Weiss, Dr. Butler stated that:

NIOSH has been given permission by OMB to conduct their study only if six changes are made in the protocol. OMB claims that these changes are needed "to correct methodological deficiencies and improve the validity of the study results." My concerns are focused on two of the changes required by OMB.

One of these changes requires the deletion of approximately sixty questions on psychological stress. OMB reasons that "(t)here is insufficient evidence relating these items to hypotheses concerning VDT exposure and adverse pregnancy outcomes." I agree that the evidence associating stress with pregnancy outcome is inconsistent. However, occupational stress is one of the leading suspected causes of the reported association between VDT exposure and pregnancy outcome. Therefore, collecting information on stress is <u>crucial</u> for the thorough investigation of this occupational health issue. Additional studies will be necessary if the stress questions are not included in the NIOSH protocol so it is a waste of resources <u>not</u> to include them.

Another of OMB's changes requires the deletion of eight questions on fertility. OMB reasons that "(m)easuring the effect of VDT exposure on fertility is not the purpose of the study." This is categorically wrong. The purpose of the study is to investigate the association between VDT exposure and adverse reproductive outcomes, including spontaneous abortions. Early spontaneous abortions are often not recognized. An increased frequency of early spontaneous abortion could thus be expressed in the form of decreased fertility. Failure to include questions on fertility will result in the inability to examine the association between VDT exposure and early pregnancy loss.

These two changes required by OMB, though it is claimed they correct deficiencies and improve validity, severely restrict the range of scientific inquiry of the study. These restrictions will result in the study providing inconclusive results and almost guarantee that additional, equally expensive studies will need to be conducted. The protocol submitted by NIOSH to OMB had already benefited from reviews by researchers in the government and academia and was scientifically and methodologically sound.<sup>23</sup>

Evaluating the review process as it applies to the VDT study, we find that the need for a study on this issue was well-established. NIOSH, the NIOSH review patel, and many scientific experts, all felt that the study would fill an important need. Labor and industry agreed that a welldocumented NIOSH study would assist informed decisionmaking on issues related to pregnant workers and VDT exposure. A panel of 5 peer reviewers discussed the design extensively, revisions were made, and the study was approved.

Following approval by the peer review panel, OMB used the Bell South consultants' report as a second scientific review to override the NIOSH panel, and disapprove the study. Subsequently, following Congressional inquiry, OMB approved the study with the condition that certain fertility and stress questions be removed.

Bowever, the OMB review process diverted substantial resources from productive research into paperwork clearance activities. Because NIOSH believed that the study should go forward, the agency made a commitment to seeing the study through the review process. In the VDT case, NIOSH spent \$53,451 in personnel costs for paperwork review.<sup>24</sup> Thus, we see that a substantial commitment of time, effort and tax dollars had to be made to gain approval of a study that was considered necessary and appropriate by NIOSH. These resources were diverted from actual research to manipulation of the review process.

Had the clearance process at OMB resulted in an improved product, it might be argued that the final product justified the costs. However, a large number of experts believe that the OMB review resulted in a weaker study design. The original intent of the NIOSH study was to establish an extremely credible study that would allow labor and industry to formulate policy confidently. These experts contend that this function of the study has been undermined by OMB's removal of the fertility and stress questions. Thus, we have a case where OMB's Office of Information and Regulatory Affairs engaged in a clearance process that duplicated the function of the peer review panel, increased costs, and may have lowered the quality of the final product.

## NIOSH Investigation of Workers Exposed to MBOCA

This study by the National Institute for Occupational Safety and Bealth (NIOSH) was designed to evaluate the carcinogenic risk to humans due to exposure to 4,4' methylenebis 2-chloroaniline (MBOCA). The chemical has been found to be carcinogenic in three species of mammals and is similar in chemical structure to known human bladder carcinogens. The issue of MBOCA exposure evaluation became an important public health issue in 1979, in Adrian, Michigan, when state and local health officials had to close a plant and attempt a community cleanup following MBOCA contamination. The Michigan Department of Public Health requested CDC's assistance in evaluating cancer incidence among MEOCA manufacturing workers formerly employed by the Anderson Development Company in Adrian.

Moreover, health officials have expressed concern about MBOCA exposure because it has been estimated that 1,300 to 33,000 U.S. workers have been exposed to MBOCA.<sup>25</sup> Current exposures are continuing without any regulatory controls.

The NIOSH study was designed to evaluate the 533 workers at the Adrian facility for incidence of bladder cancer and other malignant neoplasms. The study design involved the collection of relevant epidemiological information by interviews and by medical screening for possible bladder cancer. The study was scrutinized by four peer reviewers. The reviewers determined that MBOCA exposure in worker populations in general and the exposure in Adrian, Michigan in particular was a serious public health issue and warranted investigation by NIOSH.

Although the peer reviewers expressed some concern about the small size of the sample and the short latency period from the time of initial exposure, they determined that the study design offset these weaknesses in two ways. First, it sought to minimize problems posed by the small sample size by measuring the incidence of disease (i.e., findings of bladder tumors in living workers) rather than measuring mortality (which would only count the occurrence of death from bladder tumors). Second, if a significant number of cases of disease were found during the medical screening stage of the study, NIOSH proposed to conduct an in-depth comparison of these cases and a matched group of controls to evaluate differences in exposure (a "nested" case control study). In addition, the Anderson Development workers represented the largest group of MBOCA workers, and thus, there was no better single group to study. Thus, overall, the peer reviewers felt that study should go forward.

NIOSE submitted its request for review to OME in February, 1985. In May, 1985, OME disapproved the study stating that "the design of this study is sufficiently flawed so that the resulting data would not satisfactorily resolve the question of whether MBOCA exposure is related to bladder cancer or other types of cancer."<sup>26</sup> OMB's disapproval was apparently based on the evaluating comments of Dr. Joseph Guestworth, a statistical consultant for OMB's Office of Information and Regulatory Affairs.

Internal NIOSH documents reveal that Dr. Guestworth "had perceived his role as essentially that of a scientific peer reviewer for OMB," even though "he had received only a brief summary of the study." Moreover, Dr. Guestworth "was unaware that the full protocol had already been scrutinized at length by a peer review committee. He also was unaware of the strength of the toxicologic information implicating MBOCA as an animal carcinogen or of the chemical similarity between MBOCA and ... known carcinogens to the human bladder."27

Following their initial receipt of Dr. Guestworth's review in early April, 1985, NIOSH officials responded in detail to each of his concerns. Internal documents indicate that NIOSH was willing to discuss the scientific points more extensively with Dr. Guestworth and OME but such discussion did not take place at this point. On May 8, 1985, NIOSH received official notice from OME disapproving the MBOCA study.

At this point, NIOSH and other supporters of the MBOCA study intensified their efforts to gain OMB approval. On July 3, 1985, NIOSH resubmitted its proposal, supplementing it with a detailed response to the issues raised by Dr. Guestworth. On July 26, 1985, Congressman John D. Dingell of Michigan wrote to OMB Director David Stockman concerning the study. On August 23, 1985, OMB approved the study with the condition that the nested case control element be withdrawn.

At this time, the MBOCA study is finally in progress although medical screening of the worker population has not been completed. Among those already screened, NIOSH has detected a group with urinary abnormalities that will require additional medical evaluation. Moreover, a 29-year old male, who is part of the cohort in the study, has been independently diagnosed as suffering from a papillary bladder tumor.<sup>28</sup> The occurrence of such a tumor in a young worker is unusual. These incomplete findings are not scientifically conclusive but they do raise cause for concern.

In summary, the MBOCA case suggests major inadequacies in the OMB review process. In this case, an important study, which had been endorsed by a research agency and reviewed and approved by a four-member peer review panel, was delayed for more than 6 months. In addition, it appears that the study might have been cancelled altogether were it not for agency concern and community and Congressional action.

Evaluating the OMB review, we see that a second scientific review by a single consultant selected by OMB was superimposed on a study that previously had been adequately peer reviewed. The OMB officials and their technical consultant appeared to lack basic familiarity with the occupational medicine and public health issues addressed by the study. This second OMB review added nothing to the quality of the scienfitic product; in fact, the removal of the nested case control study weakened the overall design. Further, the OMB review resulted in a six-month delay in the medical cancer screening of several hundred individuals.

## Epidemiologic Study of Ladder Fall Injuries

On June 27, 1984, NIOSH submitted its proposed epidemiological study of ladder fall injuries to OMB for approval. As explained by NIOSH in its supporting statement, the underlying purpose of the study was to test the hypothesis that epidemiological methods, which had been successfully applied to the study of disease, could be useful in the study of traumatic injuries.

Falls from ladders were chosen by NIOSH as an accident type to test the application of epidemiological methods since: (1) it is a persistent type of accident (accounting for 1.4% of all workers' compensation cases; (2) it often results in severe injury; and (3) NIOSH had targeted occupational falls as industry's number one safety problem.

The application of epidemiological methods as proposed by NIOSH would permit a rare comparison of those suffering traumatic injuries with others taking similar risks who do not suffer such injuries. To date, epidemiological methods have seldom been used in studying traumatic injuries and never used in analyzing ladder fall injuries.

In developing the study, NIOSH consulted with eighteen outside experts in the fields of safety, data collection, and epidemiology. In addition, NIOSH conducted a public meeting to discuss the concept of epidemiology applied to traumatic injury in general and the specific protocol developed by NIOSH for use in the study of ladder falls.

On September 26, 1984, OMB disapproved the study. In its explanation, OMB stated:

OSHA, the primary federal user of the data resulting from this collection, is in the process of revising existing regulations designed to reduce accidents from falls from ladders. Since OSHA has decided to pursue a regulatory solution to this problem, it is not necessary to undertake an epidemiological investigation at this time.<sup>29</sup>

OMB offered no response to NIOSH's explanation of the underlying purpose and utility of its proposed study.

On May 3, 1985, the Assistant Secretary for Management and Budget of the Department of Health and Human Services forwarded an appeal of OMB's decision from the Director of NIOSH. The appeal was accompanied by an endorsement by the Acting Assistant Secretary for Health and a memorandum of support for the NIOSH study from the Director of OSHA's Directorate of Standards Development.

The NIOSH appeal and the OSHA memorandum strongly rebutted OMB's assertion that the proposed study was not needed by OSHA. They explained that OSHA's current regulatory initiative to modify or revoke requirements of its ladder standards was in the earliest stages of development and that "OSHA needs as good a data base as it can obtain to make clear intelligent decisions on which standard's requirements should be proposed for revision and which ones should be proposed for revocation."<sup>30</sup> In addition, the NIOSH appeal emphasized that the ongoing OSHA rulemaking only applied to the construction industry and that the results of its study would be useful to OSHA in modifying its general industry and maritime regulations.

The OSHA memorandum also underscored the importance of the NIOSH study in voluntary safety efforts. It noted that the study "will also be very useful" to the various public and private programs concerned with ladder safety.

Finally, the appeal stressed the importance of the study as a model for other occupational safety research. The OSRA document noted that "[t]his study and the development of such a model is very important to OSHA and to the occupational safety field as a whole."<sup>31</sup>

On July 12, 1985, OMB rejected the appeal, reiterating its conclusion that the information collection was unnecessary. OMB's letter stated that: "... in the case of falls from ladders, we are not convinced that the study proposed is necessary for OSHA rulemaking, and therefore conclude that it has no practical utility."<sup>32</sup>

In this case, OMB has ignored the language of the Paperwork Reduction Act, which defines "practical utility" as the "ability of an agency to use information it collects, particularly the capability to process such information in a timely and useful manner." Here, NIOSH clearly demonstrated that the proposed information collection request would serve a variety of regulatory and non-regulatory purposes.

## <u>Health Risks of Information Processing</u>

NIOSH estimates that more than half the U.S. workforce is engaged in what psychologists term information processing tasks on the job. Information processing within this NIOSH study was defined as repetitive mental tasks (<u>i.e.</u>, looking up telephone numbers).

The health risk of ladder falls are easily evident to the lay reader and are fairly easily measured; the hazards of stress from repetitive tasks are less evident and have not been extensively evaluated. This proposed NIOSH study was intended to relate these types of tasks with measurements of physiologic changes (<u>i.e.</u>, heart rate) which may be associated with the onset of so-called stress-related diseases, such as heart disease.

During any research process, there must be a first step; the question initially has to be asked "is there a problem?" This study was designed to break new ground by evaluating the relationship between the stress of repetitive mental tasks and physiologic changes. Given the large population involved in such tasks, the establishment of such a relationship could have important public health implications. The research might lead to evaluations of the workplace setting that could decrease the incidence of stress-related disorders. The NIOSH study was favorably reviewed by all seven peer reviewers and the information collection request was submitted to OMB for approval in December 1984. On February 15, 1985, OMB disapproved the study. OMB's reason for the disapproval was that: "BHS had not provided sufficient evidence of existing health and safety problems."<sup>33</sup>

The purpose of the Paperwork Reduction Act has been turned on its head in this case. The Act was intended to avoid duplicative and unnecessary research. However, OMB could not reject the study on this basis; instead it rejected the proposed study on the grounds that HHS did not have sufficient evidence of existing health and safety problems. Consistent application of this sort of policy by OMB would eliminate research in any new areas of investigation.

# Centers for Disease Control Reproductive Outcome Survey

The purpose of this study by the CDC Birth Defects Division was to monitor the reproductive outcome of CDC employees and their spouses. The term "reproductive outcome" includes a wide variety of results affecting reproductive health, including sterility, spontaneous abortion, miscarriage, stillbirth, and congenital defects. The initial indication of the need for the study was a cluster of abnormal birth outcomes occurring among some groups of CDC laboratory workers. Subsequent CDC review of their lab exposures indicated the presence of substances that are either mutagenic, terstogenic, or embryotoxic.

As noted in the review of the VDT study, the epidemiology of reproductive studies is usually controversial. The design of this study was therefore significant in two important respects. First, the population to be studied consisted exclusively of CDC employees, expected to have a high awareness of medical issues because of the nature of their employment. In view of this fact, it was expected that there would be a high participation rate. Second, since the study involved a population that was aware of epidemiologic research issues, NIOSH expected that participants also would remain involved in the study over time; thus, a strong prospective design was possible.

A strong prospective reproductive study with a high participation rate had far-reaching significance. Such a study would have provided an invaluable model of a surveillance program and important baseline data on rates of spontaneous abortion and other fertility variables. Such data also would have provided the foundation needed for other studies on reproductive issues. It should be noted that baseline data from this study would have been very useful in addressing some of the questions that were raised by OMB in the VDT study.

Peer review of this CDC study was extensive. Because of

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'the unique nature of the study, reviewers from-all sections of CDC participated in analyzing the study design.

The proposal was submitted to OMB on June 16, 1985. On August 27, 1985, CDC's information collection request was denied by OMB on the grounds that the study would "establish a large scale surveillance system for a problem that apparently does not exist nor has ever been proven to exist. In the absence of clear evidence that a health problem exists or is likely to exist, OMB considers the proposed surveillance system to be unnecessarily burdensome, intrusive and costly."<sup>34</sup> The proposal was resubmitted to OMB on March 3, 1986 and disapproved again on June 27, 1986.

Once again, it appears that OMB officials have misconstrued the intent of the Paperwork Reduction Act. Surely, if CDC employees are seeking answers to health matters of concern, their attempts to resolve such concerns should not be blocked on the grounds that they are unnecessarily burdensome and intrusive. If CDC has sufficient funds in its budget available to conduct the proposed study and the information to be derived would be valuable to the agency, the Paperwork Reduction Act does not appear to vest OIRA with authority to second-guess the agency based on cost considerations. Such action would appear to constitute the very type of substantive interference with the public health activities of CDC prohibited by the Act.

#### FOOTNOTES

- 1. 44 U.S.C. § 3502 (1980).
- 2. 44 U.S.C. § 3508 (1980).
- 3. 5 C.F.R. § 1320.4 (1986).
- 4. 5 C.F.R. § 1320.11 (1986).
- 5. S. REP. NO. 930, 96th Cong., 2d Sess. (1980).
- 6. 44 U.S.C. § 3518 (1980).
- 7. 126 CONG. REC. 30192 (1980).
- 8. S. REP. NO. 930, 96th Cong., 2d Sess. (1980).
- Clark, William C., and Majone, G., "The Critical Appraisal of Scientific Inquiries with Policy Implications," <u>Science, Technology and Human Values</u>, Vol. 10, Issue 3 (Summer, 1985).
- 10. Dioxin-Document 6 (all documents listed hereinafter are summarized in the bibliography and are on file with the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, U.S. House of Representatives).
- 11. Dioxin-Document 2.
- 12. Dioxin-Document 5.
- 13. Dioxin-Document 9.
- 14. Dioxin-Document 10.
- 15. Dioxin-Document 9.
- 16. Dioxin-Document 16.
- 17. CDC Summary-Document 2.
- 18. VDTs-Document 2.
- 19. VDTs-Document 4.
- 20. VDTs-Document 5.
- 21. VDTs-Document 11.
- 22. VDTs-Document 10.
- 23. VDTs-Document 12.
- 24. CDC Summary-Document 2.
- 25. MBOCA-Document 3.
- 26. MBOCA-Document 5.
- 20. MBOCA-Document J.
- 27. MBOCA-Document 6.
- 28. MBOCA-Document 9.
- 29. Ladder Falls-Document 6.
- 30. Ladder Falls-Document 6.
- 31. Ladder Falls-Document 6.
- 32. Ladder Falls-Document 7.
- 33. Information Processing-Document 3.
- 34. Reproductive Outcomes-Document 5.

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BIBLIOGRAPHY AND LIST OF KEY DOCUMENTS REVIEWED

#### OME Review Process

- 1. 44 U.S.C. § 3501 et seq. (1980).
- 2. 5 C.F.R. § 1320 (1986).
- 3. S. REP. No. 930, 96th Cong., 2d Sess. (1980).

#### <u>Peer Review Process</u>

- Clark, William C., and Majone, G., "The Critical Appraisal of Scientific Inquiries with Policy Implications," <u>Science, Technology and Human Values</u>, Vol. 10, Issue 3 (Summer, 1985).
- Soskolne, Colin L., "Epidemiological Research, Interest Groups and the Review Process," <u>Journal of Public Health</u> <u>Policy</u>, June 1985.

<u>Key Document Requests by the Subcommittee on Oversight and</u> <u>Investigations for CDC Information</u>

- Letter of request from John D. Dingell, Chairman, Subcommittee on Oversight and Investigations, to Dr. James D. Mason, Director, Centers for Disease Control (March 7, 1986).
- Letter of request from John D. Dingell, Chairman, Subcommittee on Oversight and Investigations, to Donald J. Millar, M.D., Director, National Institute for Occupational Safety and Health (March 25, 1986).

CDC Summary Documents

- Description of submissions by the Centers for Disease Control to the Office of Management and Budget under the Paperwork Reduction Act, January 1, 1984 to March, 1986.
- Letter from Donald J. Millar, M.D., Director, National Institute for Occupational Safety and Health, to John D. Dingell, Chairman, Subcommittee on Oversight and Investigations, regarding increased costs resulting from OMB review (September 16, 1986).

#### Key Documents Related to Dioxin Study

- 1.\* Chronology of events for Dioxin Morbidity and Reproductive Study.
- 2.\*\* Study protocol and peer review documents, including letter from Brian MacMahon, M.D., regarding peer review (December 28, 1984).
- 3.\* Supporting statement for application for information collection for Dioxin Study.
- 4.\* NIOSH answers to OMB questions for information (October 15, 1985).
- 5.\* OMB notice of refusal of information collection for Dioxin Study (October 17, 1985).

د کرنے.\* Request for appeal of proposal for Dioxin Morbidity and Reproductive Study and supporting documents (November 26, 1985), including:

- Minutes of AOWG Science Panel from September 25, 1984.
- Letter of concern from New Jersey Department of Health.
- Response to OMB's request for statistical power calculations.
- 7." Letter from Robert P. Bedell, Deputy Administrator, OMB's Office of Information and Regulatory Affairs, detailing conditions for approval of Dioxin Study (January 7, 1986).
- 8.\* OMB notification of conditional approval of Dioxin Study (March 6, 1986).
- 9.\*\* Notes of meetings, discussions, and telephone conversations related to OMB review process on Dioxin Study.
- 10. S. REP. No. 210, 99th Cong., 1st Sess. 32 (1985).

Key Documents Related to VDT Study

- 1." Chronology of events in review process of VDT Study.
- 2.\*\* Proposal for Video Display Terminal Operators Study, drafts 1 and 2 and peer review documents.
- 3.\* Supporting statement for application for information collection for VDT Study (September 30, 1985).
- 4.\* Letter from Michael R. Taylor, Esq., King & Spalding, attorneys for Bell South Corporation, to Faye Iudicello, Office of Management and Budget (September 12, 1985), including report of Brian MacMahon, M.D., and Sally Zierler, Ph.D., reviewing protocol for the VDT Study.
- 5.\* OMB notice of refusal of information collection for VDT Study (December 13, 1985).
- 6.\* Supporting ststements and documents for appeal of OMB decision on the VDT Study (March, 1986).
- 7.\* Project Officer's summary of telephone conversations related to peer review process.
- 8.\* Letter to Mark Winer, Statistical Policy Division, Office of Management and Budget, detailing NIOSH responses to report by MacMahon and Zierler (January 22, 1986).
- "OMB Approves Revised VDT Pregnancy Study," <u>Eve on</u> <u>Paperwork</u>, OMB Watch, Volume 2, No. 7, July 25, 1986, p. 19.
- 10. "Review of Questions Deleted from a NIOSH Study of Video Display Terminal Users," staff paper prepared by the Special Projects Office of the Health Program, Office of Technology Assessment, U.S. Congress, August, 1986, p. 8.

- - 12. Letter from William J. Butler, Ph.D., Assistant Professor, University of Michigan School of Public Health, to Ted Weiss, Chairman, Subcommittee on Intergovernmental Relations and Human Resources, Bouse Committee on Government Operations, July 16, 1986.

## Key Documents Related to MBOCA Study

- 1.\* Chronology of events in review process of MBOCA Study. 2.\*\* Proposal for study of MBOCA and peer review documents.
- 2.\*\* Proposal for study of MBOCA and peer review documents.
  3.\* Supporting statement for application for information collection for NBOCA Study (February 11, 1985).
- 4.\* Response of Elizabeth Ward, NIOSH Project Officer, to the OMB statistical reviewer (April 12, 1985).
- 5.\* OMB notice of disapproval of information collection on MBOCA (May 8, 1985).
- 6.\* Notes of teleconference with Dr. Joseph Guestworth, Ph.D. (June 14, 1985).
- 7.\* Addendum to Paperwork Reduction Act packet on MBOCA detailing request of Michigan Health Department for assistance (August 9, 1985).
- 8.\* Notice of OMB approval of MBOCA Study with conditions (August 23, 1985).

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9. Letter from Donald J. Millar, M.D., Director, National Institute for Occupational Safety and Health, to John Pendergrass, Assistant Secretary for Occupational Safety and Health, U.S. Department of Labor (August 7, 1986).

# Key Documents Related to Ladder Falls Study

- 1.\* Chronology of events in OMB review process related to Ladder Falls Study.
- 2.\*\* Proposal for study of ladder falls and peer review documents.
- 3.\* Supporting statement for application for information collection for Ladder Falls Study (June 27, 1984).
- 4.\* NIOSH response to OMB reviewers telephone questions (August 16, 1984 and August 22, 1984).
- 5.\* OMB notice of disapproval of information collection for Ladder Falls Study (September 26, 1984).
- 6.\* Supporting statement and documents for appeal of OMB decision on the Ladder Falls Study (May 3, 1985), including supporting memorandum from OSHA.
- 7.\* Notice of OMB disapproval of appeal on Ladder Falls Study (July 12, 1985).

# <u>Key Documents Related to Hazards of Information Collection</u> <u>Study</u>

1.\* Chronology of events in OMB review of Information Processing Study.

- ----2.\*\*\* Proposal for study of Hazards of Informaton Processing and peer review documents.
  - 3.\* Notice of OMB disapproval of information collection on Hazards of Information Processing (February 26, 1985).

<u>Key Documents Related to Study of Centers for Disease Control</u> <u>Reproductive Outcomes</u>

- 1.\* Chronology of events in OMB Review process related to CDC Reproductive Outcomes Study.
- 2.\*\*\* Proposal for CDC Reproductive Outcomes Study and peer review documents.
- 3.\* Supporting statement for application for informaton collection for CDC Reproductive Outcomes Study (June 13, 1985).
- 4.\* CDC responses to OMB questions (July 16, 1985 and July 19, 1985).
- 5.\* OMB Notice of Disapproval of Information Collection for CDC Reproductive Outcomes Study (August 27, 1985).
- 6.\* Supporting statement and documents for appeal of OME decision on CDC Reproductive Outcomes Study (November 4, 1985).
- "ONB Kills Miscarriage Study of CDC Workers," <u>Eve on</u> <u>Paperwork</u>, OMB Watch, July 25, 1986, p. 8.
- \* Document obtained in response to letter from John D. Dingell, Chairman, Subcommittee on Oversight and Investigations, to Dr. James D. Mason, Director, Centers for Disease Control (March 7, 1985).
- \*\* Document obtained in response to letter from John D. Dingell, Chairman, Subcommittee on Oversight and Investigations, to Donald J. Millar, M.D., Director, National Institute for Occupational Safety and Health (March 25, 1986).

ATTACHMENT 2

OMB NO.: 0920-0183 EXPIRES 12/31/87 NIOSH OCCUPATIONAL HEALTH STUDY 3/24/87 1=NO 2=YES 7=NOT APPLICABLE 8=DON'T KNOW 9=REFUSED

## NIOSH OCCUPATIONAL HEALTH STUDY

# MEDICAL HISTORY QUESTIONNAIRE

PARTICIPANT	ID #
PARTICIPANT	NAME:
PARTICIPANT	AGE:
DATE:	
TIME STARTED	D:
INTERVIEWER	ID #

1		OMB NO.: (	0920-0183 EXPIRE	S 12/31/87
		NIOSH	OCCUPATIONAL HE	ALTH STUDY
				3/24/87
1=NO	2=YES	7=NOT APPLICABLE	8=DON'T KNOW	9=REFUSED

# Medical History Questionnaire:

Hello, my name is \_\_\_\_\_. For the next one hour or so, I am going to be asking you some questions about medical conditions you may have had at some time in your life. The first section (A) concerns any hospitalizations that you may have had since your interview with RTI.

•	1	
		OMB NO.: 0920-0183 EXFIRES 12/31/87 NIOSH OCCUPATIONAL HEALTH STUDY 3/24/87
	1=NO	2=YES 7=NOT APPLICABLE 8=DON'T KNOW 9=REFUSED
		SECTION A
	1.	Who is your primary physician? 111111111111111111
		Address:
		City/State/Zip:////////
	2.	Have you been hospitalized overnight or longer since your interview with RTI?
		IF NO: GO TO SECTION B IF YES:
	3.	How many times were you hospitalized?
		ITALIZATION 01 ting with the first hospitalization: What month (and year) were you hospitalized? [_[_] 19[_]_[
	5.	Why were you hospitalized? (Or for what condition were you hospitalized?) Reason:
	6.	What was the name of the doctor who treated you? Doctor
	7.	What was the name and address of the hospital where you were treated? Hospital Name:
		ITALIZATION 02
•	8.	What month (and year) were you hospitalized?
	9.	Why were you hospitalized? (Or for what condition were you hospitalized?) Reason
	10.	What was the name of the doctor who treated you? Doctor
	11.	What was the name and address of the hospital where you were treated? Hospital Name:HIIIIIIIIIIIIIIIIIIIIIIIIIIIIIII

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HOSPITALIZATION 03 12. What month (and year) were you hospitalized?

19|\_|\_|

## OMB ND.: 0920-0183 EXPIRES 12/31/87 NIOSH OCCUPATIONAL HEALTH STUDY 3/24/87 1=NO 2=YES 7=NOT APPLICABLE 8=DON'T KNOW 9=REFUSED

1

## SECTION A

- 13. Why were you hospitalized? (Or for what condition were you hospitalized?) Reason \_\_\_\_\_\_

		OMB NO.:	0920-0183 EXPIRE	S 12/31/87
		NIOSH	OCCUPATIONAL HE	ALTH STUDY
				3/24/87
1=NO	2=YES	7=NOT APPLICABLE	8=DON'T KNOW	9=REFUSED

## SECTION B

Section B concerns medical conditions you may have had in the recent past or anytime in your life. Some of the conditions that I am going to ask you about are rare and you may not have heard of them, unless a doctor has specifically mentioned the condition to you.

Interviewer: Ask question "A" for every condition. Ask "B-E1" if answer to "A" is yes. Ask D2 & E2 only for questions with \*\*. <u>Ask indented subset questions if previous question is positive</u> (indentation indicates a skip pattern).

#### OMB ND.: 0920-0183 EXPIRES 12/31/87 NIOSH OCCUPATIONAL HEALTH STUDY 3/24/87 2=YES 7=NOT APPLICABLE 8=DON'T KNOW 9=REFUSED 1=NOSECTION B A В С נמ E1 Did a doctor Have you had Have you ever Have you had Are you currently \_ in the past \_\_ in the last ever tell you being treated by had \_? two weeks? six months? that you had a doctor for \_ ? \_? If yes, what year? What was his What was his name? name? CARDIOVASCULAR A heart attack \*\*1. \*\*2. Angina Ш 3. Arrhythmia (palpations or irregular heart beat that cause you problems) Hypertension (high blood pressure) 11 4. Other heart condition 5. 6. Do you remember what kind Ш of heart disease it was? 6a. Describe: \_\_\_\_\_ PULMONARY -7. Asthma L LI 11 Ы Ш Chronic bronchitis 8. LI Ш L 11 9. Emphysema LI E.T Pneumonia L 10. ப் 10a. How many times have you had pneumonia diagnosed by a doctor?

1.1.4

OMB NO.: 0920-0183 EXPIRES 12/31/87 NIOSH OCCUPATIONAL HEALTH STUDY 3/24/87

1=NO 2=YES 7=NOT APPLICABLE 8=DON'T KNOW 9=REFUSED

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## SECTION B

Have had	_?in	B you had the past weeks?	C Have you ha in the l six months?	ast	Did a ever t that y _? If what y D2 What w name?	ell you ou had yes, ear?	u bei a da	ng treat octor fo E2 : was hi	or _?
11.	Tuberculosis				Ц	Ц		Ц	
12.	Did you ever have skin test?	e a positive	<b>T</b> B	Ц					
	12a. When?			19 <u> </u>	L				
13.	Work related lung lungs, silicosis,			Ц	Ш	Ц		Ц	
14.	Asbestosis			Ц	Ш	Ш			
15.	Other lung condit	ion?		Ц	Ц	٠		Ц	
	15a. Do you remen condition it		pe of lung	Ц					
	IF YES: Describe	┉╷╷╷╷╷╷		<u> </u>	1.1.1.1				
16.	Have you ever had x-ray?	l an abnorma	l chest	L					
	16a. When did you chest x-rayi		abnormal	19_1	1				
GAST	ROINTESTINAL								
17.	Gall bladder dise	ase or prob	lems	Ц	Ц	<b>L</b>		Ц	
	17a. Have you had your gall bl		remove						
18.	Ulcerative coliti	is		Ц	Ц	L		Ц	
19.	Crohn's disease o	or Regional	Enteritis	Ц	L	Ц	LLL	Ц	
20.	Irritable bowel of	or spastic c	colon	Ц	Ц	L		ш	

OMB NO.: 0920-0183 EXPIRES 12/31/87 NIOSH OCCUPATIONAL HEALTH STUDY 3/24/87 1=NO 2=YES 7=NOT APPLICABLE 8=DON'T KNOW 9=REFUSED

## SECTION B

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Have had	A you ever _?	B Have you had in the past two weeks?	C Have you had in the last six months?	Dl Did a doctor ever tell you that you had _? If yes, what year? D2 What was his name?	El Are you currently being treated by a doctor for? E2 What was his name?
**21.	Yellow jaun (yellow ski		山 D2_ E2_		
**22.	Hepatitis		L.) D2_ B2_		
	1. Ser 2. Inf 3. Oth 4. Chr	type of hepatitis fum hepatitis or H fectious hepatitis her hepatitis conic hepatitis abination, please	3 <u>             </u> 5 or A		<u>               </u>
**23.	Cirrhosis c (scarring c	of the liver of the liver)	니 D2_ B2_		
**24.	Enlarged li	iver	D2_		
**25.	Fatty live	r	_		┶┺┹╴┢┯┇ ╅╼┹╼╄╌┖╼┖╺┠╺┠╺┠╺┠ ┖╺┠╺┠╺┠╺┠╺┠╺┠╺┠╺┠

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OMB NO.: 0920-0183 EXPIRES 12/31/87 NIOSH OCCUPATIONAL HEALTH STUDY 3/24/87 2=YES 7=NOT APPLICABLE 8=DON'T KNOW 9=REFUSED

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## SECTION B

Have had	-	B Have you had in the past two weeks?	C Have you had in the la six months?	ast	ever t that y _? If what y	vou had : yes,	u	being a doc	El treated tor for E2 was his	d by _?
**26.		ase other than or cirrhosis?		Ц	Ц	Ц	Ц	11	Ц	
				D2⊥	1.1.1			L <u>J I.</u>	<u>1.1.1.1</u>	
	26a. Tell n	ne what kind of li	ver	E2	111		11		<u>1      </u>	
		se it was [] []			111					
**27.	Porphyria	(PCT)		Ц		1-1	LL	11	L	
				D2⊥			11	LL.		
				₽2_L	111		<u> </u>			
28.	Ulcer disea	ase (stomach or du	odenal)	Ц	Ц	Ц	Ц	11	Ц	
<del>29</del> .	Pancreatit	is		Ц	Ц	L				
30.	Gastritis			L		Ц	L			
31.	Hiatal her	nia		Ц	. <b>L</b>	Ц	Ц	L.	Ц	-
32.	Diverticul	itis		Ц	LJ	L		<u> </u>	L_1	
33.	Appendicit	is			ш		Ц		Ц	
	33a. Was yo	our appendix remov	ved?	Ц						
34.	Any other	stomach problems?		Ш	Ц	Ц	L		Ц	
		ou tell me what k: em it was? <mark>[]]</mark>	ind of stomac	h 1_1_	111			<b></b> ].		
GEN	TOURINARY M	ales Only 35-39.	Skip to 40 i	f fem	ale.					
**35.		disease (scarring of the penis)	g of	Ц	Ц	Ц	1_1	11	Ш	
		or the bents,		D2	111	1.1.1	11	ш	1111	<u> </u>
				E2_1	1.1.1		11	111		1 [ ]

## OMB NO.: 0920-0183 EXPIRES 12/31/87 NIOSH OCCUPATIONAL HEALTH STUDY 3/24/87 1=NO 2=YES 7=NOT APPLICABLE 8=DON'T KNOW 9=REFUSED

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## SECTION B

Have had	A you ever _?	B Have you had in the past two weeks?	C Have you had in the las six months?		Did a c ever to that yo _? If what yo What wa name?	ell you bu had yes, ear? D2	1	being	tre tor E2 was	-
36.	Prostate gla	and enlargement	Ĺ	┛	Ц	Ц	Ц	L	Ц	
37.	Prostatitis		I	L	ப	Ц	Ц		Ц	
38.	Epididymiti	s	1	1	Ц	L	LL		Ц	
39.	Any problem	s with your breas	its?		Ц	Ц	Ц	11	Ц	
40.	Gonorrhea		i		L	ш	Ц		Ц	
41.	Syphilis		1	1	Ш	ш	LL	L.	Ц	
42.	Genital her	pes	1	<b>.</b> _	Ш	Ц	Ц	L	Ц	
43.	Kidney infe	ction	1	_	Ц	Ц	Ц	11	Ц	
44.	Kidney x-ra	y (intravenous py	velogram) 🛔	لـ	Ц	Ц	Ц		Ц	
	44a. When d	lið you have the p	yelogram? i		1					
	44b. Why di	d you have this r	procedure? 1			<u>)                                    </u>	11			
45.	Urinary inf	ection	1							
	45a. Urethr	itis	i	1	Ц	Ц	Ц	11	Ц	
	450. Cystit	is	1		Ц	L	Ц	<u></u>	Ц	
	45c. Pyelon	ephritis	1	1	Ц	Ц	Ц		L	
46.	Kidney ston	nes	I	_	Ц	Ц	Ц		Ы	
47.	Other urina	ry tract problem	1	ا	Ц	L	Ц	11	Ц	
		ou tell me what ty Ty tract problem i					L_L	<u>I I I</u>	11	
48.	Protein in	urine	l		Ц	ப	Ц		Ц	

OMB ND.: 0920-0183 EXPIRES 12/31/87 NIOSH OCCUPATIONAL HEALTH STUDY 3/24/87 8=DON'T KNOW 7=NOT APPLICABLE 9=REFUSED 1=ND 2≂YES SECTION B B С ומ A E1 Have you ever Have you had Have you had Did a doctor Are you currently in the last ever tell you had \_? in the past being treated by six months? two weeks? that you had a doctor for \_? \_? If yes, what year? E2 D2 What was his What was his name? name? GENITOURINARY Females Only 49-58. Male, skip to 59 49. How old were you when you had your | years first period? 11 50. Have you gone through menopause? 50a. At what age did you go through **\_\_\_\_**lyears menopause? 51. Have you ever been pregnant? L 52. Have you had any pelvic surgery? 11 52a. For what problem? 1 53. When was your last Pap smear? 11 54. Have you ever had an abnormal Pap smear 54a. In what year did this happen? 1.1.1.1.1 54b. What was the reason for the **[\_\_**] abnormal reading? L 55. An ovarian cyst 56. Endometriosis Ł Ш ப 57. Problems with your breasts? Ш Ш 57a. Can you tell me what the problem was? 58. A mammogram 58a. How many times? 58b. When was the last time you

:

had a mammogram?

		OMB			PIRES 12/31/87 L HEALTH STUDY	
l=NO	2=YES	7=NOT APPLIC	BLE 8=00	N'T K	3/24/87 NOW 9=REFUSED	
			SECTION E	3		
Have had	A you ever _?	B Have you had in the past two weeks?	C Have you had _ in the la six months?	ast	Dl Did a doctor ever tell you that you had ? If yes, what year? D2	El Are you currently being treated by a doctor for _? E2
	1. Nor 2. Abn 3. Oth		y LLJ1		What was his name?	What was his name?
		ORD ALL TREATMENT				<u>s 59-70.</u>
59.	SKIN CANCER IF NO OR DK IF YES:	: GO TO QUESTION	64			
**60.	Squamous ce	211		Ц		
				D2_1	╶┸╷╃╷╀╷╃╍╇┈╿╶ <u>╄</u> ╺╃	
				₽2_	1111111	
**61.	Basal cell			Ц		
				D2_1		
				E2_1		
**62.	Malignant m	nelanoma				
						<u></u>
**63.	Other type	of skin cancer				
				E2		
	63a Specif	Ey <u>1 1 1 1 1 1 1 1</u>			<sub>┶</sub> ╺┺╺┺╺┻╍┹╍┹┉╝ <sub>╴</sub> ┹	
**64-	-	skin lesions	┶┶┶┍┸╌┸╌┹┉┲╄			┶╼┷╼┶╼┙ ┨╴┨╶┨ <mark>╴</mark> ┨
	-	fy <u>                 </u>				
					·····	

		OMP.	NO.: 0920-0	183 EXP	TRES 12/31/8	7
-		C.D			HEALTH STUE 3/24/8	Y
1=NO	2=YES	7=NOT APPLIC	ABLE 8=DO	n't kno		
Have had	A you ever ?	B Have you had in the past two weeks?	SECTION C Have you ha in the 1 six months?	d D ast e t	Dl bid a doctor ever tell you that you had _? If yes, that year? D2 That was his hame?	El Are you currently being treated by a doctor for? E2 What was his name?
				D2 🔟		
				82 🔟		
**65.	Lymphoma			Ц	ы ц	
				D2		
				₿2 <u> </u> _		
**66.	Hodgkin's d	isease		Ц		
				D2		
				E2		
**67.	Leukemia			Ц		
				D2		
				E2_ _		
**68.	Liver cance	r		Ц		
				D2_L_		
				E2		
**69.	Sarcoma			ш	ш Ш	
				D2_		
				E2_]_		
70.	Were you ev you had any	ver told by a doc y other kind of c	tor that ancer?	Ц		

IF NO TO ANY OF ABOVE (59-70): SKIP TO 81 IF YES, GO TO 71.

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OMB ND.: 0920-0183 EXPIRES 12/31/87 NIOSH OOCUPATIONAL HEALTH STUDY 3/24/87 1=NO 2=YES 7=NOT APPLICABLE 8=DON'T KNOW 9=REFUSED

## SECTION B

A Bave you ever had _?	B Bave you had in the past two weeks?	C Have you had in the last six months?	Dl Did a doctor ever tell you that you had ? If yes, what year?	El Are you currently being treated by a doctor for?
			D2	<u>E2</u>
			What was his name?	What was his name?

71. What kind of cancer was it?

, **`•** ,

INTERVIEWER: HAND RESPONDENT CARD #1A OR NOTE CHANGE IN OUESTION ORDER.	1B, DEPENDING ON SEX.
**Bladder cancer - 01	$\begin{array}{cccccccccccccccccccccccccccccccccccc$
	<b>82 </b>
**Bone cancer - 02	L.I. L.I. L.I. L.I. L.I. D2 <u>                                    </u>
	12 <u>11111111111111111111111111111111111</u>
**Bowel/colon cancer - 03	L L L L L L L L L D2 L L L L L L L L L L L L L L L L L L L
	<u>B2                                      </u>
**Breast cancer - 04	$\begin{array}{cccccccccccccccccccccccccccccccccccc$
	E2
**Cervical cancer - 05	LI LI LI LI LI LI D2 <u>IIIIIIIIII</u>
	E2
**Lung cancer - 06	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
	B2

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# SECTION B

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 $\sim 10$ 

A Have you ever had?	B Have you had in the past two weeks?	C Have you had in the last six months?	Dl Did a doctor ever tell you that you had _? If yes, what year?	El Are you currently being treated by a doctor for?
			D2 What was his name?	E2 What was his name?
**Pancreatic cance	er - 07	∟i D2_		
		E2_		
**Prostate cancer	- 08	⊥⊥ ₽2_		
		E2_	<u> </u>	1 1 1 1 1 1 1 1 1 1
**Rectal cancer -	09	∐ D2_		
		E2_		<u></u>
**Soft tissue sard	coma - 10			
		E2_		
**Stomach cancer ·	- 11	L] D2_		
		E2_	<u>, , , , , , , , , , , , , , , , , , , </u>	
**Throat cancer ()	laryngeal cancer)	- 12		
		E2_		
**Testicular cance	er - 13			
		E2_		

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## SECTION B

A B C Have you ever Have you had Have you had had _? in the past in the two weeks? six months?	? that you had a doctor for _? _? If yes, what year?
	D2 E2 What was his What was his name? name?
**Endometrial/uterine - 14	LJ LJ LJ L <u>↓</u> ↓↓ LJ ₽2↓↓↓↓↓↓↓↓↓↓↓↓↓
	E2
**Oral or mouth cancer - 15	L L L L L L L L L D2_1_1_1_L L L L L L L L L L L L L L L L L
	B2
72. Other cancer - 16	<b>└</b> ┛
lf yes:	E2 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
Specify:	
INTERVIEWER: TREATMENTS ARE TO BE RECORDED	IN OUESTIONS 73-80.1
CANCER THERAPY	
73. Did you have surgery for your cancer?	<u>ш</u>
73a. What year did this surgery occur?	
73b. What did the doctors do during the surgery? (e.g., remove lung, lymph nodes, lump)	
74. During the past <u>6 months</u> , have	L

74. During the past <u>6 months</u>, have you received any type of therapy, other than surgery, for your cancer?

> IF ND: GO TO QUESTION 81 IF YES:

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1=N0

OMB ND.: 0920-0183 EXPIRES 12/31/87 NIOSH OCCUPATIONAL HEALTH STUDY 3/24/87 2=YES 7=NOT APPLICABLE 8=DON'T KNOW 9=REFUSED

#### SECTION B

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l=NO

	A you ever	B Have you had in the past two weeks?	C Have you had in the last six months?	Dl Did a doctor ever tell you that you had _? If yes, what year? D2 What was his name?	being treated by
75.	1. Radiatic 2. Chemothe 3. Combinat 4. Other ty LILL IF 1: GO 1 IF 2: GO 1 IF 3: GO 1		and chemotherar	у <u>1     1   1   1   1  </u>	<b>11</b> .
		-			
RADI	ATION THERAP	<u>, , , , , , , , , , , , , , , , , , , </u>			
76.	What month radiation t	and year did you therapy?			
77.		and year did you tion therapy?		<u>  /   </u> 4 M Y Y	
		DIATION THERAPY: TION THERAPY: GO			
	<u>OTHERAPy</u> What month your chemot	and year did you therapy?		// M M Y Y	
79.	What month your chemot	and year did you therapy?		<u>.   /      </u> K M Y Y	
80.		at drugs were/are for this chemothe			
ALLE	RGIES				
81.	watery eyes from substa	type allergies wit s and/or sinus cor ances in the air, hair, for at least	gestion like pollen,		

for two or more consecutive years?

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## SECTION B

Have had	A you ever _?	B Have you had in the past two weeks?	C Have you had in the la six months?		Did a c ever to that yo _? If what yo What wa name?	ell you ou had yes, ear? D2	u be a Wh	El e you currently ing treated by doctor for _? E2 wat was his me?
82.	cough, whee from substat cat hair or	ung allergies wit zing, or difficul nces in the air, dust, for at lea re consecutive ye	ty breathing like pollen, st 1 month	<b>L1</b>	Ц	Ц		J L.J
83.		in the creases o or behind the kne		Ц	Ц	L	<u>Ц</u> .	
84.		, skin swelling o m foods or drugs?		Ц	<b>L_1</b>	Ц	ш	
85.		, skin swelling o m anything else?	r	Ц	Ц	Ц	ш	j Lj
		e what gives you , skin swelling o						
86.	or psoriasi	r have skin rashe s as a child othe iseases (i.e., me icken pox)?	r than	IJ	Ĺ	L	┠╌┹╌┹╌	-l Ll
BLOC	D							
87.	Anemia (low	red blood cell o	count)	Ц	<b>L_1</b>	LJ		
88.	Low white b	lood cell count		ы	Ш	Ц		
89.	Blood clott	ing or bleeding p	oroblem	Ц	Ц	Ц		
90.	Low iron in	your blood		Ц	Ц			
<b>9</b> 1.	Other probl	ems with your blo	xod?	Ц	Ш	Ц		
	91a. Tell m	e what the proble	an was					

•	OMB NO.: 0920-0183 EXPIRES 12/31/87 NIOSH OCCUPATIONAL HEALTH STUDY 3/24/87									
1=NO	2=YES 7=NOT APPLICABLE 8	B=DON'T F	NOW 9	=REFUSE						
Have had	A B C you ever Have you had Have you	had e last	ever t that y _? If what y	Dl doctor cell you you had year? D2 was his						
	92a. Did you have a bad reaction to t blood transfusion?	his 📙								
NERM	OUS_SYSTEM									
93.	Epilepsy (seizure, convulsions or fit	s) 📙	Ц	L						
94.	Stroke	Ц	Ц							
95.	Parkinson's disease	Ц	Ц							
**96.	Nervous breakdown	∐ D2_∐								
		E2	ப்							
-	96a. How many times have you had a nervous breakdown?		times							
97.	Severe headaches (must lie down and take medication before headache goes away)	L	Ц	Ц	┠╼┹╼┹╶┛╴┠╼┛					
	IF NO: GO TO QUESTION 100									
<b>9</b> 8.	Are your headaches migraine headaches		Ц	Ц						
	98a. Do you take medication for your migraines?	Ц								
	985. What medication have you taken?									
	98c. How long have you taken this medication?		111	Ю, <b>₩,М</b> ,У	0					
99.	Can you tell me what your headaches are from?	Ц								
	99a. Specify									

-			OMB	ND.: 0920 NIOSH CCC					
1=ND		2=YES	7=NOT APPLIC		DON'T K		3/24/1 =REFUS	87	
1-10		▙▔▖▁▖▖▃	<i>,-101 1111</i> 0	SECTIO					
<b>P</b>	A		B Have you had	С		<b>n</b> /2 .	DÌ		El
Rave had	had _? in the past in th		Have you in the six month	last	doctor ell you ou had yes, ear? D2	u l	Are you currently being treated by a doctor for _? E2		
						What w name?	as his		What was his name?
100.	Head : consc:	injury iousne:	with loss of ss (blacked out)		Ц	Ц	Ц	L	
	100a.		ou have any long is from this head		L.J				
	100b.	Expla: you h	in to me what eff ad	fects					
101.	Multi	ple sc	lerosis			Ц	Ц	LL	
**102.			th the nerves in et (such as perig		Ц		Ц		
	neuro	pathy,	or numbness or hands or feet)	AVELAT	D2				
	CHIGT.	ша ш	Tailds of Teet/		E2_ _		111		
	102a.		et	ar hands,	L				
	10 <b>2</b> 5.		he doctor tell ye d this problem?	ou what	ш				
	102c.	Speci	fy						
103.	in yo	ur han	ems with the ner ds, feet, back as of your body?		Ц	Ц	Ц	L	11 11
	103a.	Can y it wa	ou describe what s?	problem				<u>   </u>	
EARS	_EYES	, NOSE							
104.	Are y	ou con	sidered legally	blind?	Ц	Ц	Ц	LJ.	

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OMB NO.: 0920-0183 EXPIRES 12/31/87 NIOSH OCCUPATIONAL HEALTH STUDY 3/24/87 7=NOT APPLICABLE 8=DON'T KNOW 9=REFUSED

# SECTION B

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1=NO

2=YES

Bave had	A you ever _?	B Have you had in the past two weeks?	you had Have you h the pastin the		last ever tell you			El Are you currently being treated by a doctor for _? E2			
					What wa name?			What name?	was his		
105.	Cataracts			ш	Ц	Ц	LL	ل. ا.			
106.	Severe eye : or sties	infection, conjunt	tivitis,	المسا	Ц	L	LL	1.1	L		
107.	Blepharitis eyelids)	(eye infection of	f the	Ц	Ц	Ц	Ц	11	<b>L_1</b>		
108.	Hearing los	S		Ц	Ц	Ц	11	11	LJ		
109.	Sinus proble	ens		L		LI	L		Ц		
110.	More than o	ne middle ear infe	ection	L	L	L	Ц	ш	Ц		
111.	Perforated	eardrum		Ц	Ц	L	Ц				
112.	Vertigo (la	byrinthitis)		Ц	Ц	Ц	Ц	Ц	Ц		
113.		s due to foreign mical burns or idents)		Ц	<b>L</b> .	Ц	LL	11	1_1		
114.	Other proble eye, ear, of	ems with your r nose		ப		<b>L_1</b>	LL	<b></b>			
		ou tell me what t ems were?	he		<u>       </u> 						
MUSC	ULOSKELETAL										
115.	Rheumatoid	arthritis		Ц	Ц	Ц	LL		Ц		
116.	Osteoarthri	tis or degenerativ	ve arthrit:	is 📙	Ц	Ц	Ц	11			
117.	Other arthr	itis		Ц	Ш	Ц	Ц	11	Ц		
		ou tell me what p Specify	roblem it								
118.	Slipped dis	c in back		Ц	الــا	Ц	Ц		Ц		

## OMB ND.: 0920-0183 EXPIRES 12/31/87 NIOSH OCCUPATIONAL HEALTH STUDY 3/24/87 1=NO 2=YES 7=NOT APPLICABLE 8=DON'T KNOW 9=REFUSED

## SECTION B

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	A you ever _?	B Have you had in the past two weeks?	C Have you had in the las six months?		that yo _? If what yo	ell you ou had yes, ear? D2 as his	1	being a doo	treat ctor fo E2 was hi	r _?
119.	Surgery on	spine		11	Ц	L	LL	<b></b>		
	119a. Was 1. N 2. B 3. B	leck lack		L	·					
120.	Carpal tun	nel syndrome		Ц	Ц		Ц	11	Ц	
	1. R	it on your tight hand left hand woth		L						
121.	Sciatica			Ц	Ы	Ц	Ц	11	L	
122.	Broken bon (Record in	es formation on 1st 1		L	Ц	Ш	L		Ц	
<u>lop 1</u> 123.	I22a. What Bone Bone Bone Bone Done Done Done Done Done Done Done D	RECORD EACE EPISO bones were broken #11111 #211111 #311111 #411111 #511111 blems with your bon you tell me what Specify to your nerves, e.on ht, trauma, etc.	n? 1 1 1 1 1 1 1 1 1 1 1 1 1 nes? the problem 1 g., in D2							L_L_L

,		OMB	NO.: 0920-0183 1 NIOSH OCCUPATION	-		
1=NO	2=YES	7=NOT APPLIC	ABLE 8=DON'T	KNOW 9	=REFUSED	
			SECTION B			
Have	A you ever ?	B Have you had in the past two weeks?	C Have you had in the last six months?	that y _? If what y	ell you ou had yes,	El Are you currently being treated by a doctor for _? E2 What was his name?
	URY	nerves were inju 1		X, B.G. ↓ 19 ↓ ↓ 19 ↓ ↓ 19 ↓ ↓ 19 ↓ ↓ 19 ↓	, NERVE 11 J J J	NURED AND DATE OF I
**125.	to illness (include fr	ems with your ne: (other than from om medications)	injury)? D2 E2			
		ou tell me what t Specify	the problem []]			
GENE	RAL AND META	BOLIC				
126.	Diabetes		L	Ц	L.L L	
	1. Tj	type is it? pe I or Juvenile pe II or Adult O				

-

- 2. Type II or Adult Onset 3. Other

126b. Is it controlled by

- 1. Diet 2. Insulin
- 3. Medication other than insulin (Record name of medication) []]]] 4. Combination of diet and medication 1 ÷

LI

126c. Is your diabetes not treated? Ц

127. Abnormal "diabetes test" or glucose 19 tolerance test?

· · · ,					_	
٠	OMB NO.: 0920 NIOSH OCC			TH STUD	PΥ	
l=NO 2=YES 7=NO	TAPPLICABLE 8	=DON'T K	NOW 9	3/24/8 =REFUSE	-	
A Have you ever Have you had _?in the two week	had Have you he past in the	had last		ell you	ı being	El you currently treated by ctor for _?
• •			? If what y What w name?	yes, ear? D2		E2 was his
128. Gout		L	Ц	Ц		L
129. Systemic lupus erytl	nematosus (or lupus	» Ц	Ц		يبي	Ц
130. Ankylosing spondylit	tis	LI	Ц	Ц		L
131. Are you on thyroid m	medication?	1_1				
132. Goiter, thyroid pro Graves disease	blems, or	Ц	Ц	L		Ц
133. Have you had surger thyroid?	y on your	LJ				
**134. A high cholesterol 1	level in your blood		Ц	Ш		L
		D2				
		E2				
135. Poor immunity		Ц	Ц	Ц	LLL	L
136. Hypoganmaglobulinem	ia	L	L	Ц		LL ·
SKIN						
**137. Chloracne		Ц	1_1	L		L
IF NO: GO TO QUEST IF YES:	ION 142	D2				
138. Did you have chlora Face Neck Chest Back L Arms L Legs Buttocks J Scrotum and tes Other, Specify	-					

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## SECTION B

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A B C Have you ever Have you had Have you had _? in the past in the two weeks? six month	last ever tell you being treated by						
139. Were you working at the time the chloracne developed?							
139a. For what company were you workin	?						
139b. What was your job?							
(Please describe your title and duties.)							
139c. In what department were you							
working?							
140. Did the chloracne clear up?	Ľ						
140a. In what year was this?	19[1_]						
141. Did you have chloracne more than once?							
141a. How many times did you have chloracne (new flare ups)?	<u>l 1 ]</u> times						
141b. Did you receive treatment?	L						
IF NO: GO TO QUESTION 142 IF YES:							
<pre>141c. Did you receive any of the following treatments?</pre>	<u>I I I I I I I I I I I I I I I I I I I </u>						

142. A skin condition other than chloracne

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1=NO	2=YES	7=NOT APPLIC	ARLE 8=DON'	T KI	NOW 9	3/24/ =REFUS					
			SECTION B								
Bave yo had _7	A Su ever	B Have you had in the past two weeks?	C Bave you had in the last six months?		Did a ever t that y ? If what y What w name?	ell yo ou had yes, ear? D2	u b   a ; W	El Are you currently being treated by a doctor for? E2 What was his name?			
IF NO: GO TO QUESTION 170 IF YES: WHICE ONE OF THE FOLLOWING SKIN CONDITION(S) BAS A DOCTOR TOLD YOU THAT YOU HAD?											
143. Ps	soriasis		1	1	Ц	11	111		Ц		
144. Ex	czema or ó	dermatitis	L	1	LI	Ц		1	Ц		
145. A	ctinic ker	ratosis	L		Ц	Ц		_	ш		
146. S	leroderma	2	L	_	Ц	Ц	LLI		Ц		
147. De	ermatomyos	sitis	L		LJ	ப			LJ		
148. He	erpes of t	the skin	L	┛	Ц	Ц		_	Ш		
o	ther type	foot, ringworm or of skin fungus (jock itch for mal	-	L	Ц	Ļ	<u> ]_i</u>	1	Ш		
150. A	one (other	r than chloracne)	L		Ц	LI		1	ш		
151. E	rythema m	ultiforme	L	┛	LJ		ш		Ш		
152. E	rythema no	odosum	1	┛	L	Ц		1	Ц		
153. D	iscoid lup	pus erythematosus	I		Ц	Ц	Ш		Ц		
154. A	lopecia a	reata	i		Ц	Ц		1	Ш		
155. V	itiligo		1	1	Ц				Ц		
156. D	ermatitis	herpetiformis	1		Ц	Ц			Ц		
157. B	ullous per	mphigoid pemphigus	s <u>1</u>	1	Ш	LJ		1	Ц		
158. L	ichen pla	nus	L	<b>_</b>	Ц	Ц		<u> </u>	Ц		
159. S	arcoidosi:	s	1	-	Ц	LJ			Ц		
160.G	ranuloma a	annulare	i	1	Ц	L			Ц		

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			OMB	NO.: 092 NIOSH OC			TH STU	DY		
1=N0		2=yes	7=NOT APPLIC	ABLE (	8≖DON'T K	NOW 9	3/24/ REFUS=			
Have had	A you ev _?		B Have you had in the past two weeks?	SECT C Have you in th six mont	had e last	ever t that y _? If what y	Dl doctor cell yo you had f yes, year? D2 was his	u bein I ada	El you cur og treate octor for E2 t was his e?	d by ¯
161.	Sebori	cheic de	ermatitis	-	Ц	Ц	Ц		LJ	
162.	Atopic	c dermai	titis		Ц	Ш	Ц	ш	Ц	
163.	Dyshid	drotic (	eczena	·	Ц	لــبا	Ц		L	
164.	Numul	lar ecz	ena		Ц	Ц	Ц		Ц	
165.	Xerosi	is/aste	atic eczema		Ц	Ц	Ц		Ц	
166.	Stasis	s derma	titis		L	Ш	ш		L	
167.		sensiti nlight)	vity (rash caus	eđ	Ц	Ц	Ц			
168.	Solar	elasto	sis		L	Ш	Ц		Ш	
169.	Contac	ct derm	atitis		LI	Ц	ГТ		Ц	
	169a.	substar bliste J Je Go Mo Pe So De Ba Gl Gl Gl Gl Gl Fo Po	ny of the follo nces caused ras rs on your skin welry smetics isturizers rfumes, cologne aps, detergents odorants ir dyes/colorin oves oes othing ues, adhesives pical medicatio ison ivy her <u>           </u>	hes or ? s or after gs	shaves	_1_1_4		- <u>1</u> - <u>1</u> -1 <u>1</u> -	L	·
170.	Other	types	of skin conditi	ons	ш					
	170a.		u tell me what ondition it was		<b>Ⅰ</b> L		1_1_i_ L, <b>L_</b>		₋↓↓↓ ₋┨╌┨	

, <b></b>												
		OMB	NO.: 0920		XPIRES 12/ AL HEALTH							
	2-10C	7-1100 1001 10			3/	24/87						
1=ND	2=YES	7=NOT APPLIC		DON'T K	NOW 9=RE	FUSED						
	A	В	SECTION C	ON B	Dl		El					
	you ever	Have you had	Have you		Did a doc	tor	Are you	currently				
had .	_?	_ in the past two weeks?	in thein month		ever tell that you		being tre a doctor					
					_? If ye what year			-				
					_ D	2	-	2				
					What was name?	his	What was name?	his				
**171.		er had abnormal (		Ц		I LL						
	face above ;	r temples (the as your check bones		D2								
	next to you	-		₿2								
	IF ND: GO ! IF YES:	TO QUESTION 177										
	171a. Did ti	his hair ever di	sappear?	Ц								
172.	About how lo	ong did it last?		L.L.L	<u>I I D</u> W :	MY						
173.		rking at the tim his hair at your		Ц								
174.	For what co	mpany were you w	orking?	ш	┸╢┸┚┸							
					1111							
175.		ur job? (please	describe	111								
	your duties	and job title)										
176.	In what dep	artment were you	working		11111							
	you develop	ore or during th ed this hair?	etime		<u></u>							
**177.		er had a darkeni her than from a		Ц		1 11						
			D2									
				E2_								
	177a. When	did you first no	tice this?	19_1_	İ							
**178.		ever a time when		Ц		┛┸┸						
		fter exposure to same time, you		D2				┶┶┶┷				
	reoutsu uti	714:		B2								

OMB ND.: 0920-0163 EXPIRES 12/31/87 NIOSH OCCUPATIONAL HEALTH STUDY 3/24/87

#### 8=DON'T KNOW 2=YES 7=NOT APPLICABLE 9=REFUSED l=ND SECTION B С D1 A В E1 Have you had Have you had Did a doctor Are you currently Have you ever \_ in the last ever tell you had ? in the past being treated by two weeks? six months? a doctor for \_? that you had \_? If yes, what year? **D2** E2What was his What was his name? name? 178a. About how long did that problem | | | | | ] D W M Y last? 178b. Were you working at the time you 🔝 developed the problem? 178c. For what company were you working? 1111 1 ł 11 178d. What was your job? (job titles 1 . . . . . - 1 - 1 Ł and duties) . . . . 1 178e. In what department were you working

While we are talking about skin conditions, I would like to know a bit more about skin conditions you may have had when you were younger.

- 179. Did you ever have pimples or blackheads that started when you were a teenager (between the ages of 12 and 19)?
  - 179a. Approximately how many pimples or blackheads did you have between the ages of 12 and 19? 1. <10 2. 10-50 3. 50-100 4. 100-1000
    - 4. 100-100
    - 5. >1000

OMB NO.: 0920-0183 EXPIRES 12/31/87 NIOSH OCCUPATIONAL HEALTH STUDY 3/24/87 7=NOT APPLICABLE 8=DON'T KNOW 9=REFUSED 2=YES 1=NO SECTION B E1 A В С D1 Have you had Have you had Did a doctor Are you currently Have you ever \_\_\_\_ in the last ever tell you \_ in the past being treated by had \_? two weeks? six months? that you had a doctor for \_? \_? If yes, what year? E2 D2 What was his What was his name? name? 179b. Did you have them on your Face **Neck** \_] Chest \_\_ Back \_ Arms Leqs Buttocks Scrotum and testicles L Other, specify L 179c. Did they clear up? L lyears 179d. How old were you when they cleared up? LJ 180. Did you have pimples or blackheads that started after age 20? D2 | | 11 111 180a. How old were you when you first **[]]years** noticed them? 180b. Approximately how many pimples or blackheads did you have after age 20? 1. <10 2. 10-50 3. 50-100 4. 100-1000

5. >1000

OMB NO.: 0920-0183 EXPIRES 12/31/87 NIOSH OOCUPATIONAL HEALTH STUDY 3/24/87 1=NO 2=YES 7=NOT APPLICABLE 8=DON'T KNOW 9=REFUSED

## SECTION B

A Have you had _?	B ever Have you had in the past two weeks?	C Have you had in the las six months?	Dl Did a doctor ever tell you that you had _? If yes, what year? D2 What was his name?	El Are you currently being treated by a doctor for _? E2 What was his name?						
180c	Did you have them on Face Neck Chest Back L Back L Legs Buttocks Scrotum and test: Other specify	_	1 1 1 1 1 1 1 1 1	┺╌┇╺╹┈┇╶╽╺╹╶┇╶╢╍┚						
1803	. Did they clear up?	Ц								
IF Y	ES:									
180e	. How long did they tal	ke to clear up?]	<u>       </u> D W M Y							
pinp	you working at the tip les and blackheads deve YES:									
	At what company were at the time?	you working								
		I								
1815	. What was your job time at the time?	tle and duties								
		I								
181c	. In what department we shortly before or du	ere you working]		<u></u>						
	you developed these									
(PREE TE2	t to elaborate on any :	SPECIFIC QUESTIC	ns in section B:)							
	1 1 1 1 1 1 1 1 1 1 1 1 1	╴╏╴┦╴┨╶┨╶┨								
╏╶┨┈┨┈┨┈										

		OMB NO.:	0920-0183 EXPIRE	S 12/31/87
		NIOSH	OCCUPATIONAL HE	ALTH STUDY
				3/24/87
1=NO	2=YES	7=NOT APPLICABLE	8=DON'T KNOW	9=REFUSED

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## SECTION C

I would like to ask you about certain health symptoms you may have now, or had in the past. Symptoms are things you may have noticed or felt, but for which you have not necessarily seen a doctor.

Interviewer: Ask parts "A" and "B" for each question; ask "C" and "D" for each person who answers yes to question "B".

OMB ND.: 0920-0183 EXPIRES 12/31/87 NIOSH OCCUPATIONAL HEALTH STUDY 3/24/87 2=YES 7=NOT APPLICABLE 8=DON'T KNOW 9=REFUSED

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l=ND

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SECTION C

	A Have you ever had _?	B Have you had in the past month?	In what	first	D When was the most recent episode of? Month/year				
GAST	ROINTESTINAL	X D	<b>C</b> .	D					
1.	An unexplained loss of app more two weeks	а в ЦЦЦЦ	மப்						
2.	Unexplained weight loss of pounds (does not include d			נ נו	MMYY				
	2a. Over what length of ti weight loss occur?		<u>L   D W M</u>	Y					
3.	Recurrent and unexplained swallowing food	difficulty		19_1_1	MMYY				
4.	Recurrent abdominal pain		ц ц	19					
5.	Vomiting up blood			19					
6.	A bloody stool			ษา					
7.	A black, tar-like stool			꼬그					
8.	Abnormally frequent or loc over several weeks	ose stools		19_1_1					
9.	Clay colored or chalky sto	∞ls	ЦЦ	19					
10.	Nausea (recurring)		ы ц	19_1_1					
11.	Vomiting over a long perio (other than when had an in	od of time ntestinal virus)		19_1_1					
12.	Pressure in your stomach :	> 2 weeks		19					
13.	Abdominal cramping > 1 wee	ek		لـلـ قد					
	13a. When does it occur? 1. Continuously 2. Only after meals 3. Other times, spec.	ify							
14.	Burning in your stomach la days	asting several	цЦ	19_1_1	M M Y Y				

OMB ND.: 0920-0183 EXPIRES 12/31/87 NIOSH OCCUPATIONAL HEALTH STUDY 3/24/87 1=NO 2=YES 7=NOT APPLICABLE 8=DON'T KNOW 9=REFUSED

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	A Have you ever had?	B Have you had in the past month?	di		C year first ?	D When was the most recent episode of? Month/year			
15.	Heartburn/reflux longer than	3 days	ப	Ц	19				
16.	Frequent constipation lastin	g <b>several w</b> ks	Ц		ษาา				
17.	Persistent intolerance to so	me foods	Ц	Ц	נג פנ				
18.	Loss of taste for tobacco		Ц		ரா				
19.	Do you frequently take antac (Tums, Rolaids, Mylanta, etc		L			Pi [1] I			
	19a. What kind?		L	1.1.1					
			11	111					
	196. What do they help?		LL						
20.	Do you frequently take bulk like Metamucil or laxatives or enemas?		Ц						
	20a. What kind?		LL						
			LL	111		╶┛┈┨╶┨╌┨╶┨╶┨			
	20b. What do they help?		Ц.						
			LL	11					
זאדן	TRATEWER: WRITE ANY FURTHER	TNPORMATION REZ	CW.I						

L	IINTERVIEWER: WRITE ANY FURTHER INFORMATION BELOW.																											
L			Ц		L	L	L	1	<u> </u>	1.	L	l.	L	L	L	L		1	1	1	L	!	I.	1	I.	1	L	L
L		_1_	L	1	1	L	L	L	1	L	1	1	L		1	L	t	.1_	L	L		1	L	1	1	L	1	1
L		_1_	1_1		⊥	t	1	L	T		L	L	L	1		1	I	t.	1	L	.L.	L	T	L		1	1	L

OMB ND.: 0920-0183 EXPIRES 12/31/87 NIOSH OCCUPATIONAL HEALTH STUDY 3/24/87 1=ND 2=YES 7=NOT APPLICABLE 8=DON'T KNOW 9=REFUSED SECTION C A B С D Have you ever Have you had In what year When was the had \_? \_ in the past did you first most recent have \_? month? episode of \_? Month/year EYES, EARS, NOSE С D 21. A sudden partial or complete loss L Ш 19 1 1 of vision MM 22. Experience of seeing double ו בנו MM YY 23. Extreme pain when you look at a Ш 19 11 bright light MM YY 24. Constant ringing, pulsating, roaring, or buzzing sound in one or both ears which MM YY interfered with your daily routine 25. Severe spinning sensation (when not п п вт under the influence of alcohol or drugs) MM YY 26. A nose bleed that you could not stop L 19 L 1 MM YY 27. Difficulty hearing or understanding what Ш 19 11 someone says because you cannot hear MM ΥY 28. Pimples or cysts on your eyelids 19\_\_\_\_ Ł.L MM YY Ц 19\_\_\_\_ 29. Problems with blurry vision L MM ΥY L1 30. Do you wear contact lenses? 31. Recurrent mouth sores, cold sores, or fever blisters (more than one time per month) MM YY INTERVIEWER: WRITE ANY FURTHER INFORMATION BELOW 1 111 

## RESPIRATORY

٦.

32. Shortness of breath while at rest (other than just after exercise)

В С A ררמ Ц MM YY

1=NO

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# 2=YES 7=NOT APPLICABLE 8=DON'T KNOW 9=REFUSED

### SECTION C

	A Have you ever had?	B Have you had in the past month?	die	what	C year first ?	D When was the most recent episode of? Month/year
33.	A persistent cough for 3 mon	ths or longer	Ц	Ц	19	
	33a. Did you bring up phlegm cough for 3 months or 1		Ц	Ц	19_1_1	M M Y Y L L / L L M M Y Y
34.	A coughing spell brought on exercise or cold air	by	L	Ц	19	
35.	Trouble breathing brought on exercise or cold	n by	Ц	Ц	19	
36.	Shortness of breath while wa up stairs at your own pace	alking	Ц	L	19	
	36a. How many stairs will ca shortness of breath?	use this		<b>ist</b> steps	airs = 1 flic	ght)
37.	Have you ever had shortness walking at your own pace on		L	Ц	19	
	37a. How many blocks can you stopping to catch your walking at your own pac	breath while		<u>і і</u> ы	ocks	
38.	Shortness of breath or cough exposed to smoke, irritants,		, <b>I</b> I	Ц	19	
39.	Sneezing spells		Ц	Ц	19_1_1	
40.	Sudden attacks of wheezing		Ц	Ц	19	
41.	An episode of coughing up bl	lood	اسا	L	19_1_1	
INTERVIEWER: WRITE ANY FURTHER INFORMATION BELOW						
LL			1.1.1		11	

		D.: 0920-0183 NIOSH OCCUPATIO				
l=ND					3/24/87 REFUSED	
	had _?	SECTION C B Have you had _ in the past month?	dið	what	first	D When was the most recent episode of? Month/year
CARD	IOVASCULAR					-
42.	Pain or pressure in your ches walked fast or walked up a hi			Ц	19	
	IF ND: GO TO QUESTION 44	• • • • • • • • • • •				
	42a. Does this happen every t fast or walk up a hill v		Ц			
	42b. How long does it take for pain/pressure to go away		_			
43.	Have you ever used nitroglyce	erin?	ГТ			
	43a. Does it help?		Ц			
	43b. How long after you take nitroglycerin does the p pressure go away?			H 1		
44.	Unexplained episodes of your rapidly or pounding in your o		Ц	L	19_1_1	
45.	An episode of fainting or los consciousness	sing	Ц	Ш	19	
46.	Awakening in the middle of the because of difficulty breath		Ц	Ц	19_1_1	
47.	Severe pain or cramping in 1 muscles brought on by walking				רד 6ג	
	<b>47a.</b> How far do you walk before pain or cramping in your					
	47b. Do you get the pain or o your calf muscles every a walk or climb the sta:	time you take	Ц			
INI	ERVIEWER: WRITE ANY FURTHER	INFORMATION BEL	WI			
11				11		
LL		1111111		11	Ц	
LL	<u>, , , , , , , , , , , , , , , , , , , </u>		1.1.1	1.1	11	

. 4.

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1=NO

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2=YES 7=NOT APPLICABLE 8=DON'T KNOW 9=REFUSED

### SECTION C

	had _?	B Have you had in the past month?	dia	what	C year first ?	D When was the most recent episode of? Month/year
GENI	TOURINARY (Males and Females)					
48.	Unexplained frequent urination	n	Ц	Ц	19	
49.	Repeated loss of bladder contr	rol	Ц	Г	<u>لـــ ور</u>	
50.	The need to urinate more than	once a night	<u>L</u> 1	Ц	19	
51.	Difficulty starting to urinate	9	Ш	Ц	19	
52.	A weak, dribbling urinary stre	eam	Ц	ப	ரா	
53.	A burning or painful urination	n	Ц	L	19	
54.	A full bladder but were unable urinate (requiring a catheter)		11	<b>L_1</b>	19	
55.	Blood in your urine		Ц	Ц	19	ليبا / ليبا
	(Males Only, Questions 56-62)					ММ ҮҮ
56.	A discharge from your penis		Ц	Ц	19_1_1	ЃП\ЃП
57.	Any sores, growths, or warts of	on your penis	Ц	Ц	ங்ட	
58.	A swelling of your testicles of	or scrotum	Ц	Ц	பட	
59.	Often have difficulty maintain an erection hard enough to have		Ш	Ц	19	
	59a. Do you have a morning ero more times per week?	ection 3 or	Ц			
60.	Any persistent difficulty get an ejaculation	ting	Ц	LJ	19	
61.	Is your penis crooked when it	is erect	Ш	Ц	19	
62.	Do you experience pain when yo have an erection	ou	Ц	Ц	لــلـ 19	MMYY LI/LI MMYY

### OMB NO.: 0920-0183 EXPIRES 12/31/87 NIOSH OCCUPATIONAL HEALTH STUDY 3/24/87 2=YES 7=NOT APPLICABLE 8=DON'T KNOW 9=REFUSED

### SECTION C

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1=ND

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	A Have you ever had?	B Have you had in the past month?	đić	what	C year first ?	D When was the most recent episode of? Month/year
IINI	ERVIEWER: WRITE ANY FORTHE	R INFORMATION BEL	OWI			
1			1.1.1	.1.1		
LL			<u>  ]  </u>	11	Ц	
LL			1.1.1	<u>. t. t</u> .		
	MALE AND FEMALE, QUESTION	S 6367)				
63.	Do you examine your breast	.s?	Ц			
64.	Have you noticed any lumps in your breasts?	or masses	L	Ц	19_1_1	
65.	A discharge from your nipp	oles	Ц		19	
66.	Growths or warts on your g	genitals	L	Ц	9	
67.	Is intercourse painful?		Ш	Ц	19	
	(PEMALES ONLY, QUESTION 68	3)				
68.	Spotting or irregular vagi	inal bleeding	Ц	Ц	19	
HEMA	TOLOGY-ONCOLOGY					
69.	A tendency to bleed or bru	nise very easily	Ц	Ц	19	
70.	Enlarged or swollen lymph (glands) in your underarms		Ц	Ц	ษาา	
71.	A sore that won't heal		ш	Ц	19	
72.	Skin lesion such as a wart changing color or bleeding		Ц	Ц	19_1_1	
73.	A lump or thickening arour neck, or elsewhere on your		Ц	Ц	19]	
74.	Chronic or nagging cough		Ц	Ц	꼬그	

OMB ND.: 0920-0183 EXPIRES 12/31/87 NIOSH OCCUPATIONAL HEALTH STUDY 3/24/87 2=YES 7=NOT APPLICABLE 8=DON'T KNOW 9=REFUSED

#### SECTION C

l=ND

		SECTION C				
,	A Have you ever had _?	B Have you had in the past month?	dio	what	first	D When was the most recent episode of? Month/year
75.	Continual hoarseness that is related to a cold or the flu		Ц	Ш	19	
76.	Drenching night sweats		Ц	Ш	דד פו	
77.	Recurrent fevers		Ц	Ц	נו פנ	
78.	Persistent change in bowel h	abits	ш	Ш	19	
IINT	ERVLEWER: WRITE ANY FURTHER	INFORMATION BELO	<u>ज्य</u>		1.1	
	<u> </u>		L.1. (		4_4	
<u>L</u> .					1_1	
1.1				11	1.1	
NEUR	OLOGY					
79.	Unusually frequent or severe	e headaches	Ц	Ц	רד הנ	
	79a. Did you have nausea or the headaches	vomiting with	L			
	<ul> <li>79b. How often does this hap</li> <li>1. More than once a day</li> <li>2. Once a day</li> <li>3. Once a week</li> <li>4. Several times a mont</li> <li>5. Less than once a mort</li> </ul>	:h	Ц		·	
80.	Difficulty maintaining your	balance	Ц	Ц	19	
·	<ul> <li>80a. How often does this hap</li> <li>1. More than once a day</li> <li>2. Once a day</li> <li>3. Once a week</li> <li>4. Several times a mont</li> <li>5. Less than once a more</li> </ul>	.h	L			, , , , , , , , , , , , , , , , , , ,
81.	Paralysis involving 1 or most that comes and goes?	e limbs	Ц	L	19	

OMB NO.: 0920-0183 EXPIRES 12/31/87 NIOSH OCCUPATIONAL HEALTH STUDY 3/24/87 9=REFUSED

l=NO

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#### 8=DON'T KNOW 2=YES 7=NOT APPLICABLE

#### SECTION C

,	A Have you ever had?	B Have you had in the past month?	C In what year did you first have?	D When was the most recent episode of _? Month/year
	81a. How long does the para on the average?	lysis last		M Y
82.	A seizure or convulsion		பப	
	82a. Do they require treatm	ent?	L	
	825. Specify			<mark>┙┙╴╽╶╽╶╽╶╽╶╽</mark>
				┟╺┟╶╽╼╽╶╢╴╢
83.	An unusual memory loss or p of confusion	æriod	└┘ └┘ 19⊥⊥	
84.	Severe cramping or weakness your legs	s in	Ц Ц 19—	
85.	Numbness of your arms or le	egs	Ц Ц 19 Ц	

INTERVIEWER: PROBE FOR "DEAD-ASLEEP NUMBNESS"; "PRICKLING-ASLEEP NUMBNESS" SHOULD! BE RECORDED UNDER "TINGLING", NEXT SYMPTOM. RECORD "NO" IF NUMENESS IS CLEARLY DUE! TO ETTHER STITING OR LYING TOO LONG IN ONE POSITION AND THE SYMPTOM DISAPPEARS APTER! IA PEN MINUTES. INCLUDE HANDS AS PART OF ARMS, AND FEET AS PART OF LEGS.)

85a. Which limb or limbs have been affected by the numbress **I** Right leg | Right arm ∐ Left leg L Left arm Both arms and both legs

85b. Thinking back to the time when you first felt the numbness, which limb or limbs were affected? 1. Same as now 2. Fewer than now 3. More than now

86. Tingling sensation in your arms or legs \_\_\_\_ 19\_\_\_ 19\_\_\_

MM YY

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		OMB	NO.: 0920-018: NIOSH OCCUPAT:	IONAL HEALTH STU	<b>D</b> Y			
1=ND	2=YES	7=NOT APPLI	CABLE 8=DON'	3/24/ TKNOW 9=REFUS				
			SECTION C					
		A ave you ever ad _?	B Have you had in the past month?					
IND IF	INTERVIEWER: PROBE FOR "PINS AND NEEDLES" OR "PRICKLING-ASLEEP" SENSATION. RECORD I I"NO" IF TINGLING IS CLEARLY DUE TO EITHER SITTING OR LYING TOO LONG IN ONE POSITION I LAND THE SYMPTOM DISAPPEARS AFTER A FEW MINUTES. INCLUDE HANDS AS PART OF ARMS, AND I IFEET AS PART OF LESS.							
86a	affected Righ Righ Li Righ Left Left	t arm leg	ng?					
<b>8</b> 6b	first fe or limbs 1. Same 2. Fewer	back to the t lt the tinglin were affected as now than now than now	ng, which limb	L				
87. Bur	ning sensa	tion in your a	arms or legs	니 니 19_				

INTERVIEWER: PROBE FOR "PINS AND NEEDLES" OR "PRICKLING-ASLEEP" SENSATION, RECORD | "NO" IF TINGLING IS CLEARLY DUE TO EITHER SITTING OR LYING TOO LONG IN ONE POSITION | AND THE SIMPTOM DISAPPEARS AFTER A FEW MINUTES. INCLUDE HANDS AS PART OF ARMS, AND | IFRET AS PART OF LEGS.

Ш

87a. Which limb or limbs have been affected by the burning sensation?
|\_| Right leg
|\_| Right arm
|\_| Left leg
|\_| Left arm
|\_| Both arms and both legs
87b. Thinking back to the time when you first felt the burning sensation, which limb or limbs were affected?
1. Same as now
2. Fewer than now
3. More than now

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		OMB NO.: 0920-018 NIOSH OCCUPAT	3 EXPIRES 12/31/8 IONAL HEALTH STUDY 3/24/8	t.
1=ND	2=YES 7=NOT	APPLICABLE 8=DON	T KNOW 9=REFUSEI	<b>)</b> .
·	A Have you e had?	SECTION C B ver Have you had in the pas month?	C In what year	
88.	Weakness such that you out of a chair or clim		LI LI 19	
	ERVIEWER: RECORD "NO" DMA. E.G., PULLED MUSCI			e to musculoskeletal !
	88a. Which part or par by weakness? [_] Weak all over [_] Right leg [_] Right arm [_] Left leg [_] Left arm		:đ	
89.	Finger or hand weaknes was difficult for you shirt or unscrew tops	to button your	LI LI 19 <u>1</u>	
	ERVIEWER: RECORD "NO"			E TO MUSCULOSKELETAL
	89a. Which side of you affected by your or hand weakness? 1. Right 2. Left 3. Both	finger	<b>L1</b>	
<b>9</b> 0.	Finger or hand numbres sensation so that it i you to button your clo and handle small items	s difficult for thes or pick up	<u>іі іі 19</u> .і.,	
	90a. Which hands and f affected by this [_] Right thumb [_] Right index f [_] Right middle [_] Right ring fi [_] Right little [_] Right palm [_] Whole right b	numbness? inger finger nger finger	Left thumb L Left index L Left middle L Left ring f L Left little L Left palm Whole left	finger inger finger

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OMB NO.: 0920-0183 EXPIRES 12/31/87 NIOSH OCCUPATIONAL HEALTH STUDY 3/24/87 l=NO 2=YES 7=NOT APPLICABLE 8=DON'T KNOW 9=REFUSED SECTION C В С D A Have you had In what year Have you ever When was the had \_? \_ in the past did you first most recent month? have \_? episode of \_? Month/year 91. Persistent twitching or rippling of muscles in your arms or legs while MM YY you were at rest 91a. Which limb or limbs have been affected by twitching? LI Right leg Right arm L Left leq L Left arm Both arms and both legs RHEUMATOLOGY 92. Persistent pain or stiffness in your neck lasting more than 2 weeks MM YY 93. Low back pain that interfered with your daily activities MM YY 94. Pain, stiffness or swelling of any of your joints, other than your back MM YY or neck, lasting more than 2 weeks 94a. Which joints are affected? 📙 Right shoulder 🔛 Right fingers and thumbs | Right knee L Left fingers and thumb Left shoulder L Left knee 🔟 Both shoulders 🔟 Fingers & thumbs, both sides L Both knees **I** Right elbow 📙 Right jaw joint **1** Right ankle L Left ankle L Left jaw joint L Left elbow L Both elbows L] Both jaw joints L | Both ankles Right wrist L] Right hip **I** Right toes L Left wrist L Left toes L Left hip 1 | Both wrists Both hips All toes ☐ Other joint

. *					·	
		OM			EXPIRES 12/31/ NAL HEALTH STU 3/24/	DY
1=ND	2=YES	7=NOT APPL	ICABLE	8=DON'T	KNOW 9=REFUS	
			s	ECTION C		
		A ave you ever ad _?		the past	C In what year did you firs have?	
IINGER	VIEWER: WRI	TE ANY FURTH	R INFORM	ATION BELO	Wİ	
		1.1.1.1.1.1.1	└ <sub>┻</sub> ┠╌┃╌┠╌┨			
		<u>1 1 1 E E I I I</u>				
111.		111111			1	
	∐ Righ ∐ Left	oints are affe t shoulder   shoulder	└─ Right └─ Left	fingers an	nd thumbs d thumb s, both sides	M M Y Y Right knee Left knee Both knees
	🗌 Left	elbow	└ <u></u> Left	jaw joint jaw joint jaw joints		L Right ankl L Left ankle L Both ankle
	L   Left	wrist	L Right L Left L Both	hip		L Right toes L Left toes L All toes
	L Othe Spec	er joint ify <u>     </u>			111111	<u></u>
INTER	VIEWER: WRI	TE ANY FURTH	R INFOR	PATION BELC	MI	

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OMB NO.: 0920-0183 EXPIRES 12/31/87 NIOSH OCCUPATIONAL HEALTH STUDY 3/24/87 7=NOT APPLICABLE 8=DON'T KNOW 9=REFUSED

#### SECTION C

A	В	С	D
Have you ever had?	Have you had in the past month?	In what year điđ you first have?	When was the most recent episode of? Month/year

96. This concludes the section on symptoms that you may have had. Do you have any other current symptoms or health problems I did not mention?

96a. Specify

2=YES

1=NO

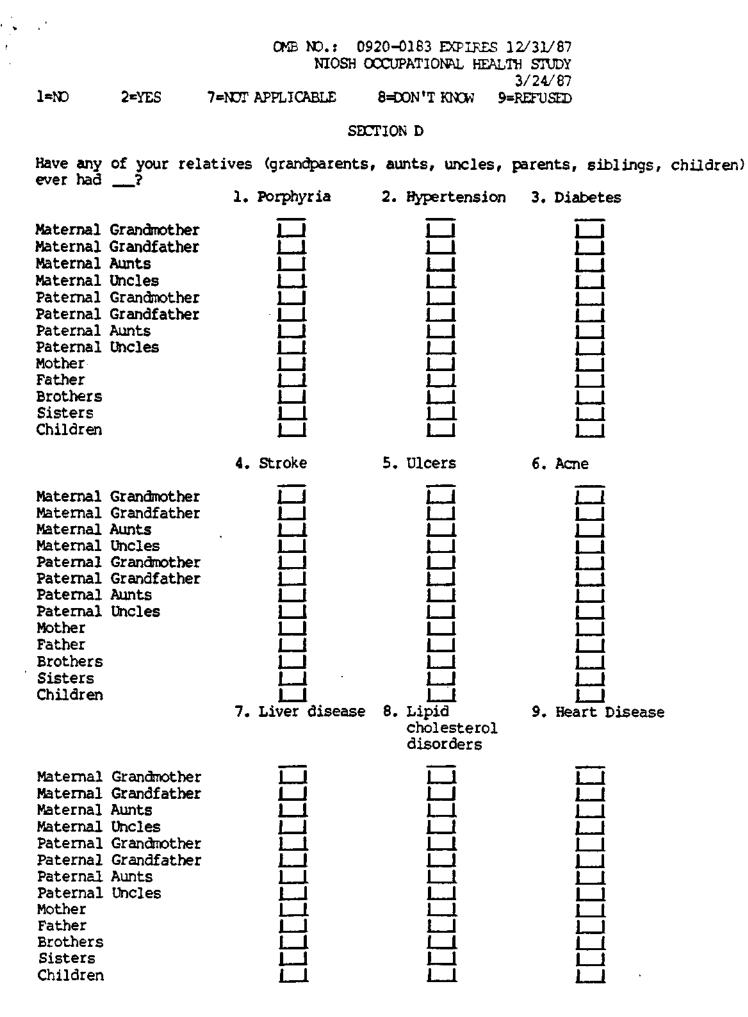
INTERVIEWER: WRITE ANY FURTHER INFORMATION BELOW!

<b>`</b>		OMB ND.: 0920-0183 E	
		NIOSH OCCUPATION	$\frac{1}{3/24/87}$
l≖ND	2=YES	7=NOT APPLICABLE 8=DON'T K	NOW 9=REFUSED

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SECTION D

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OMB NO.:	0920-0183 EXPIR	ES 12/31/87
NIOSH	OCCUPATIONAL H	EALTH STUDY
		3/24/87
7=NOT APPLICABLE	8=DON'T KNOW	9=REFUSED

# SECTION D

• • • •

1=NO 2=YES

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Have any of your relatives (grandparents, aunts, uncles, parents, siblings, children) ever had \_\_\_?

	10. Mental Illness	ll. Lung Disease
Maternal Grandmother Maternal Grandfather Maternal Aunts Maternal Uncles Paternal Grandmother Paternal Grandfather Paternal Aunts Paternal Uncles Mother Father Brothers Sisters Children		
Maternal Grandmother	12. Cancer	Type
Maternal Grandfather	╘──┤	
Maternal Aunts	L	
Maternal Uncles	<b>ا</b> ــــا	
Paternal Grandmother	┠╌┛	┠┨┠┨┛╹
Paternal Grandfather	<b>L</b>	
Paternal Aunts	<b>1_1</b>	<mark>┟╶┨┈┨╶┨╶┨╶┨╶┩╶</mark> ┩╌
Paternal Uncles	L	
Mother	L	
Father	السبا	
Brothers	ii	<u><u>↓</u>↓<u>↓</u>↓<u>↓</u>↓<u>↓</u></u>
Sisters	ليسل	<u><u> </u></u>
Children	1_1	

Type 	<u>↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓</u>
111111	

		OMB NO .: (	920-0183 EXPIRE	S 12/31/87
		NIOSH	OCCUPATIONAL HE	ALTH STUDY
				3/24/87
l=ND	2=YES	7=NOT APPLICABLE	8=DON'T KNOW	9=REFUSED

#### SECTION E

INTERVIEWER: We are interested in determining what medications the respondent has taken during the two weeks before his/her participation in the study. We also want to know what conditions the medications were prescribed for, how long the medication has been taken, and at what dosage.

For each medication listed by respondent, ask questions "B", "C", and "D". Ask respondent if he/she has brought medications to the clinic, and if possible confirm name and dosage.

For each medication on this list, ask the respondent questions "A". If the answer to question "A" is NO, ask question "B"; if the response to "A" is YES, ask question "C". If the response to question "C" is NO, ask question "D".

How much do How long

1=NO 2=YES 7=NOT APPLICABLE 8=DON'T KNOW 9=REFUSED

#### SECTION E

1. In the past 2 weeks have you taken any medications that were prescribed or recommended by your doctor?

IF NO: GO TO SECTION F

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a.	Medication	For what condition are you taking Med?	How much do you take each day? Total mg/day	How long have you taken it? D, W, M, Y <u>         </u>
b.				
c.				
			1.1.1.1.1	
d.				
e.				
f.	┟╌┟╌╽╶╽╶┠╴╢╶┨╴┻╴╢			
g.				
h.				
i.	<u>└</u> <u>╷</u> ┙		┟╍┟╍╎╌╽╶╻╽	
	<del>┃ ┛╹╹╹╹╹╹╹╹╹╹╹</del>			
j.				
-	و الا الذي المحمد الله الله الله عنه الله التي عن جي عنه المحمد عنه 10 10 10 10 10 10 10 10			

INTERVIEWER: WRITE ANY FURTHER INFORMATION ON NEXT PAGE!

OMB NO.: 0920-0183 EXPIRES 12/31/87 NIOSH OCCUPATIONAL HEALTH STUDY 3/24/87 l=NO 2=YES 7=NOT APPLICABLE 8=DON'T KNOW 9=REFUSED

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MEDICATION	FREE TI	EXT			
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		111	 1 1 1 1		

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		OMB NO.:	0920-0183 EXPIRE	S 12/31/87
		NIOSH	OCCUPATIONAL HE	ALTH STUDY
				3/24/87
l=ND	2=YES	7=NOT APPLICABLE	8=DON'T KNOW	9=REFUSED

# SECTION F

### AUTONOMIC NERVOUS SYMPTOMS

INTERVIEWER: PROBE FOR SYMPTOMS THAT OCCUR PERSISTENILY AND/OR UNDER "UNUSUAL OR UNEXPLAINED" CONDITIONS.

•								
	OMB NO.: 0920-0183 EXPIRES 12/31/87 NIOSH OCCUPATIONAL HEALTH STUDY 3/24/87							
1=NO	2=YES	7=NOT APPLICABLE	8=DON'T KNOW					
·	SECTION F							
At any time in the past year have you had								
1.	Nausea and vomiting after meals?							
2.	. Fullness that lasts more than 2 hrs after eating? (even after eating a small amount of food)							
3.	Less sweating o	n arms and legs th	an usual?		ш.			
4.	More sweating of	n your chest and s	tomach?		<b>L</b> I			
5.	Sweating after a	most meals? (even	when the room is	cool)				
6.	Dizziness, like quickly?	you are going to	faint, when you s	stand				

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7. A loss of control of your bladder?

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OMB NO.: 0920-0183 EXPIRES 12/31/87 NIOSH OCCUPATIONAL HEALTH STUDY 3/24/87 1=NO 2=YES 7=NOT APPLICABLE 8=DON'T KNOW 9=REFUSED

#### SECTION G

#### EVALUATION REPORT

### INTERVIEWER: COMPLETE THESE QUESTIONS AFTER THE EXAMINEE DEPARTS! IANSWER SECTION & REPORE COMPLETING SECTION G

1.	Was the respondent's cooperation: l=Very good 2=Good 3=Fair 4=Poor	ii
2.	The quality of the interview was: l=Unsatisfactory 2=Questionable 3=Generally reliable 4=High quality	i_J
3.	The main reason for the unsatisfactory or quality was that the respondent: Was ill or disabled Spoke English poorly Was evasive or suspicious Was bored or uninterested Was upset or depressed by the topic	questionable

- Was upset or depressed by the topic
  Was intoxicated
- L Had poor hearing or speech
- Was confused by frequent interruptions Was insufficiently knowledgeable
- Was mentally disturbed
- Something else,

specify
---------

## OMB NO.: 0920-0183 EXPIRES 12/31/87 NIOSH OCCUPATIONAL HEALTH STUDY 3/24/87 1=NO 2=YES 7=NOT APPLICABLE 8=DON'T KNOW 9=REFUSED

#### SECTION H

#### HABITS

INTERVIEWER: ANSWERS TO QUESTIONS IN THIS SECTION ARE FOR THE USE OF STUDY DIAGNOSTI-CLANS ONLY. INFORM THAT WE KNOW THAT PARTICIPANT ANSWERED SIMILAR QUESTIONS DURING RTI INTERVIEW, BUT THAT THIS INFORMATION IS NOT AVAILABLE TO US HERE IN THE CLINIC. WE NEED THIS INFORMATION TO GIVE ACCURATE FEEDBACK ON MEDICAL CONDITIONS AND RESULTS.

PARTICIPANT ID

PARTICIPANT NAME

DATE \_\_\_\_\_

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INTERVIEWER ID # \_\_\_\_\_

### OMB NO.: 0920-0183 EXPIRES 12/31/87 NIOSH OCCUPATIONAL HEALTH STUDY 3/24/87 1=NO 2=YES 7=NOT APPLICABLE 8=DON'T KNOW 9=REFUSED

#### SECTION H

Now I would like to ask you a few questions about the use of wine, beer or liquorall kinds of alcoholic beverages.

# INTERVIEWER: PROBE FOR BEST ESTIMATE.

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1.	On the average, how many days <u>per month</u> do you drink beverages containing alcohol?	l_l_jdays
	la. A drink is 1 can or bottle of beer, 1 glass of wine, or 1 cocktail or shot of liquor. On the days that you drink, how many drinks do you have per day on the average	<u>L.L.I</u> <u>e</u> ?
	1b. How many times during the past 4 weeks did you have 5 or more drinks on an occasion?	LLL
	Ic. During the past 4 weeks, how many times have you driven when you've had perhaps too much to drink?	
Now	some questions about cigarette smoking:	
2.	Have you <u>ever</u> smoked cigarettes regularly, that is, at least one a day?	Ц
	IF NO: END OF INTERVIEW	
3.	Do you <u>now</u> smoke cigarettes regularly, that is, at least one a day?	. <b>L.</b>
	3a. <u>On the average</u> , how many cigarettes a day do you currently smoke?	LCigarettes
	3b. How many <u>years</u> altogether have you been a regular cigarette smoker?	Lilyears
4.	How long has it been since you quit?	<u>         </u> D,W,M,Y
5.	On the average, how many cigarettes a day did you smoke when you were a regular smoker?	LCigarettes
6.	How many years altogether were you a regular cigarette smoker?	L lyears

#### MALE REPRODUCTION QUESTIONNAIRE

A1. PARTICIPANT ID#\_\_\_\_\_\_ PARTICIPANT NAME\_\_\_\_\_\_ A2. EXAM DATE\_\_\_\_\_\_ A3.EXAM TIME\_\_\_\_\_ A4. INTERVIEWER ID\_\_\_\_\_ A5. EXAM STATUS: \_\_\_\_\_l=COMPLETE; 2=INCOMPLETE; 9=REFUSED A6. FORM #\_\_\_\_\_\_ A7. TOTAL NUMBER OF FORMS\_\_\_\_\_ MUST ALWAYS HAVE FORM # 1. USE A SEPARATE FORM FOR EACH WIFE. USE A SEPARATE FORM FOR EACH WIFE. USE A SEPARATE FORM IF MORE THAN 3 PREGNANCIES IN A MARRI

USE A SEPARATE FORM FOR MACH WITE. USE A SEPARATE FORM IF MORE THAN 3 PREGNANCIES IN A MARRIAGE. A1-A6 MUST BE FILLED IN FOR ALL FORMS. A7 MUST BE FILLED IN ON FORM # 1 AT END OF INTERVIEW.

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	l=NO	2=YES	8=DON'T K	NOW	9=REFUSED
1.	AS IF YOU WE 1=NO (END OF 2=YES, MARRI	ed With Woman F	r at least	TWO YEARS?	N
2.	HOW MANY TIM	ES HAVE YOU B		D?	<u> </u>
			ived with	someone for	at least two
3.		ES HAVE YOU L ARS) BUT WERE			AT
of	terviewer: M this intervie r wife.)	w, we'll ref	ement: "Fr er to each	person you	or the purpose lived with as
4.	A PREGNANCY?	ES ALTOGETHER PLEASE BE S N A LIVE BIRT	HAVE YOU URE TO INC	BEEN THE FATI Lude any pred	GNANCIES
5.	HAVE YOU HAD	A VASECTOMY?			<u> </u>
	5a. WHAT YEA	R WAS IT PERF	ORMED?		(19) / / /
	riages/relati	ask you a few onships. *********	-		-
Thi	nking now abo	ut the (lst,	2nd, etc.)	marriage:	
6.	WIFE #				1_1_1
	6a. IN WHAT	Month and yea:	R DID YOU	BEGIN LIVING	TOGETHER?
				1_1_	<u>/ MO ///</u> YR
7.	HOW OLD WAS LIVING TOGET	YOUR WIFE WHE HER?	N YOU WERE	MARRIED/BEGA	AN /

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1=NO	2=YES	8=DON'T KNOW	9=REFUSED

8. WHAT IS/WAS YOUR WIFE'S NAME? (MAIDEN, FIRST)

\_\_\_**`** 

9. ARE YOU CURRENTLY? 1=MARRIED TO HER 2=LIVING WITH HER 3=DIVORCED 4=SEPARATED 5=WIDOWED 6=SEPARATED FROM LIVING RELATIONSHIP

If currently married or living together, go to question 11.

10. IN WHAT MONTH AND YEAR WERE YOU (DIVORCED, SEPARATED, WIDOWED)?

<u>/ / / MO</u>	/_/_YR
11. DID YOUR WIFE WORK DURING YOUR MARRIAGE? If yes,	//
11a. HOW MANY YEARS HAS/DID SHE WORKED DURING THE MARRIAGE/RELATIONSHIP?	1_1_1
12. DID YOUR WIFE HAVE ANY CHILDREN FROM A PREVIOUS MARRIAGE? If yes,	1_1
12a. HOW MANY CHILDREN DID SHE HAVE?	1_1_1
13. HOW MANY PRENGANCIES WERE THERE IN THIS MARRIAGE/RELATIONSHIP?	<u> _ _</u>

Now I would like to ask some questions about whether you and your wife had any difficulties in having children, or whether you or your wife had any surgery that prevented pregnancy.

- 14. DID YOU AND YOUR WIFE EVER TRY FOR AT LEAST ONE YEAR TO BECOME PREGNANT WITHOUT SUCCESS? /// (IF NO, SKIP TO QUESTION 15.)
  - 14A. DID YOU OR YOUR WIFE SEE A DOCTOR BECAUSE OF THIS DIFFICULTY?

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	l=NO	2=YES	8=DON'T	KNOW	9=REFUSED	
	YOU THAT GETTING M 1.LOW SPERM ( 2.IMPOTENCY 3.HORMONE/GL/ 4.PROBLEM WIT 5.HORMONE/GL/ 6.PROBLEM WIT 7.UNKNOWN PRO 8.NO PROBLEM	ANY OF THE PREGNANT? COUNT (UNABLE TO GE' AND PROBLEM I) TH YOUR MALE ( AND PROBLEM I) TH YOUR WIFE'	SE WAS ( F ERECTION YOU ORGANS N YOUR WI S FEMALE	THE CAUSE ON) (FE ORGANS	IF A DOCTOR ( OF DIFFICULT)	
15.		E HAVE A HYST MY; 2=TUBAL I			R TUBES TIED? IER	<u> </u>
	15A. IN WHAT	T YEAR WAS IT	PERFORM			<u> </u>
shir If T	ps, END of int multiple marr:	terview.	nships,	jo to next	packet,ques.6	
<b>L</b>	******		********	**********	****	
Thir	******	*****	********	**********	*** *tc)	J
Thir 16.	**************************************	*****	********	**********	**** etc)	
Thir 16. 17A.	**************************************	THE Pregnan The pregnan FE HAVE: N CHILD AGE N CHILD ABORTION NANCY	ncies(1st	**********	**** etc)	
Thir 16. 17A.	**************************************	TE HAVE: It the pregname N CHILD AGE N CHILD ABORTION NANCY PREGNANT	ncies(1st	**********	**** etc)	1_1
Thir 16. 17A. 17B.	**************************************	The pregname The pregname The pregname The pregname The pregname The pregname The pregname The pregname The precipy The precipy	y) -/////	/ / / / / / /	*** tc) / / / each birth a	

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	1=NO	2=YES	8=DON'T KNOW	9=REFUSED
		es: l.If more 2.If no m go to n	ontinue with question pregnancies, go to que ore pregnancies in th ext marriage. ore marriages, go to	uestion 24 is marriage,
19.	WAS THIS BABY 1=BOY 2=GIRL	A BOY OR GI	RL?	//
20.	IN WHAT CITY	AND STATE WA	S HE/SHE BORN?	
	111111		<u>/////////</u> CITY	<u>/_/ /</u> STATE
21.	If no, go to If yes,	question 22.	DEFECT OR HEALTH PROBL	
			///////////////////////////////////////	
			A DOCTOR BECAUSE OF	
	21c. WHAT WAS WAS TREA		ND LOCATION OF HOSPIT?	AL WHERE HE/SHE
	11111			
			CITY	<u>/</u> STATE
		U GIVE YOUR RECORDS?	PERMISSION FOR US TO	
	2. If no mor	. If more pre	question 22. gnancies in marriage, s in marriage go to n	go to Ques. 24
22.	WHAT IS HIS/	HER NAME? (LA	ST,FIRST)	
1	111111		///////////////////////////////////////	

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23. DID HE/SHE EVER DEVELOP LEUKEMIA OR CANCER? If no, go to question 24. If yes,

.

1 = NO2≈YES 8=DON'T KNOW 9=REFUSED 23a. WHAT TYPE OF CANCER DID HE/SHE DEVELOP? (RECORD VERBATIM) 23b. IN WHAT MONTH AND YEAR WAS IT DIAGNOSED BY A DOCTOR? /\_/\_/ MO /// YR 23c. WHAT WAS THE NAME AND LOCATION OF THE HOSPITAL WHERE HE/SHE WAS TREATED? 23d. WILL YOU GIVE YOUR PERMISSION FOR US TO OBTAIN HIS/HER MEDICAL RECORDS? 11 .If more pregnancies in this marriage, go to question 24 2.If no more pregnancies in this marriage, go to next marriage. B.If no more marriages, go to END. Thinking now about the pregnancies (2nd, 5th, 8th, etc) 24A.PREGNANCY # LLL11 24B.DID YOUR WIFE HAVE: 1=A LIVE BORN CHILD 2=A MISCARRIAGE 3=A STILLBORN CHILD 4=AN INDUCED ABORTION 5=TUBAL PREGNANCY **6=CURRENTLY PREGNANT** 7=OTHER (if other, specify) (Interviewer: If multiple births, record each birth as a separate pregnancy, but keep the same pregnancy number.) 25. WHAT WAS THE MONTH AND YEAR OF THE OUTCOME? / / / MO / / / YR (Interviewer: For current pregnancies, code all 9's)

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	l=NO	2=YES	8=DON'T	KNOW	9=REFUSED
	other outcome 2.If no mor	s: 1.If more	pregnand s in mari	with question 2 cies, go to que ciage,go to nex ND.	estion 31 t marriage.
26.	WAS THIS BABY 1=BOY 2=GIRL	A BOY OR GI	RL?		
27.	IN WHAT CITY	AND STATE WAS	S HE/SHE	BORN?	
	111111		1.11.1	<u>////</u> CITY /_	<u>/_/</u> STATE
28.	DID HE/SHE HA If no, go to If yes,		EFECT OR	HEALTH PROBLEM	AT BIRTH?/_/
		D OF BIRTH D	EFECT OR	HEALTH PROBLEM	I WAS THAT?
	1111				
	28b. WAS THE	BABY SEEN BY	A DOCTO	R BECAUSE OF (C	CONDITION)?/_/
	WAS TREA	TED?		ON OF HOSPITAL	
	1.1.1.1.1	111111		<u>////</u> CITY/_	/_/STATE
		J GIVE YOUR I RECORDS?		ON FOR US TO C	11
		If more pregnancies	question nancies in marr:	29. in marriage, go iage, go to nex	to ques. 31.
29.	WHAT IS HIS/H	IER NAME? (LA	ST,FIRST	)	
4			1111	1.1.1.1.1.1	
30.	DID HE/SHE EV If no, go to			DR CANCER?	/
	30a. WHAT TYP	PE OF CANCER	DID HE/SI	HE DEVELOP? (REC	ORD VERBATIM)
	, , , , , , , , ,		1111		, , , , , , , , ,

,

1=NO 2=YES 8=DON'T KNOW 9=REFUSED

30b. IN WHAT MONTH AND YEAR WAS IT DIAGNOSED BY A DOCTOR?

/\_/\_/ MO /\_/\_/ YR

30c. WHAT WAS THE NAME AND LOCATION OF THE HOSPITAL WHERE HE/SHE WAS TREATED?

30d. WILL YOU GIVE YOUR PERMISSION FOR US TO OBTAIN HIS/HER MEDICAL RECORDS?  $L_{L}$ 1. If more pregnancies in this marriage, go to question 31. 2.If no more pregnancies in this marriage, go to next marriage. B.If no more marriages, go to END. \_\_\_\_ Thinking now about the pregnancies(3rd,6th,9th,etc) 31A.PREGNANCY # L L31B.DID YOUR WIFE HAVE: 1.1 1=A LIVE BORN CHILD 2=A MISCARRIAGE 3=A STILLBORN CHILD 4=AN INDUCED ABORTION 5=TUBAL PREGNANCY 6=CURRENTLY PREGNANT 7=OTHER (if other, specify) (Interviewer: If multiple births, record each birth as a separate pregnancy, but keep the same pregnancy number.) 32. WHAT WAS THE MONTH AND YEAR OF THE OUTCOME? / / / MO / / / YR (Interviewer: For current pregnancies, code all 9's) If live birth or stillborn, continue with question 33. All other outcomes: l.If more pregnancies, go to next packet,Q 16 2.If no more pregnancies in marriage, go to next marriage.

3.If no more marriages, go to END.

1.1

1=NO 2=YES 8=DON'T KNOW 9=REFUSED

- 33. WAS THIS BABY A BOY OR GIRL? 1=BOY 2=GIRL
- 34. IN WHAT CITY AND STATE WAS HE/SHE BORN?

35. DID HE/SHE HAVE A BIRTH DEFECT OR HEALTH PROBLEM AT BIRTH?/\_/ If no, go to question 36. If yes.

35a. WHAT KIND OF BIRTH DEFECT OR HEALTH PROBLEM WAS THAT?

35b. WAS THE BABY SEEN BY A DOCTOR BECAUSE OF (CONDITION)?/\_/

35c. WHAT WAS THE NAME AND LOCATION OF HOSPITAL WHERE HE/SHE WAS TREATED?

35d. WILL YOU GIVE YOUR PERMISSION FOR US TO OBTAIN HIS/HER MEDICAL RECORDS?

If live birth, continue with question 36. If stillbirth, l. If more pregnancies in marriage, go to next packet, question 16 2. If no more pregnancies in marriage, go to next marriage. 3. If no more marriages, go to END.

36. WHAT IS HIS/HER NAME? (LAST, FIRST)

37. DID HE/SHE EVER DEVELOP LEUKEMIA OR CANCER? /// If no, go to END. If yes,

37a. WHAT TYPE OF CANCER DID HE/SHE DEVELOP? (RECORD VERBATIM)

\$ 24

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1=NO 2=YES 8=DON'T KNOW 9=REFUSED

37b. IN WHAT MONTH AND YEAR WAS IT DIAGNOSED BY A DOCTOR?

/// MO /// YR

37c. WHAT WAS THE NAME AND LOCATION OF THE HOSPITAL WHERE HE/SHE WAS TREATED?

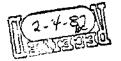
/////////////////////////////STATE

37d. WILL YOU GIVE YOUR PERMISSION FOR US TO OBTAIN HIS/HER MEDICAL RECORDS?

\*

If more pregnancies in this marriage, go to next packet. If more marriages, go to next packet. Otherwise, go to END.

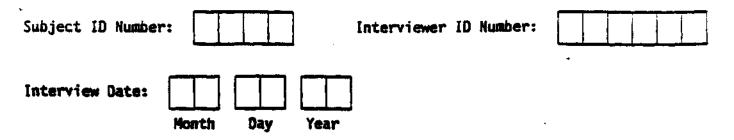
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. OMB NO.:0920-0183; EXPIRES 12/31/8

### NIOSH OCCUPATIONAL HEALTH STUDY

#### DEMOGRAPHIC AND OCCUPATIONAL HISTORY QUESTIONNAIRE



1. FOLLOW CONTROL CARD PROCEDURES TO IDENTIFY AND VERIFY RESPONDENT INFORMATION.

2. COVER CONSENT INFORMATION WITH RESPONDENT AND ASK FOR SIGNATURE, THEN SAY:

Before we start the interview let me tell you a little about the questions. I will be asking you about such things as medical information, jobs you have held, your family, and places you have lived. I also will want to know when certain events occurred. Sometimes the period of time I ask about will be your entire life and other times it will be since you were 16 years old, or some other time period.

If you do not understand the time period or the question, ask me to repeat the question or to clarify, if possible. We want to make sure the information is as accurate as possible.

The questions will take an average of one hour to complete. If you want to take a break at some point, just let me know.

THE RESPONDENT HAS BEEN INFORMED ABOUT THE STUDY AND GIVEN HIS/HER CONSENT.

SIGNATURE OF INTERVIEWER

A. CURRENT MEDICAL CONDITION

First I am going to ask you a few general questions about your health and medical history.

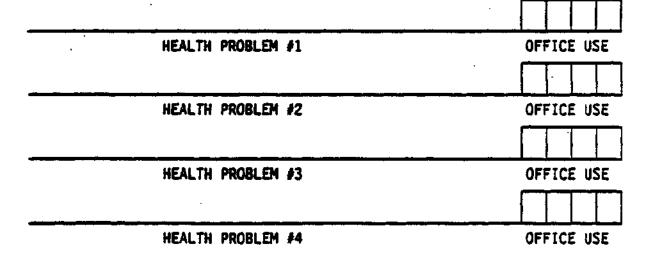
Al. In general, compared with other people your age, would you say your health excellent, good, fair, or poor?

EXCELLENT.....01 GOOD.....02 FAIR.....03 POOR.....04

A2. Do you feel you have a health problem?

YES.....01 NO.....02 DON'T KNOW.....94 + GO TO A3. REFUSED.....97

a. [IF YES] What (is/are) the health problem(s)?



A3. Does any health problem keep you from working either full or part-time? ([IF RETIRED:] Did any health problem cause your retirement?)

```
YES.....01
NO.....02
DON'T KNOW.....94 + GO TO A4.
REFUSED.....97
```

a. [IF YES] What (is/are) the health problem(s)?

HEALTH PROBLEM #1	OFFICE USE
HEALTH PROBLEM #2	OFFICE USE
HEALTH PROBLEM #3	OFFICE USE
· · · · · · · · · · · · · · · · · · ·	
HEALTH PROBLEM #4	OFFICE USE

A4. During the past 3 months did you see a doctor, or spend at least 2 days in a row in bed due to an illness?

SAW A DOCTOR01	
SPENT 2 DAYS IN A ROW IN BED02	
BOTH 1 AND 203	- -
ND	
DON'T KNOW94	+ GO TO SECTION B
REFUSED97	)

a. [IF ANSWER 01, 02, OR 03] What caused you to (see a doctor/spend 2 or more consecutive days in bed/both see a doctor and spend 2 or more consecutive days in bed)?

.

GO TO SECTION B

# 8. HOSPITALIZATIONS

B1. Throughout your life, have you ever been hospitalized overnight or longer not including when you were born?

YES.....01 NO.....02 DON'T KNOW.....94 + GO TO B4 REFUSED.....97

B2. How many times, in your life, have you been hospitalized overnight or longer?

NUMBER OF TIMES

S3. [ASK QUESTIONS a. THRU d. FOR EACH HOSPITALIZATION INDICATED IN QUESTION B2. THEN SAY:] We would like to obtain the hospital records for each time that you were hospitalized. I need you to sign a form that gives us your permission to ask for your records.

	HOSPITALIZATION #1
a. In what month and year were you (first/next) hospitalized?	MONTH YEAR
b. What was the reason for this overnight hospitalization? [CODE TRAUMATIC, NON- TRAUMATIC, OTHER]	TRAUMATIC 01 NON-TRAUMATIC . 02 OTHER 03 OFFICE USE
c. What was the name and address of the hospital you stayed in?	ADORESS
·	CITY, STATE ZIP
d. What was the name and address of the doctor who treated you?	DOCTOR'S NAME
	CITY, STATE ZIP
e. WHAT IS THE PERMISSION FORM NUMBER FOR This stay?	
	GO TO NEXT HOSPITAL VISIT OR, AFTER ALL VISITS, 84.

FILL OUT A CONSENT FORM FOR EACH DIFFERENT HOSPITAL AND HAVE RESPONDENT SIGN THEM ALL. ONCE ALL CONSENT FORMS ARE SIGNED AND CLIPPED TOGETHER, GO TO THE NEXT SECTION. THERE MUST BE A CONSENT FORM FOR EACH DIFFERENT HOSPITAL. IF THE RESPONDENT REFUSES TO SIGN A FORM, MARK "REFUSED" IN THE SIGNATURE SPACE. BE SURE TO ENTER CONSECUTIVE CONSENT FORM NUMBERS ON EACH FORM AND IN EACH PART e. FOR EACH REPORTED HOSPITALIZATION.

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HOSPITALIZATION #2	HOSPITALIZATION #3	HOSPITALIZATION #4
MONTH YEAR	MONTH YEAR	MONTH YEAR
TRAUMATIC 01 NON-TRAUMATIC . 02 OFFICE USE OTHER 03	TRAUMATIC 01 NON-TRAUMATIC . 02 OFFICE USE OTHER 03	TRAUMATIC 01 NON-TRAUMATIC . 02 OFFICE OTHER 03
NAME OF HOSPITAL	NAME OF HOSPITAL	NAME OF HOSPITAL
ADDRESS	ADORESS	ADDRESS
CITY, STATE ZIP	CITY, STATE ZIP	CITY, STATE Z.
DOCTOR'S NAME	DOCTOR'S NAME	DOCTOR'S NAME
ADDRESS	ADDRESS	ADDRESS
CITY, STATE ZIP	CITY, STATE ZIP	CITY, STATE ZI
GO TO NEXT HOSPITAL VISIT OR, AFTER ALL VISITS, 84.	GO TO NEXT HOSPITAL VISIT OR, AFTER ALL VISITS, B4.	GO TO NEXT HOSPITAL VISIT OR AFTER ALL VISITS, B4.

B4. In your entire life, have you ever had a serious condition which you felt you should have been hospitalized for but were <u>not</u>?

> YES.....01 NO.....02 DON'T KNOW.....94 - GO TO B5. REFUSED.....97

a. [IF YES,] please describe the condition.

OFFICE USE

B5. In your entire life, have you ever had a biopsy or surgery for which you were <u>not</u> hospitalized?

YES.....01 NO.....02 DON'T KNOW.....94 + GO TO SECTION C REFUSED.....97

a. [IF YES,] please describe the biopsy or surgery.

-	• • •						-
		·	·	[	Τ	OFFICE USE	

GO TO SECTION C

# C. MEDICATION HISTORY

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Now I'd like to ask you about any medicines you have taken or currently take.

C1.	you	ring the past two (2) years, have u taken any of the following dicines?				
		Anti-convulsantsanti-seizure medicines (e.g. dilantin.	YES	NO	DON'T <u>KNOW</u>	<u>REFUSED</u>
		phenurone, tridione)	01	02		97
	Ь.	Antituberculous drugs (e.g., INH, PAS, Pyrazinamide, ethionamide)	01	02		97
_	c.	Antibiotics (e.g., penicillin, tetra- cycline, sulfonamides)	01	02		97
	d.	Pills for diabetes (e.g., Diabinese, Orinase, Dymelor, Tolinase)	01	02		97
	e.	Blood pressure medicines or water pills (e.g., Aldomet, Diuril, Hydro- diuril)	01	02	94	97
	f.	Male Hormones (e.g., methyltestosterone)	01	02	94	97
	g.	Female Hormones or birth control pills	01	02	94	97
	h.	Antithyroid drugs (e.g., Tapazole, propylthiouracil)	01	02	94	97
	i.	Antidepressants or major tranquilizers (including barbiturates, valium, librium, thorazine, sparine, mellaril stelazine, compazine, niamid, nardil, marplan, parnate, tofranil, elavil, etc.)	01	02	94	97

e2.	Are you currently taking, or have you taken within the past two (2) weeks,	DON'T YES NO KNOW REFUSED
	any prescription medicines	NO, DK, OR RE, GO TO C4.
СЗ.	[IF YES TO C2], could I see the bottles them correctly?	MEDICATION #1
	[RECORD NAME OF MEDICATION FROM SOURCE OR IF NOT AVAILABLE SAY:] "What is the name of the (first/next) medication you are currently taking?"	OFFICE USE
b.	For what condition are you currently taking (MEDICATION FROM a)?	
		OFFICE USE
c.	How much do you take a day? [RECORD # AND CODE METHOD]	#         PER DAY           CAPS/PILLS         01           OUNCES         02
		ML 03 OTHER 04
ď.	How long have you taken (MEDICATION FROM a)? [RECORD # AND CODE TIME PERIOD]	
		DAYS 01 WEEKS 02
		MONTHS 03 YEARS 04
		GO TO NEXT MEDICATION OR, AFTER ALL MEDICATIONS, C4.

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. . . INTERVIEWER: LIST BELOW THE NAMES OF ALL MEDICATIONS TAKEN BY THE RESPONDENT IN THE LAST TWO WEEKS. [LAST TWO WEEKS IS SAME AS TAKEN CURRENTLY.]

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MEDICATION #2	MEDICATION #3
OFFICE USE	OFFICE USE
PER DAY           CAPS/PILLS         01           OUNCES         02           ML         03           OTHER         04	PER DAY           CAPS/PILLS         01           OUNCES         02           ML         03           OTHER         04
#	#
GO TO NEXT MEDICATION OR, AFTER ALL MEDICATIONS, C4.	GO TO NEXT MEDICATION OR, AFTER ALL MEDICATIONS, C4.

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		(3)
(1)	(2)	Other <u>Non-prescription</u> <u>medicines</u> such as pil- tonics, vitamins, or remedies? (SPECIFY)
Vitamin 8-6	Vitamin A	OFFICE USE
YES01 NO02 ] DONT'T KNOW94 } + REFUSED97 J	YES 01 NO 02 ] DONT'T KNOW 94 }+ REFUSED 97 J	YES01 NO027 DONT'T KNOW94} REFUSED97J
OFFICE USE	OFFICE USE	OFFICE USE

ΰ.	For what con- dition are you currently taking?	OFFICE USE	OFFICE USE	
<u>с.</u>	How much do you take a day? [RECORD # AND CODE METHOD]	PER DAY           CAPS/PILLS         01           OUNCES         02           ML	PER DAY           CAPS/PILLS         .01           OUNCES         .02           ML         .03           OTHER         .04	PER DAY           CAPS/PILLS         .01           OUNCES         .02           ML         .03           OTHER         .04
d.	How long have you taken ? [RECORD # AND CODE TIME PERIOD]	#	# DAYS	#
		GO TO COLUMN (2)	GO TO COLUMN (3)	GO TO COLUMN (4)

C4.

a.

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Are you cur-rently taking

IF YES

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	(\$)	(0)
Other <u>Non-prescription</u> <u>medicines</u> such as pills, tonics, vitamins, or remedies? (SPECIFY)	Other <u>Non-prescription</u> <u>medicines</u> such as pills, tonics, vitamins, or remedies? (SPECIFY)	Other <u>Non-prescription</u> <u>medicines</u> such as pills, tonics, vitamins, or remedies? (SPECIFY)
OFFICE USE	OFFICE USE	OFFICE USE
YES01 NO027 I GO DONT'T KNOW94} TO I D. REFUSED97J	YES01 NO027 I GO DONT'T KNOW94} TO I D. REFUSED97J	YES01 NO021   GO DONT'T KNOW94} TO   D. REFUSED97J
OFFICE USE	OFFICE USE	OFFICE USE
# PER DAY CAPS/PILLS01 OUNCES02 ML03 OTHER04	#         PER DAY           CAPS/PILLS	PER DAY           CAPS/PILLS         01           OUNCES
# DAYS	# DAYS	#
GO TO COLUMN (5)	GO TO COLUMN (6)	GO TO NEXT OTHER NON- PRESCRIPTION MEDICINE. WHEN FINISHED WITH ALL, GO TO SECTION D.

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#### CONTINUE

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#### D. SMOKING HISTORY

Now I'd like to ask a few questions about the use of tobacco products.

D1. Have you smoked 100 or more cigarettes during your lifetime?

YES.....01 NO.....02 DON'T KNOW.....94 + GO TO D2 REFUSED.....97

IF YES:

a. How old were you when you first started smoking at least 2 cigarettes a d. or 1/2 pack a week?



[IF NEVER, CODE "00", and GO TO D2.]

b. Overall, for how many years did you smoke cigarettes, regularly (at least cigarettes a day or 1/2 pack per week)?



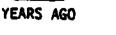
c. Over the entire time you smoked regularly, on the average how many cigarette did you smoke per day?



d. Have you smoked cigarettes regularly within the past year?

YES.....01 + GO TO D2 NO.....02 DON'T KNOW.....94 + GO TO D2 REFUSED.....97 + GO TO D2

e. [IF NO TO d.,] How many years ago did you last smoke cigarettes regularly?



D2. Have you ever smoked an average of one or more cigars a week for a year?

IF YES:

a. How many years altogether did you smoke an average of one or more cigars a week for a year?



b. Over that time period how many cigars a week did you smoke, on the average?



# CIGARS/WEEK

D3. Did you ever smoke an average of one or more pipefuls of tobacco a week for a year?

YES.....01 NO.....02 DON'T KNOW......94 + GO TO 04 REFUSED......97

IF YES:

a. How many years altogether did you smoke an average of one or more pipefuls of tobacco a week for a year?



b. Over that time period how many pipefuls of tobacco a week did you smoke, on the average?



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# PIPEFULS OF TOBACCO/WEEK

D4. Have you ever used smokeless tobacco like snuff or chewing tobacco an average cone or more times a week for a year?

```
YES.....01
NO.....02
DON'T KNOW.....94 + GO TO SECTION E
REFUSED.....97
```

IF YES:

a. How many years altogether did you use smokeless tobacco an average of c or more times a week for a year?



b. Over that time period how many times a week did you use smokeless tobacco, on the average?



# TIMES USED SMOKELESS TOBACCO/WEEK

E. ALCOHOLIC BEVERAGES

The next series of questions covers the consumption of alcoholic beverages.  $\exists$  alcoholic beverages we mean beer, wine, or liquor.

EL. Have you, in your entire life, consumed a total of 12 or more alcoholic beverage: in a single year?

YES01				
NO02				
DON'T KNOW94		GO TO	SECTION	F.
REFUSED97	)			

a. At what age did you first drink 12 or more an alcoholic beverages in a single year?

AGE	
DON'T KNOW	•
REFUSED	,

b. At what age did you last drink 12 or more alcoholic beverages in a single year?

AGE	
DON'T	KNOW94
REFUSE	

c. For how many years altogether did you drink at least 12 or more alcoholic beverages in a year?

ŧ	YEARS	

E2. On the average, how many days a month do or did you usually drink?

DAYS/MC	нти [		
DON'T	KNOW	9	)4
REFUSE	ED	9	)7

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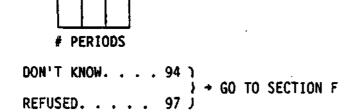
E3. On average, when you drink or when you drank, how many [COMPLETE FOR EACH TYPE OF BEVERAGE, ONE AT A TIME] do or did you usually drink a day?

à.	b.	с.
12 OZ. GLASSES OF	4 OZ. GLASSES OF	1 1/2 OZ. SHOTS OF
BEER	WINE	LIQUOR
NUMBER OF BEERS/DAY	NUMBER OF WINES/DAY	SHOTS/DAY
DON'T KNOW 94	DON'T KNOW 94	DON'T KNOW . 94
REFUSED 97	REFUSED 97	REFUSED 97

E4. Were there ever periods of 3 or more consecutive months when you drank considerably more than you normally did?

YES.....01 NO.....02 DON'T KNOW.....94 + GO TO SECTION F REFUSED.....97

E5. How many of these periods, when you drank considerably more than usual, have you ever had?



E6. At what age did the first period of drinking more than was usual begin?

AGE DON'T KNOW. . . . 94 REFUSED. . . . . 97

E7. At what age did the <u>last</u> period of drinking more than was usual begin?

AGE

**REFUSED.... 97** 

E8. For how many months on average did (this period/these periods) last?



E9. On average, when you drank during (this period/these periods), how many [COMPLETE FOR EACH TYPE OF BEVERAGE ONE AT A TIME] did you usually drink a day?

a.	b.	с.
12 OZ. GLASSES OF BEER	4 OZ. GLASSES OF WINE	1 1/2 OZ. SHOTS OF LIQUOR
NUMBER OF BEERS/DAY           NONE.         00           DON'T KNOW         94           REFUSED         97	NUMBER OF WINES/DAY         00           NONE.         00           DON'T KNOW         94           REFUSED         97	SHOTS/DAY       00         NONE.       00         DON'T KNOW.       94         REFUSED       97

#### F. EXPOSURES AWAY FROM THE WORKPLACE

I would like to ask you questions about the chemicals or toxic materials you may have used or handled in hobbies or activities away from your regular job or work. These non-job activities might include developing photographs, refinishing furniture, spray painting, lawn work, or any other spare time activity involving chemicals. We want to include only those activities you took part in 2 or more times per month, on average. F1. Did you ever have a hobby or engage in other activities on an average of 2 or more times per month that involved exposures to chemicals, toxic materials, or dusts?

YES01 NO02 DON'T KNOW94 + GO TO F2. REFUSED97	
[IF YES]:	HOBBY/ACTIVITY #1
a. What was the (first/next) hobby or activity that involved exposures to chemicals, toxic materials, or dusts? [GET THE TITLES OF ALL HOBBIES/ ACTIVITIES, THEN CONTINUE WITH b-e FOR EACH HOBBY/ACTIVITY.]	
b. What chemicals, toxic materials, or dusts were you exposed to in (HOBBY/ACTIVITY)?	1.       2.       3.
c. In what year did you start (HOBBY/ACTIVITY)?	19 DON'T KNOW
d. For how many years have you done (HOBBY/ACTIVITY)?	YEARS DON'T KNOW
e. How often would you say that you do or did (HOBBY/ACTIVITY)? Was it daily, at least once a week, at least twice a month, or less than twice a month?	DAILY
	GO TO NEXT ACTIVITY. WHEN FINISHED WITH ALL ACTIVITIES, GO TO F2.

HOBBY/ACTIVITY #2	HOBBY/ACTIVITY #3	HOBBY/ACTIVITY #4
1	1 2 3	1.
19 DON'T KNOW	19	19
YEARS	YEARS	YEARS DON'T KNOW
DAILY 01 1/WEEK 02 2/MONTH	1/WEEK 02	1/WEEK
LESS THAN 2/MONTH 04		
FINISHED WITH ALL ACTIVITIES,	GO TO NEXT ACTIVITY. WHEN FINISHED WITH ALL ACTIVITIES, GO TO F2.	GO TO NEXT ACTIVITY. WHEN FINISHED WITH ALL ACTIVITIES GO TO F2

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F2. Have you or anyone in your household [IF YES] .1 .2 .3 What (was/were) the name(s) of the spray(s)How many times For per year? how many years ? (company)? a...personally applied household bug spray more than 4 times a TIMES/YEAR # YEARS year in your home? YES . . . . . 01 + + DON'T KNOW. .94 DON'T KNOW . . 94 DON'T KNOW . . 94 NO 02 1 GO TO b. DON'T KNOW. . 94 J 1 b...had any pest control company treat the inside of your home more than 4 times a year? TIMES/YEAR # YEARS YES . . . . . 01 + + DON'T KNOW. .94 DON'T KNOW . . 94 DON'T KNOW . . 94 02 ) NO GO TO c. DON'T KNOW. . 94 J 4 c...personally sprayed weed killers more than 4 times a year in areas around the outside of your home? TIMES/YEAR # YEARS YES . . . . . 01 + + DON'T KNOW. .94 DON'T KNOW . . 94 DON'T KNOW . . 94 NO 02 ) DON'T KNOW. . 94 J 1 GO TO d. d...had a chemical company spray weed killers around the outside of your home more than 4 TIMES/YEAR # YEARS times a year? DON'T KNOW. .94 DON'T KNOW . . 94 YES . . . . . 01 + + DON'T KNOW . . 94 02 I DON'T KNOW. . 94 J 1

F3. Has anyone in your household other than yourself worked at a chemical plant tr manufactured herbicides (weed killers)?

	YES01 NO02 DON'T KNOW94	+ GO TO SECTION G				
	REFUSED97					
a.	[IF YES], please tell the name and address			r person	to you	ŝ
RELAT	IONSHIP	<u> </u>	<u>.</u>			
NAME	OF COMPANY	<u></u>		····-		_
STREE	T ADDRESS					
CITY,	STATE			ZIP		

#### G. MISCELLANEOUS

This section asks about places where you might have visited or lived and bee exposed to certain types of chemicals.

G1. Have you ever traveled or lived outside of the United States either on your ow or because of your job, including military service?

YES.....01 NO.....02 DON'T KNOW.....94 + GD TO G16 REFUSED.....97

G2. While you were living or traveling outside of the United States did you ever spend more than just a few hours in Vietnam after September of 1964?

YES01				
NO02				
DON'T KNOW 94	+	GO	то	G16
REFUSED97				

G3. Were you in Vietnam while serving in the military?

YES01				
NO02				
DON'T KNOW	+	GO	TQ	Gδ
REFUSED97				

G4. What branch(es) of service were you in while in Vietnam?

	[CIRCLE	ALL	THAT	APPLY]
ARMY	* * * * * * * * *	.01		
NAVY		.02		
AIR FOR	E	.03		
MARINES		04		

G5. What was your service number?

.



DON'T KNOW......94 REFUSED......97

G6. During what years were you in Vietnam?

FROM 19	T0 19	
FROM 19	T0 19	
FROM 19	TO 19	
DON'T KNOW REFUSED	-	·

G7. What were your activities or duties while in Vietnam?

.

G8. Did you come into contact with herbicides, insecticides, or pesticides Vietnam?

> YES.....01 NO.....02 DON'T KNOW.....94 + GO TO G12 REFUSED.....97

G9. What were the chemicals used for, that is, were they used to kill insects destroy vegetation, or for some other purpose? [CIRCLE ALL THAT APPLY.]

KILL INSECTS.....01 DESTROY VEGETATION....02 OTHER (SPECIFY)....03

G10. Did you spray or apply these chemicals?

YES.....01 NO.....02 DON'T KNOW.....94 REFUSED.....97

a. [IF YES], for how many days in total did you spray or apply herbicide: insecticides, or pesticides in Vietnam?

DAYS			
		_	

DON'T KNOW.....94 REFUSED.....97

- b. Do you know the names of the chemicals that you sprayed or applied? YES.....01 NO.....02 REFUSED......97 + GO TO GI1
- c. [IF YES], what were their names?

G11. Were you present when others were spraying these chemicals?

YES.....01 NO.....02 DON'T KNOW.....94 + GO TO G12 REFUSED.....97

a. [IF YES], for how many days in total were you present while others wer spraying or applying these chemicals?

DAYS		
DON'T	KNOW	 94
REFUSE	:D	 97

b. Do you know any of the names of the herbicides, insecticides, or pesticide that you worked with or came in contact with?

YES.....01 NO.....02 REFUSED......97 + GO TO G12

c. [IF YES], what were their names?

G12. Did you pass through any area that looked like it had been defoliated (that is, sprayed with a chemical to kill vegetation; trees, and grass)?

YES.....01 NO.....02 DON'T KNOW.....94 REFUSED.....97 [IF AGENT ORANGE IS LISTED IN GIOC OF GIIC, AUTOMATICALLY CODE GI3 - 01 - 4EL AND CONTINUE WITH GI4. IF NOT, ASK GI3.]

G13. One of the herbicides used in Vietnam was Agent Orange. Did you ever come contact with Agent Orange?

> YES.....01 NO.....02 DON'T KNOW.....94 + GO TO G16 REFUSED.....97

G14. How did you come in contact with Agent Orange while in Vietnam?

G15. On how many days in total, did you come in contact with Agent Orange while i Vietnam?

DAYS		
DON'T	KNOW.	
REFUSI	ED	

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RURAL QUESTIONS

GIG. During any part of your life'did you live' or work on a farm, a ranch, or in rural area?

YES.....01 NO.....02 DON'T KNOW.....94 REFUSED.....97 FT-3

- [IF YES:]
- a. In what year did you first live or work on a farm or ranch or in a rural area?



b. In what year did you last live or work on a farm or ranch or in a rural area?



c. In total, for how many years did you live or work on a farm or ranch or in a rural area?



G17. While living or working on a farm, ranch, or in a rural area, were any herbicides, pesticides, or insecticides ever used on the land or crops?

YES.....01 . NO.....02 DON'T KNOW......94 REFUSED......97

G18. Did you ever apply or spray, or mix or prepare, herbicides, insecticides or pesticides, or work in or near an area where they were used?

YES.....01 NO.....02 DON'T KNOW.....94 + GO TO SECTION H REFUSED......97

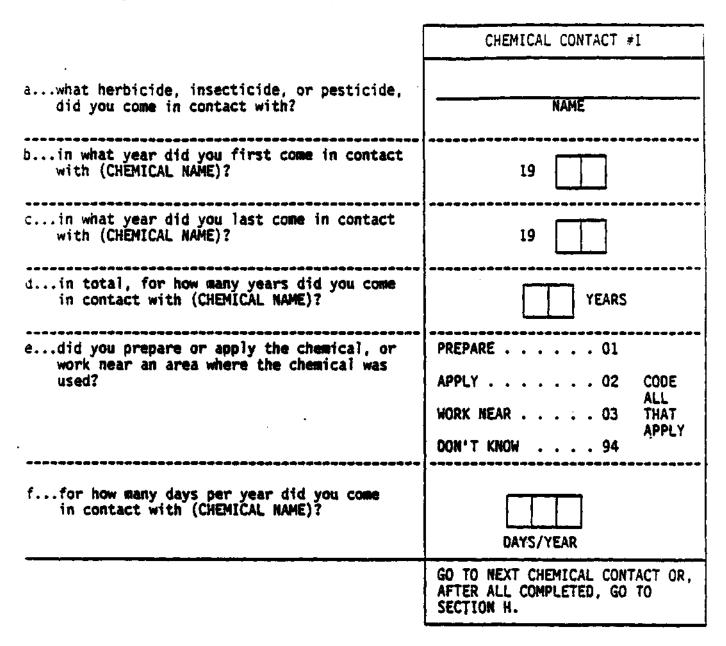
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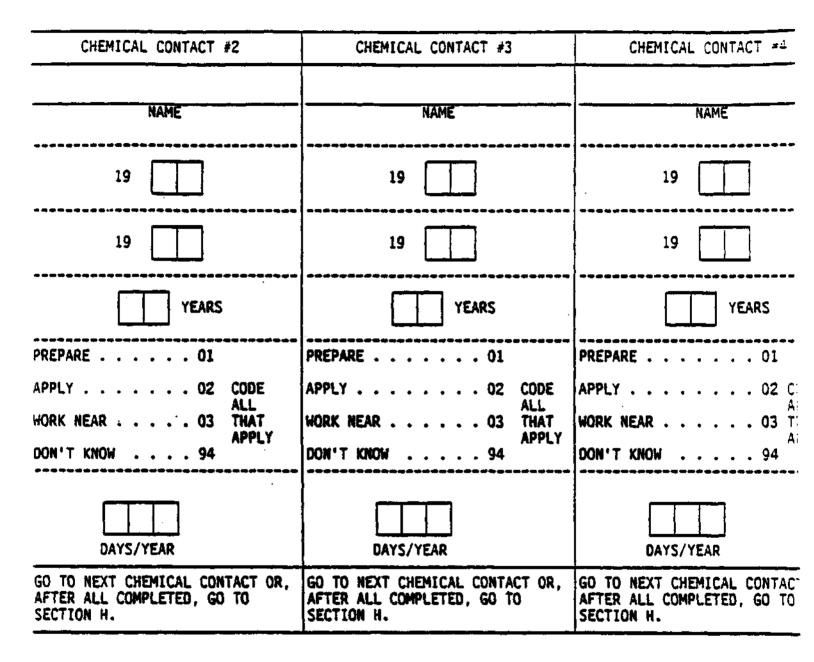
CONTINUE

G19. While you were on a farm, ranch, or in a rural area . . .

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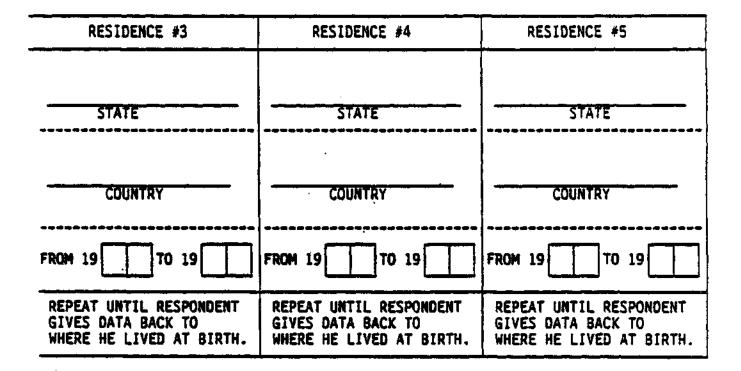
H. SUNLIGHT EXPOSURE AND SENSITIVITY

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In the next few questions I will be asking you about places you have lived, no much time you spend in the sun, and your sensitivity to sunlight.

H1. Beginning with the state in which you currently live, and then going backwards please list the states and countries in which you have lived for more than months since you were born. If you were in the military, include places wher you were stationed for more than 6 months.

		RESIDENCE #1	RESIDENCE #2
a.	What state (do/did) you (now/previously) live in?	STATE	STATE
b.	[ASK ONLY IF YOU DON'T KNOW] What country is that state in?	COUNTRY	COUNTRY
c.	During which years did you live there?	FROM 19 70 19	FROM 19 TO 19
		REPEAT UNTIL RESPONDENT GIVES DATA BACK TO WHERE HE LIVED AT BIRTH.	REPEAT UNTIL RESPONDENT GIVES DATA BACK TO WHERE HE LIVED AT BIRTH.



H2. IF RESPONDENT DID NOT REPORT "LIVED IN NEW JERSEY" (IN H1 a:), GO TO H6. IF RESPONDENT DID REPORT "LIVED IN NEW JERSEY" (IN H1 a:) SAY:

Did you ever live in Newark, New Jersey?

YES.....01 NO.....02 DON'T KNOW.....94 + GO TO H6. REFUSED.....97

H3. Did you ever live on any of the following streets: Albert, Joseph, Euclic Lister, Cornelia, or Lockwood?

> YES.....01 NO.....02 DON'T KNOW.....94 + GO TO H6. REFUSED.....97

H4. During what years did you live on any of these streets?

1)	•	FROM 19 . TO 19	3)	FROM 19 TO 19
2)		FROM 19 TO 19	4)	FROM 19 TO 19
ð.		In total, for how many months did you	live on	any of these streets?
		MONTHS		
•		DONT'T KNOW94		
		<b>REFUSED97</b>		

H5. Can you please give the address(es)?

NO. AND STREET	
CITY AND STATE	
ZIP CODE	
-	
NO. AND STREET	
CITY AND STATE	
-	
-	

Now I have a few questions about you and your sensitivity to sunlight.

H6. When you were a child, did you have many freckles, a few freckles, or no freckles at all?

MANY.....01 A FEW.....02 NO FRECKLES....03 DON'T KNOW.....94

[HAND RESPONDENT CARD H7:] Please look at this card.

H7. What usually happens to your skin after your first half-hour of sun exposure the summer?

H8. Have you ever, in your life, had a severe, blistering sunburn?

YES.....01 NO.....02 DON'T KNOW......94 + GO TO H10 H9. How many times have you had a severe, blistering sunburn?

ONCE	OR	TWIC	E	• • • • •	01
3-10	TI₽	IES		• • • • •	02
MORE	THA	N 10	TIME	s	03
DON'I	r KN	IOW	••••	••••	94

H10. What is the natural color of your eyes?

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BLUE01
GREEN
BROWN
HAZEL04
OTHER

. .

H11. What was your natural hair color at age 16?

BLOND	
RED02	
BROWN03	
BLACK04	
OTHER05	_

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H12. Did you ever have medical treatment or therapy with radiation or isotopes?

YES.....01 NO.....02 DON'T KNOW.....94 + GO TO H13. REFUSED.....97

		TREATMENT #1	TREATMENT #2	TREATMENT #3
a.	What part of your body was treated?			
b.	For how long were you treated? [RECORD # AND CODE TIME PERIOD.]	WEEKS 02 Months 03	WEEKS 02 Months 03	#
L <b></b>		GO TO NEXT TREATMENT AFTER ALL TREATMENTS, GO TO H13.		

H13. Did you ever receive ultraviolet or sunlamp therapy for a medical or ski condition?

YES.....01 NO.....02 OON'T KNOW.....94 + GO TO H14. REFUSED.....97

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		TREATMENT #1	TREATMENT #2	TREATMENT #3
a.	What part of your body was treated?		·	
b.	For how long were you treated? [RECORD # AND CODE TIME PERIOD.]	WEEKS 02 Months 03	MONTHS 03	# DAYS 01 WEEKS 02 MONTHS 03 YEARS 04
 c.	Did you take psoralin pills with this therapy?	NO 02 DON'T KNOW . 94	YES 01 NO 02 DON'T KNOW . 94 REFUSED 97	YES 01 NO 02 DON'T KNOW . 94 REFUSED 97
·	······		TO NEXT TREATMEN L TREATMENTS, GO	

DOHQ H-7

In the next set of questions, I will be asking you to estimate the average number of hours per day you spend outdoors during your leisure time between the nours 9:00 a.m. and 5:00 p.m. By leisure time I mean, the time not working at pousual job, for example time spent hunting, fishing, playing golf, swimming gardening. Please do not include sunbathing.

-		a.	b.	с.
H14.	When you were	on the average how many leisure days (do/did) you spend out of doors each year?	on the average how many hours per week (did/ do) you spend outdoors during your leisure time during the Spring and Summer (April- September)	on the average how many hours per week (did/ do you spend outdoors during your leisure time during the Fall and Winter (Oct-March)?
	16-21 YEARS OLD	DAYS/YEAR	HOURS/WEEK	HOURS/WEEK [GO TO NEXT AGE]
	22-30 YEARS OLD	DAYS/YEAR	HOURS/WEEK	HOURS/WEEK [GO TO NEXT AGE]
•	31-40 YEARS OLD	DAYS/YEAR	HOURS/WEEK	HOURS/WEEK [GO TO NEXT AGE]
	41-60 YEARS OLD	DAYS/YEAR	HOURS/WEEK	HOURS/WEEK [GO TO NEXT AGE]
·	61+ YEARS OLD	DAYS/YEAR	HOURS/WEEK	HOURS/WEEK [GO TO H15]

	a.	b	с.	۵.	
H15. When you were	how often did you use sun- screen or tanning lotion? Would you say	how often did you wear a hat, long sleeves, and long pants as protective clothing from the sun? Would you say	on the average, how many days per year did you sunbathe outdoors?	on the average how many days per year did ys sunbathe using sunlamps or tanning booths:	
	-	Usually 01			
16-21 YEARS OLD	1	Sometimes 02	DAYS/YEAR	DAYS/YEAR	
		Never 03		GO TO NEXT AGE	
		Usually 01			
22-30 YEARS OLD		Sometimes 02	DAYS/YEAR	DAYS/YEAR	
	Never 03	Never 03		[GO TO NEXT AGE	
1	Usually 01	Usually 01			
31-40 YEARS OLD	Sometimes 02	Sometimes 02	DAYS/YEAR	DAYS/YEAR	
	Never 03	Never 03		[GO TO NEXT AGE	
	Usually 01	Usually 01			
41-60 YEARS OLD	Sometimes 02	Sometimes 02	DAYS/YEAR	DAYS/YEAR	
		Never 03		[GO TO NEXT AGE	
	Usually 01	Usually 01	[		
61+ YEARS OLD	Sometimes 02	Sometimes 02	DAYS/YEAR	DAYS/YEAR	
	Never 03	Never 03		[GO TO SECTION I]	

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## DOHQ H-9

#### I. DATA CONCERNING MARITAL STATUS

INTERVIEWER: SKIP THIS SECTION IF THE STUDY MEMBER IS FEMALE.

This section is about your marital history. For the purposes of this interview, I will use the word "wife" to refer to a person you were married to for any length of time or a woman you lived with for 2 or more years.

Part of our study deals with the possible reproductive problems resulting from exposure to chemical-herbicides. Because women are better at remembering the details about their pregnancies, we will be interviewing wives and former wives about their pregnancies. The interview will be conducted by phone and will take about 30 minutes to complete.

II. Are you currently married or living with a woman as though married?

YES.....01 NO.....02 DON'T KNOW....94 REFUSED.....97

PLACE A LARGE "X" THROUGH "CURRENT WIFE" NAME
 AND ADDRESS INFORMATION ON THE CONTROL CARD AND GO TO 13.

I2. What is your current wife's or partner's name, address, and telephone number?

RECORD INFORMATION IN THE CURRENT WIFE COLUMN ON THE CONTROL CARD FOR THIS RESPONDENT. BE CERTAIN TO ASK AND RECORD CURRENT WIFE BIRTHDATE.

USE THE QUESTION PROVIDED ON THE CONTROL CARD TO SECURE WIFE LOCATOR INFORMATION.

IF DECEASED, RECORD ALL INFORMATION AND DATE OF DEATH ON CONTROL CARD.

I3. (Other than your current wife or partner) how many times have you been married or lived with a woman for at least 2 years as though married?

TIMES MARRIED/LIVED AS MARRIED



IF "00" GO TO SECTION J

DOHQ I-1

14. What (is/are) the name(s), telephone number(s), and last address(es) of your former (wife/wives)?

MAKE CERTAIN THE NUMBER OF NAMES AND ADDRESSES ENTERED FOR "OTHER WIVES" ON THE CONTROL CARD MATCHES THE NUMBER ENTERED IN Q.I3. REMEMBER TO ASK AND RECORD BIRTHDATE(S).

USE THE QUESTION PROVIDED ON THE CONTROL CARD TO SECURE WIFE LOCATOR INFORMATION.

IF DECEASED, RECORD ALL INFORMATION AND DATE OF DEATH ON CONTROL CARD.

J. OCCUPATIONAL HISTORY

SECTION I - SPECIFIC

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*		A	LL	RE	FE	RE	КI	rs.	SI	CIP	Ţ	0	J.	0	CCU	PA	TI	ONA	L	HI	STO	RY		SEC		[ON	I	۷.	-	G	ENE	ER/	۱L.		*
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-		-	-	-	-	•	•				<b>.</b>	-	•	÷.	<b>.</b> .		-		•	•	* *						•	-	•	•				•	

This next series of questions asks about specific companies and locations where you might have worked and your jobs at those places.

We have obtained employment records from (COMPANY NAME). I am going to ask you questions about your work at (COMPANY NAME).

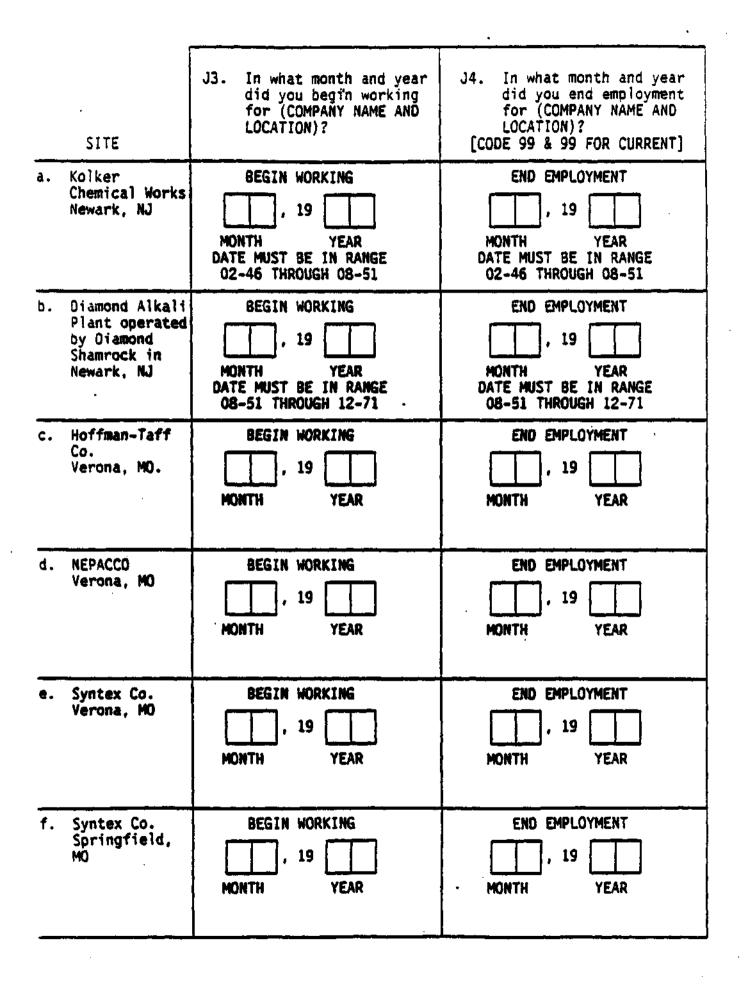
I would like you to refer to a copy of the work history information we obtained from (COMPANY NAME) before answering the questions. The information may be correct or it may include errors. Please look at it carefully and try to give me the most correct information possible.

HAND RESPONDENT THE COPY OF THE WORK HISTORY SHEET AND RETAIN A COPY FOR YOUR USE.

BE CERTAIN THAT ANY DATA COLLECTED ABOUT THE KOLKER OR DIAMOND ALKALI PLANT IN NEWARK SPECIFICALLY REFERS TO THE PLANT LOCATED JUST SOUTH OF THE PASSAIC RIVER AT 80 LISTER STREET.

	SITE	INTERVIEWER, IS J1. WORK HISTORY INCLUDED?	ASK FOR EVERY COMPANY WITH "NO" IN J1. J2. Have you ever worked for (COMPANY NAME AND LOCATION)?
3.	Koiker Chemical Works Newark, NJ	YES 01 + GO TO J3 NO 02 + + + + +	YES 01 NO 02 ) GO TO DON'T KNOW 94 } + NEXT CO. REFUSED 97 J
<b>b.</b>	Diamond Alkali Plant operated by Diamond Shamrock in Newark, NJ	YES 01 + GO TO J3 NO 02 + + + + +	YES 01 NO 02 ) GO TO DON'T KNOW 94 } + NEXT CO. REFUSED 97 J
c.	Hoffman-Taff Co. Verona, MO.	YES 01 + GO TO J3 NO 02 + + + + +	YES 01 NO 02 ) GO TO DON'T KNOW 94 } + NEXT CO.
d.	NEPACCO Verona, MO	YES 01 + 60 TO J3 NO 02 + + + + +	YES 01 NO 02 ) GO TO DON'T KNOW 94 } + NEXT CO. REFUSED 97 J
e.	Syntex Co. Verona, MD	YES 01 + GO TO J3 NO 02 + + + + +	YES 01 NO 02 ] GO TO DON'T KNOW 94 } + NEXT CO. REFUSED 97 J
f.	Syntex Co. Springfield, MO	YES 01 + GO TO J3 NO 02 + + + + +	YES 01 NO 02 ) GO TO DON'T KNOW 94 } + J SECTION II REFUSED 97 J

.



	SITE	J5. Were you first assigned to production, maintenance/trades, laboratory, or office/ clerical?	J6. HAND RESPONDENT CARD J6/J18a Using this card and your work histor sheet, tell me to what process you were first assigned.
a.	Kolker Chemical Works	PRODUCTION 01	CODE FROM CARD
	Newark, NJ	MAINTENANCE/TRADES 02	(IF 28, SPECIFY)
		LABORATORY 03	28=
		OFFICE/CLERICAL 04	
b.	Diamond Alkali Plant operated	PRODUCTION 01	CODE FROM CARD
	by Diamond Shamrock in	MAINTENANCE/TRADES 02	(IF 28, SPECIFY)
	Newark, NJ	LABORATORY 03	
		OFFICE/CLERICAL 04	<u>28=</u>
ç.	Hoffman-Taff Co.	PRODUCTION 01	CODE FROM CARD
	Verona, MQ.	MAINTENANCE/TRADES 02	(IF 28, SPECIFY)
		LABORATORY 03	29-
		OFFICE/CLERICAL 04	28=
d.	NEPACCO Verona, MO.	PRODUCTION 01	CODE FROM CARD
	Telone, no.	MAINTENANCE/TRADES 02	(IF 28, SPECIFY)
		LABORATORY	28.
		OFFICE/CLERICAL 04	28=
e.	Syntex Co. Verona, MD.	PRODUCTION 01	CODE FROM CARD
	verona, my.	MAINTENANCE/TRADES 02	(IF 28, SPECIFY)
		LABORATORY 03	
		OFFICE/CLERICAL 04	28=
f.		PRODUCTION 01	CODE FROM CARD
	Springfield, MO.	MAINTENANCE/TRADES 02	(IF 28, SPECIFY)
	•	LABORATORY 03	
		OFFICE/CLERICAL 04	· <u>28=</u>

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	SITE	J7. [HAND RESPONDENT CARD J7:] What was the first job title you held for a month or more in (PROCESS FROM J6)?
a.	Kolker Chemical Works Newark, NJ	<u>JOB TITLE:</u>
		OFFICE USE
b.	Diamond Alkali Plant operated by Diamond Shamrock in	JOB TITLE:
	Newark, NJ	
c.	Hoffman-Taff Co. Verona, MO.	JOB TITLE:
d.	NEPACCO Verona, MD.	<u>JOB TITLE:</u>
		OFFICE USE
<b>e.</b>	Syntex Co. Verona, MO.	JOB TITLE:
f.	Syntex Co. Springfield, MD.	JOB TITLE:
•		OFFICE USE

• -

		J8. When did you first and last work as (JOB TITLE IN J7)?	J9. Please tell me your duties as a (JOB TITLE FROM J7)?
	SITE	IN 577:	
à.	Kolker Chemical Works Newark, NJ	MONTH         YEAR           FIRST	DUTIES:
Þ.	Diamond Alkali Plant operated by Diamond Shamrock in Newark, NJ	MONTH         YEAR           FIRST	<u>OUTIES:</u>
c.,	Hoff <b>man-Taff</b> Co. Verona, MO.	MONTH         YEAR           FIRST	<u>DUTIES:</u>
d.	NEPACCO Verona, MO.	MONTH         YEAR           FIRST	<u>OUTIES:</u>
e.	Syntex Co. Verona, MO.	MONTH         YEAR           FIRST         .         .         19	<u>DUTIES:</u>
f.	Syntex Co. Springfield, MO.	MONTH         YEAR           FIRST	<u>DUTIES:</u>

' r

	SITE	J10. HAND RESPONDENT CARD What kind of protect wear as a (JOB TITLE	ive clothing or equipment did you
ā.	Kolker Chemical Works	RUBBER BOOTS01	RUBBER/CARTRIDGE RESPIRATOR04
	Newark, NJ	GLOVES	SUPPLIED AIR RESPIRATOR05
		MASK	NONE
		OTHER (SPECIFY)07	
b.	Diamond Alkali	RUBBER BOOTS01	RUBBER/CARTRIDGE RESPIRATOR04
	plant <b>operated</b> by Di <b>amond</b> Shamrock in Newark, NJ	GLOVES	SUPPLIED AIR RESPIRATOR05
		MASK	NONE
		OTHER (SPECIFY)07	·
c.	Hoffman-Taff Co.	RU88ER 800TS01	RUBBER/CARTRIDGE RESPIRATOR04
	Verona, MD.	GLOVES	SUPPLIED AIR RESPIRATOR05
		MASK	NONE
		OTHER (SPECIFY)07	
d.	NEPACCO Verona, MO	RU88ER 800TS01	RUBBER/CARTRIDGE RESPIRATOR04
	Terona, no	GLOVES	SUPPLIED AIR RESPIRATOR05
		MASK	NONE
		OTHER (SPECIFY)07	
e.	Syntex Co. Verona, MO	RU88ER BOOTS01	RUBBER/CARTRIDGE RESPIRATOR04
	VELONE, MY	GLOVES	SUPPLIED AIR RESPIRATOR05
		MASK	NONE
	i	OTHER (SPECIFY)07	· · ·
f.	Syntex Co.	RUBBER BOOTS01	RUBBER/CARTRIDGE RESPIRATOR04
	Springfield, MO	GLOVES	SUPPLIED AIR RESPIRATOR05
		MASK	NONE
	-	OTHER (SPECIFY)07	· · ·

	SITE	J11. When you worked as a (JOB TITLE IN J7) how many hours did you usually spend outdoors during your work shift?
5		HOURS OUTDOORS
а.	Kolker Chaminal Hanks	LESS THAN 1 HOUR 01 4-5 HOURS 05
	Chemical Works Newark, NJ	1-2 HOURS 02 5-6 HOURS 06
	•	2-3 HOURS 03 MORE THAN 6 HOURS 07
		3-4 HOURS 04
b.	Diamond Alkali	
	Plant operated by Diamond Shamrock in Newark, NJ	1-2 HOURS 02 5-6 HOURS 06
		2-3 HOURS MORE THAN 5 HOURS 07
		3-4 HOURS 04
c.	Hoffman-Taff	LESS THAN 1 HOUR 01 4-5 HOURS 05
	Co. Verona, MD.	1-2 HOURS 02 5-6 HOURS 06
		2-3 HOURS 03 MORE THAN 6 HOURS 07
		3-4 HOURS 04
d.	.NEPACCO	LESS THAN 1 HOUR 01 4-5 HOURS 05
	Verona, MO.	1-2 HOURS 02 5-6 HOURS 06
		2-3 HOURS 03 MORE THAN 6 HOURS 07
		3-4 HOURS 04
e.	Syntex Co.	LESS THAN 1 HOUR 01 4-5 HOURS 05
	Verona, MO	1-2 HOURS 02 5-6 HOURS 06
		2-3 HOURS 03 MORE THAN 6 HOURS 07
		3-4 HOURS 04
f.	Syntex Co.	LESS THAN 1 HOUR 01 4-5 HOURS 05
	Springfield, MO	1-2 HOURS 02 5-6 HOURS 06
		2-3 HOURS 03 MORE THAN 6 HOURS 07
		3-4 HOURS 04 -

[HAND RESPONDENT CARD # J-12 AND SAY:] Please tell me the letter which corresponds to your answer.

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	· · ·	J12. When you ender (JOB TITLE IN you do? [CIRC	J7) what did	
a.	Kolker Chemical Works	A01 D	04	
	Newark, NJ	802 E	05	· ·
		С03		ANSWER ROUTING INSTRUCTIONS
<b>b</b> .	Diamond Alkali Plant operated	A01 D	· · · · · 04 [	01 = GO TO CONTINUATION AND REPEA
· -	by Diamond Shamrock in		05	OS.J5-J16. LABEL COMPANY HAT IN PART a f.
	Newark, NJ	C03		02 = GO TO NAMED STUDY COMPANY AN
с.	Hoffman-Taff Co.	·····	04	START WITH Q.J1. WHEN ALL (a-f) FINISHED, GO TO
	Verona, MO.	B02 E	05	J SECTION II.
		C03		<pre>03 = TELL THE RESPONDENT: We will     talk about that job a little</pre>
d.	NEPACCO	A01 D	04	Tater. GO TO NEXT UNANSWERE: STUDY COMPANY AND START WITH
	Verona, MO		05	Q.J1. WHEN ALL (a-f) FINISHED, GO TO J. SECTION II
		C03		04 = 60 TO J13.
e.	Syntex Co. Verona, MD	A01 D	04	05 - GO TO NEXT UNANSWERED STUDY
	•	802 E	05	COMPANY AND START WITH Q.J1. WHEN ALL (a-f) FINISHED, GO
		C03		TO J SECTION II.
f.		A01 D	04	
	Springfield, MO	B02 E	05	
		C03		

	SITE	J13. What was the reason for being out of work for a month or more?	J14. On what month, day, and year were you (ANSWER FROM J13)?
à.	Kolker Chemical Works Newark, NJ	LAID OFF 01 DISABLED (SICK) 02 RETIRED 03 QUIT 04 OTHER	DATE OUT OF WORK
	·····	(SPECIFY) 05	
b.	Diamond Alkali Plant operated by Diamond Shamrock in Newark, NJ	LAID OFF 01 DISABLED (SICK) 02 RETIRED 03 QUIT 04 OTHER (SPECIFY) 05	DATE OUT OF WORK
с.	Hoffman-Taff Co. Verona, MO.	LAID OFF 01 DISABLED (SICK). 02 RETIRED 03 QUIT 04 OTHER (SPECIFY) 05	DATE OUT OF WORK
d.	NEPACCO Verona, MO	LAID OFF 01 DISABLED (SICK) 02 RETIRED 03 QUIT 04 OTHER (SPECIFY) 05	DATE OUT OF WORK
e.	Syntex Co. Verona, MO	LAID OFF 01 DISABLED (SICK) 02 RETIRED 03 QUIT 04 OTHER (SPECIFY) 05	DATE OUT OF WORK
f.	Syntex Co. Springfield, MO	LAID OFF 01 DISABLED (SICK) 02 RETIRED 03 QUIT 04 OTHER (SPECIFY) 05	DATE OUT OF WORK

		J15. On what month, day, and year did you go back to work?
	SITE	IF NEVER, ENTER 99-99-99 AND GO TO NEXT COMPANY (a f.) OR GO TO J SECTION II.
C	olker hemical Works ewark, NJ	DATE BACK TO WORK -
P b S	iamond Alkali lant operated y Diamond hamrock in ewark, NJ	DATE BACK TO WORK
C	offman-Taff o. erona, MO.	DATE BACK TO WORK
	EPACCO erona, MO	DATE BACK TO WORK
	yntex Co. erona, MO	DATE BACK TO WORK
S	iyntex Co. pringfield, D	DATE BACK TO WORK

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		J16. Where did you go back to work?	
	SITE	WHERE BACK TO WORK	·
a.	Kolker Chemical Works Newark, NJ	AT ANOTHER STUDY COMPANY/	
		LOCATION LISTED	
b.	Diamond Alkali Plant operated by Diamond Shamrock in	AT ANOTHER STUDY COMPANY/	01 = GO TO A CONTINUATION AND REPEAT QS J5-J16. LABEL COMPANY NAME IN PART a-f.
	Snampock in Newark, NJ	LOCATION LISTED	02 = GO TO NAMED STUDY COMPANY AND START WITH QJ1. WHEN ALL (a-f) FINISHED, GO TO J SECTION II.
c.	Hoffman-Taff Co.	AT SAME STUDY COMPANY/LOCATION 01	03 = TELL THE RESPONDENT:
	Verona, MO.	AT ANOTHER STUDY COMPANY/ LOCATION LISTED	We will talk about that company later. GD TO NEX UNANSWERED STUDY COMPANY
	·	TOOK ANOTHER JOB AT ANY OTHER COMPANY OR COMPANY/LOCATION 03	AND START WITH QJ1. WHEN ALL (a-f) FINISHED, GO TO J SECTION II.
d.	NEPACCO Verona, MO	AT SAME STUDY COMPANY/LOCATION 01 AT ANOTHER STUDY COMPANY/ LOCATION LISTED 02	
		TOOK ANOTHER JOB AT ANY OTHER COMPANY OR COMPANY/LOCATION 03	
e.	Syntex Co. Verona, MD	AT SAME STUDY COMPANY/LOCATION 01	
		AT ANOTHER STUDY COMPANY/ LOCATION LISTED	
		TOOK ANOTHER JOB AT ANY OTHER COMPANY OR COMPANY/LOCATION 03	
f,	Syntex Co. Springfield,	AT SAME STUDY COMPANY/LOCATION 01	
	MO	AT ANOTHER STUDY COMPANY/ LOCATION LISTED	
		TOOK ANOTHER JOB AT ANY OTHER COMPANY OR COMPANY/LOCATION 03	
		AFTER ALL SECTIONS a f. AND CONTINUAT	TONS ARE ETHISHED

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AFTER ALL SECTIONS a.-f. AND CONTINUATIONS ARE FINISHED, GO TO J. SECTION II.

#### J. OCCUPATIONAL HISTORY

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SECTION II - AUXILIARY QUESTIONS FOR KOLKER AND DIAMOND SHAMROCK EMPLOYEES

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	-	a. KOLKER CHEMICAL WORKS IN NEWARK, NJ	D. DIAMOND SHAMROCK ALKALI PLANT IN NEWARK, NJ
J17.	REVIEW QJ1. DID THIS PERSON EVER WORK AT [CODE EACH COLUMN]	YES 01 NO 02 ) i GO TO DON'T KNOW . 94 }+COLUMN b. REFUSED 97 J	YES 01 NO 02 )   GO TO J DON'T KNOW 94 >+ SECTION   III REFUSED 97 J
J18.	Were you present at work on a day when there was an explo- sion or major fire?	YES 01 NO 02 GO TO COLUMN D.	YES 01 NO 02 GO TO NEXT SECTION
	a. HAND CARD J6/J18a. To what process were you assigned?	CODE FROM CARD J6/J18a (IF 28, SPECIFY) 28 =	CODE FROM CARD J6/J18a (IF 28, SPECIFY) 28 =
J19.	What sub- stance exploded or burned?		
J20.	What month and year did that happen?	MONTH YEAR	MONTH YEAR
J21.	Were you in the immediate area of the mishap, in an area adjacent to the area where the mishap occur- red or were you in some other area of the plant?	ADJACENT AREA 02 SOME OTHER AREA 03	IMMEDIATE AREA 01 ADJACENT AREA 02 SOME OTHER AREA 03

		a. KOLKER CHEMICAL WORKS IN NEWARK, NJ	<b>b. DIAMOND SHAMROCK ALKALI</b> PLANT IN NEWARK, NJ
J22.	Did you get any dust, ash or debris on your clothes or skin from the explosion or fire?	DON'T KNOW . 94	YES 01 NO 02 DON'T KNOW . 94 REFUSED 97
J23.	Were you in- volved in the clean-up after the mishap?	YES 01 NO 02 + GO TO J26	YES 01 NO 02 + GO TO J26
J24.	What were your clean-up duties?		
J25.	For how many days were you involved with the clean-up?	DAYS	DAYS
J26.	Were you present at another explosion or major fire at (NAME FROM COLUMN a. or b.)		YES 01 + GO TO NEXT MISHAP NO 02 + GO TO J27

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### J. OCCUPATIONAL HISTORY

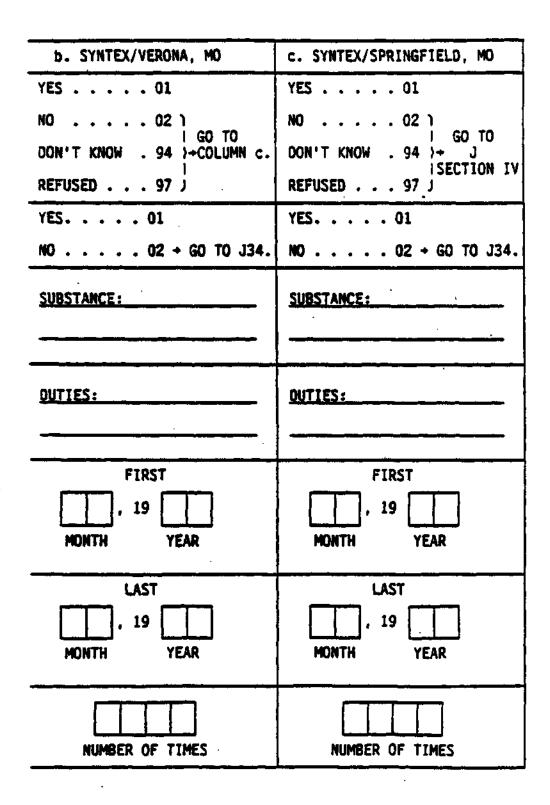
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#### SECTION III - AUXILIARY QUESTIONS FOR NEPACCO AND SYNTEX EMPLOYEES

	-	a. NEPACCO/VERONA, MO
J27.	REVIEW QJ1. DID THIS PERSON EVER WORK AT NEPACCO/VERONA OR SYNTEX/VERONA OR SYNTEX/SPRINGFIELD? [CODE EACH COLUMN]	YES 01 NO 02 ) DON'T KNOW . 94 }+GO TO   COLUMN REFUSED 97 J
J28.	Did you ever <u>dispose</u> of still bottom or any other kinds of wastes?	YES 01 NO 02 + GO TO J3
J29.	What substance did you <u>dispose</u> of?	SUBSTANCE:
J30.	What were your duties in <u>disposing</u> of (SUBSTANCE(S) LISTED IN J29)?	<u>OUTIES:</u>
J31.	In what month and year did you first <u>dispose</u> of any of these substances?	FIRST , 19 MONTH YEAR
J32.	In what month and year did you last <u>dispose</u> of any of these substances?	LAST . 19 MONTH YEAR
J33.	In all, how many times did you <u>dispose</u> of any of these wastes?	NUMBER OF TIMES



	a. NEPACCD/VERONA, MO
J34. Did you ever <u>store</u> still bottom or any other kinds of wastes?	YES 01 NO 02 +60 TO J=
J35. What substance was <u>stored</u> ?	SUBSTANCE:
J35. What were your duties in <u>storing</u> (SÜBSTANCE(S) LISTED IN J35.)?	DUTIES:
J37. In what month and year did you first <u>store</u> any of these substances?	FIRST MONTH YEAR
J38. In what month and year did you last <u>store</u> any of these wastes?	LAST , 19 MONTH YEAR
J39. In all how many times did you store any of these wastes?	NUMBER OF TIMES
J40. Did you ever <u>handle</u> , other than dispose of or store, still bottom or any other kinds of waste?	YES 01 NO 02 + GO TO COLUMN
J41. What substance(s) was <u>handled</u> ?	SUBSTANCE:
J42. What were your duties in <u>handling</u> (SUBSTANCE(S) IN J41)?	DUTIES:

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b. SYNTEX/VERONA, MO	C. SYNTEX/SPRINGFIELD, MO
res 01 .	YES 01
₩0 02 + GO TO J40.	NO 02 + GO TO J40.
SUBSTANCE:	SUBSTANCE:
	DUTIES:
FIRST	FIRST
MONTH YEAR	MONTH YEAR
LAST	LAST
MONTH YEAR	MONTH YEAR
NUMBER OF TIMES	NUMBER OF TIMES
YES 01	YES01
NO 02 + GO TO COLUMN c.	NO 02 + GO TO J SECTION IV
SUBSTANCE:	SUBSTANCE:
DUTIES:	DUTIES:
······································	

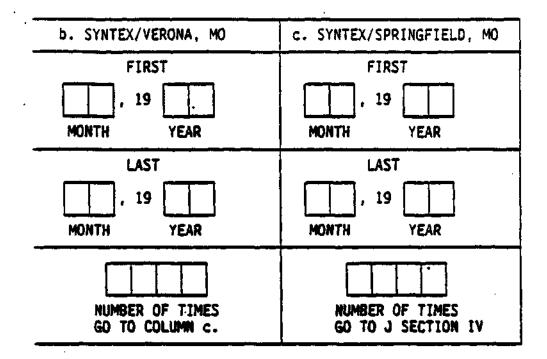
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		a. NEPACCO/VERONA, MO
J43.	In what month and year did you first <u>handle</u> any of these substances?	FIRST
		MONTH YEAR
J44.	In what month and year did you last <u>handle</u> any of these substances?	LAST
		MONTH YEAR
J45.	In all, how many times did you <u>handle</u> any of these wastes?	
		NUMBER OF TIMES GO TO COLUMN D.

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#### J. OCCUPATIONAL HISTORY

SECTION IV - GENERAL

This section asks about places you worked for 6 months or longer since your 16th birthday including part-time work. You should be careful to mention each place you worked so we don't forget any employment.

We will start with the company where you are currently working and go backwards, ending with the company where you were working at age 16. If you are not presently working, for whatever reason, start with the company where you last worked.

INTERVIEWER: BE CAREFUL TO GET EACH EMPLOYER AND FOLLOW SKIP INSTRUCTIONS CAREFULLY.

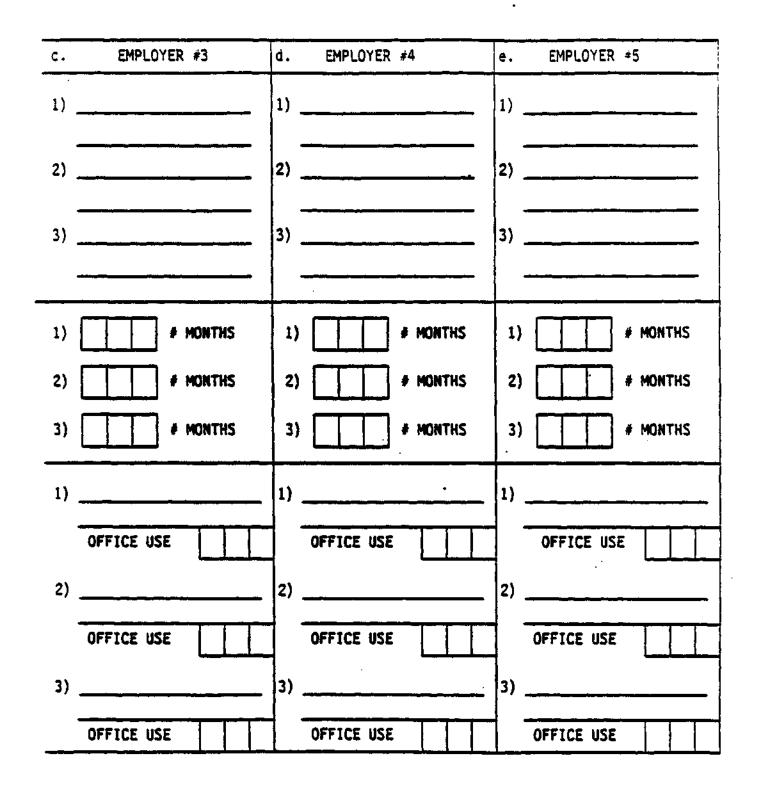
J46. Are you currently employed, unemployed, retired, or something else?

EMPLOYED.....01 UNEMPLOYED.....02 RETIRED.....03 OTHER.....04 (SPECIFY) \_\_\_\_\_

	· .	a.	EMPLOYER #1	Ь.	EMPLOYER #2
J47.	What (is/was) the name of the (current/previous) company where you (are/ were) employed?	COMPANY:			ANY :
J48.	In what city and state (is/was) the company located?	CITY: STATE:		CITY STAT	
J49.	What month and year did you start working at (COMPANY)?	MONTH	START ], 19 YEAR	MO	START , 19 NTH YEAR
	What month and year did you stop working at (COMPANY)? [IF CURRENTLY EMPLOYED, PUT 99 99.]	MONTH	STOP ], 19 YEAR	MO	STOP , 19
J51.	IS THE COMPANY LISTED ONE OF THE STUDY COMPANY/LOCATIONS?	YES	01 + GO TO J57 02		01 + GO TO J57
J52.	What is the main product or service provided by (COMPANY)?	PROD/SVC	·	PROD	/SVC:
		OFFICE			

c. EMPLOYER #3	d. EMPLOYER #4	e. EMPLOYER #5
COMPANY:	COMPANY:	COMPANY :
CITY:	CITY:	CITY:
STATE:	STATE:	STATE:
START	START	START
MONTH YEAR	MONTH YEAR	MONTH YEAR
STOP	STOP	STOP
MONTH YEAR	MONTH YEAR	MONTH YEAR
YES01 + GO TO J57	YES01 + 60 TO J57	YES01 + GO TO J57
NO02	NO02	N002
PROD/SVC:	PROD/SVC:	PROD/SVC:

	a. EMPLOYER #1	b. EMPLOYER #2
J53. What different positions did you hold while working for (COMPANY FROM J47)?	1)	1)
	2)	2)
•	3)	3)
a. For how many months were you (a/an) [NAME EACH POSITON	1) # MONTHS	1) # MONTHS
FROM J53 ONE AT A TIME]?	2) # MONTHS	2) # MONTHS
	3) # MONTHS	3) # MONTHS
J54. What were your duties as [NAME EACH POSITION FROM J53 ONE AT A TIME]?	1)	1)
· · ·	OFFICE USE	OFFICE USE
	2)	2)
	OFFICE USE	OFFICE USE
	3)	3)
· •	OFFICE USE	OFFICE USE



		a. EMPLOYER #1	b. EMPLOYER ≠2
J5 <b>5</b> .	Was the work full-time or part-time?	FULL-TIME 01	FULL-TIME 01
		PART-TIME 02	PART-TIME 02
J56.	•••	LESS THAN 1 HOUR 01	LESS THAN 1 HOUR 01
	on the average, how many hours (did/do) you usually spend outdoors?	1-2 HOURS 02	1-2 HOURS 02
usually spend outdoors:		2-3 HOURS 03	2-3 HOURS 03
		3-4 HOURS 04	3-4 HOURS 04
	,	4-5 HOURS 05	4-5 HOURS 05
		5-6 HOURS 06	5-6 HOURS 06
		MORE THAN 6 HOURS 07	MORE THAN 6 HOURS 07

c. EMPLOYER #3	d. EMPLOYER #4 .	e. EMPLOYER #5
FULL-TIME 01	FULL-TIME 01	FULL-TIME 01
PART-TIME 02	PART-TIME 02	PART-TIME 02
LESS THAN 1 HOUR 01	LESS THAN 1 HOUR 01	LESS THAN 1 HOUR 01
1-2 HOURS 02	1-2 HOURS 02	1-2 HOURS 02
2-3 HOURS 03	2-3 HOURS 03	2-3 HOURS 03
3-4 HOURS 04	3-4 HOURS 04	3-4 HOURS 04
4-5 HOURS 05	4-5 HOURS 05	4-5 HOURS 05
5-6 HOURS 06	5-6 HOURS 06	5-6 HOURS 06
MORE THAN 6 HOURS 07	MORE THAN 6 HOURS 07	MORE THAN 6 HOURS 07

		a. EMPLOYER #1	b. EMPLOYER #2
-	Previous to working at (COMPANY IN J47.) did you have a job at another company or were you out of work for one month or	JOB AT ANOTHER COMPANY 01+GO TO J47 COLUMN b.	JOB AT ANOTHER COMPANY 01+GO TO J47 COLUMN C.
	longer?	OUT OF WORK 02	OUT OF WORK . 02
	What was the reason you were off work?	NEVER WORKED 00+GO TO	NEVER WORKED00 + GO TO
		LAID OFF01	LAID OFF01
		DISABLED (SICK)02	DISABLED (SICK)02
		RETIRED03	RETIRED03
		QUIT04	QUIT04
		OTHER (SPECIFY)05	OTHER (SPECIFY)05
		00N'T KNOW 94	DON'T KNOW94
		REFUSED97	REFUSED97
		GO TO PREVIOUS EMPLOYER AT J47.	GO TO PREVIOUS EMPLOYER AT J47.

c. EMPLOYER #3	d. EMPLOYER #4	e. EMPLOYER ≠5 '
JOB AT ANOTHER COMPANY 01+GO TO J47 Column d.	JOB AT ANOTHER COMPANY 01+GO TO J47 Column e.	JOB AT ANOTHER COMPANY 01 + GO TO J47 IN CONTINUATION BOOKLET
OUT OF WORK 02	OUT OF WORK . 02	OUT OF WORK . 02
NEVER WORKED	NEVER WORKED00 + GO TO	NEVER WORKED00 + GO TO
LAID OFF01	LAID OFF01	LAID OFF01
DISABLED (SICK)02	DISABLED (SICK)02 .	DISABLED (SICK)02
RETIRED03	RETIRED03	RETIRED03
QUIT04	QUIT04	QUIT04
OTHER (SPECIFY)05	OTHER (SPECIFY)05	OTHER (SPECIFY)05
DON'T KNOW 94	DON'T KNOW	DON'T KNOW 94
REFUSED97	REFUSED97	REFUSED97
GO TO PREVIOUS EMPLOYER AT J47.	GO TO PREVIOUS EMPLOYER AT J47.	GO TO PREVIOUS EMPLOYER AT J47.

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CONTINUE

# J. OCCUPATIONAL HISTORY

# SECTION V - OTHER OCCUPATIONAL EXPOSURES

Now that we have talked about your jobs, I would like to review chemicals, materia and equipment you may have worked with regularly on your job for 30 days or long IF SUBJECT IS A WORKER, SAY "Do not refer to chemicals you worked with at (COMF NAME ANSWERED YES IN JI OR J2) unless you also worked with these chemicals at anot company".

INTERVIEWER: ASK QUESTIONS CONCERNING ALL EXPOSURES FIRST. THEN, GO BACK DETERMINE THE COMPANY, JOB AND THE PERIOD OF TIME THE SUBJECT WAS EXPOSED.

Where are going to ask about equipment, metals and chemicals you may have been exposed to work. By exposed, we mean that you made, used, or handled the material or worked in near an area where the material was made, used, or handled.

	DO NOT INCLUDE EXPOSURES	A. EQUIPMENT	EXPOSURES :
	AT ANY OF OUR STUDY COMPANY/LOCATIONS.	1. ELECTRICAL CAPACITORS	2. ELECTRICAL CONDENSERS
J59.	In any job you have held, have you ever worked for 30 days or more with (NAME OF EQUIPMENT/ CHEMICAL)? IF YES + +	YES 01 NO 02) I GO TO DON'T KNOW 94}+NEXT I ITEM REFUSED 97J	YES 01 NO 02)   GO TO DON'T KNOW 94}+NEXT   ITEM REFUSED 97J
J60.	At what company and in which city did you work with (NAME OF EQUIPMENT/ CHEMICAL)?	<u>COMPANY:</u> <u>CITY:</u> <u>STATE:</u>	<u>COMPANY:</u> <u>CITY:</u> <u>STATE:</u>
J61.	What was your job title when you worked with (NAME OF EQUIPMENT/ CHEMICAL)?	JOB TITLE:	JOB TITLE:
J62.	In what year did you start working with (NAME OF EQUIPMENT/CHEMICAL)?	START 19	START 19
J63.	In what year did you last work with (EQUIPMENT/ CHEMICAL)?	LAST 19	LAST 19
J64.	For how many months did you work with (EQUIPMENT/ CHEMICAL)?	# MONTHS	# MONTHS

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A. EQUIPMENT EXPOSURES			
3. ELECTRICAL TRANSFORMERS	4. GAS TRANSMISSION TURBINES	5. HEAT TRANSFER OR EXCHANGE UNITS	
YES 01 NO 021 I GO TO DON'T KNOW 943+NEXT I ITEM REFUSED 97J	YES 01 NO 021 I GO TO DON'T KNOW 94}+NEXT I ITEM REFUSED 97J	YES 01 NO 021 I GO TO DON'T KNOW 94}+NEXT I ITEM REFUSED 97J	
COMPANY:	COMPANY:	COMPANY :	
CITY:	CITY:	<u>CITY:</u>	
STATE:	STATE:	STATE:	
JOB TITLE:	JOB TITLE:	JOB TITLE:	
OFFICE USE	OFFICE USE	OFFICE USE	
START	START	START	
LAST 19	LAST 19	LAST 19	
# MONTHS	# MONTHS	# MONTHS	

	DO NOT THELLIDE EXPOSURES	A. EQUIPMENT EXPOSURES	
	DO NOT INCLUDE EXPOSURES AT ANY OF OUR STUDY COMPANY/LOCATIONS.	6. HYDRAULIC SYSTEMS	7. INSULATED ELECTRICAL WIRES AND CABLES
	In any job you have held, have you ever worked for 30 days or more with (NAME OF EQUIPMENT/ CHEMICAL)?	YES 01 NO 027 I GO TO DON'T KNOW 94}+NEXT I ITEM REFUSED 97J	DON'T KNOW 94}+NEXT I ITEM REFUSED 97J
J60.	At what company and in which city did you work with (NAME OF EQUIPMENT/ CHEMICAL)?	COMPANY:           CITY:           STATE:	COMPANY: CITY: STATE:
J61.	What was your job title when you worked with (NAME OF EQUIPMENT/ CHEMICAL)?	JOB TITLE:	JOB TITLE:
J62.	In what year did you start working with (NAME OF EQUIPMENT/CHEMICAL)?	START . 19	START
J63.	In what year did you last work with (EQUIPMENT/ CHEMICAL)?	LAST 19	LAST 19
J64.	For how many months did you work with (EQUIPMENT/ CHEMICAL)?	# MONTHS	# MONTHS

A. EQUIPMENT EXPOSURES	B. METAL EXPOSURES	
8. VACUUM PUMPS	9. INORGANIC ARSENIC	10. LEAD
YES 01 NO 021 I GO TO DON'T KNOW 94}+NEXT I ITEM REFUSED 97J	YES 01 NO 021 GO TO DON'T KNOW 94}+NEXT I ITEM REFUSED 973	YES 01 NO 02) GO TO DON'T KNOW 94}+NEXT I ITEM REFUSED 97J
COMPANY:		<u>COMPANY :</u>
CITY:	CITY:	<u>CITY:</u>
STATE:	STATE:	STATE:
JOB TITLE:	JOB TITLE:	JOB TITLE:
OFFICE USE	OFFICE USE	OFFICE USE
START	START	START
LAST 19	LAST 19	LAST 19
# MONTHS	# MONTHS	MONTHS

		B. METAL EXPOSURES	C. CHEMICAL EXPOSURES
	DO NOT INCLUDE EXPOSURES AT ANY OF OUR STUDY COMPANY/LOCATIONS.	11. MERCURY	12. AROCLOR, ASKAREL, INERTEEN, THERMINOL, OR OTHER PCB'S
J59.	In any job you have held, have you ever worked for 30 days or more with (NAME OF EQUIPMENT/ CHEMICAL)?	YES 01 NO 02) I GO TO DON'T KNOW 94}+NEXT I ITEM REFUSED 97J	YES01 NO027 I GO TO DON'T KNOW94}+NEXT I ITEM REFUSED97J
J60.	At what company and in which city did you work with (NAME OF EQUIPMENT/ CHEMICAL)?	COMPANY:	COMPANY: CITY: STATE:
J61.	What was your job title when you worked with (NAME OF EQUIPMENT/ CHEMICAL)?	JOB TITLE:	JOB TITLE:
J62.	In what year did you start working with (NAME OF EQUIPMENT/CHEMICAL)?	START 19	START 19
J63.	In what year did you last work with (EQUIPMENT/ CHEMICAL)?	LAST 19	LAST 19
J64.			

	C. CHEMICAL EXPOSURES			
13. HOLLOWAX OR CHLORI- NATED NAPTHALENE	14. (2,4,5-T) TRI- CHLOROPHENOXY- ACETIC ACID	15. 2,4,0 (DICHLORO- PHENOXYACETIC ACID		
YES 01 NO 021 I GO TO DON'T KNOW 94}+NEXT I ITEM REFUSED 97J	YES 01 NO 02)   GO TO DON'T KNOW 94}→NEXT   ITEM REFUSED 97J 	YES 01 NO 02) I GO TO DON'T KNOW 94}+NEXT I ITEM REFUSED 97J		
<u>CITY:</u>		<u>CITY:</u>		
OFFICE USE		JOB TITLE:		
START 19	START 19	START		
LAST 19	LAST 19	LAST 19		
# MONTHS	# MONTHS .	# MONTHS		

		C. CHEMICAL	EXPOSURES
	DO NOT INCLUDE EXPOSURES AT ANY OF OUR STUDY COMPANY/LOCATIONS.	16. HEXACHLOROPHENE	17. AGENT ORANGE
J59.	In any job you have held, have you ever worked for 30 days or more with (NAME OF EQUIPMENT/ CHEMICAL)?	YES 01 NO 02)   GO TO   DON'T KNOW 94}+NEXT   ITEM REFUSED 97J	YES 01 NO 02) I GO TO DON'T KNOW 94}+NEXT I ITEM REFUSED 97J
J60.	At what company and in which city did you work with (NAME OF EQUIPMENT/ CHEMICAL)?	COMPANY: CITY: STATE:	COMPANY: CITY: STATE:
J61.	What was your job title when you worked with (NAME OF EQUIPMENT/ CHEMICAL)?	JOB TITLE:	JOS TITLE:
J62.	In what year did you start working with (NAME OF EQUIPMENT/CHEMICAL)?	START 19	START 19
J63.	In what year did you last work with (EQUIPMENT/ CHEMICAL)?	LAST 19	LAST 19
J64.	For how many months did you work with (EQUIPMENT/ CHEMICAL)?	# MONTHS	# MONTHS

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	C. CHEMICAL EXPOSURES	•
18. DOT	19. TCB-TETRACHLORO- BENZENE	20. HCB-HEXACHLORO- BENZENE
YES 01 NO 02) J GO TO DON'T KNOW 94}+NEXT I ITEM REFUSED 97J	YES 01 NO 02) I GO TO DON'T KNOW 94}+NEXT I ITEM REFUSED 97J	YES 01 NO 02) I GO TO DON'T KNOW 94}+NEXT I ITEM REFUSED 97J
CITY: STATE: JOB TITLE: OFFICE USE	CITY: STATE: JOB TITLE: OFFICE USE	CITY: STATE: JOB TITLE: OFFICE USE
START	START 19	START
LAST 19	LAST	LAST 19
# MONTHS	# MONTHS	# MONTHS

	DO NOT INCLUDE EXPOSURES	C. CHEMICAL	EXPOSURES
	AT ANY OF OUR STUDY COMPANY/LOCATIONS.	21. TETRACHLORO- AZOBENZENE	22. TETRACHLOROAZOOXY- BENZENE
	In any job you have held, have you ever worked for 30 days or more with (NAME OF EQUIPMENT/ CHEMICAL)?		YES 01 NO 02) I GO TO DON'T KNOW 94}+NEXT I ITEM REFUSED 97J
J60.	At what company and in which city did you work with (NAME OF EQUIPMENT/ CHEMICAL)?	<u>COMPANY:</u> <u>CITY:</u> <u>STATE:</u>	COMPANY: CITY: STATE:
J61.	What was your job title when you worked with (NAME OF EQUIPMENT/ CHEMICAL)?	JOB TITLE:	JOB TITLE:
J62.	In what year did you start working with (NAME OF EQUIPMENT/CHEMICAL)?	START	START 19
J63.	In what year did you last work with (EQUIPMENT/ CHEMICAL)?	LAST 19	LAST 19
J64.	For how many months did you work with (EQUIPMENT/ CHEMICAL)?	# MONTHS	# MONTHS

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C. CHEMICAL EXPOSURES		
23. 3,4 DICHLORO- ANILINE	24. ETO-ETHYLENE OXIDE	25. DURSBAN, LEPTOPHOS, MALATHION, PARATHION
YES 01 NO 02) I GO TO DON'T KNOW 94}+NEXT I ITEM REFUSED 97J	YES01 NO	YES
COMPANY:	COMPANY :	<u>COMPANY :</u>
CITY:	<u>CITY:</u>	<u>CITY:</u>
STATE:	STATE:	STATE:
JOB TITLE:	JOB_TITLE:	JOB TITLE:
OFFICE USE		OFFICE USE
START	START	START
LAST 19	LAST	LAST 19
# MONTHS	# MONTHS	# MONTHS

,		C. CHEMICAL	EXPOSURES
	DO NOT INCLUDE EXPOSURES AT ANY OF OUR STUDY COMPANY/LOCATIONS.	26. PENTACHLOROPHENOL PCP, DOWCIDE-7, PENCHLOROL	27. SILVĖX
J59.	In any job you have held, have you ever worked for 30 days or more with (NAME OF EQUIPMENT/ CHEMICAL)?	YES 01 NO 02) I GO TO DON'T KNOW 94}+NEXT I ITEM REFUSED 97J	YES 01 NO 021 I GO TO DON'T KNOW 94}+NEXT J ITEM REFUSED 97J
J60.	At what company and in which city did you work with (NAME OF EQUIPMENT/ CHEMICAL)?	COMPANY:	<u>COMPANY:</u> <u>CITY:</u> <u>STATE:</u>
J <b>61.</b>	What was your job title when you worked with (NAME OF EQUIPMENT/ CHEMICAL)?	JOB TITLE:	JOB TITLE:
J62.	In what year did you start working with (NAME OF EQUIPMENT/CHEMICAL)?	START 19	START
J63.	In what year did you last work with (EQUIPMENT/ CHEMICAL)?	LAST 19	LAST 19
J64.	For how many months did you work with (EQUIPMENT/ CHEMICAL)?	MONTHS	# MONTHS

C. CHEMICAL EXPOSURES	D. S	OLVENTS
28. MCPA .	29. CS2-CARBON DISULFIDE	30. HEX: N-HEXANE
1 ES 01 NO 02) I GO TO DON'T KNOW 94}+NEXT I ITEM REFUSED 97J	YES 01 NO 02) I GO TO DON'T KNOW 94}+NEXT I ITEM REFUSED 973	YES 01 NO 02) I GO TO DON'T KNOW 94}+NEXT I ITEM REFUSED 97J
COMPANY:	<u>COMPANY:</u>	COMPANY: CITY: STATE:
JOB TITLE:	JOB_TITLE:	JOB TITLE:
START 19	START 19	START 19
LAST 19	LAST 19	LAST 19
# MONTHS	# MONTHS	# MONTHS

	DO NOT INCLUDE EXPOSURES	D. SC	DLVENTS
	AT ANY OF OUR STUDY COMPANY/LOCATIONS.	31. MBK - METHYL-N- BUTYLKETONE	32. VINYL CHLORIDE MONOMER
	In any job you have held, have you ever worked for 30 days or more with (NAME OF EQUIPMENT/ CHEMICAL)?	YES 01 NO 02) I GO TO DON'T KNOW 94}+NEXT I ITEM REFUSED 97J	YES 01 NO 021 I GO TO DON'T KNOW 94}-NEXT I ITEM REFUSED 97J
	At what company and in which city did you work with (NAME OF EQUIPMENT/ CHEMICAL)?	COMPANY: 	<u>COMPANY:</u> <u>CITY:</u> <u>STATE:</u>
<b>J61.</b>	What was your job title when you worked with (NAME OF EQUIPMENT/ CHEMICAL)?	JOB TITLE:	JOB_TITLE:
J62.	In what year did you start working with (NAME OF EQUIPMENT/CHEMICAL)?	START 19	START 19
J63.	In what year did you last work with (EQUIPMENT/ CHEMICAL)?	LAST 19	LAST 19
J64.	For how many months did you work with (EQUIPMENT/ CHEMICAL)?	# MONTHS	# MONTHS

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	D. SOLVENTS	
33. PERCHLOROETHYLENE OR TRICHLOROETHYLENE	34. BENZENE	35. CARBON TETRACHLORIDE
NO 01 NO 02) I GO TO DON'T KNOW 943+NEXT I ITEM REFUSED 97J	YES 01 NO 02) I GO TO DON'T KNOW 94}+NEXT I ITEM REFUSED 97J	YES 01 NO 02) I GO TO DON'T KNOW 94}+NEXT I ITEM REFUSED 97J
COMPANY: CITY: STATE:	COMPANY: CITY: STATE:	COMPANY: CITY: STATE:
JOB TITLE:	JOB TITLE:	JOB_TITLE:
START	START	START
LAST 19	LAST 19	LAST 19
# MONTHS	# MONTHS	# MONTHS

		D. SOLVEN	ITS
	OO NOT INCLUDE EXPOSURES AT ANY OF OUR STUDY COMPANY/LOCATIONS.	36. TOLUENE	37. METHYLENE CHLORIDE
J <b>59</b> .	In any job you have held, have you ever worked for 30 days or more with (NAME OF EQUIPMENT/ CHEMICAL)?	YES01 NO027 I GO TO DON'T KNOW94}+NEXT I ITEM REFUSED97J	YES 01 NO 02) I GO TO DON'T KNOW 94}+NEXT I ITEM REFUSED 97J
J60.	At what company and in which city did you work with (NAME OF EQUIPMENT/ CHEMICAL)?	COMPANY:	<u>COMPANY:</u>
	······································	<u>CITY:</u>	<u>CITY:</u>
		STATE:	STATE:
J61.	What was your job title when you worked with (NAME OF EQUIPMENT/ CHEMICAL)?	JOB TITLE:	JOB_TITLE:
		OFFICE USE	OFFICE USE
J62.	In what year did you start working with (NAME OF EQUIPMENT/CHEMICAL)?	START - 19	START 19
J63.	In what year did you last work with (EQUIPMENT/ CHEMICAL)?	LAST 19	LAST 19
J64.	For how many months did you work with (EQUIPMENT/ CHEMICAL)?	# MONTHS	# MONTHS

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38. ACRYLAMIDE	39. PBB'S - POLYBROMI- NATED BIPHENYL'S	40. PHENOBARBITOL OR BARBITURATES
IES:	YES 01 NO 02) I GO TO DON'.T KNOW 94}+NEXT I ITEM REFUSED 97J CITY:	YES 01 NO 027 I GO TO DON'T KNOW 94}+NEXT I ITEM REFUSED 97J
STATE:	STATE:	STATE:
JOB TITLE:	JOB TITLE:	JOB TITLE:
OFFICE USE	OFFICE USE	
START 19	START 19	START 19
LAST 19	LAST 19	LAST 19
# MONTHS	# MONTHS	# MONTHS

E. OTHER CHEMICAL EXPOSURES

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	DO NOT INCLUDE EXPOSURES	E. OTHER CHEN	AICAL EXPOSURES
	AT ANY OF OUR STUDY COMPANY/LOCATIONS.	41. CARBON MONOXIDE	42. WOOD PRESERVATIVES
J59.	In any job you have held, have you ever worked for 30 days or more with (NAME OF EQUIPMENT/ CHEMICAL)?	YES 01 NO 02) I GO TO DON'T KNOW 94}+NEXT I ITEM REFUSED 97J	YES 01 NO 02) I GO TO DON'T KNOW 94}+NEXT I ITEM REFUSED 97J
J <b>60</b> .	At what company and in which city did you work with (NAME OF EQUIPMENT/ CHEMICAL)?	COMPANY:	COMPANY:
J61.	What was your job title when you worked with (NAME OF EQUIPMENT/ CHEMICAL)?	JOB TITLE:	JOB TITLE:
J62.	In what year did you start working with (NAME OF EQUIPMENT/CHEMICAL)?	START	START 19
J63.	In what year did you last work with (EQUIPMENT/ CHEMICAL)?	LAST 19	LAST 19
J64.	For how many months did you work with (EQUIPMENT/ CHEMICAL)?	# MONTHS	# MONTHS

E. OTHER CHEMICAL EXPOSURES		
43. CYANIDE	44. DIMETHYLAMINO- PROPIONITRILE(DMAPN)	45. METHYL BROMIDE
YES 01 NO 02 J GO TO DON'T KNOW 94}+NEXT J ITEM REFUSED 97J	YES 01 NO 02) J GO TO DON'T KNOW 94}+NEXT I ITEM REFUSED 97J	YES
COMPANY:	COMPANY:	<u>COMPANY:</u>
STATE:	STATE:	STATE:
JOB TITLE:	JOB TITLE:	JOB_TITLE:
OFFICE USE	OFFICE USE	OFFICE USE
START 19	START 19	START 19
LAST	LAST 19	LAST 19
# MONTHS	# MONTHS	# MONTHS

	•	E. OTHER CHE	EMICAL EXPOSURES
	DO <u>NOT</u> INCLUDE EXPOSURES AT ANY OF OUR STUDY COMPANY/LOCATIONS.	46. ORGANOPHOSPHORUS ESTERS	47. OTHER HERBICIDES
	In any job you have held, have you ever worked for 30 days or more with (NAME OF EQUIPMENT/ CHEMICAL)?		YES 01 NO 02) I GO TO DON'T KNOW 94}+NEXT I ITEM REFUSED 97J
	At what company and in which city did you work with (NAME OF EQUIPMENT/ CHEMICAL)?	COMPANY: CITY: STATE:	<u>COMPANY:</u> <u>CITY:</u> <u>STATE:</u>
J61.	What was your job title when you worked with (NAME OF EQUIPMENT/ CHEMICAL)?	JOB TITLE:	JOB TITLE:
J62.	In what year did you start working with (NAME OF EQUIPMENT/CHEMICAL)?	START 19	START 19
J63.	In what year did you last work with (EQUIPMENT/ CHEMICAL)?	LAST 19	LAST 19
J64.	For how many months did you work with (EQUIPMENT/ CHEMICAL)?	# MONTHS	# MONTHS

E. OTHER CHEMIC	CAL EXPOSURES	F. OTHERS NOT MENTIONED
48. THALLIUM	49. DUSTS (i.e., WOOD, LEATHER, ETC.)	50
YES: 01	YES 01	YES01
NO	NO 021 1 GO TO	NO 02) GO TO 1J60-64
DON'T KNOW 94}+NEXT I ITEM	DON'T KNOW 94}+NEXT	DON'T KNOW 94}→FOR I EACH
REFUSED 97J	REFUSED 97J	REFUSED 97J YES
<u>COMPANY :</u>	COMPANY:	COMPANY:
		· · · · · · · · · · · · · · · · · · ·
CITY:	CITY:	CITY:
STATE:	STATE:	STATE:
JOB TITLE:	JOB_TITLE:	JOB TITLE:
OFFICE USE	OFFICE USE	OFFICE USE
START	START	STÀRT
19	19	19
LAST	LAST	LAST
19	19	19
# MONTHS	# MONTHS	# MONTHS
	AETER 160-6	A HAS BEEN ASKED

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AFTER J60-64 HAS BEEN ASKED FOR EACH YES, GO TO J65.

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		F. OTHERS NOT	MENTIONED
		51	52
	'In any job you have held, have you ever worked for 30 days or more with (NAME OF EQUIPMENT/ CHEMICAL)? DO NOT INCLUDE EXPOSURES AT ANY OF OUR STUDY COMPANY/LOCATIONS.	YES 01 NO 02) GO TO IJ60-64 DON'T KNOW . 94}+FOR I EACH REFUSED 97J YES	YES 01 NO 02) GO TO J50-64 DON'T KNOW 94}+FOR I EACH REFUSED 97J YES
J60.	At what company and in which city did you work with (NAME OF EQUIPMENT/ CHEMICAL)?	<u>COMPANY:</u> <u>CITY:</u> <u>STATE:</u>	COMPANY:
J61.	What was your job title when you worked with (NAME OF EQUIPMENT/ CHEMICAL)?	JOB TITLE:	JOB TITLE:
J62.	In what year did you start working with (NAME OF EQUIPMENT/CHEMICAL)?	START 19	START 19
J63.	In what year did you last work with (EQUIPMENT/ CHEMICAL)?	LAST - 19	LAST
J64.	For how many months did you work with (EQUIPMENT/ CHEMICAL)?	# MONTHS	# MONTHS

AFTER J60-64 HAS BEEN ASKED FOR EACH YES, GO TO J65. •

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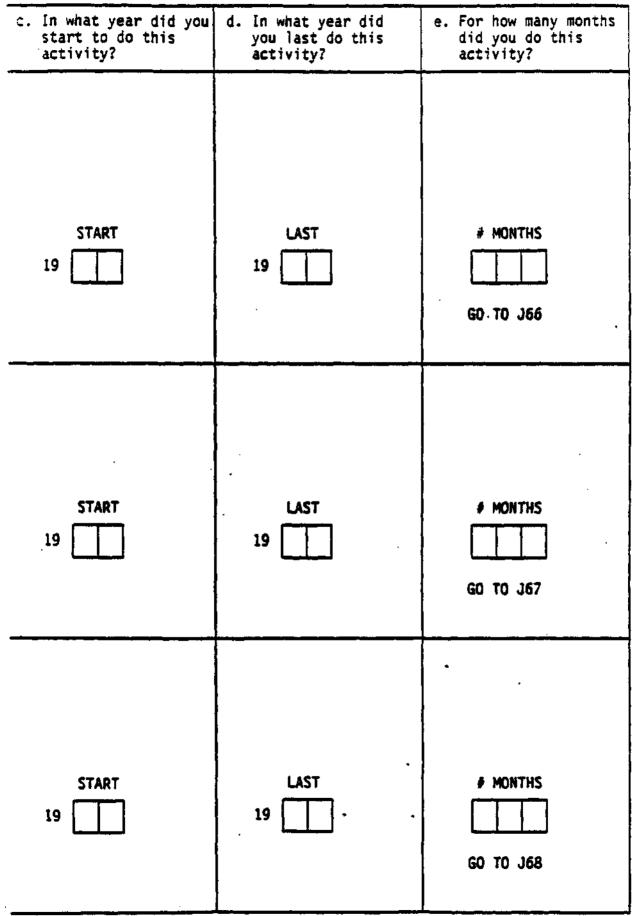
CONTINUE

Now I'm going to ask about certain types of tasks you might have done at any of your jour ([IF WORKER, CONTINUE:]) For these questions, you should include tasks done at (ST SITE).)

. . . .

	and the second second second second second second second second second second second second second second second	,
	a. At what company and in which city and state was that?	b. What was your job title when you were doing this activity?
J65. Did you ever have a job that required repeating a task over and over again with your hands like on a production line? PLEASE SPECIFY:		
YES 01 + + + NO 02 )	COMPANY:	JOB_TITLE;
DON'T KNOW 94 GO TO	CITY:	
REFUSED 97		OFFICE USE
REFUSED 97 /	STATE:	
J66. Did you ever have a job that required repeated heavy lifting? PLEASE SPECIFY:		
YES	COMPANY:	JOB TITLE:
DON'T KNOW 94 GO TO		
REFUSED 97 )	STATE:	OFFICE USE
J67. Did you ever have a job that required you to work with your hands over your head for most of the day? PLEASE SPECIFY:	•	×
YES 01 + + +	COMPANY:	JOB TITLE:
NO		
DON'T KNOW 94 GO TO	CITY:	·
REFUSED 97 ) J68	STATE:	OFFICE USE
		ا المسلم الم

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		a. At what company and in which city and state was that?	b. What was your job title when you were doing this activity?
J68.	Did you ever have a job that required you to handle heavy vibrating equipment such as jack hammers, drills, etc.? PLEASE SPECIFY:	•	
	YES 01 + + +	COMPANY:	JOB TITLE:
	NO 02 ]		
		CITY:	
	I SECTION REFUSED 97 J K	STATE:	OFFICE USE

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c.	In what year did you	d. In what year did	e. For how many months
	start to do this	you last do this	did you do this
	activity?	activity?	activity?
	START 19	LAST 19	# MONTHS

### K. DEMOGRAPHIC INFORMATION

K1. RACE: BY OBSERVATION. ([IF UNCERTAIN ASK:] Do you consider yourself white. black, Asian, American Indian, or something else?)

K2. Are you of Hispanic (Spanish) origin or descent?

YES.....01 NO.....02 DON'T KNOW.....94 REFUSED.....97

K3. What is your country of birth?

COUNTRY

К4.

a. What was the highest grade in school which you completed? [CODE ONLY ONE.]

NO FORMAL SCHOOLING
1 TO 8 YEARS (GRADE SCHOOL)02
9 TO 12 YEARS (HIGH SCHOOL)
AFTER HIGH SCHOOL VOCATIONAL OR TECHNICAL TRAINING04
SOME COLLEGE GRADUATE, POST GRADUATE WORK
DON'T KNOW
DON'T KNOW

b. How old were you when you finished (HIGHEST GRADE)?

AGE			•			
DON	T I	KNOH	i	• • •	• • •	.94
REF	JSEI	)		• • •		.97

HAND RESPONDENT CARD # K-5

K5. Please look at the card and tell me the letter which corresponds to you religious preference. [IF THE RESPONSE IS "e", ASK: "What is the othe religion?"]

a.	PROTESTANT01	
<b>b.</b>	CATHOLIC02	
c.	JEWISH03	
đ.	SEVENTH DAY ADVENTIST04	
ę.	OTHER (SPECIFY)05	
f.	NO RELIGION	
g.	DON'T KNOW94	
ħ.	REFUSED97	

HAND RESPONDENT CARD # K-6.

- K6. Please look at this card and indicate the letter of the category which contain the amount of your family's total income. [CODE ONLY ONE.]
  - a. LESS THAN \$10,000.....01 b. \$10,000 - \$19,999.....02

  - c. \$20,000 \$29,999.....03 d. \$30,000 - \$39,999.....04
  - d. \$30,000 \$39,999.....04
  - e. \$40,000 \$49,999.....05
  - f. \$50,000 OR MORE.....06

K7. For how many hours do you normally sleep during a 24-hour period?

HOURS		
DON'T	KNOW	
REFUSE	)	

- K8. Do you exercise vigorously and regularly for at least a half-hour, 3 times weekly (include jogging, swimming, tennis, bicycling, aerobics, etc.)?
  - YES.....01 NO.....02 DON'T KNOW.....94 REFUSED.....97
- K9. a. THANK RESPONDENT FOR COOPERATION,
  - **b.** SET UP TRAVEL PLANS,
  - c. MAKE CERTAIN YOU HAVE ACCOUNTED FOR ALL PERMISSION FORMS,
  - d. REMEMBER TO COMPLETE SECTION L.

## L. INTERVIEWER OBSERVATIONS AND EVALUATION

COMPLETE THIS SECTION AS SOON AFTER LEAVING THE RESPONDENT AS POSSIBLE.

L1. What was the language in which the interview was conducted?

ENGLISH01	
SPANISH02	
OTHER	
SPECIFY:	

L2. What was the level of respondent cooperation?

VERY	GOOD01	
GOOD		
FAIR	, OR03	
POOR	?	

L3. Overall, what is the quality of the interview?

HIGH QUALITY01	
GENERALLY RELIABLE	
QUESTIONABLE, OR	
UNSATISFACTORY?04	

### L4. IF UNSATISFACTORY OR QUESTIONABLE:

What was the main reason for the unsatisfactory or questionable quality of the interview?

THE RESPONDENT:	WAS ILL OR DISABLED
	SPOKE ENGLISH POORLY02
	WAS EVASIVE OR SUSPICIOUS
	WAS BORED OR UNINTERESTED04
	WAS UPSET OR DEPRESSED BY THE TOPIC
	WAS DRUNK OR ON DRUGS
·	HAD POOR HEARING OR SPEECH
	WAS CONFUSED BY FREQUENT INTERRUPTION
	WAS INSUFFICIENTLY KNOWLEDGEABLE
	WAS MENTALLY DISTURBED
OR:	SOMETHING ELSE
	SPECIFY:

L5. Was the respondent assisted by another person during most of the interview?

YES......01 NO......02 + GO TO L8

L6. Who assisted the respondent? [CODE ALL THAT APPLY.]

SPOUSE	01
CHILD	02
SIBLING	03
OTHER RELATIVE	04
OTHER	05
SPECIFY:	-

L7. Why was the respondent assisted? [CODE ALL THAT APPLY.]

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L8. RECORD ANY OTHER RELEVANT OBSERVATIONS, COMMENTS, OR IMPRESSIONS YOU HAVE ABOUTHIS INTERVIEW.

DOHQ L-3

OMB NO.:0920-0183; EXPIRES 12/31/87

ATTACHMENT 3

#### NIOSH OCCUPATIONAL HEALTH STUDY

#### WIVES REPRODUCTIVE QUESTIONNAIRE

Subject ID Number:	Interviewer ID Number:	
Interview Date:	Checked By:	]

1. FOLLOW CONTROL CARD PROCEDURES TO IDENTIFY AND VERIFY RESPONDENT INFORMATION.

2. COVER CONSENT INFORMATION WITH RESPONDENT AND ASK FOR SIGNATURE, THEN SAY:

Before we start the interview let me tell you a little about the questions. I will be asking you about such things as medical information, job information, and other information from different times during your life. Sometimes the period of time I ask about will be your entire life and other times it will be when you were pregnant or another time period.

If you do not understand the time period or the question, ask me to repeat the question or to clarify, if possible. We want to make sure the information is as accurate as possible.

The questions will take an average of 45 minutes to complete. If you want to take a break at some point, just let me know.

THE STUDY SUBJECT HAS BEEN INFORMED OF THE INFORMATION CONTAINED IN THE INTRODUCTORY LETTER.

SIGNATURE OF INTERVIEWER

# A. PERSONAL DATA

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First I have some general questions about you.

A1. What is your date of birth?



A2.	What wa	as the highest grade in school which you completed? [CODE ONLY ONE.]
		NO FORMAL SCHOOLING
		1 TO 8 YEARS (GRADE SCHOOL)
		9 TO 12 YEARS (HIGH SCHOOL)
·		AFTER HIGH SCHOOL VOCATIONAL OR TECHNICAL TRAINING04
		SOME COLLEGE GRADUATE, POST GRADUATE WORK05
		DON'T KNOW
		REFUSED
A3.	Do you	consider yourself white, black, Asian, American Indian, or something else?
	•	WHITE01
		BLACK02
		ASIAN (ORIENTAL OR PACIFIC ISLANDER)03
		AMERICAN INDIAN (ALASKAN NATIVE)04
		OTHER05

(SPECIFY) \_\_\_\_\_

A4. Are you of Hispanic (Spanish) origin or descent?

YES01
N002
DON'T KNOW94
REFUSED97

A5. What is your religion?

PROTESTANT0	1
CATHOLIC0	2
JEWISH0	3
SEVENTH DAY ADVENTIST	4
OTHER (SPECIFY)0	5

NO RELIGION
DON'T KNOW
REFUSED

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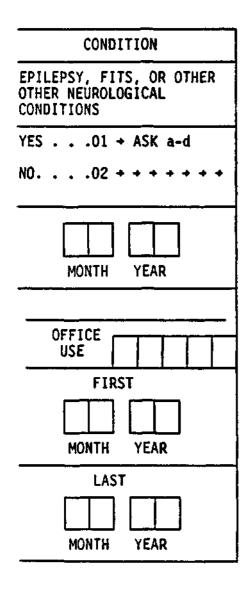
## CONTINUE

### B. MEDICAL CONDITIONS

This next group of questions is about your health in general. I'm going to read a list of health conditions which can only be diagnosed by a doctor.

B1. Has a doctor ever told you that you had (CONDITION)?

	CONDITIONS	
	SUGAR DIABETES	THYROID CONDITION
	YES01 + ASK a-d NO02 + + + + + + +	YES01 + ASK a-d NO02 + + + + + + +
a. In what month and year were you first told you had (CONDITION)?	MONTH YEAR	MONTH YEAR
<pre>b. What medicine/treatment were you given for (CONDITION)?</pre>	OFFICE USE	OFFICE USE
c. What was the month and year of your first treat- for (CONDITION)?	FIRST MONTH YEAR	FIRST MONTH YEAR
d. What was the month and year of your last treat- ment for (CONDITION)?	LAST MONTH YEAR	LAST MONTH YEAR
REPEAT 81. FOR NEXT CONDITION		· · · · · · · · · · · · · · · · · · ·



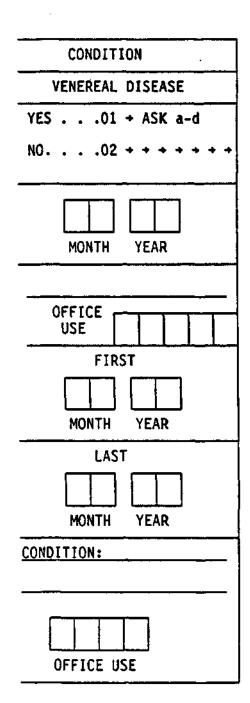
B1. Has a doctor ever told you that you had (CONDITION)?

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	CONDITIONS	
	LIVER CONDITION	HEART CONDITION
	YES01 + ASK a-d	YES01 + ASK a-d
	NO02 + + + + + + +	NO02 + + + + + + +
a. In what month and year were you first told you had (CONDITION)?	MONTH YEAR	MONTH YEAR
b. What medicine/treatment		
were you given for (CONDITION)?	OFFICE USE	OFFICE USE
c. What was the month and year of your first treat- for (CONDITION)?	FIRST MONTH YEAR	FIRST
d. What was the month and year of your last treat- ment for (CONDITION)?	LAST	LAST MONTH YEAR
e. What kind of (CONDITION) did you have?	CONDITION:	CONDITION:
<b>1</b>	OFFICE USE	OFFICE USE
REPEAT B1. FOR NEXT CONDITION		

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	CANCER
	YES01 + ASK a-g
	NO02 + GO TO SECTION C
a. In what month and year were you first told you had cancer?	MONTH YEAR
b. What medicine/treatment were you given for cancer?	
	OFFICE USE
c. What was the month and year of your first treatment for cancer?	FIRST
d. What was the month and year of your	LAST
last treatment for cancer?	MONTH YEAR
e. What kind of cancer did you have?	CONDITION:
	OFFICE USE
f. What is the name and address of the hospital (or doctor) where you were treated for cancer?	HOSPITAL/DR:
	CITY:
	STATE:
	ZIP:
g. Will you give permission to obtain your medical records?	YES 01 + GO TO PERMISSION WORKSHEET NO 02

GO TO SECTION C

### C. MARITAL HISTORY

In this next section I will ask you questions about your marital history but there will be some questions about your pregnancies mixed in. We have mixed the questions so we will be sure not to miss any information.

For the purposes of this study we define "being married" as any legal marriage regardless of length <u>or</u> living with a man for 2 years or more.

C1. How many times have you ever been pregnant? Please be sure to include any pregnancies that ended in the birth of a child, a stillborn child, a miscarriage, or an induced abortion? [NEVER, ENTER "00"]

TIMES PREGNANT ENTER HERE AND ON PAGE D-1 AT Q.D1

a. Did you ever have a hysterectomy or have your tubes tied?

YES01	
NO02	+ GO TO C2

- b. [IF YES], In what year was it performed?
  - 19
- C2. Are you currently married, widowed, divorced, or separated?

MARRIED	)1
WIDOWED	)2
DIVORCED	)3
SEPARATED	)4

C3. Including any times you were actually married or lived as married with a man for 2 years or more, how many times have you been married?

[INTERVIEWER: INCLUDE LIVING RELATIONSHIP WITH INDEX MALE AS A MARRIAGE.]

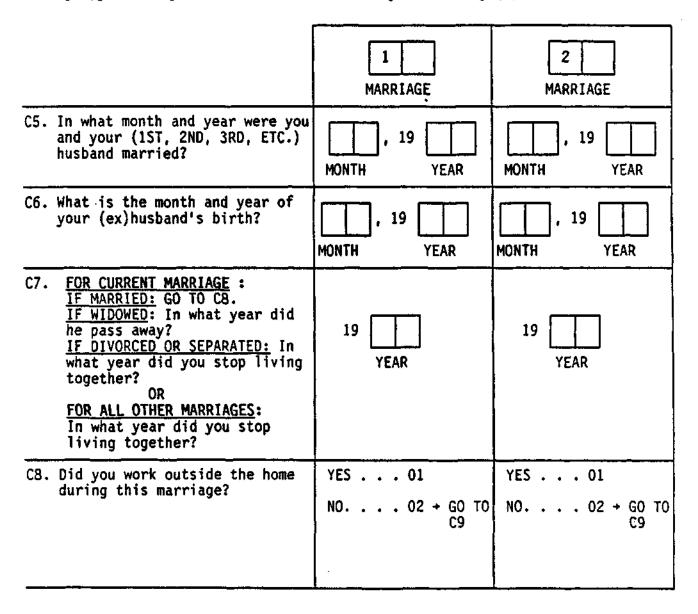
TIMES MARRIED	
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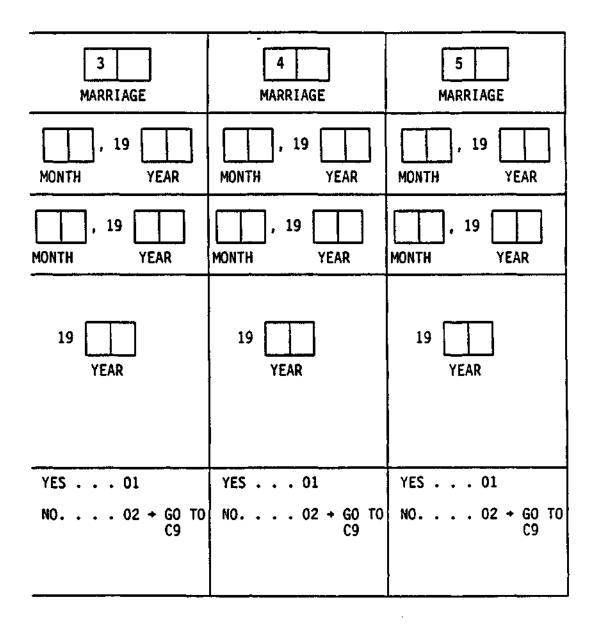
C4. Which marriage/relationship was to Mr. \_\_\_\_\_?

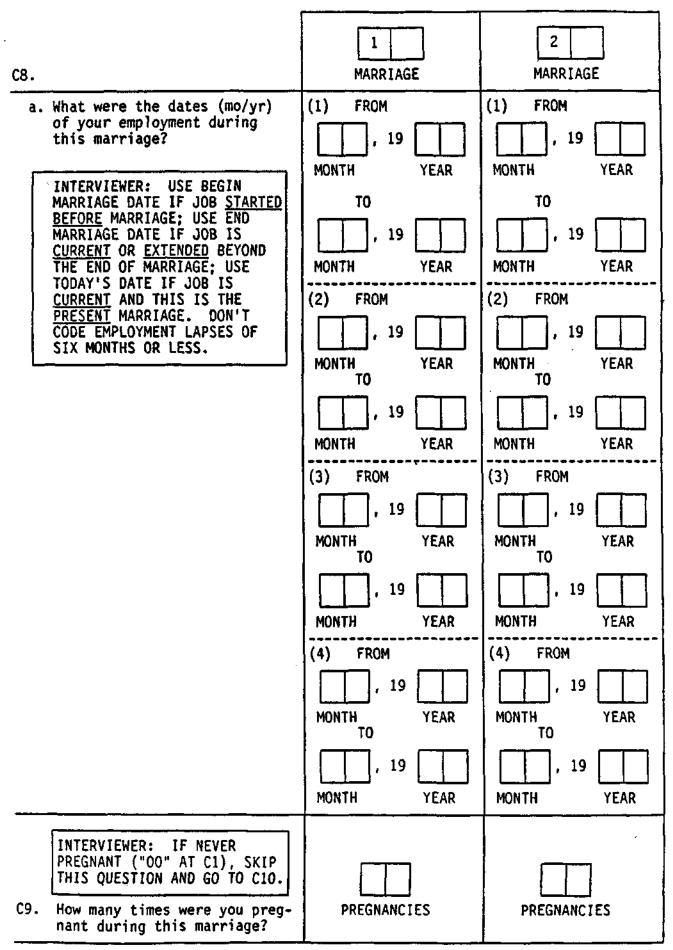
INTERVIEWER: CODE "1" IN SECOND BOX IF THE MARRIAGE WAS TO THE INDEX MALE. OTHERWISE, CODE "0" IN THE SECOND BOX.

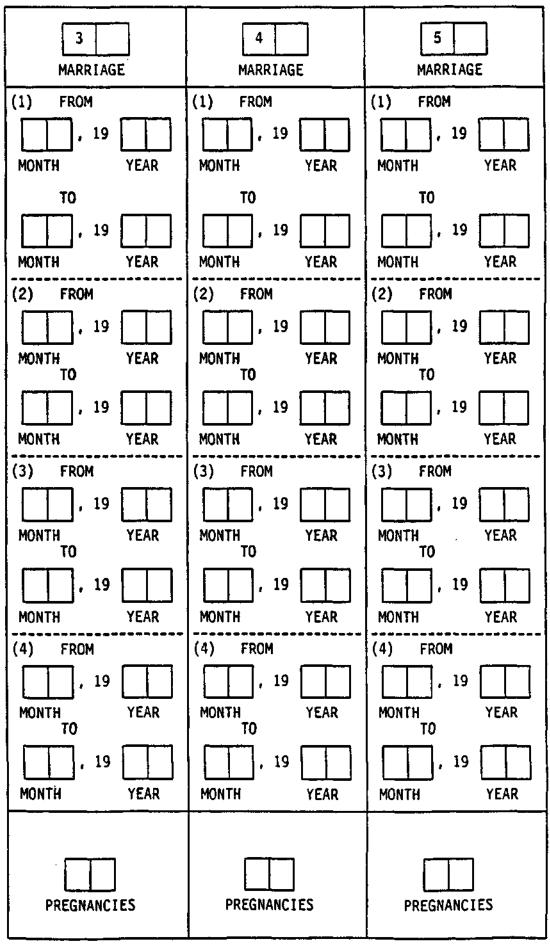
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I am going to ask you for some details about your marriage(s).









Wives Reproductive C-5

	1 MARRIAGE	2 MARRIAGE
CIO. During this marriage, did you ever want to get pregnant but were unable to? IF YES ↓	YES 01 NO 02 + GO TO C12	YES 01 NO 02 → GO TO C12
a. Did you ever try for at least 1 year and were unable to get pregnant? IF YES ↓	a. YES 01 NO 02 + GO TO c	a. YES 01 NO 02 + GO TO c
<pre>b. In what year did you begin trying? </pre>	b. 19	b. 19
<pre>c. Did <u>you</u> ever see a doctor be- cause you had trouble getting pregnant? IF YES ↓</pre>	c. YES 01 NO 02 + GO TO C11	c. YES 01 NO 02 + GO TO C11
(1) What was the doctor's diagnosis?	PROBLEM WITH FEMALE ORGANS 01 HORMONAL/ GLANDULAR 02 NO REPORTED ABNORMALITY 03 OTHER 04	PROBLEM WITH FEMALE ORGANS 01 HORMONAL/ GLANDULAR 02 NO REPORTED ABNORMALITY 03 OTHER 04

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3 MARRIAGE	4 MARRIAGE	5 MARRIAGE
YES 01	YES 01	YES 01
NO 02 → GO TO C12	NO 02 + GO TO C12	NO 02 + GO TO C12
a. YES 01	a. YES 01	a. YES 01
NO 02 + GO TO c	NO 02 + GO TO c	NO 02 + GO TO C
b. 19	b. 19	b. 19
c. YES 01	c. YES 01	c. YES 01
NO 02 → GO TO C11	NO 02 + GO TO C11	NO 02 + GO TO C11
PROBLEM WITH FEMALE ORGANS 01	PROBLEM WITH FEMALE ORGANS 01	PROBLEM WITH FEMALE ORGANS 01
HORMONAL/ GLANDULAR02	HORMONAL/ GLANDULAR 02	HORMONAL/ GLANDULAR 02
NO REPORTED ABNORMALITY 03	NO REPORTED ABNORMALITY 03	NO REPORTED ABNORMALITY 03
OTHER 04	OTHER 04	OTHER 04
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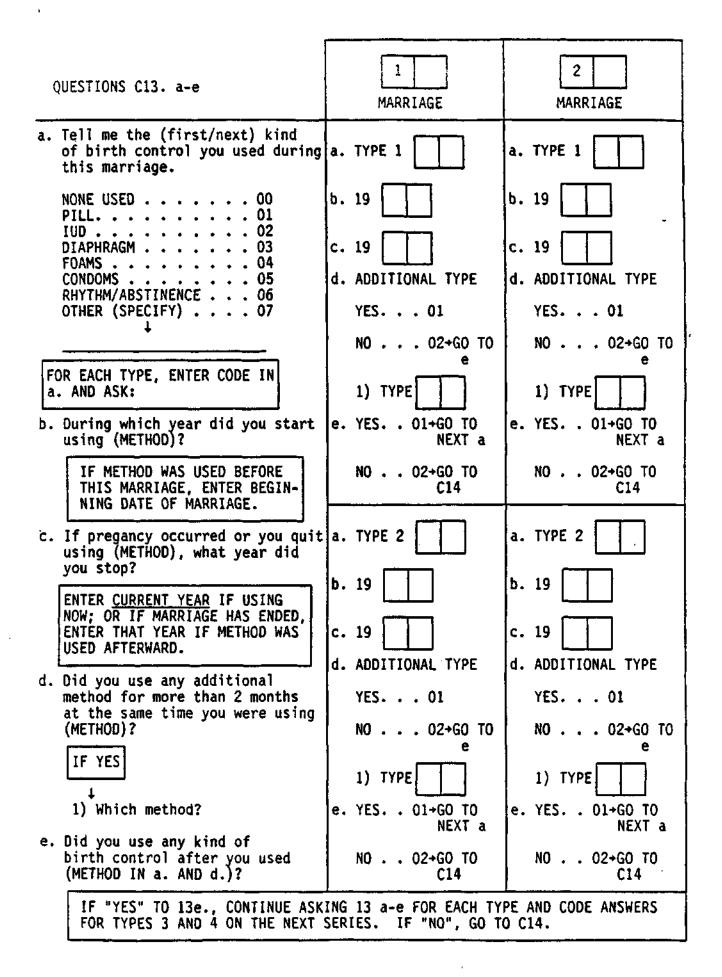
	1 MARRIAGE	2 MARRIAGE
C11. Did your (ex)husband ever see a doctor because you had trouble getting pregnant? IF YES ↓	YES 01 NO 02 + GO TO C12	YES 01 NO 02 + GO TO C12
a. What was the doctor's diagnosis?	PROBLEM WITH MALE ORGANS 01 HORMONAL/ GLANDULAR 02 SPERM COUNT LOW 03 IMPOTENCY 04 NO REPORTED ABNORMALITY 05 OTHER 06	PROBLEM WITH MALE ORGANS 01 HORMONAL/ GLANDULAR 02 SPERM COUNT LOW 03 IMPOTENCY 04 NO REPORTED ABNORMALITY 05 OTHER 06
C12. Did your (ex)husband ever have a vasectomy?	YES 01 NO 02 + GO TO C13	YES 01 NO 02 + GO TO C13
a. In what year was it performed?	19	19
C13. During your (1ST, 2ND, 3RD, ETC.) marriage, did you and your (ex)husband use anything to prevent you from getting pregnant?	YES 01 NO 02 + GO TO C14	YES 01 NO 02 + GO TO C14

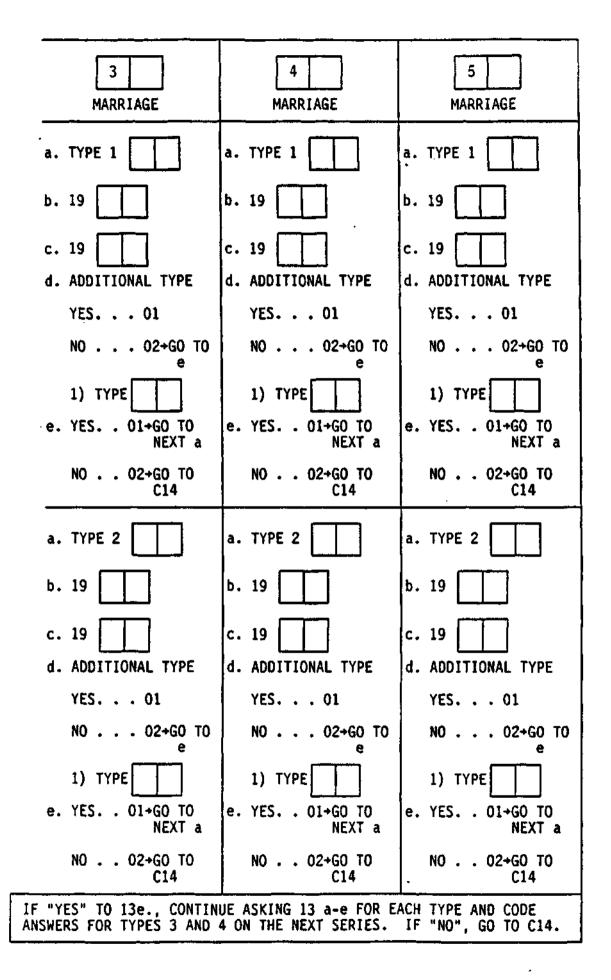
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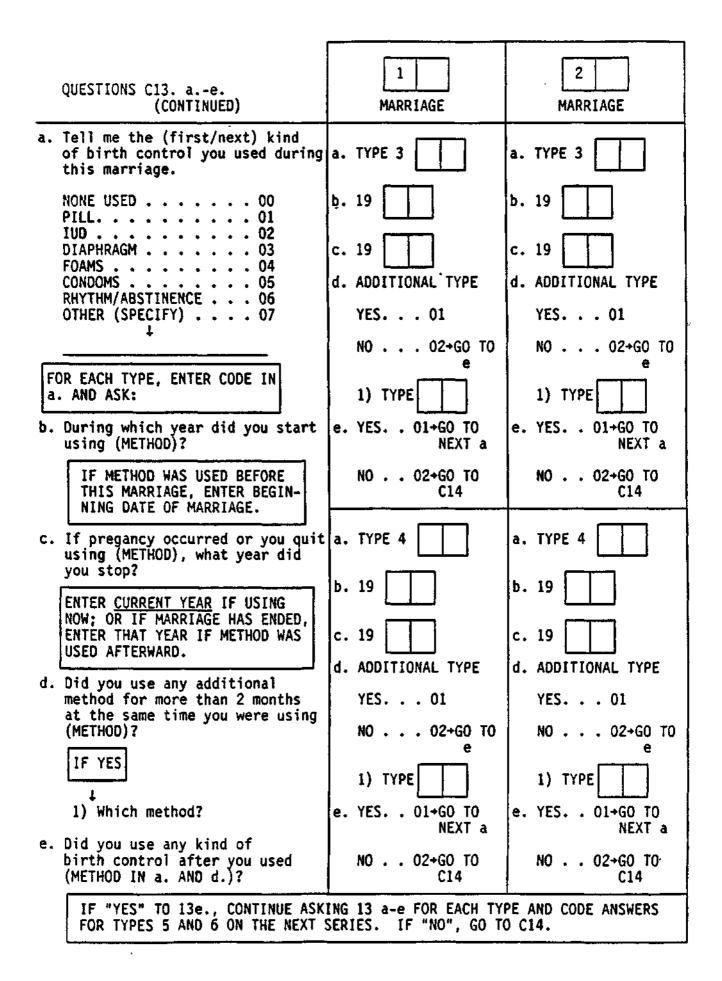
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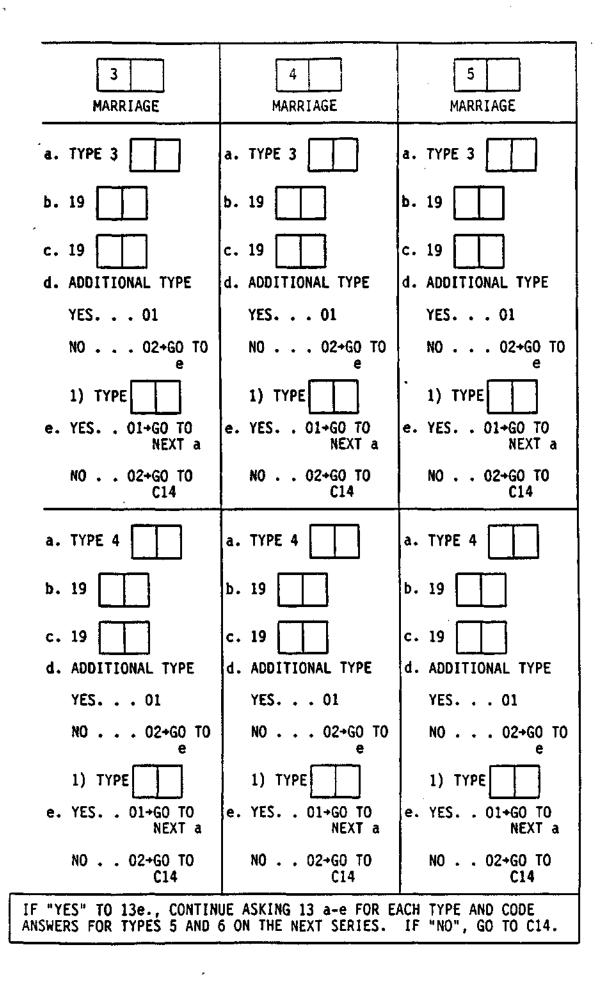
3     MARRIAGE	4 MARRIAGE	5 MARRIAGE
YES 01	YES 01	YES 01
NO 02 → GO TO C12	NO 02 + GO TO C12	NO 02 + GO TO C12
PROBLEM WITH MALE ORGANS 01	PROBLEM WITH MALE ORGANS 01	PROBLEM WITH MALE ORGANS 01
HORMONAL/ GLANDULAR02	HORMONAL/ GLANDULAR02	HORMONAL/ Glandular 02
SPERM COUNT	SPERM COUNT LOW 03	SPERM COUNT LOW 03
IMPOTENCY 04	IMPOTENCY 04	IMPOTENCY 04
NO REPORTED ABNORMALITY05	NO REPORTED ABNORMALITY 05	NO REPORTED ABNORMALITY 05
OTHER 06	OTHER 06	OTHER 06
· · · · · · · · · · · · · · · · · · ·		
YES 01	YES 01	YES 01
NO 02 + GO TO C14	NO 02 + GO TO C14	NO 02 → GO TO C14
19	19	19
YES 01	YES 01	YES 01
NO 02 → GO TO C14	NO 02 + GO TO C14	NO 02 + GO TO C14
	l	L

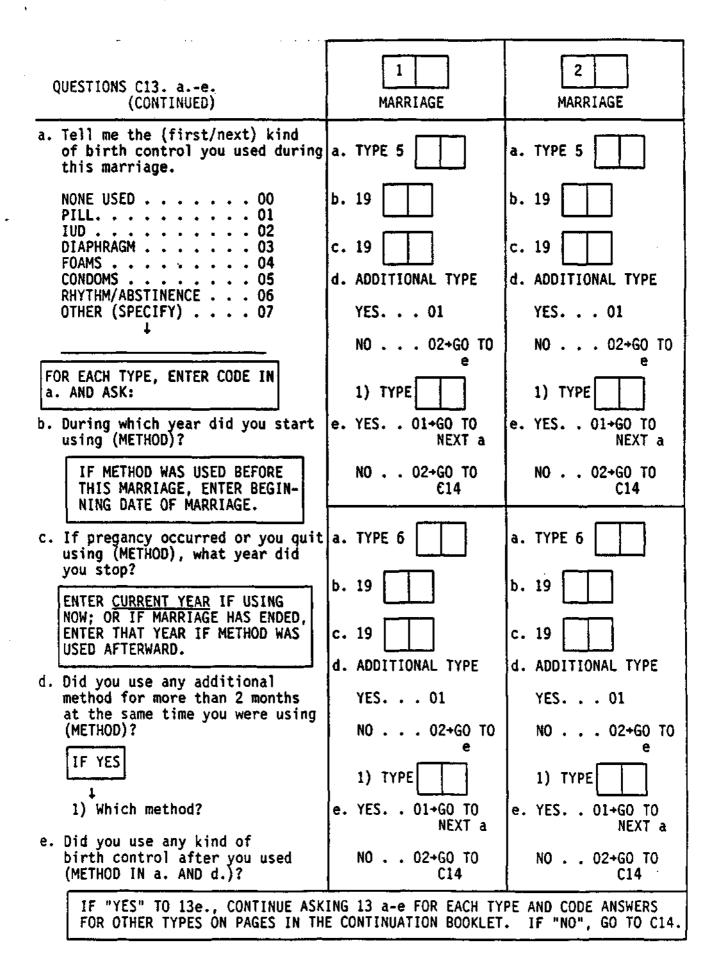
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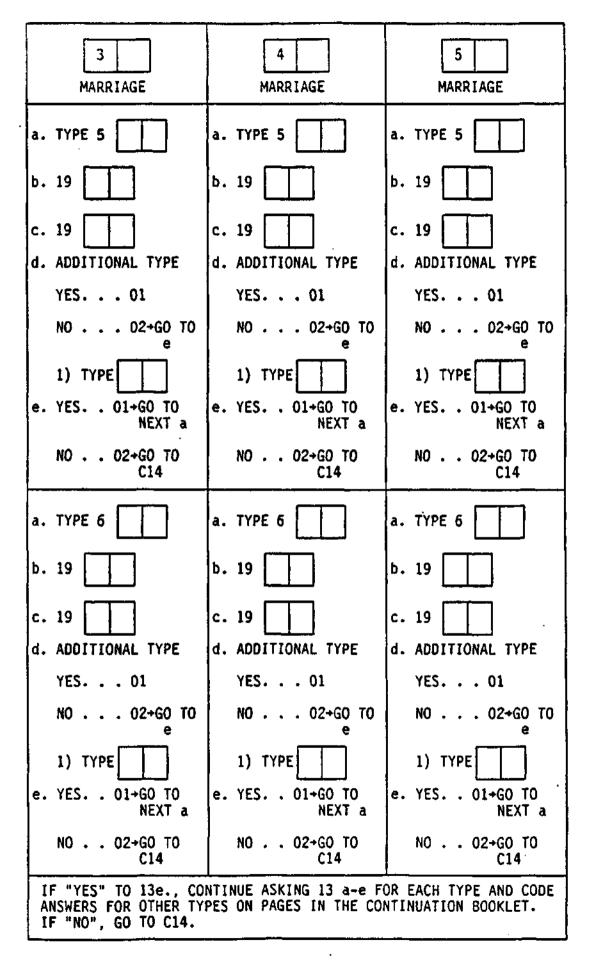












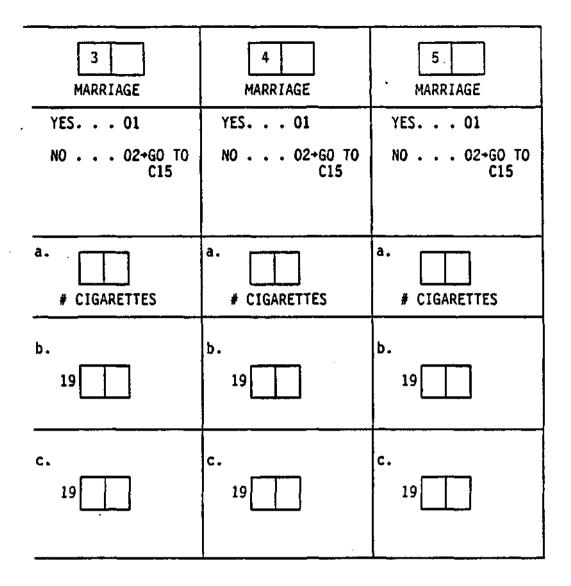
	1 MARRIAGE	2 MARRIAGE
C14. During this marriage did you smoke 1 or more cigarettes per day? IF YES 4	YES 01 NO 02+GO TO C15	YES 01 NO 02+GO TO C15
a. About how many cigarettes did you smoke a day during this marriage?	a # CIGARETTES	a # CIGARETTES
b. In what year did you first smoke during this marriage? IF SMOKED BEFORE MARRIAGE ENTER YEAR OF MARRIAGE.	b. 19	b. 19
c. In what year did you last smoke during this marriage? IF MARRIAGE ENDED BEFORE STOPPED SMOKING, ENTER YEAR MARRIAGE ENDED.	c. 19	c. 19

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	1 MARRIAGE	2 MARRIAGE
C15. During this marriage, did you use any <u>other</u> tobacco products like snuff, chewing tobacco, pipe tobacco, or cigars? IF YES	YES 01 NO 02+GO TO C16	YES 01 NO 02+GO TO C16
a. What did you use?	a. SNUFF/CH. TOB01 PIPE 02 CIGARS03 ANY COMBINATION OF THE ABOVE . 04	a. SNUFF/CH. TOB 01 PIPE 02 CIGARS 03 ANY COMBINATION OF THE ABOVE 04
<ul> <li>b. In what year did you first use other tobacco products in this marriage?</li> <li>IF USED BEFORE MARRIAGE ENTER YEAR OF MARRIAGE.</li> </ul>	b. 19	b. 19
c. In what year did you last use other tobacco products in this marriage? IF MARRIAGE ENDED BEFORE STOPPED USING, ENTER YEAR MARRIAGE ENDED.	c. 19	c. 19

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3	4	5
MARRIAGE	MARRIAGE	MARRIAGE
YES 01	YES 01	YES 01
NO 02+GO TO	NO 02+GO TO	NO 02+GO TO
C16	C16	C16
a.	a.	a.
SNUFF/CH. TOB. 01	SNUFF/CH. TOB 01	SNUFF/CH. TOB 01
PIPE 02	PIPE 02	PIPE 02
CIGARS 03	CIGARS 03	CIGARS 03
ANY COMBINATION	ANY COMBINATION	ANY COMBINATION
OF THE ABOVE . 04	OF THE ABOVE 04	OF THE ABOVE 04
b.	b.	b.
19	19	19
c.	c.	c.
19	19	19

	r <u></u>	
	1 MARRIAGE	2 MARRIAGE
C16. During this marriage, how	EVERY DAY 01	EVERY DAY 01
often did you drink an alco- holic beverage like beer,	3-4 X/WK 02	3-4 X/WK 02
wine, or whiskey?	1-2 X/WK 03	1-2 X/WK 03
	1-2 X/MO : 04	1-2 X/MO 04
	< 1 X/MO 05	< 1 X/MO 05
	NEVER 00	NEVER 00
	UNKNOWN 94	UNKNOWN 94
IF CODED 01, 02, 03, 04, 0R 05	IF CODED 00 OR 94, GO TO C16d.	IF CODED 00 OR 94, GO TO C16d.
•	•	
a. About how many cans, glasses, or drinks did you usually have on each occasion?	a # DRINKS	a # DRINKS
b. In what year did you first drink alcoholic beverages during this marriage?	b.	<b>b.</b>
IF DRANK BEFORE MARRIAGE ENTER YEAR OF MARRIAGE.	19	19
c. In what year did you last drink alcoholic beverages during this marriage?	c.	с.
IF MARRIAGE ENDED BEFORE STOPPED DRINKING, ENTER YEAR MARRIAGE ENDED.	19	19
d. REPEAT QUESTIONS 5-16 FOR THE NEXT MARRIAGE. IF NO MORE MARRIAGES, GO TO SECTION D. IF NEVER PREGNANT AND ALL MARRIAGES COVERED, THIS IS THE END OF THE INTERVIEW BUT COMPLETE SECTION J.		·

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3 MARRIAGE	4 MARRIAGE	5 MARRIAGE
EVERY DAY 01	EVERY DAY 01	EVERY DAY 01
3-4 X/WK 02	3-4 X/WK 02	3-4 X/WK 02
1-2 X/WK 03	1-2 X/WK 03	1-2 X/WK 03
1-2 X/MO 04	1-2 X/MO 04	1-2 X/MO 04
< 1 X/MO 05	< 1 X/MO 05	< 1 X/MO 05
NEVER 00	NEVER 00	NEVER 00
UNKNOWN94	UNKNOWN94	UNKNOWN94
IF CODED OO OR 94, GO TO C16d.	IF CODED 00 OR 94, GO TO C16d.	IF CODED 00 OR 94, GO TO C16d.
a. DRINKS	a # DRINKS	a. # DRINKS
b.	b.	b.
19	19	19
с.	с.	с.
19	19	19

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### D. PREGNANCY OUTCOME

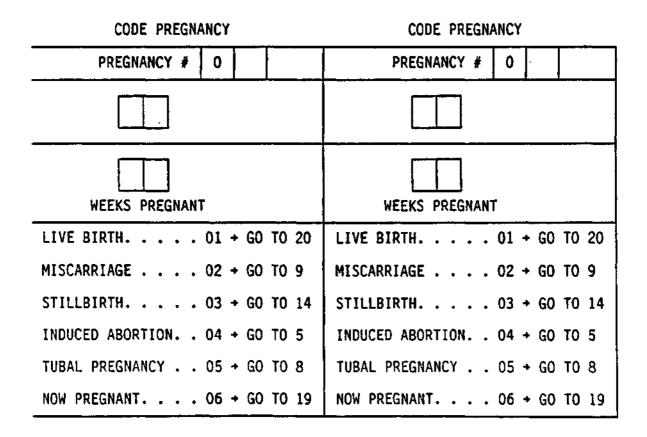
D1. ENTER NUMBER OF PREGNANCIES FROM C1:

REVIEW D1: IF RESPONDENT NEVER PREGNANT ("OO"), END INTERVIEW. IF "O1" OR MORE ENTERED, CONTINUE.

IF A RESPONDENT REPORTS A MULTIPLE BIRTH, RECORD THE DETAILS ABOUT EACH BABY IN A SEPARATE PREGNANCY COLUMN. FOR EACH ADDITIONAL CHILD (2ND, 3RD, ETC.) BE CERTAIN THAT THE PREGNANCY NUMBER FOR EACH COLUMN MATCHES THAT OF THE 1ST OF THE MULTIPLE CHILDREN, RECODE QUESTIONS D2 AND D3, AND CONTINUE FROM D4 ASKING ABOUT EACH OF THE MULTIPLE BABIES.

In this part of the interview, I'll be asking some questions about each of your pregnancies. Let's start with your first pregnancy.

	PREGNANCY # 0 1
D2. In which marriage did your (first/next) pregnancy occur? [USE NUMBERS ASSIGNED AT OR BEFORE Q.C4. CODE "00" IF UNMARRIED.]	
D3. How many weeks pregnant were you when you went to see a doctor?	WEEKS PREGNANT
D4. Did your (1st, 2nd, etc.) pregnancy end with a live birth, miscarriage, stillbirth, induced abortion, tubal pregnancy, (or are you now pregnant)? OR FOR MULTIPLE BIRTHS: Was this baby live born or stillborn?	LIVE BIRTH 01 + GO TO 20 MISCARRIAGE 02 + GO TO 9 STILLBIRTH 03 + GO TO 14 INDUCED ABORTION 04 + GO TO 5 TUBAL PREGNANCY 05 + GO TO 8 NOW PREGNANT 06 + GO TO 19



Wives Reproductive D-2

	PREGNANCY # 0 1
FOR INDUCED ABORTIONS D5. In what year did you have the abortion?	19
D6. Did the medical person suggest you have an abortion for health reasons?	YES 01 NO 02 → GO TO D7
a. What was the health reason? [RECORD VERBATIM <u>AND</u> CIRCLE CODE]	a. PROBLEM WITH MOTHER 01 PROBLEM WITH CHILD 02 BOTH MOTHER AND CHILD 03
D7. How many weeks pregnant were you when you had the abortion?	• WEEKS PREGNANT
IF ABORTION OCCURRED IN INDEX MARRIAGE, CONTINUE WITH SECTIONS E, F, G, AND H. IF IT OCCURRED IN ANY OTHER MARRIAGE, GO TO NEXT PREGNANCY.	
AFTER ALL PREGNANCIES/MULTIPLE BIRTHS, GO TO SECTION I.	

CODE PREGNANCY	CODE PREGNANCY
PREGNANCY # 0	PREGNANCY # 0
19	19
YES 01	YES 01
NO 02 + GO TO D7	NO 02 + GO TO D7
a.	a.
PROBLEM WITH MOTHER 01	PROBLEM WITH MOTHER 01
PROBLEM WITH CHILD 02	PROBLEM WITH CHILD 02
BOTH MOTHER AND CHILD 03	BOTH MOTHER AND CHILD 03
WEEKS PREGNANT	WEEKS PREGNANT

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÷	PREGNANCY # 0 1
FOR TUBAL PREGNANCIES D8. In what year was this pregnancy?	19
a. What is the name and address of the hospital or doctor where you went for treatment of the tubal pregnancy?	HOSP: DR: STREET: CITY: STATE: ZIP:
b. Will you give permission for us to obtain copies of the medical records?	YES 01 + COMPLETE PER- MISSION WORK- SHEET NO 02
C. IF TUBAL PREGNANCY OCCURRED IN INDEX MARRIAGE, CONTINUE WITH SECTIONS E, F, G, AND H. IF IT OCCURRED IN ANOTHER MARRIAGE, GO TO NEXT PREGNANCY.	-
AFTER ALL PREGNANCIES/MULTIPLE BIRTHS, GO TO SECTION I.	] .

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CODE PREGNANCY	CODE PREGNANCY
PREGNANCY # 0	PREGNANCY # 0
19	19
HOSP:	HOSP:
DR:	DR:
STREET:	STREET:
<u>CITY:</u>	<u>CITY:</u>
STATE:	<u>STATE:</u>
<u>Z1P:</u>	<u>ZIP:</u>
YES 01 + COMPLETE PER- MISSION WORK- SHEET NO 02	YES 01 + COMPLETE PER- MISSION WORK- SHEET NO 02

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·	PREGNANCY # 0 1
FOR MISCARRIAGES D9. In what month and year did you miscarry?	MONTH YEAR
D10. How many weeks pregnant were you when you miscarried?	WEEKS
D11. In what city and state did the miscarriage occur?	CITY: STATE:
D12. Did you see a doctor or go to a hospital when you miscarried? IF YES ↓	YES 01 NO 02 + GO TO D13a
a. What is the name and address of the hospital or doctor?	HOSP:         DR:         STREET:         CITY:         STATE:         ZIP:
D13. Will you give permission for us to obtain copies of the medical records?	YES 01 + COMPLETE PER- MISSION WORK- SHEET NO 02
D13a. IF MISCARRIAGE OCCURRED IN INDEX MARRIAGE, CONTINUE WITH SECTIONS E, F, G, AND H. IF IT OCCURRED IN ANOTHER MARRIAGE, GO TO NEXT PREGNANCY.	
AFTER ALL PREGNANCIES/MULTIPLE BIRTHS, GO TO SECTION 1.	

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CODE PREGNANCY	CODE PREGNANCY
PREGNANCY # 0	PREGNANCY # 0
MONTH YEAR	MONTH YEAR
WEEKS	WEEKS
CITY: STATE:	<u>CITY:</u> STATE:
YES 01 NO 02 + GO TO D13a	YES 01 NO 02 + GO TO D13a
HOSP: DR: STREET: CITY: STATE:	HOSP: DR: STREET: CITY: STATE:
<u>ZIP:</u>	
YES 01 + COMPLETE PER- MISSION WORK- SHEET NO 02	YES 01 + COMPLETE PER- MISSION WORK- SHEET NO 02

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FOR STILLBIRTHS D14. In what month and year did the stillbirth occur?	MONTH YEAR		
D15. Did the doctor say the baby was born early, late, or on time? IF EARLY OR LATE a. How many weeks? D16. Did the baby have any birth defects? IF YES	EARLY 01 LATE 03 ON TIME 02 } + GO TO D16 DON'T KNOW 94 } a. WEEKS YES 01 NO 02 + GO TO D17		
a. What type of birth defect? [RECORD VERBATIM.]	DEFECTS		
D17. In what city and state did this birth occur?	CITY: STATE:		
D18. What was the name and address of your hospital and doctor?	HOSP: DR: STREET: CITY: STATE: ZIP:		
D19. Will you give permission for us to obtain medical records? IF STILLBIRTH OCCURRED IN INDEX MARRIAGE, CON- TINUE WITH SECTIONS E, F, G, AND H. IF IT OC- CURRED IN ANOTHER MARRIAGE, GO TO NEXT PREGNANCY. AFTER ALL PREGNANCIES/MULTIPLE BIRTHS, YES 01 + COMPLETE PERMI SION WORKSHEET NO 02 [SEE SKIP INSTRUCTIONS IN QUESTION COLUMN.]			

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GO TO SECTION I.

CODE PREGNANCY	CODE PREGNANCY
PREGNANCY # 0	PREGNANCY # 0
MONTH YEAR	MONTH . 19 YEAR
EARLY 01 LATE 03	EARLY 01 LATE
ON TIME 02 ) }+ GO TO D16 DON'T KNOW 94 J	ON TIME 02 ) }+ GO TO D16 DON'T KNOW 94 J
a. WEEKS	a. WEEKS
YES 01	YES 01
NO 02 + GO TO D17	NO 02 + GO TO D17
DEFECTS	DEFECTS
•	1
OFFICE USE	OFFICE
OFFICE USE	OFFICE
OFFICE USE	OFFICE
OFFICE USE	
OFFICE USE OFFICE USE OFFICE USE CITY:	OFFICE CITY:
OFFICE USE	OFFICE
OFFICE USE OFFICE USE OFFICE USE	OFFICE CITY:
OFFICE USE OFFICE USE OFFICE USE CITY: STATE:	OFFICE CITY: STATE:
OFFICE USE OFFICE USE OFFICE USE CITY: STATE: HOSP: DR: STREET:	OFFICE CITY: STATE: HOSP: DR: STREET:
OFFICE USE  OFFICE USE  OFFICE USE  CITY:  STATE:  HOSP: DR:  STREET:	OFFICE CITY: STATE: HOSP: DR:
OFFICE USE           OFFICE USE           OFFICE USE           CITY:           STATE:           HOSP:           DR:           STREET:           CITY:           STATE:	OFFICE           OFFICE           CITY:           STATE:           HOSP:           DR:           STREET:           CITY:           STATE:
OFFICE USE OFFICE USE OFFICE USE OFFICE USE CITY: STATE: HOSP: DR: STREET: CITY:	OFFICE CITY: STATE: HOSP: DR: STREET: CITY:

	PREGNANCY # 0 1
FOR LIVE BIRTHS D20. In what month and year was your baby born?	MONTH YEAR
D21. Did the doctor say your baby was born early, late, or on time? IF EARLY OR LATE 4 a. How many weeks (early/late)?	EARLY 01 LATE 03 ON TIME 02 ) + GO TO D22 DON'T KNOW 94 J WEEKS
D22. In what city and state was your baby born?	CITY: STATE:
D23. What was the name and address of your hospital and doctor?	HOSP: DR: STREET: CITY: STATE: ZIP:
D24. Was it a boy or a girl?	BOY 01 GIRL 02
D25. How much (# LBS/OZS) did he/she weigh at birth?	LBS OZS
a. Will you give permission for us to obtain copies of the medical records?	YES 01 + COMPLETE PER- MISSION WORKSHEET NO 02

CODE PREGNANCY	CODE PREGNANCY		
PREGNANCY # 0	PREGNANCY # 0		
MONTH YEAR	MONTH YEAR		
EARLY 01 LATE 03	EARLY 01 LATE 03		
ON TIME 02 ) }+ GO TO D22 DON'T KNOW 94 J	ON TIME 02 ) }+ GO TO D22 DON'T KNOW 94 J		
a. WEEKS	a. WEEKS		
<u>CITY:</u>	CITY:		
STATE:	STATE:		
HOSP:	HOSP:		
DR:	<u>DR:</u>		
STREET:	STREET:		
<u>CITY:</u>	CITY:		
STATE: ZIP:	STATE: ZIP:		
BOY 01	BOY 01		
GIRL02	GIRL02		
	LBS OZS		
YES O1 + COMPLETE PER- MISSION WORKSHEET NO 02	YES 01 + COMPLETE PER- MISSION WORKSHEET NO 02		

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Wives Reproductive D-12

:	PREGNANCY # 0 1		
D26. Was he/she born with any birth defects?	YES 01		
IF YES	NO O2 + GO TO D27		
a. What type of birth defect?	DEFECTS:		
[RECORD VERBATIM.]			
	OFFICE USE		
	OFFICE USE		

CODE PREGNANCY	CODE PREGNANCY
. PREGNANCY # 0	PREGNANCY # 0
YES 01 NO 02 + GO TO D27	YES 01 NO 02 → GO TO D27
DEFECTS:	DEFECTS:
OFFICE USE	OFFICE USE
OFFICE USE	OFFICE USE

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	PREGNANCY # 0 1
D27. Did a doctor find any (OTHER) birth defects later?	YES 01
IF YES	NO 02 → GO TO D28
4	
a. What type of birth defect?	DEFECTS:
[RECORD VERBATIM.]	
	OFFICE USE
	OFFICE USE
b. What was his/her age when this was	b. DAYS 01
found? [CODE THE APPROPRIATE LABEL.]	MONTHS 02
	YEARS 03
c. What was the name and address of your	HOSP:
hospital and doctor?	
	STREET:
	CITY:
	STATE: ZIP:
d. Will you give permission for us to obtamedical records?	n YES 01 + COMPLETE PERMIS- SION WORKSHEET
	NO 02

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CODE PREGNANCY	CODE PREGNANCY
PREGNANCY # 0	PREGNANCY # 0
YES 01	YES 01
NO 02 + GO TO D28	NO 02 + GO TO D28
DEFECTS:	DEFECTS:
OFFICE USE	OFFICE USE
<u> </u>	
OFFICE USE	OFFICE USE
b DAYS 01	b. DAYS 01
MONTHS 02	MONTHS 02
YEARS 03	YEARS 03
HOSP:	HOSP:
DR:	DR:
STREET:	STREET:
CITY:	CITY:
STATE: ZIP:	STATE: ZIP:
YES 01 + COMPLETE PERMIS- SION WORKSHEET NO 02	YES 01 + COMPLETE PERMIS- SION WORKSHEET NO 02

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	•	PREGNANCY # 0 1		
D23.	Was he/she found to have any mental con- dition such as mental retardation or a learning disability which required special care or education?	YES 01 + GO TO a. NO 02 +GO TO CHECKPOINT ON PAGE D-19		
·	a. What is the condition?	CONDITION:		
	[RECORD VERBATIM.]			
	、			
		OFFICE USE		
		OFFICE USE		

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CODE PREGNANCY	CODE PREGNANCY	
PREGNANCY # 0	PREGNANCY # 0	
YES 01 + GO TO a.	YES 01 + GO TO a.	
NO 02 +GO TO CHECKPOINT ON PAGE D-19	NO 02 +GO TO CHECKPOINT ON PAGE D-19	
CONDITION:	CONDITION:	
OFFICE USE	• OFFICE USE	
OFFICE USE	OFFICE USE	

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CHECKPOINT	PREGNANCY # 0 1
IS THERE A YES ANSWER FOR QUESTION D26, D27, OR D28?	YES 01
	NO 02 + 60 TO D30
D23. Does any relative have the same (birth defect(s)/mental condition(s)/birth	YES 01
defect(s) or mental condition(s))?	NO 02 + GO TO D30
IF YES	
t	
a. What is the condition?	<u>CONDITION:</u>
	OFFICE USE
b. What is this relative's relationship to you?	RELATIONSHIP:
	· · · · · ·
	OFFICE USE
	RELATIONSHIP:
	OFFICE USE
232. IF LIVE BIRTH OCCURRED IN INDEX MARRIAGE, CONTINUE WITH SECTIONS E, F, G, AND H. IF IT OCCURRED IN ANOTHER MARRIAGE, RETURN TO D2 FOR NEXT PREGNANCY.	· · · · · · · · · · · · · · · · · · ·
AFTER ALL PREGNANCIES/MULTIPLE BIRTHS, GO TO SECTION I.	

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CODE PREGNA	NCY	CODE PREG	NANCY	
PREGNANCY # 0		PREGNANCY #	0	
YES 01		YES 01		
NO 02 +	GO TO D30	NO 02	+ 60	TO D30
YES 01	•	YES 01		
NO 02 +	GO TO D30	NO 02	+ 60	TO D30
CONDITION:		CONDITION:		,
<u> </u>	[ ] ] [ ]			
	OFFICE USE	·		OFFICE USE
·····				-
<u></u>	OFFICE USE			OFFICE USE
RELATIONSHIP:		RELATIONSHIP:		
		· · · · · · · · · · · · · · · · · · ·		
				OFFICE USE
RELATIONSHIP:		RELATIONSHIP:		······
<u> </u>				[
<u></u>	OFFICE USE			OFFICE USE

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Wives Reproductive D-20

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## E. CONTRACEPTIVE HISTORY

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INTERVIEWER: REMEMBER THAT SECTIONS E, F, G, AND H ARE ONLY TO BE ASKED FOR PREGNANCIES BY THE INDEX MALE. IF THE SECOND DIGIT OF THE MARRIAGE IDENTIFIER (Q.D2) IS A "1", ASK SECTIONS E, F, G, AND H.

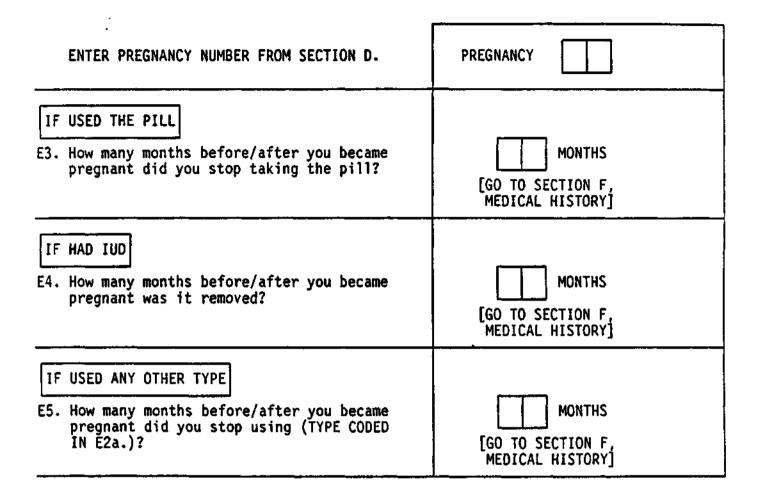
E1. ENTER PREGNANCY NUMBER FROM SECTION D.	PREGNANCY
E2. At the time you became pregnant, were you and your husband using birth control? IF YES	YES 01 NO 02 + GO TO E2b
<ul> <li>a. What kind of birth control were you using?</li> <li>CIRCLE ONLY ONE RESPONSE CODE.</li> </ul>	PILL.       .
b. What was the last kind of birth control that you used? [USE CODES FROM ABOVE. IF NONE, ENTER "00".]	BIRTH CONTROL [FOLLOW SKIPS FROM 2a. IF "00" IS ENTERED, GO TO SECTION F, MEDICAL HISTORY.]

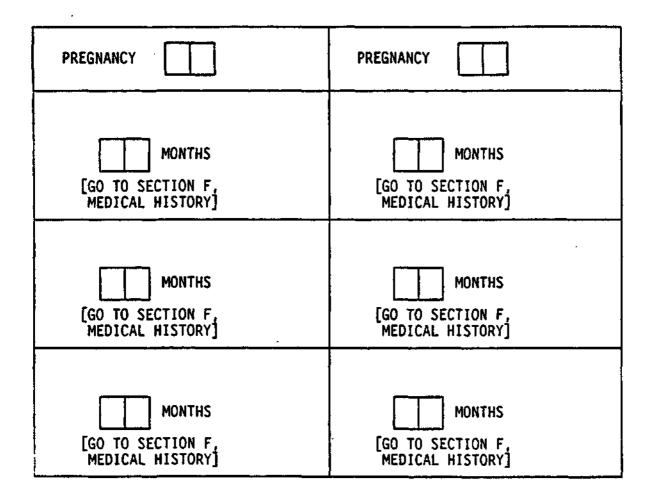
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PREGNANCY	PREGNANCY
YES 01	YES 01
NO 02 + GO TO E2b	NO 02 → GO TO E2b
PILL 01 + GO TO E3	PILL 01 + GO TO E3
IUD 02 → GO TO E4	IUD 02 + GO TO E4
DIAPHRAGM 03 י	DIAPHRAGM 03 ו
FOAMS 04	FOAMS 04
CONDOMS 05	CONDOMS 05
RHYTHM/ ABSTINENCE 06 ≯+GO TO E5	RHYTHM/ ABSTINENCE06 }→GO TO E5
OTHER 07	OTHER 07
COMBINATION OF DIAPHRAGM/FOAM, CONDOM/FOAM, OR OTHER COMBINATION WITH FOAM 08 J	COMBINATION OF DIAPHRAGM/FOAM, CONDOM/FOAM, OR OTHER COMBINATION WITH FOAM 08 J
FOLLOW SKIPS FROM 2a. IF "00" IS ENTERED, GO TO SECTION F, MEDICAL HISTORY.]	FOLLOW SKIPS FROM 2a. IF "00" IS ENTERED, GO TO SECTION F, MEDICAL HISTORY.]

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F. MEDICAL HISTORY		
FI. ENTER PREGNANCY NUMBER FROM SECTION E.	PREGNANCY #	
F2. Thinking back to around the time when you became pregnant, were you given any pills or injections to start your period?	YES 01 NO 02 DON'T KNOW 94 REFUSED 97	
F3. At any time during this pregnancy, did a doctor tell you that you had a kidney or bladder condition? IF YES 4	YES 01 NO 02 + GO TO F4	
a. What was the condition?	a. URINARY/BLADDER INFECTION 01 KIDNEY STONES 02 OTHER (SPECIFY) 03	
D. In which month of pregnancy did the doctor first tell you that you had (CONDITION FROM F3a.)? [CODE 1-9]	b. MONTH	
<pre>c. Were you given any kind of medicine/ treatment? IF YES 4</pre>	c. YES 01 NO 02 + GO TO F4	
i. What medicine/treatment were you given? i. the time you became program did a	d. OFFICE USE DON'T KNOW 94 REFUSED 97 YES 01	
<pre>* At the time you became pregnant, did a</pre>	NO	

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PREGNANCY #	PREGNANCY #
YES 01	YES 01
NO 02	NO 02
DON'T KNOW 94	DON'T KNOW 94
REFUSED 97	REFUSED 97
YES 01	YES 01
NO 02 + GO TO F4	NO 02 + GO TO F4
	·
a	a
URINARY/BLADDER INFECTION 01	URINARY/BLADDER INFECTION 01
KIDNEY STONES 02	KIDNEY STONES 02
OTHER (SPECIFY) 03	<b>OTHER (SPECIFY)</b> 03
b. MONTH	b. MONTH
c. YES 01	c. YES 01
NO 02 + GO TO F4	NO 02 → GO TO F4
d.	d.
OFFICE USE	OFFICE USE
DON'T KNOW 94	DON'T KNOW 94
REFUSED 97	REFUŞED 97
YES 01	YES 01

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Wives Reproductive F-2

ENTER PREGNANCY NUMBER FROM SECTION E.	PREGNANCY #
FE. During this pregnancy, did you ever take: ([IF UNCERTAIN SAY:] Can you remember at least one time during the pregnancy when you took)	
a. Aspirin or Tylenol (aspirin substitute)? [PLEASE SPECIFY]	a. YES 01 NO 02 + GO TO b <u>SPECIFY:</u> USE
b. Cold pills/antihistamines [PLEASE SPECIFY]	<pre>b. YES 01 NO 02 + GO TO c SPECIFY: OFFICE USE </pre>
c. Diet pills [PLEASE SPECIFY]	c. YES 01 NO 02 + GO TO d <u>SPECIFY:</u> USE
<pre>d. Antibiotics/pills for infections (OTHER    THAN THOSE LISTED IN F3.)    [PLEASE SPECIFY]</pre>	d. YES 01 NO 02 + GO TO e <u>SPECIFY:</u> USE
e. Sleeping pills/nerve medicines [PLEASE SPECIFY]	e. YES 01 NO 02 + GO TO f <u>SPECIFY:</u> USE
<pre>f. Diuretics/water pills    [PLEASE SPECIFY]</pre>	f. YES 01 NO 02 + GO TO g <u>SPECIFY:</u> USE

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PREGNANCY #	PREGNANCY #
•	
a. YES 01	a. YES 01
NO 02 + GO TO b	
	NO 02 + GO TO b
SPECIFY: OFFICE	OFFICE
USE	USE
b. YES 01	b. YES 01
NO 02 + GO TO c	NO 02 + GO TO c
SPECIFY:	SPECIFY:
	- OFFICE USE
c. YES 01	c. YES 01
NO $02 + 60$ TO d	NO 02 + GO TO d
SPECIFY:	SPECIFY:
d. YES 01	d. YES 01
NO 02 + GO TO e	NO 02 + GO TO e
OFFICE	OFFICE
USE	USE
e. YES01	e. YES 01
NO 02 + GO TO f	NO 02 + GO TO f
SPECIFY:	SPECIFY:
f. YES 01	f. YES01
NO 02 + GO TO g	NO 02 + GO TO g
SPECIFY:	SPECIFY:
OFFICE	OFFICE
USE	USE

Wives Reproductive F-4

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ENTER PREGNANCY NUMBER FROM SECTION E.	PREGNANCY #
FE. During this pregnancy, did you ever take: ([IF UNCERTAIN SAY:] Can you remember at least one time during the pregnancy when you took)	
<pre>g. Prenatal vitamins or other multivitamin supplements? [PLEASE SPECIFY] IF YES </pre>	g. YES 01 NQ 02 + GO TO h <u>SPECIFY:</u> USE
1) During which trimesters did you take any of these medications?	1ST TRIMESTER 01 2ND TRIMESTER 02 3RD TRIMESTER 03 [CODE ALL ANSWERS]
h. Anti-nausea pills? [PLEASE SPECIFY] IF YES 4	h. YES 01 NO 02 → GO TO i. <u>SPECIFY:</u> . USE USE
<ol> <li>During which trimesters in this pregnancy did you take anti-nausea pills?</li> </ol>	1ST TRIMESTER 01 2ND TRIMESTER 02 3RD TRIMESTER 03 [CODE ALL ANSWERS]
<pre>Medicine to prevent miscarriage? [PLEASE SPECIFY] IF YES </pre>	i. YES 01 NO 02 + GO TO F6 <u>SPECIFY:</u> USE
1) During which trimesters in this pregnancy did you take (MEDICINE FROM i)?	1ST TRIMESTER 01 2ND TRIMESTER 02 3RD TRIMESTER 03 [CODE ALL ANSWERS]

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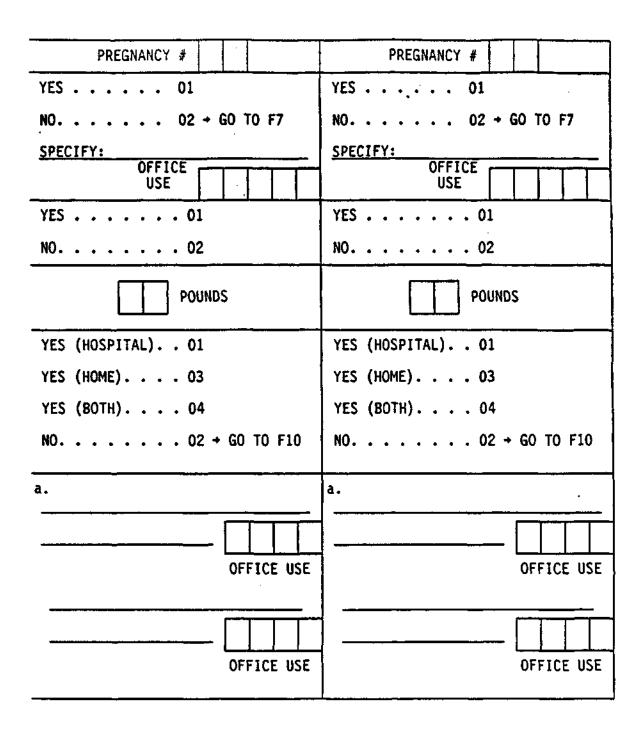
PREGNANCY #	PREGNANCY #
g. YES 01	g. YES 01
NO 02 + GO TO h	NO 02 → GO TO h
SPECIFY: USE	SPECIFY: OFFICE USE
1ST TRIMESTER 01[CODE2ND TRIMESTER 02ALLANSWERS]3RD TRIMESTER 03	1ST TRIMESTER 01 2ND TRIMESTER 02 ALL ANSWERS] 3RD TRIMESTER 03
h. YES 01	h. YES 01
NO 02 + GO TO i	NO 02 + GO TO i
SPECIFY:	SPECIFY:
OFFICE	OFFICE
USE	USE
1ST TRIMESTER 01	1ST TRIMESTER 01
2ND TRIMESTER 02	2ND TRIMESTER 02
3RD TRIMESTER 03	3RD TRIMESTER 03
i. YES 01	i. YES 01
NO 02 + GO TO F6	NO 02 + GO TO F6
OFFICE USE	SPECIFY: OFFICE USE
1ST TRIMESTER 01	1ST TRIMESTER 01
2ND TRIMESTER 02	2ND TRIMESTER 02
3RD TRIMESTER 03	3RD TRIMESTER 03
[CODE	[CODE
ALL	ALL
ANSWERS]	ANSWERS]

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	ENTER PREGNANCY NUMBER FROM SECTION E.	PREGNANCY #
F6.	Did you regularly take any other medicine during this pregnancy? [PLEASE SPECIFY]	YES 01 NO 02 + GO TO F7 <u>SPECIFY:</u> USE
F7.	Did you use artificial sweeteners or diet drinks while you were pregnant?	YES 01 NO 02
F8.	How many pounds did you gain while you were pregnant; that is, before you delivered?	POUNDS
F9.	Were you a hospital inpatient for any length of time or in bed at home for 2 weeks or more at any time during this pregnancy? [DON'T COUNT DELIVERY OF THE BABY.] IF YES 4	YES (HOSPITAL) 01 YES (HOME) 03 YES (BOTH) 04 NO 02 + GO TO F10
	a. What was the reason?	a. OFFICE USE OFFICE USE OFFICE USE

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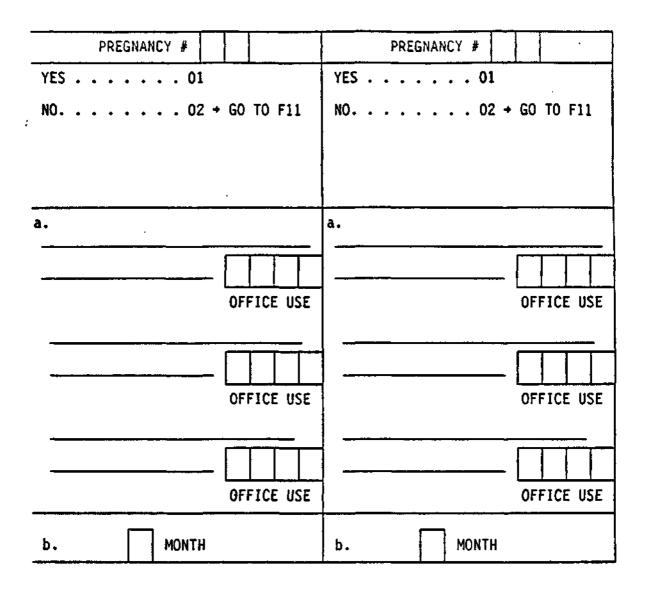


ENTER PREGNANCY NUMBER FROM SECTION E.	PREGNANCY #
F10. Did you have (any/any other) accidents or injuries, such as falls or auto accidents during this pregnancy for which you saw a doctor? IF YES	YES 01 NO 02 + GO TO F11
a. What kind of injury?	a.
b. In which month of this pregnancy did the injury happen? [CODE 1-9]	DFFICE USE

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ENTER PREGNANCY NUMBER FROM SECTION E.	PREGNANCY #
F11. Did you have any kind of an x-ray while you were pregnant or in the 3 months before you became pregnant? IF YES	YES 01 NO 02 ) DON'T KNOW 94 } + GO TO F12 REFUSED 97 J
a. Which month of this pregnancy were you x-rayed? [CODE EARLIEST MONTH, 1-9, OR IF BEFORE, CODE 0.]	MONTH
b. What part of your body was x-rayed?	b.
IF ABDOMINAL AREA NECK TO PELVIS AREAS, GO TO F12	OFFICE USE
c. Why were you x-rayed?	c.
d. Was a shield or some type of metal placed over your abdomen?	<ul> <li>d. YES 01</li> <li>NO 02</li> <li>DON'T KNOW 94</li> <li>REFUSED 97</li> </ul>
F12. During this pregnancy, did you have any illnesses where you had a fever or rash? IF YES ↓	YES 01 NO 02 ) DON'T KNOW 94 } → GO TO F13 REFUSED 97 J
a. What kind of illness?	a 0FFICE USE

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PREGNANCY #	PREGNANCY #
YES 01 NO 02 DON'T KNOW 94 + GO TO F12 REFUSED 97 J	YES 01 NO 02 DON'T KNOW 94 } + GO TO F12 REFUSED 97 J
MONTH	MONTH
b.	b [] OFFICE USE
OFFICE USE	OFFICE USE
d. YES 01 NO 02 DON'T KNOW 94 REFUSED 97	d. YES 01 NO 02 DON'T KNOW 94 REFUSED 97
YES 01 NO 02 ] DON'T KNOW 94 } + GO TO F13 REFUSED 97 J	YES 01 NO 02 DON'T KNOW 94 } + GO TO F13 REFUSED 97 }
a.	a. 

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ENTER PREGNANCY NUMBER FROM SECTION E.		PREGNANCY #
F13. Ca	Can you remember having any any other infections, contagious diseases or other illnesses that we haven't talked about? [INCLUDE INFLUENZA, EXCLUDE COLDS.] IF YES	YES 01
<b>i</b> 1		NO
Ē		DON'T KNOW 94 } + GO TO F14
Ľ	+	REFUSED 97 J
a.	What was it?	ā.
		OFFICE USE
		(2)
	- 	OFFICE USE
Þ.	. In what month of your pregnancy did you have (ILLNESS FROM a.)?	b. (1) MONTH
		(2) MONTH
F14. Di	Did a doctor ever tell you that you had high blood pressure or hypertension during this pregnancy?	YES 01
		NO 02
		DON'T KNOW 94
		REFUSED 97
F15. Di	Did a doctor ever tell you that you had toxemia, or eclampsia during this pregnancy?	YES 01
		NO 02
		DON'T KNOW 94
		REFUSED 97
	Did a doctor every tell you that you had preeclampsia during this pregnancy?	YES 01
pr		NO 02
		DON'T KNOW 94
		REFUSED 97

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PREGNANCY #	PREGNANCY #
YES 01	YES 01
NO	NO
DON'T KNOW 94 } + GO TO F14	DON'T KNOW 94 + 60 TO F14
REFUSED 97 J	REFUSED 97 J
· · · · · · · · · · · · · · · · · · ·	
a. (1)	a. (1)
OFFICE USE	OFFICE USE
(2)	(2)
OFFICE USE	OFFICE USE
b. (1) MONTH	b. (1) MONTH
(2) MONTH	(2) MONTH
YES 01	YES 01
NO 02	NO 02
DON'T KNOW 94	DON'T KNOW 94
REFUSED 97	REFUSED 97
YES 01	YES 01
NO 02	NO 02
DON'T KNOW 94	DON'T KNOW 94
REFUSED 97	REFUSED 97
YES 01	YES 01
NO 02	NO 02
DON'T KNOW 94	DON'T KNOW 94
REFUSED 97	REFUSED 97

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G. WORK HISTORY

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G1.	ENTER PREGNANCY NUMBER FROM SECTION F.	PREGNANCY
di bi	Did you work outside the home at any time during this pregnancy or during the 3 months before you became pregnant?	YES 01
		NO 02 + GO TO
	IF YES	SECTION H
		, 
	a. During which months of this pregnancy did you work? [CODE 1 TO 9; CODE "O" IF BEGAN BEFORE PREGNANCY.]	TO MONTHS
	b. What was the company's name?	b. COMPANY NAME
c.		·
	c. What kind of company was it? (What did they do/make there?)	<u>c.</u>
		OFFICE USE
<u> </u>	d. What was your job title?	JOB TITLE:
	• •	
		OFFICE USE
	e. What were your duties at this job? (What kind of work did you do most	DUTIES:
	of the time?)	
	f. While you were working during this	f.
	pregnancy, did you	· · · · · · · · · · · · · · · · · · ·
	1) do heavy lifting	1) YES01 NO02
	2) do continual standing/walking	2) YES 01 NO 02
	<ol><li>do continual sitting</li></ol>	3) YES01 NO02
	4) work with tools that vibrate?	4) YES01 NO02
	WINNING CONS CHECK THE CONSTRUCT	

PREGNANCY	PREGNANCY
YES 01	YES 01
NO 02 + GO TO SECTION H	NO 02 + GO TO SECTION H
TO MONTHS	TO MONTHS
<b>b.</b> COMPANY NAME	b. COMPANY NAME
	•
c.	c
OFFICE USE	OFFICE USE
JOB TITLE:	JOB TITLE:
OFFICE USE	OFFICE USE
DUTIES:	DUTIES:
f.	f.
1) YES 01 NO 02	1) YES 01 NO 02
2) YES 01 NO 02	2) YES 01 NO 02
3) YES 01 NO 02	3) YES 01 NO 02
4) YES 01 NO 02	4) YES 01 NO 02

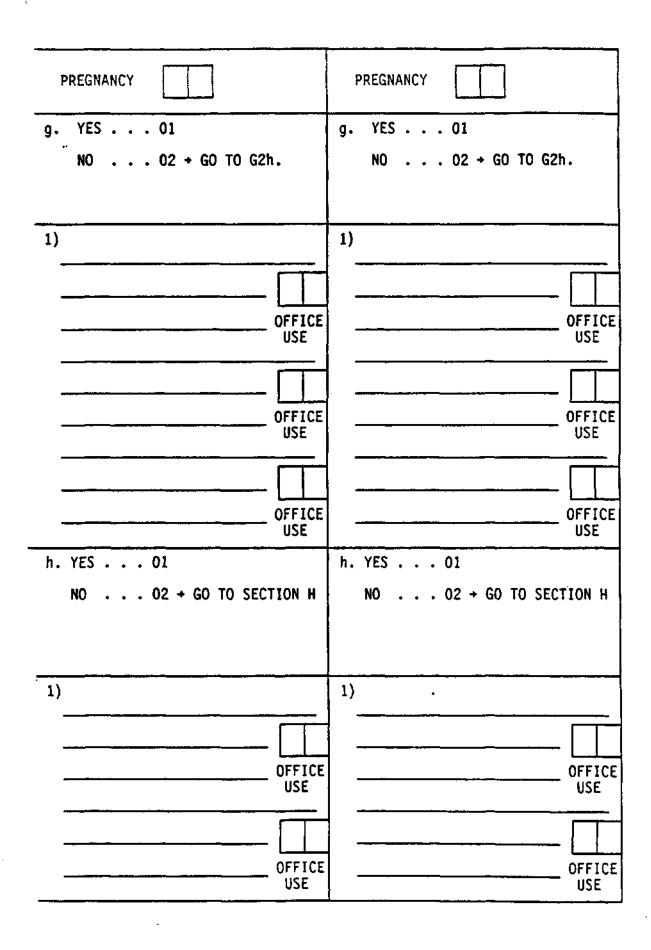
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Wives Reproductive G-2

ENTER PREGNANCY NUMBER FROM SECTION F.	PREGNANCY
g. During this pregnancy did you work with any chemicals? IF YES ↓	g. YES 01 NO 02 + GO TO G2h.
1) What chemicals did you work with?	1)
h. During this pregnancy, did you work with any radiation, like x-rays, fluoroscopy, radioisotopes, or microwaves? IF YES	h. YES 01 NO 02 + GO TO SECTION H
1) What types of radiation did you work with?	1) OFFICE USE OFFICE USE

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H. SOCIAL HISTORY

	· · · · · · · · · · · · · · · · · · ·	
	ENTER PREGNANCY NUMBER FROM F1.	PREGNANCY #
H1.	During the 3 months <u>before</u> you were pregnant, did you smoke 1 or more cigarettes per day? IF YES ↓	YES 01 NO 02 + GO TO H2
	a. About how many cigarettes did you smoke a day?	a. CIGARETTES/DAY
H2.	Did you smoke 1 or more cigarettes a day during this pregnancy? IF YES	YES 01 NO 02 → GO TO H3
	a. During which months did you smoke? [CODE 1-9]	a to MONTHS SMOKED
	b. About how many cigarettes did you usually smoke a day?	b CIGARETTES SMOKED
Н3.	During this pregnancy, did you use any <u>other</u> tobacco products like snuff, pipe tobacco, or cigars? IF YES ↓	YES 01 NO 02 + GO TO H4
	a. What did you use?	a. SNUFF 01 PIPE 02 CIGARS 03 ANY COMBINATION OF THE ABOVE 04
	b. During which months of pregnancy did you did you use (it/them)? [CODE 1-9]	b to MONTHS USED

PREGNANCY #	PREGNANCY #
YES 01	YES 01
NO 02 + GO TO H2	NO 02 + GO TO H2
a. CIGARETTES/DAY	a. CIGARETTES/DAY
YES 01	YES 01
NO 02 + GO TO H3	NO 02 → GO TO H3
a to MONTHS SMOKED	atoMONTHS SMOKED
b. CIGARETTES SMOKED	b. CIGARETTES SMOKED
YES 01	YES 01
NO 02 + GO TO H4	NO 02 + GO TO H4
a. SNUFF 01	a. SNUFF 01
PIPE 02	PIPE 02
CIGARS 03	CIGARS 03
ANY COMBINATION OF THE ABOVE 04	ANY COMBINATION OF THE ABOVE 04
b to MONTHS USED	btoMONTHS USED

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ENTER PREGNANCY NUMBER FROM F1.	PREGNANCY #
H4. During the 3 months before you were pregnant, how often did you drink an alcoholic beverage	ALMOST EVERY DAY01
(beer, wine, or whiskey)?	3-4 TIMES/WEEK02
	1-2 TIMES/WEEK03
	1-2 TIMES/MONTH04
	LESS THAN 1/MONTH05
	NOT AT ALL
IF YOU DID DRINK	DON'T KNOW
+	REFUSED
a. About how many cans, glasses, or drinks did you usually have on each occasion?	a. DRINKS
H5. When you were pregnant how often did you drink an alcoholic beverage?	ALMOST EVERY DAY01
at the all accoloric beverage.	3-4 TIMES/WEEK02
	1-2 TIMES/WEEK03
	1-2 TIMES/MONTH04
	LESS THAN 1/MONTH05
	NOT AT ALL
IF YOU DID DRINK	DON'T KNOW
4	REFUSED
a. About how many cans, glasses, or drinks did you usually have on each occasion?	a. DRINKS

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PREGNANCY #	PREGNANCY #
ALMOST EVERY DAY01	ALMOST EVERY DAY01
3-4 TIMES/WEEK02	3-4 TIMES/WEEK02
1-2 TIMES/WEEK03	1-2 TIMES/WEEK03
1-2 TIMES/MONTH04	1-2 TIMES/MONTH04
LESS THAN 1/MONTH05	LESS THAN 1/MONTH05
NOT AT ALL 06 א	NOT AT ALL
DON'T KNOW	DON'T KNOW
REFUSED	REFUSED
a. DRINKS	a DRINKS
ALMOST EVERY DAY01	ALMOST EVERY DAY01
3-4 TIMES/WEEK02	3-4 TIMES/WEEK02
1-2 TIMES/WEEK03	1-2 TIMES/WEEK03
1-2 TIMES/MONTH04	1-2 TIMES/MONTH04
LESS THAN 1/MONTH05	LESS THAN 1/MONTH05
NOT AT ALL	NOT AT ALL
DON'T KNOW	DON'T KNOW
REFUSED	REFUSED
a. DRINKS	a DRINKS

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ENTER PREGNANCY NUMBER FROM F1.	PREGNANCY #
H6. While you were pregnant, was your house exterminated or sprayed to get rid of pests, like insects or mice? IF YES	YES 01 NO 02 DON'T KNOW 94 ) }+GO TO H7 REFUSED 97 }
<pre>4 a. What was the house treated for? [CODE ALL ANSWERS]</pre>	ROACHES 01 TERMITES 02
	RODENTS         03           OTHER         04
b. Who treated the house, you yourself, a family member, or a professional exterminator?	SELF 01 FAMILY MEMBER 02
[CODE ALL ANSWERS]	PRO
H7. Is there anything else you would like to tell me about this pregnancy?	YES 01 NO 02 + GO TO H8
a. What is it?	a
H8. IF THERE ARE MORE PREGNANCIES, RETURN TO PAGE D1 AND AGAIN ASK ALL APPROPRIATE QUESTIONS THROUGH THIS PAGE. IF NO MORE PREGNANCIES, GO TO SECTION I.	

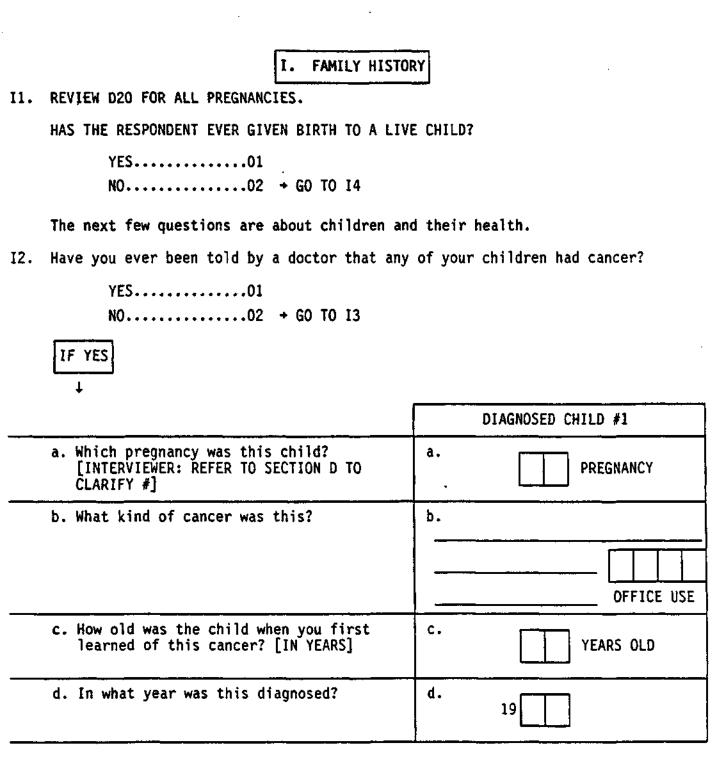
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PREGNANCY #	PREGNANCY #
YES 01	YES 01
NO 02	NO 02
DON'T KNOW 94 ) >+GO TO H7	DON'T KNOW 94 ) +GO TO H7
REFUSED	REFUSED
ROACHES 01	ROACHES 01
TERMITES 02	TERMITES 02
RODENTS 03	RODENTS 03
OTHER 04	OTHER 04
SELF	SELF
FAMILY MEMBER 02	FAMILY MEMBER 02
PRO 03	PRO 03
OTHER 04	OTHER 04
YES01	YES01
NO 02 + GO TO H8	NO 02 + GO TO H8
a.	a.
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	DIAGNOSED CHILD #2	DIAGNOSED CHILD #3
a.	PREGNANCY	a PREGNANCY
b	· · · · · · · · · · · · · · · · · · ·	b.
	OFFICE USE	OFFICE USE
с.	YEARS OLD	C. YEARS OLD
d.	19	d. 19

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12.	• <b>·</b>	DIAGNOSED CHILD #1
е.	What is the name of the hospital/doctor where he/she was treated?	e. HOSP:
		<u>DR.:</u>
		STREET:
		<u>CITY:</u>
		STATE:
f.	f. Will you give permission to obtain his/her medical records?	f. YES 01 + COMPLETE PERMIS- SION WORKSHEET
		NO 02
g.	Have any of your other children had cancer?	g. YES 01 + GO TO NEXT CHILD
		NO 02 → GO TO I3

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DIAGNOSED CHILD #2	DIAGNOSED CHILD #3
e. HOSP:	e. HOSP:
<u>DR.:</u>	DR.:
STREET:	STREET:
CITY:	CITY:
<u>STATE:</u>	STATE:
<u>ZIP:</u>	<u>ZIP:</u>
<pre>f. YES 01 → COMPLETE PERMIS- SION WORKSHEET NO 02</pre>	<pre>f. YES 01 → COMPLETE PERMIS- SION WORKSHEET NO 02</pre>
g. YES 01 + GO TO NEXT CHILD NO 02 + GO TO I3	g. YES 01 → GO TO NEXT CHILD NO 02 → GO TO I3

I3. Are all of your children living?	
YES01 + GO TO 14 NO02	
IF NO TO I3 I would like to ask a few questions about (this/each) child.	DECEASED CHILD #1
<ul> <li>a. Which pregnancy was (this/the first/ the next) child?</li> <li>(INTERVIEWER: REFER TO SECTION D TO CLARIFY #.)</li> </ul>	a. PREGNANCY
b. In what year did the child pass away?	19
c. How old was he/she? (IN MONTHS)	C. MONTHS
d. What was the cause of death?	c
e. In what city and state did he/she pass away?	e. <u>STY:</u> <u>STY:</u>

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DECEASED CHILD #2	DECEASED CHILD #3
a. PREGNANCY	a. PREGNANCY
b. 19	b. 19
C. MONTHS	C. MONTHS
d	d
e. CITY: STATE:	e. CITY: STATE:

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13.	DECEASED CHILD #1
f. IS THE AGE IN Q.I3.c. ONE MONTH?	f. YES 01
:	NO 02 + GO TO i
g. What is the name and address of the hospital/doctor where he/she was	g. HOSP:
treated?	DR.:
	STREET:
	<u>CITY:</u>
	STATE:
	<u>Z1P:</u>
h. Will you give permission to obtain	h. YES O1 + COMPLETE PERMIS- SION WORKSHEET
his/her médical records?	NO 02
i. Are all of your other children living?	i. YES 01 + GO TO I4.
	NO 02 + GO TO NEXT CHILD

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DECEASED CHILD #2	DECEASED CHILD #3
f. YES 01	f. YES01
NO 02 + GO TO i	NO 02 + GO TO i
g. HOSP:	g. HOSP:
DR.:	DR.:
STREET:	STREET:
CITY:	CITY:
STATE:	STATE:
<u>ZIP:</u>	<u>ZIP:</u>
h. YES 01 + COMPLETE PERMIS- SION WORKSHEET	h. YES O1 → COMPLETE PERMIS- SION WORKSHEET
NO 02	NO 02
i. YES 01 + GO TO I4	i. YES 01 + GO TO 14
NO 02 + GO TO NEXT CHILD	NO 02 + GO TO NEXT CHILD

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I4. Finally, I would like to know your Social Security Number since it is very useful in helping us do followup studies. Under law, you cannot be required to tell us your number and regardless of your decision no current or future benefits will be affected. Will you tell me your Social Security Number?

> YES.....01 NO.....02 + GO TO I5

> > .

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a. What is it?

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. . . .

RECORD ALL 9 DIGITS IN THE BOXES PROVIDED IN PART A OF CONTROL CARD AND GO TO 15.

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15. END INTERVIEW BY THANKING RESPONDENT AND REMINDING HER OF POSSIBLE RECONTACT.

# J. INTERVIEWER OBSERVATIONS AND EVALUATION

COMPLETE THIS SECTION AS SOON AFTER LEAVING THE RESPONDENT AS POSSIBLE.

J1. What was the language in which the interview was conducted?

ENGLISH.....01 SPANISH.....02 OTHER.....03 SPECIFY:

•

 $\overline{a}$ 

J2. What was the level of respondent cooperation?

VERY GOOD01
GOOD02
FAIR, OR03
POOR?04

J3. Overall, what is the quality of the interview?

HIGH QUALITY01	
HIGH QUALITY01 GENERALLY RELIABLE02	GO TO J5
QUESTIONABLE, OR03	,
UNSATISFACTORY?04	

# J4. IF UNSATISFACTORY OR QUESTIONABLE:

What was the main reason for the unsatisfactory or questionable quality of the interview?

THE RESPONDENT:	WAS ILL OR DISABLED01
	SPOKE ENGLISH POORLY02
	WAS EVASIVE OR SUSPICIOUS
	WAS BORED OR UNINTERESTED
	WAS UPSET OR DEPRESSED BY THE TOPIC
	WAS DRUNK OR ON DRUGS
	HAD POOR HEARING OR SPEECH
	WAS CONFUSED BY FREQUENT INTERRUPTION
	WAS INSUFFICIENTLY KNOWLEDGEABLE
	WAS MENTALLY DISTURBED
QR:	SOMETHING ELSE11
	SPECIFY:

J5. Was the respondent assisted by another person during most of the interview?

YES.....01 NO.....02 + GO TO J8

J6. Who assisted the respondent? [CODE ALL THAT APPLY]

SPOUSE	.01
CHILD	.02
SIBLING	.03
OTHER RELATIVE	.04
OTHER	.05
SPECIFY:	-

J7. Why was the respondent assisted? [CODE ALL THAT APPLY]

TOO ILL.....01 LANGUAGE PROBLEM.....02 RESPONDENT REQUEST.....03 SOMETHING ELSE.....04 SPECIFY:\_\_\_\_\_

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J8. RECORD ANY OTHER RELEVANT OBSERVATIONS, COMMENTS, OR IMPRESSIONS YOU HAVE ABOUT THIS INTERVIEW.

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Wives Reproductive J-3

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH) CENTERS FOR DISEASE CONTROL U.S. PUBLIC HEALTH SERVICE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

You have been asked to participate in a NIOSH research study. We explain here the nature of your participation, describe your rights, and specify how NIOSH and Lovelace Medical Foundation will treat your records

#### I. DESCRIPTION

#### 1. Title:

Study of Persistent Health Effects in Chemical-Herbicides Manufacturing Workers and in Community Residents of Unknown Exposure Status.

2. Sponsor and/or Project Officer

Marie Haring Sweeney, MPH; IWSB, DSHEFS, NIOSH, CDC, PHS

3. Purpose and Benefits:

You are being asked to participate in a research study conducted by NIOSH and performed by the Lovelace Medical Foundation. The purpose of this study is to determine if there is a relationship between an individual's past workplace exposure to chemical-herbicides and certain health outcomes.

Benefits to each participant include: a free comprehensive health evaluation; information about test results; test results sent to physician of your choice, if requested; a final report of the results of the study and the NIOSH assessment of the persistent health effects of dioxin on chemical-herbicide workers and community residents; a \$300 stipend upon the completion of the health evaluation; free travel, lodging and meals; and the opportunity to participate in an important public health study on the health effects of exposure to chemicals. The foreseeable risks of participation have been minimized by using routine, or tested medical procedures and examinations. All tests and examinations will be conducted and performed by trained physicians, psychologists, nurses and technicians.

Page 1 of 7\_\_\_\_\_(Initials of Participant)

#### CONSENT FORM

#### CONSENT to participate in medical research study

#### II. CONDITIONS OF THE STUDY

1. I understand that I will have to travel to the Lovelace Medical Center in Albuquerque, New Mexico in order to take part in this study.

I also understand that my participation will involve the following interviews and tests:

a. Confidential questionnaire about my health, and personal habits.

b. Examinations by an internist, a dermatologist, a gynecologist (female participants) and a neurologist. The internist will perform a complete general physical examination; the dermatologist will examine my skin, and the neurologist will test muscle strength and nerve function. For female participants, the gynecologist will perform a pelvic and breast examination, and a pap smear will be done. None of these examinations involve any invasive or surgical procedures.

c. Special tests (called neurophysiological tests) which evaluate the ability of the nerves to feel vibration and temperature changes. (see page 4 concerning risks and discomforts.)

d. Hearing, vision and lung function tests.

e. Blood tests will be taken at the start of the first day of testing. The blood tests will involve a withdrawal of approximately 220 milliliters of blood drawn by venipuncture. This is equal to approximately seven ounces of blood which is less than half the amount given when a person donates blood.

f. Chest x-ray.

During the orientation session on the day of my arrival, I will complete a brief questionnaire to determine if I should have 220 milliliters of blood withdrawn. If my answers to the questions indicate that a 220 milliliter blood withdrawal is unlikely to cause unnecessary risk to my health, I will undergo the blood withdrawal procedure on the morning of the first day of testing, while I am in a fasting state.

Page 2 of 7\_\_\_\_\_(Initials of participant)

If the answers to the pre-screening questions indicate that a 220 milliliter blood withdrawal may cause an adverse reaction or unnecessary risk to my health, I will undergo a blood test involving the withdrawal of approximately 4 ounces (120 milliliters) of blood. This is about the same amount of blood taken for tests when a patient is admitted to a hospital for a diagnostic evaluation. The 120ml blood specimen will be used to perform the following tests: the hematocrit (count of the number and kind of cells in my blood), liver function tests, cholesterol or fat level, blood sugar level, thyroid function, immunologic function, vitamin B12 and other vitamin levels and hormone levels. These tests will be conducted on everyone who consents to participate in the examination. The other 100ml blood specimen will be analyzed at the Centers for Disease Control in Atlanta, Georgia for serum dioxin level. A small amount of blood drawn during this time will not be analyzed immediately but will be frozen and stored at the Centers for Disease Control. This small sample will be kept to test the blood in the future for serum dioxin level.

f. The urine sample will be used to conduct routine urine chemistries and determine levels of certain enzymes including D-glucaric acid and porphyrin levels.

There will be two urine collections; one, a 12 hour urine, will begin the evening of my arrival, and a second small amount or urine will be collected the next day during my medical examination.

- g. I will undergo tests to evaluate my sensitivity to three allergens commonly present in the environment. This skin test will be performed the evening before the examinations begin and will be read 24 and 48 hours after administration.
- h. A special skin examination by a licensed dermatologist will be conducted. During this examination the technician will take pictures of the front and both sides of the face and of certain marks, scars, sores or other types of skin conditions.
- i. I will be requested to take neurobehavioral and psychological tests which evaluate coordination, memory, mood, and perception. The tests involve answering sets of questions, and doing timed dexterity and coordination tests. It will take approximately three and one-half hours to complete the full set of tests.

Page 3 of 7\_\_\_\_\_(Initials of Participant)

#### I further understand:

My medical examination will be scheduled by the Occupational Health Study Schedulers at the Lovelace Medical Center in Albuquerque, New Mexico. My travel to the examination site, including airplane fares, taxi and automobile mileage, food, lodging, will be paid by the Federal Government. If I choose to travel by automobile, I will be reimbursed at the rate of 20.5 cents per mile up to the cost of round trip air fare. Room and transportation reservations related to the study will be made by Lovelace. I will receive a stipend of \$300 when I complete the interviews and medical tests.

I understand that the total examination will take approximately 12 hours to complete but the examination will be conducted over a two day period. On the evening prior to the first day of the medical examination, I will participate in an orientation meeting which describes the tests and activities that can be expected during the two days of the examination. I understand that I will be expected to fast for 12 hours on the night before the first day of examinations, and to refrain from drinking alcohol. I will also be expected to collect a sample of my urine in a container provided during the inbriefing meeting. Transportation to the Medical Center will be provided by Lovelace.

I understand that my participation is voluntary and that I am free to refuse without penalty, other than loss of the \$300 stipend, to take any of the tests given as part of the study. If I withdraw from the examination entirely before the tests are completed, my meals, lodging and transportation to and from the examination will still be paid by the government.

#### 2. Risks or discomforts:

Any discomforts or risks are described below and, unless noted are minimal: The blood tests will require drawing blood from a vein in the arm, just as is often done on visits to the doctor. Having blood drawn is slightly uncomfortable but poses minimum health risk. There is a slight risk of becoming light-headed when the blood is drawn and/or experiencing transient pain, swelling, bruising and/or an infection at the blood drawing site on my arm. The amount of blood required for these tests will be about 220 milliliters or about 7.0 ounces. For individuals whose pre-screening indicates the possibility of an adverse reaction to this volume of blood withdrawal, 120 milliliters or about 4.0 ounces will be taken. This is about the same amount of blood taken for tests when a patient is admitted to a hospital for a diagnostic evaluation. If the results of your blood tests show that you have a higher than normal amount of sugar in your blood, you will be asked to allow us to repeat the blood sugar test on the following morning. This will involve refraining from eating or drinking anything except water from 10:00 in the evening, until a small amount of blood is drawn the next morning. The amount of blood taken will be approximately one teaspoon.

Page 4 of 7 (Initials of Participant\_\_\_\_\_)

The neurophysiological evaluation includes: quantitative sensory tests and a nerve conduction velocity test. The quantitative sensory tests are conducted to test the health of nerves in the hands and feet. These tests require the subject to determine the different temperature between two metal pads and to determine the difference in vibration between two vibrating knobs. There is no discomfort or health risk associated with these tests.

The nerve conduction velocity test is conducted to evaluate the ability of the nerve to carry a stimulation from one point to another. The test is performed by electrically stimulating, one at a time, nerves in the arm and the leg. The test requires that an electrode pad be placed on at least two places on the arm or leg to be tested. The sensation is slightly unpleasant for some people, since it feels like a mild electric shock. There is no health risk in nerve conduction testing.

The skin test will be administered by three injections directly under the skin. These injections may be temporarily painful but the risks are minimal. You may experience swelling, itching or redness at the prick site. A very small percentage of the population may experience difficulty breathing and general swelling. All symptoms that occur will be treated by trained medical personnel located on the premises.

If you have any reaction to the test procedures, there will be a physician there whom you can consult. If you have a reaction later, you will be told to contact Dr. William Christensen at (505) 262-7600.

- 3. Injury from this project is unlikely. But if it results, medical care will be provided by Lovelace Medical Center. If you are injured through negligence of a NIOSH employee or an agent of NIOSH, you may be able to obtain compensation under the Federal Tort Claims Act. If an injury should occur to you as the result of your participation, you should contact: Marie Haring-Sweeney, Project Director, NIOSH (513) 841 4482.
- 4. If you have questions about this research or your rights as a member of this study, contact; Marie Haring-Sweeney, Project Director, NIOSH, (513) 841-4482, or Dr. Teresa Coons, Lovelace Project Director, (505) 262-7600.

Page 5 of 7\_\_\_\_\_(Initials of participant)

#### III. USE OF INFORMATION

- 1. NIOSH's authority for collecting information in this study is the Occupational Safety and Health Act of 1970.
- 2. You do not have to furnish any information. Nothing will happen to you if you don't answer our questions, except that we may not ask you to continue to participate in the study.
- 3. The information you and other persons give us will be used by us to help answer research questions about humans exposed to dioxin and what effect that exposure may have on a person's health.
- 4. The information you provide us is covered by the Privacy Act, a federal law. We will not reveal your information in identifiable form to anyone without your permission, unless it is permitted by the Privacy Act. If requested, the Privacy Act permits the release of information in identifiable form under several specific conditions. All 11 conditions possible are stated on the BACK SIDE OF THIS SHEET. These releases are infrequently used, in general. When these kinds of requests occur, each is reviewed by us to ensure that a person would not unreasonably object. The two reasons most often used to seek records subject to the Privacy Act are:
  - (1) When the records are needed to protect the health and safety of other persons.
  - (2) When a researcher (for example, at a university) asks for information and it will be used only for statistical purposes.
- 5. Your records are also covered by the Freedom of Information Act, a federal law. This law permits persons to request information held in our files. All Freedom of Information requests are reviewed to insure that the release of this information would not be clearly unwarranted invasion of personal privacy.

Page 6 of 7\_\_\_\_\_(Initials of participant)

The Privacy Act, a federal law, prohibits the release of your records from the study without your written permission. However, there are ll situations written into this law which <u>do</u> permit releasing your information in identifiable form, without your permission. Your records could be released if:

- 1. They are necessary for <u>PROTECTING THE HEALTH AND SAFETY</u> of other persons.
- 2. A <u>RESEARCHER</u> uses them only for <u>SPATISTICAL RESEARCH.</u>
- 3. NIOSH OFFICIALS, or groups working with NIOSH, need the records for USES compatible with the purpose for which the information was collected.
- 4. They are needed by <u>AGENCY PERSONNEL</u>, who need the records in performance of their duties.
- 5. The release is <u>REOUIRED BY LAW.</u>
- 6. The BUREAU OF CENSUS needs them for census or survey work.
- 7. The <u>NATIONAL ARCHIVES</u> needs them for historical purposes.
- 8. Either House of CONGRESS requests your records.
- 9. The COMPTROLLER GENERAL needs them for the General Accounting Office.
- 10. A <u>COURT ORDERS</u> them; or
- 11. The records are requested under the terms and conditions of the Freedom of Information Act, and their release would not invade your privacy.

Page 6b

# IV. SIGNATURES

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I have read this consent form and I agree to participate in this study.

PARTICIPANT		Age	
	(signature)		
Date			
WITNESS:	····	Date	

(Signature)

Page 7 of 7\_\_\_\_\_(Initials of participant)

#### PROTOTYPE INTRODUCTION TO WORKER

Hello, I am (NAME) from Research Triangle Institute. We are conducting a survey for the National Institute for Occupational Safety and Health (NIOSH) on the effects of chemicals on people exposed to them.

NIOSH has given us (your/STUDY MEMBER'S) name as a person who worked in the chemical industry.

I hope you received a letter and fact sheet from NIOSH explaining the study and the purpose of my call/visit. Did you receive this letter?

(IF NO, READ THROUGH LETTER OR GIVE THE LETTER TO THE PERSON.)

(IF YES):

First I need to verify some information to be sure I have the correct person. Under Federal Law, people participating in our surveys do not have to tell us their Social Security Number. However, it is very useful and helps us identify you as the correct person.

(ASK STUDY MEMBER TO VERIFY SOCIAL SECURITY NUMBER, BIRTHDATE, EMPLOYER, ADDRESS, AND DATES OF EMPLOYMENT FROM SECTION A OF THE WORKER CONTROL CARD.)

As the letter explained, the purpose of the study is to determine if the health of these workers has been affected by working around these chemicals. We would like to interview you in person at your home or another place of your choosing, about your work history. The information you provide will be protected from unwarranted exposure by the Privacy Act of 1974. You have the right to refuse to be interviewed or to refuse to answer any specific questions, during the interview, if you choose.

A follow-up of this interview will be a thorough medical examination at a highly regarded medical foundation clinic. Again, you have the right to refuse to participate in this examination but, as we explained in the letter, your participation in the health study will cost you nothing. You will be compensated for your time by a monetary award of \$300.00, to be paid upon completion of the interview and medical examination.

Do you have any questions about the study?

(IF NO):

The interview will take about one hour. Would (<u>suggested day of week and</u> <u>date</u>) be a good day for your interview?

(IF DATE IS AGREEABLE, ESTABLISH TIME OF DAY.)

(IF DATE IS NOT CONVENIENT): Which day is best for you?

(AFTER A DATE IS SET, ESTABLISH THE TIME OF DAY FOR THE INTERVIEW.)

Thank you for agreeing to participate in the interview about your work. We can discuss more about the medical examination after we complete your interview. I look forward to meeting you on (<u>CONFIRM DAY, DATE, AND TIME OF</u> SCHEDULED INTERVIEW).

Good-bye.

ATTACHMENT 6

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Attachment 6 OMB Approval No.\_\_\_\_\_ Expiration Date \_\_\_\_\_

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Introduction script for comparison persons--initial personal visit: United States Public Health Service-NIOSH Health Study of Chemical Workers and Neighborhood Residents

. . I REPRESENT THE UNITED HELLO, MY NAME IS STATES PUBLIC HEALTH SERVICE AND THE NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH. WE'RE CONDUCTING A VERY IMPORTANT HEALTH STUDY OF CHEMICAL WORKERS WHO HAVE IN THE PAST MANUFACTURED CERTAIN CHEMICALS LIKE WEED KILLERS. IN ADDITION TO STUDYING THOSE WORKERS, WE ALSO WANT TO STUDY THE HEALTH OF COMMUNITY RESIDENTS WHO LIVE IN THE SAME NEIGHBORHOOD AS THOSE WORKERS. ONLY CERTAIN COMMUNITY RESIDENTS ARE ELIGIBLE TO PARTICIPATE, AND RIGHT NOW I'M VISITING VARIOUS HOMES IN THE NEIGHBORHOOD TO DETERMINE WHO MIGHT BE ELIGIBLE FOR THE STUDY. IF SOMEONE IN YOUR HOUSEHOLD IS ELIGIBLE. THEN I'D LIKE TO FIND OUT WHETHER HE (SHE) IS INTERESTED IN PARTICIPATING. THE STUDY WILL CONSIST OF AN INTERVIEW IN THE HOME, FOLLOWED BY AN EXTENSIVE, FREE MEDICAL EXAMINATION BY A SPECIALIST STAFF AT MEDICAL CENTER. ALL PEOPLE WHO PARTICIPATE WILL HAVE THEIR EXPENSES PAID TO, FROM, AND DURING THE MEDICAL EXAMINATION, AND THEY WILL ALSO BE PAID COMPENSATION FOR THEIR TIME SPENT ON THE EXAMINATION. PEOPLE INVOLVED IN THE STUDY WILL RECEIVE COPIES OF THEIR OWN TEST RESULTS, BUT OTHERWISE THE INDIVIDUAL TEST RESULTS WILL BE CONFIDENTIAL. YOUR PARTICIPATION IS VOLUNTARY AND YOU MAY WITHDRAW AT ANY TIME. I WONDER IF YOU'D BE KIND ENOUGH TO ANSWER A FEW QUESTIONS SO THAT I CAN TELL WHETHER ANYONE IN YOUR HOUSEHOLD IS ELIGIBLE FOR THE MEDICAL STUDY?

(If the person refuses to talk further, thank them and leave.)

(If they agree to answer a few questions, ask:

1. ARE THERE ANY ADULT MALES (ADULT FEMALES) IN THE HOUSEHOLD WHO ARE BETWEEN THE AGES OF \_\_\_\_\_\_ AND \_\_\_\_? Yes \_\_\_\_\_ No \_\_\_\_\_ If yes, age \_\_\_\_\_\_

2. TO WHAT RACE DO THEY BELONG?

(If person identifies self as the potentially eligible person, address remaining comments to him/her.)

3. HOW LONG HAVE YOU/HAS THIS MEMBER OF YOUR HOUSEHOLD LIVED IN THIS NEIGHBORHOOD? \_\_\_\_\_\_ years \_\_\_\_\_ months

(If no one in the house is eligible, thank him/her and explain that no one from that household will be able to enroll in the study.

(If eligible and the eligible person is the one to whom you are speaking, ask if you may explain more about the study, if you have not already done so. If the eligible person is not at home, arrange a time when you can return to describe the study and discuss participation.)

(Explanation should contain the information in "STUDY INFORMATION". You should also tell them that you will leave them with A "FACT SHEET" which will give them a written description of the study.)

(If the eligible person declines to participate, try to provide encouragement and explain again the benefits in greater detail: paid expenses, a free and excellent medical examination worth hundreds of dollars, \$100 per day for the two days involved in the examination, and an opportunity to participate in an important public health study. If he still refuses, ask him if you may ask a few questions, since it's important to the study to know something about the persons who refuse. Emphasize that you do not need to know any identifying information such as name, SSN, etc. Administer the REFUSANT QUESTIONNAIRE. Also leave a card with your name and toll free phone number on it to call you if they reconsider.)

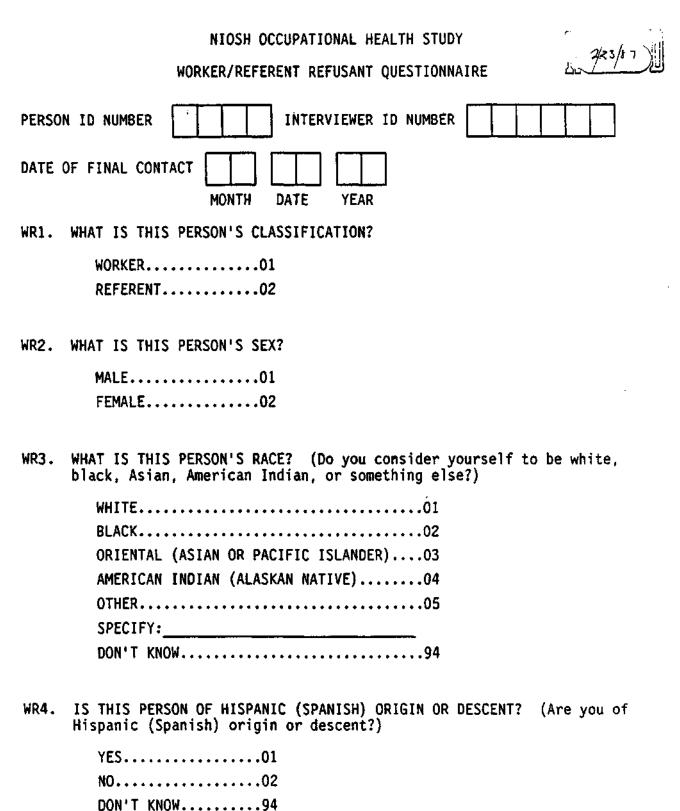
(If the person agrees to participate, you should schedule a time for the interview. Explain again that the interview will require about one to one-and-a-half hours to complete, and that if at all possible, it should be conducted privately. Be sure to obtain a telephone number at which the person can be reached, and be sure to leave a toll free number at which a contractor representative can be reached. Explain that the interview will be conducted by two different persons, since it is important to collect information about health and about exposures separately.)PHONE (\_\_\_\_\_\_\_)-

PHONE ()-

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(Thank the person very warmly. Every interaction should be maximally courteous and positive, whenever possible.)

ATTACHMENT 7



WR5. HOW MANY YEARS HAS THIS PERSON LIVED AT THEIR CURRENT ADDRESS? (How many years have you lived at your current address?)

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YEARS		]	
DON'T KI	VOW	-	94

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WR6. WHAT IS THIS PERSON'S EDUCATIONAL LEVEL? (What was the highest grade in school which you completed?)

NO FORMAL SCHOOLING.....01

1 TO 8 YEARS (GRADE SCHOOL)...02

9 TO 12 YEARS (HIGH SCHOOL)...03

AFTER HIGH SCHOOL VOCATIONAL OR TECHNICAL....04

SOME COLLEGE, GRADUATE, POSTGRADUATE.....05

DON'T KNOW......94

WR7. WHAT IS THE TOTAL INCOME LEVEL OF THE HOUSEHOLD IN WHICH THIS PERSON LIVES? (What is the total income for all people in your household? Is it. . .)

less than	\$10,00001
\$10,000 -	\$19,99902
\$20,000 -	\$29,99903
\$30,000 -	\$39,99904
\$40,000 -	\$49,99905
\$50,000 or	r more06
DON'T KNOW	<b>V</b>

WHAT IS THE MAIN REASON FOR THIS PERSON NOT WANTING TO PARTICIPATE IN WR8. THE SURVEY? (What is the main reason you do not want to participate in this survey?)

NO TIME01
NOT INTERESTED02
DOES NOT LIKE MEDICAL TESTING
TOO ILL TO RESPOND04
TOO ILL TO TRAVEL
TOO FAR TO TRAVEL
CAN'T GET OR TAKE TIME OFF WORK
DOES NOT WANT TO GET INVOLVED08
PERSONAL REASONS (NOT SPECIFIED)09
ALREADY TAKING PART IN SIMILAR STUDY10
OTHER (SPECIFY)11

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DON'T KNOW......94

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WR9. IF POSSIBLE ASK: I know you said you could not participate, but could you answer just a few questions so we will know some very basic information about you?

> YES.....01 (GO ON TO QUESTIONS 10-14 AND IF POSSIBLE GET INFORMATION ON QUESTIONS 3-8 USING THE ALTERNATE WORDING PROVIDED)

(THANK AND TERMINATE)

WR10. Compared to other people your age, would you say your health is excellent, good, fair, or poor?

EXCELLENT01
GOOD02
FAIR03
POOR04
DON'T KNOW94
REFUSED97

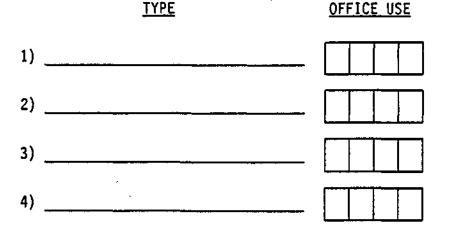
WR11. Has a doctor ever told you that you have/had?

DON! T YES NO KNOW REFUSED heart disease......01......02......94......97 a. b. IF YES TO CANCER: What type of cancer? c. <u>TYPE</u> OFFICE USE 1) 2) 3) \_\_\_\_\_ 4)

WR12. How many children have you (fathered/had)?

CHILDREN		
----------	--	--

- a. IF ANY CHILDREN: Did any of your children have a birth defect?
  YES.....01
  NO.....02 )
  DON'T KNOW.....94 } + GO TO WR13
  REFUSED......97 ;
- b. IF BIRTH DEFECTS: What were the birth defects?



WR13. Have you ever (fathered/had) a pregnancy that ended in a miscarriage?

•

YES	.01					
NO	.02	Ϋ́				
DON'T KNOW	.94	ł	+	GO	T0	WR14
REFUSED	.97	J				

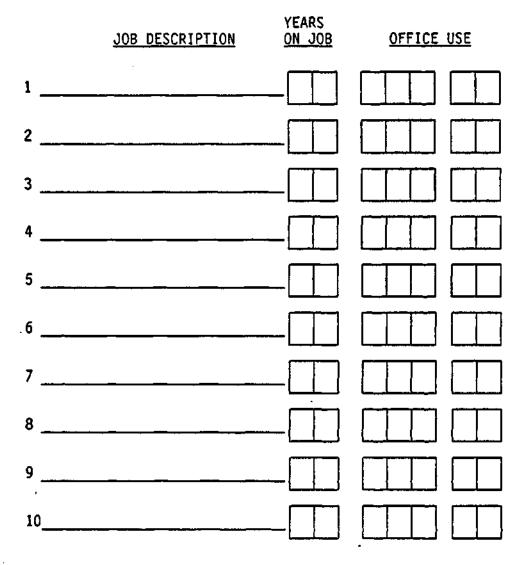
a. IF MISCARRIAGE(S): How many?

	 _
MISCARRIAGES	

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WR14. Please tell me the types of jobs you have held for 3 years or more including part-time jobs?

۰.



### NIOSH OCCUPATIONAL HEALTH STUDY FACT SHEET

## WHAT IS THE NIOSH OCCUPATIONAL HEALTH STUDY?

- The NIOSH Occupational Health Study is a scientific research study about the health of people who worked with chemical-herbicides.
- The purpose of the study is to determine if people who worked with chemicalherbicides have more health problems than people who did not work with chemicalherbicides.
- More than 1000 people will participate in the study.

WHO IS CONDUCTING THE STUDY?

- The National Institute for Occupational Safety and Health (NIOSH), a part of the Centers for Disease Control, is conducting the study.
- Two private research organizations are collecting the study information:
  - Lovelace Medical Foundation in Albuquerque, New Mexico is the prime contractor responsible for conducting the medical examinations for NIOSH.
  - Research Triangle Institute is the subccontractor to Lovelace Medical Foundation and is responsible for conducting the in-home interviews.

### WHAT ARE THE BENEFITS TO ME?

Your participation in the study will give you:

- The opportunity to have a thorough medical examination, valued at hundreds of dollars, but at no cost to you.
- \$300.00 in cash for completing the medical examination.
- Transportation to and from Albuquerque, meals and lodging arranged by Lovelace Medical Foundation and paid <u>in full</u> by NIOSH.
- An opportunity to enjoy sightseeing, shopping, and dining in sunny Albuquerque.
- A summary of all results of your medical tests. If you request, we will send the results to your personal physician.

WHY SHOULD I TAKE PART IN THE STUDY?

- This a very important study whose findings are of great interest to:
  - workers involved in the production of chemical-herbicides
  - farmers who applied chemical-herbicides to their crops
  - people who live in communities contaminated with chemical-herbicides
- You will be performing a service to yourself by obtaining a complete medical examination at no charge.

## HOW WAS I SELECTED?

 All people who worked at the Diamond Alkali plant in Newark, New Jersey will be studied by NIOSH. Your name was randomly chosen as one of the first 80 people to be invited to participate in the study.

## WHAT WILL MY PARTICIPATION INVOLVE?

- An hour-long INTERVIEW, conducted in your home or another place of your choice by an RTI interviewer. Prior to the in-home interview, you will be asked to read and sign a consent form agreeing to complete this interview.
- A two-day, comprehensive MEDICAL EXAMINATION at Lovelace Medical Foundation in Albuquerque. Prior to the medical examination, you will be asked to read and sign a separate consent form agreeing to this medical examination.
- Your wife and/or former wives will be asked to participate in a half-hour telephone interview about their pregnancy history and childbearing experiences. They will <u>not</u> be offered a medical exam.
- Your participation in the study is voluntary, and you may refuse to answer any question or stop participating at any time.

#### WHAT ARE THE INTERVIEW AND MEDICAL EXAMINATION ABOUT?

- The INTERVIEW covers your health and job experiences.
- The MEDICAL EXAMINATION includes a thorough review of your past medical history and examination of your heart, lungs, blood and other organ systems. The RTI interviewer will show a videotape that provides information about the medical examination. Answers to other questions about the medical examination may be obtained from Lovelace Medical Foundation by calling Dr. Teresa Coons toll-free at 1-(800)-843-8387 between 8:30 a.m. and 5:00 p.m., Mountain time.

## WILL MY PRIVACY AND OTHER RIGHTS BE PROTECTED?

Your privacy is protected:

- from unwarranted disclosure by the Privacy Act of 1974,
- from unwarranted invasion of personal privacy by the Freedom of Information Act.
- Knowledge about who participated and their answers will be kept confidential. The results of the study will be presented in summary form so that no individual can be identified.

WHO SHOULD I CONTACT IF HAVE QUESTIONS ABOUT THE STUDY?

<ul> <li>Marie Haring Sweeney of NIOSH</li> </ul>	Kirk Pate of RTI
Collect: 513-841-4411	Toll-free: 1-800-334-8571
8:00 a.m. to 4:30 p.m. (ET)	9:00 a.m. to 5:00 p.m. (ET)

 Diana Kiel of New Jersey Department of Health Collect: 609-292-8812 9:00 a.m. to 4:30 p.m. (ET)

#### NIOSH OCCUPATIONAL HEALTH STUDY FACT SHEET

## WHAT IS THE NIOSH OCCUPATIONAL HEALTH STUDY?

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# WHY SHOULD I TAKE PART IN THE STUDY?

- This a very important study whose findings are of great interest to:
  - workers involved in the production of chemical-herbicides
  - farmers who applied chemical-herbicides to their crops
  - people who live in communities contaminated with chemical-herbicides
- You will be performing a service to yourself by obtaining a complete medical examination at no charge.

#### HOW WAS I SELECTED?

You were randomly selected from people in your community and invited to participate in the study because:

- You live in the same community as a worker and are the same age, race, and sex as the worker.
- You <u>never</u> worked in the production of chemical-herbicides.

#### WHAT WILL MY PARTICIPATION INVOLVE?

- An hour-long INTERVIEW, conducted in your home or another place of your choice by an RTI interviewer. Prior to the in-home interview, you will be asked to read and sign a consent form agreeing to complete this interview.
- A two-day, comprehensive MEDICAL EXAMINATION at Lovelace Medical Foundation in Albuquerque. Prior to the medical examination, you will be asked to read and sign a separate consent form agreeing to this medical examination.
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- Your participation in the study is voluntary, and you may refuse to answer any question or stop participating at any time.

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		Toll-free: 1-800-334-8571
	9:00 a.m. to 5:00 p.m. (ET)	

 Diana Kiel of New Jersey Department of Health Collect: 609-292-8812 9:00 a.m. to 4:30 p.m. (ET) ATTACHMENT 9

Attachment	9
OMB Approva	al No
Expiration	Date

### FACT SHEET USPHS-NIOSH HEALTH STUDY

#### INTRODUCTION

--The United States Public Health Service and the National Institute for Occupational Safety and Health (NIOSH) are conducting this study of former and present chemical manufacturing workers and of similar persons living in their community, in conjunction with several state health departments

--You are being invited to participate so that we can evaluate your health and determine whether you have been exposed to certain chemicals or medications

#### PURPOSE OF THE STUDY

--To determine whether there is a relationship between illness and exposure to certain chemicals like herbicides and pesticides

#### WHAT WILL BE DONE DURING THE STUDY

--You will first be interviewed in your own home by two trained interviewers who will ask you detailed information about your health, your work, and various personal habits, such as smoking and alcohol use. These interviewers are obliged to keep all information you give to them strictly confidential. The interview is expected to take about one-and-one-half hours.

---Following the interview, within a few weeks, we will schedule at your convenience your medical examination at the \_\_\_\_\_\_ medical center. We will arrange for your travel or reimburse you at the rate of 20.3*é*/mile if you choose to drive your own car. We will also make a room reservation for you at the \_\_\_\_\_\_ motel near the medical center, where you will stay for two nights, at our expense. In addition, you will be provided with meals. It is our intention that you incur no personal expense during the conduct of the medical examination and that you be compensated for the time you spend.

On the evening of your arrival prior to the first day of the medical examination, you will participate in an orientation meeting which describes in detail the sorts of tests and activities you can expect during the next day and a half. We will ask that you fast for 12 hours on the first night preceding your medical examination (7 PM to 7 AM) so that your blood can be drawn when you have not consumed any calories for 12 hours. You should also collect your first urine specimen on that morning in a container that will be provided. You will be transported by van to the medical center, where a physician or trained lab technician will obtain a blood sample from you. After that, we will offer you breakfast before proceeding with the rest of the testing.

--Physicians and trained technicians from our research team will examine you and administer several special tests. These will include a general medical exam by a trained internist, a special neurological exam, and a special skin exam by a dermatologist--the sort of physical examinations you would receive if you went to a specialist of your own choice. In addition, special tests your nervous system function and lungs will be conducted. The blood and urine collected from you will provide information about your liver, metabolism, immune system, and blood forming organs. The only uncomfortable parts of the examinations may be the blood drawing, and the test called nerve conduction tests, in which a mild electric stimulation is delivered to a nerve in the arm and in the leg in order to test its function. None of the tests poses any risk to you, but they will provide you and us with valuable information about your health.

--The medical testing will take about 10 hours, which will require that you stay overnight again between the first and the second day.

-Travel expenses, food, and lodging will be paid by the USPHS.

--\$200 will be paid to you in partial compensation for the time required for your participation in the medical examination.

--Confidentiality of your test results will be strictly maintained within the limitations of the Privacy Act of 1974. The exceptions to this Act are detailed in the consent form which will be brought with the interviewers who come to your home to conduct your interview.

#### BENEFITS TO YOU

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--You will receive a free health review, an extensive physical examination, and special medical testing worth about \$500

-You will be fully informed of your test results

7

--Your test results will be sent to a doctor of your choosing, if you so request

--You will be participating in an important public health study and making a contribution to answering important public health questions about the health effects of chemicals.

Center for Survey Research

## Dear <u>(Name of Wife or Former Wife)</u>:

Thank you for agreeing to participate in the public health study sponsored by the National Institute for Occupational Safety and Health. As discussed with a telephone interviewer from the Research Triangle Institute, enclosed is a consent form for each hospital or physician who has medical information concerning your reproductive experiences or the health of your children. The consent form will allow us to look at medical records on your reproductive experiences and your childrens' health. The information will also allow us to evaluate these health records in light of your husband's or former husband's exposure to certain chemicals.

Please sign and date the consent form and return it in the postage paid envelope provided.

If you have questions, please do not hesitate to call me toll-free at (800) 334-8571 or Dr. Teresa Schnorr collect at (513) 841-4481 between 8:00 a.m. to 5:00 p.m. Eastern standard time.

Sincerely,

Kirk Pate Project Director

DKP/cs

Enclosure

Center for Survey Research

## Dear <u>(Name of Wife or Former Wife)</u>:

Thank you for agreeing to participate in the public health study sponsored by the National Institute for Occupational Safety and Health. As discussed with a telephone interviewer from the Research Triangle Institute, enclosed is a consent form for each hospital or physician who has medical information concerning your reproductive experiences or the health of your children. The consent form will allow us to look at medical records on your reproductive experiences and your childrens' health. The information will also allow us to evaluate these health records in light of your husband's or former husband's exposure to certain chemicals.

Please sign and date the consent form and return it in the postage paid envelope provided.

If you have questions, please do not hesitate to call me toll-free at (800) 334-8571 or Dr. Teresa Schnorr collect at (513) 841-4481 between 8:00 a.m. to 5:00 p.m. Eastern standard time.

Sincerely,

Kirk Pate Project Director

DKP/cs

Enclosure

Hello, my name is <u>I</u> am calling from the Research Triangle Institute in North Carolina. We are working on a health study, conducted by NIOSH, of chemical-herbicide manufacturing workers and community residents. The study is called the NIOSH Occupational Health Study. The purpose of the study is to examine whether work with chemicals affects the pregnancies among the wives (and former wives) of men in the study. Did you receive a letter explaining the study from one of our field interviewers or by mail?

(IF NO, READ THROUGH LETTER, THEN CONTINUE. IF YES, CONTINUE.)

As the letter explained, the purpose of the study is to determine if the reproductive health of these men is affected. Since women often remember details about their pregnancies better than their husbands, we would like to interview you about your childbearing experiences and other factors in you life that might have affected them. The information you provide will be protected from unwarranted disclosure by the Privacy Act of 1974. You have the right to refuse to be interviewed or to refuse to answer any specific questions during the interview if you choose.

Do you have any questions about the letter or the study in general?

(IF NO) The interview will take about 45 minutes. Is now a good time for you?

(IF NO) What would be a good time for me to call back?

Wives/Former Wives Telephone Intro. Script

# GENERAL PHYSICAL EXAM

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PAR	PICIPART ID #:	;	NAME	:			•			_ ·
2)	DATE:									
3)	EXAMINATION S	STATUS :	·	(1-0	Comp	plete; 2 used)	!-Pa	arti	ally	Complete;
4)	SEX: (1-	MALE;	2-FEMALE		xert	1860)				
5)	NURSE ID #:		6) 1	'IMB	:	<u>,</u>	-			
VIT	AL SIGNS:									
7)	HEIGHT:	ι	]СМ	12)	BP	SUPINE	-	RT	[	]MMHG
8)	weight:	<b>I</b> .	]KG	13)	BP	SUPINE	-	LT	1	] MMHG
9)	PULSE RATE	[	]/MIN	14)	BP	SITTING	; -	RT	Ţ	]mmhg
10)	PULSE REGULAR (1-Yes; 2-No)	R [	1	15)	BP	SITTING	; -	LT	I	] MMHG
	RESPIRATION		1 / 1 7 12	16)	BP	STANDIN	iG−	RT	I	]MMHG
11,	KESP1 KATIOM	L	1/MIN	17)	BP	STANDIN	iG-	LT	]	] MMHG
	*****7-nor	APPLIC	ABLE; 8-	-DON	'T 1	KNOW; 9-	-RE	pose	D***	***
18)	PHYSICIAN ID	}:		19)	TI	MB:				
λ.	1) SKULL [	1	(l-Norm	mal;	2-1	Abnormal	.)			
	IF ABNORMAL,	DESCRI	BB BBLO	Ĩ						
						· .				
в.	eyes									

2) BYELIDS/CONJUNCTIVAL ABNORMALITY [ ] (1-No: 2-Yes) IF YES, THEN SPECIFY: (1-NO; 2-R; 3-L; 4-BOTH) 3) ENTROPION ] 4) ECTROPION 5) XANTHELASMA 6) PALPEBRAL EDEMA 1 7) INFLAMMATION [ ] UPPER [ ] LOWER [ ] MEDIAL [ ] LATERAL [ ] 8) PALPEBRAL/PERIORBITAL MASSES 9) CONJUNCTIVAL DISCHARGE, ERYTHEMA [ 1 10) CONJUNCTIVAL MASS [ 1 11) CORNEAL/MEDIAL ABNORMALITIES [ ] (1-No; 2-Yes) IF YES, THEN SPECIFY: (1-No; 2-R; 3-L; 4-Both) 12) Ĩ. SCARRING 1 13) CATARACT 1 14) SCLERAL ICTERUS [ 1 15) RETINAL ABNORMALITIES [ ] (1-No; 2-Yes) IF YES, THEN SPECIFY: (1-No; 2-R; 3-L; 4-Both) 16) A-V NICKING ľ 1 17) ARTERIOLAR SPASM 19) LIGHT REFLEX 18) EXUDATES ] 20) PAPILLEDEMA 21) CUPPING 1 j · 22) DISC PALLOR 23) HEMORRHAGES [ 24) LID LAG [ ] (1-NO; 2-YES) C. BARS 1) BAR CANALS [ ] (1-Normal; 2-Abnormal) IF ABNORMAL, THEN SPECIFY: (1-No; 2-R; 3-L; 4-Both) 2) CERUMEN IMPACTED I 1 3) F INFLAMMATION

	4)	MIDDLE EAR [ ] (1-Normal; 2-Abnormal; 8- Don't Know)
		IF ABNORMAL, THEN SPECIFY: (1-No; 2-R; 3-L; 4-Both)
		5) DRUM PERFORATED [ ] 6) DRUM RETRACTED [ ] 7) DRUM SCARRED [ ] 8) DRUM BULGING [ ] 9) DRUM INFLAMED [ ]
D.	1)	NOSE [ ] (1-Normal; 2-Abnormal)
		IF ABNORMAL, THEN SPECIFY: (1-No; 2-Yes)
		2) PERFORATION OF SEPTUM [ ] 3) NASAL POLYPS [ ] 4) ULCERATION [ ] 5) BLEEDING [ ] 6) MUCOSA [ ] IF 2, THEN GO TO Q6A
		6A) INJECTED [ ] 6B) PALE [ ]
		7) DISCHARGE [ ] IF 2, THEN GO TO 7A
		7A) CLEAR [ ] 7B) MUCOPURULENT [ ]
B.	1)	THROAT [ ] (1-Normal; 2-Abnormal)
		IF ABNORMAL, THEN SPECIFY:
		<pre>2) PHARYNGITIS [ ] (1-No; 2-Yes) 3) TONSILS [ ] (1-Normal; 2-Enlarged; 3-Abscessed; 4-Both enlarged and abscessed; 5-Exudate present; 6-Absent)</pre>
F.	MOUT	
	1)	DENTAL STATUS [ ] (1-Good; 2-Fair; 3-Poor; 4-Edentulous)
	2)	DENTURES WORN [ ] (1-No; 2-Yes)
	3) 4)	ULCBRS [ ] (1-No; 2-Yes) PLAQUES [ ] (1-No; 2-Yes)
	5)	MASS [] (1-No; 2-Yes)
	IF	"MASS" YES, THEN DESCRIBE

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6) GLOSSITIS I -1 (l-No; 2-Yes) 73 ſ Ĵ (1-Normal; 2-Abnormal) GUMS IF ABNORMAL, THEN SPECIFY: (1-No; 2-Yes;) 8) GINGIVITIS [ ] HYPERTROPHY/HYPERPLASIA [ ] 9) G. 1) SINUSES t ] (1-Normal; 2-Abnormal) IF ABNORMAL, THEN SPECIFY: (1-Normal; 2-R Tender; 3-L Tender; 4-Both Tender) 2) FRONTAL 3) MAXILLARY Ħ. 1) SALIVARY GLANDS [ ] (1-Normal; 2-Abnormal) IF ABNORMAL, THEN SPECIFY: (1-No; 2-R; 3-L; 4-Both) 2) SUBMENTAL [ ] IF ABNORNAL: 3) ENLARGED [ 1 4) TENDER 1 1 5) MASS 1 ſ 6) PAROTID [ 1 IF ABNORMAL: 7) ENLARGED [ ] 8) TENDER 1 1 Ī 9) MASS 1 10) SUBLINGUAL [ 1 IF ABNORMAL: 11) ENLARGED [ ] 12) TENDER 1 Ι 1

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13) MASS

I

### I. NECK

TRACHEA [ ] (1-Normal; 2-Abnormal) 1) IF ABNORMAL, THEN 2) DEVIATED [ 1 (1-Normal; 2-To R; 3-To L) (1-Normal; 2-Stridor)
(1-Normal; 2-Hoarse) AIR SOUNDS 1 3) I VOICE Ī 1 4) 5) THYROID ſ ] (1-Normal; 2-Abnormal) IF ABNORMAL, THEN 6) SIZE 1 (1-Normal; 2-Large) I (1-No; Yes) 7) TENDERNESS ĺ 1 (1-Absent; 2-Solitary; NODULES I 8) 1 3-Multiple) 9) CAROTID PULSES [ (1-Normal; 2-Reduced; 1 3-Increased)

10) NECK MASSES OTHER THAN ENLARGED LYMPH NODES [ ] (1-No; 2-Yes)

IF YES, THEN DESCRIBE BELOW

### J. CHEST

 EXCURSION SYMMETRICAL [ ] (1-Yes; 2-Decreased R; 3-Decreased L)
 SHAPE [ ] (1-Normal; 2-Pectus Excavatum; 3-Pectus Carinatum; 4-Other Deformity)

IF 4, THEN SPECIFY

3) EXPANSION [ ] (1-Normal; 2-Fair; 3-Poor)

4) **RESONANCE** [ ] (1-Normal; 2-Abnormal) IF ABNORMAL, THEN ] (1-No; 2-R; 3-L; 4-Bilateral) 5) HYPERRESONANT [ 6) DULLNESS ZONES [ ] (1-Absent; 2-Present) IF PRESENT, THEN 1-No; 2-Yes 7} ANTERIOR [ ] IF YES, THEN RIGHT: 8) Upper [ LEFT: 11) Upper [ ] 9) Middle [ ] 10) Lower ] 13) Lower ] 12) Middle [ 1 14) POSTERIOR [ ] IF YES, THEN RIGHT: 15) Upper [ ] 16) Middle [ ] 17) Lower ] LEFT: 18) Upper [ ] 19) Middle [ ] 20) Lower ſ 1 21} **DIMINISHED BREATH SOUNDS** [ ] (1-Absent; 2-Present) IF PRESENT, THEN (1-No; 2-Yes) 22) ANTERIOR [ ] IF YES, THEN ] 24) Middle [ ] 25) Lower ] 27) Middle [ ] 28) Lower RIGHT: 23) Upper [ LEFT: 26) Upper [ 1 29) ] IF YES, THEN POSTERIOR [ RIGHT: 30) Upper [ ] 31) Middle [ ] 32) Lower ] 34) Middle [ LEFT: 33) Upper [ ] 35) Lower Ŧ 1 ADVENTITIAL SOUNDS [ ] (1-Absent; 2-Present) 36) (IF 1, SKIP TO Q67) IF PRESENT, THEN 37) CRACKLES [ ] (1-No; 2-Yes) (IF 1, SKIP TO Q52) IF PRESENT, THEN [ ] (1-No; 2-Yes) 38) ANTERIOR IF YES, THEN ENTER CODE FOR PREDOMINANT SOUND IN APPROPRIATE REGION(S) (1-Absent; 2-Fine; 3-Medium; 4-Coarse) RIGHT: 39) Upper [ ] 40) Middle [ ] 41) Lower

] 44) Lower

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LEFT: 42) Upper [ ] 43) Middle [

45) POSTERIOR [ ] (1-No; 2-Yes) IF YES, THEN ENTER CODE FOR PREDOMINANT SOUND IN APPROPRIATE REGION(S) (1-Absent; 2-Fine; 3-Medium; 4-Coarse) RIGHT: 46) Upper [ ] 47) Middle [ LEFT: 49) Upper [ ] 50) Middle [ ] 48) Lower ] 51) Lower I. 1 52) WHEEZES [ I (1-Absent; 2-Present) (IF 1, SKIP TO Q67) IF PRESENT, THEN (1-No; 2-Yes) 53) ANTERIOR [ ] (1-No; 2-Yes) IF YES, THEN (1-No; 2-Yes) RIGHT: 54) Upper [ ] 55) Middle [ ] 56) Lower LEFT: 57) Upper [ ] 58) Middle [ ] 59) Lower 1 [ ] (1-No; 2-Yes) 60) POSTERIOR IF YES, THEN (1-No; 2-Yes) ] 62) Middle [ RIGHT: 61) Upper [ ] 63) Lower LEFT: 64) Upper [ ] 65) Middle [ ] 66) Lower 1 1 67) **PLEURAL FRICTION RUB** [ ] (1-Absent; 2-Present) IF PRESENT, THEN (1-No; 2-Yes) 68) ANTERIOR [ ] IF YES, THEN (1-No; 2-Yes) RIGHT: 69) Upper [ ] 70) Middle ĺ ] 71) Lower 1 LEFT: 72) Upper [ ] 73) Middle [ ] 74) Lower 1 75) POSTERIOR [ ] IF YES, THEN (1-No; 2-Yes) RIGHT: 76) Upper [ ] 77) Middle [ ] 78) Lower I LEFT: 79) Upper [ ] 80) Middle [ ] 81) Lower [ ] HEART 1) INCREASED PRECORDIAL IMPULSE [ ] (1-No; 2-Palpable; 3-Visual; 4-Both) 2) LOCATION OF PRECORDIAL IMPULSE [ ] (1-Normal; 2-Displaced Laterally; 3-Displaced Inferiorly: 4-Dis placed Both)

,

K.

3) **THRILL** [ ] (1-No: 2-Yes) 4) ABNORMAL SOUNDS [ ] (1-No; 2-Yes) IF NO, THEN SKIP TO PAGE 13, ITEM #64; IF YES THEN: 5) MURMURS [ ] (1-No; 2-Yes) IP NO, THEN SKIP TO PAGE 12, ITEM #57; IF YES THEN: 6) SYSTOLIC MURMUR(S) [ ] (1-No; 2-Yes) IP NO, THEN SKIP TO PAGE 9, ITEM #29; IF YES THEN: 7) NUMBER OF SYSTOLIC MURMURS PRESENT [ ] (1, 2, 3) IF ONLY ONE (1) SYSTOLIC MURMUR PRESENT, ENTER: 8) [] (1-6) INTENSITY 9) [ ] (1-Low; 2-Medium; 3-High) PITCH 10) CONFIGURATION [ ] (1-Cresendo; 2-Decresendo; 3-Cresendo-decresendo; 4-Plateau) 11) (1-Midsystolic; 2-Holosystolic TIMING Ē 1 3-Early Systolic; 4-Late Systolic) 12) SITE OF MAXIMAL INTENSITY [ ] (1-2nd R ICS; 2-Base of Neck; 3-2nd/3rd L ICS; 4-4th/5th L ICS; 5-3rd/4th R ICS; 6-Epigastrium; 7-Cardiac Apex; 8-Other, Specify IF 8, SPECIFY

.

13. RADIATION [ ] (1-Absent; 2-Present)

IF PRESENT, THEN (14) [ ] (1-2nd R ICS; 2-Base of Neck; 3-2nd/3rd L ICS; 4-4th/5th L ICS; 5-3rd/4th R ICS; 6-Epigastrium; 7-Cardiac Apex; 8-Other, Specify Next Page

#### IP 8, SPECIFY

FOR A SECOND SYSTOLIC MURMUR, ENTER: 15) INTENSITY [] (1-6)PITCH [ ] 16) (1-Low; 2-Medium; 3-High) 17) CONFIGURATION [ ] (1-Cresendo; 2-Decresendo; 3-Cresendo-decresendo; 4-Plateau) 18) TIMING ] 1 (1-Midsvstolic: 2-Holosvstolic 3-Early Systolic; 4-Late Systolic) 19) SITE OF MAXIMAL INTENSITY [ ] (1-2nd R ICS; 2-Base of Neck; 3-2nd/3rd L ICS; 4-4th/5th L ICS; 5-3rd/4th R ICS; 6-Epigastrium; 7-Cardiac Apex; 8-Other, Specify

IF 8, SPECIFY

IF 8, SPECIFY

FOR A THIRD SYSTOLIC MURMUR, ENTER:

22) INTENSITY [ 1 (1-6) 23) PITCH [ ] (1-Low; 2-Medium; 3-High) 24) CONFIGURATION [ ] (1-Cresendo; 2-Decresendo; 3-Cresendo-decresendo; 4-Plateau) 25) TIMING 1 1 (1-Midsystolic; 2-Holosystolic 3-Early Systolic; 4-Late Systolic)

26) SITE OF MAXIMAL INTENSITY [ ] (1-2nd R ICS; 2-Base of Neck; 3-2nd/3rd L ICS; 4-4th/5th L ICS; 5-3rd/4th R ICS; 6-Epigastrium; 7-Cardiac Apex; 8-Other, Specify

IP 8, SPECIPY

27) RADIATION [ ] (1-Absent; 2-Present)

IF PRESENT, THEN (28) [ ] (1-2nd R ICS; 2-Base of Neck; 3-2nd/3rd L ICS; 4-4th/5th L ICS; 5-3rd/4th R ICS; 6-Epigastrium; 7-Cardiac Apex; 8-Other, Specify

IF 8, SPECIFY

29) DIASTOLIC MURMURS [ ] (1-No; 2-Yes) IF NO, THEN SKIP TO PAGE 12, ITEM #52; IF YES, THEN GO TO PAGE 10, ITEM #30 30) NUMBER OF DIASTOLIC MURMURS PRESENT [ ] 1, 2, 3. IF ONLY ONE (1) DIASTOLIC MURMUR PRESENT, ENTER: 31) INTENSITY [ ] (1-6) PITCH [ ] (1-Low; 2-Medium; 3-High) 32) CONFIGURATION [ ] 33) (1-Cresendo; 2-Decresendo; 3-Cresendo-Decresendo; 4-Plateau) 34) TIMING [ ] (1-Early Diastolic; 2-Mid Diastolic; 3-Late Diastolic (Presystolic) 35) SITE OF MAXIMAL INTENSITY [ ] (1-2nd R ICS; 2-Base of neck; 2nd/3rd L ICS; 4-4th/5th L ICS; 5-3rd/4th R ICS; 6-Epigastrium; 7-Cardiac Apex; 8-Other, Specify:

IF 8, SPECIFY

36) RADIATION [ ] (1-Absent; 2-Present)

IF PRESENT, THEN (37) [ ] (1-2ND R ICS; 2-Base of neck; 3-2nd/3rd L ICS; 4-4th/5th R ICS; 5-3rd/4th R ICS; 6-Epigastrium; 7-Cardiac Apex; 8-Other, Specify:

IF 8, SPECIFY

FOR A SECOND DIASTOLIC MURMUR, ENTER:

38) **INTENSITY** [ ] (1-6) 39) PITCH [ ] (1-Low; 2-Medium; 3-High) 40) CONFIGURATION [ ] (1-Cresendo; 2-Decresendo; 3-Cresendo-Decresendo; 4-Plateau) 41) TIMING [ 1 (1-Early Diastolic; 2-Mid Diastolic; 3-Late Diastolic (Presystolic)) 42) SITE OF MAXIMAL INTENSITY [ ] (1-2nd R ICS; 2-Base of neck; 3-2nd/3rd L ICS; 4-4th/5th L ICS; 5-3rd/4th R ICS; 6-Epigastrium; 7-Cardiac Apex; 8-Other, Specify:

IF 8, SPECIFY

IF 8, SPECIFY

FOR A THIRD DIASTOLIC MURMUR, ENTER:

45) INTENSITY [ ] (1-6) PITCH [ ] (1-Low; 2-Medium; 3-High) 46) 47) CONFIGURATION [ ] (1-Cresendo; 2-Decresendo; 3-Cresendo-Decresendo; 4-Plateau) 48) 1 (1-Early Diastolic; 2-Mid TIMING [ Diastolic; 3-Late Diastolic (Presystolic)) SITE OF MAXIMAL INTENSITY [ ] (1-2nd R ICS; 49) 2-Base of neck; 3-2nd/3rd L ICS; 4-4th/5th L ICS; 5-3rd/4th R ICS; 6-Epigastrium; 7-Cardiac Apex; 8-Other, Specify:

IF 8, SPECIFY

50) RADIATION [ ] (1-Absent; 2-Present)

IF 8, SPECIFY

52) <u>CONTINUOUS MURMURS</u> [ ] (1-No; 2-Yes)

2 12

IF NO, THEN SKIP TO ITEM \$57; IF YES, THEN

> 53) INTENSITY [ ] (1-6) 54) SITE OF MAXIMAL INTENSITY [ ] (1-2nd R ICS; 2-Base of neck; 3-2nd/3rd L ICS; 4-4th/5th L ICS; 5-3rd/4th R ICS; 6-Epigastrium; 7-Cardiac Apex; 8-Other, Specify:

IF 8, SPECIFY

55) RADIATION [ ] (1-Absent; 2-Present) IF PRESENT, THEN (56) [ ] (1-2ND R ICS; 2-Base of neck; 3-2nd/3rd L ICS; 4-4th/5th L ICS; 5-3rd/4th R ICS; 6-Epigastrium; 7-Cardiac Apex; 8-Other, Specify: IF 8, SPECIFY 57) SYSTOLIC CLICK [ ] (1-Absent; 2-Present) IF PRESENT, THEN 58) MULTIPLE [ ] (1-No; 2-Yes) ] (1-Early Systolic; 2-Mid-systolic; 59) TIMING [ 3-Late Systolic) 60) GALLOP [ ] (1-Absent; 2-Present) IF PRESENT, THEN (1-atrial gallop (Presystolic); 61) TIMING [ ] 2-ventricular diastolic gallop; 3-summation gallop) 62) VARIES WITH INSPIRATION [ ] (1-No; 2-Louder During Expiration; 3-Louder During Inspiration) 63) PERICARDIAL FRICTION RUB [ ] (1-Absent; 2-Present) OTHER CARDIAC ABNORMALITY [ ] (1-No;2-Yes) 64) IF YES, DESCRIBE BELOW:

L. BREAST (MALES ONLY)

1)	PRESENCE [ ]	(1-BOTH; 2-R; 3-L; 4-NEITHER)
2)	GYNECOMASTIA	[ ] (1-Absent; 2-Present)
3)	NIPPLE DISCHARGE	[ ] (1-Absent; 2-Present)
4)	MASSES [ ]	(1-NO; 2-YES)
	5) LEFT [ ]	(1-NO; 2-YES)
	6) QUADRANT	[ ] (1-AXILLA; 2-UPPER OUTER;
		3-UPPER INNER; 4-LOWER INNER)
	7) SIZE	
	8) RIGHT [ ]	(1-NO; 2-YES)
	9) QUADRANT	[ ] (AXILLA; 2-UPPER OUTER; 3-UPPER INNER; 4-LOWER INNER)
	10) SIZE	[ ]CM

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M. ABDOMEN
     1) VISIBLE ABNORMALITY [ ] (1-No; 2-Yes)
         IP YES, THEN (1-No; 2-Yes)
         2) ASCITES [ ]
         2a) IF YES, RECORD SHIFTING DULLNESS IN CM [ ]
         3) MASS [ ]
         4) SPIDERS [ ]
         4a) IF YES, DESCRIBE BELOW
     5) PALPABLE MASS [ ] (1-No; 2-Yes)
         IF YES, THEN (1-No; 2-Yes)
             RUQ [ ] 7) LUQ [ ] 8) RLQ [ ]
LLQ [ ] 10) SUPRAPUBIC [ ]
         6)
         9)
     IF THERE IS AN ABDOMINAL MASS, THEN DESCRIBE BELOW
    11) TENDERNESS [ ] (1-No; 2-Yes)
         IF YES, THEN (1-No, 2-Yes)
           12) RUQ [ ] 13) LUQ [ ] 14) RLQ [ ]
15) LLQ [ ] 16) SUPRAPUBIC [ ]
    17) DIFFUSE TENDERNESS [ ] (1-No; 2-Yes)
    18)
         REBOUND TENDERNESS [ ] (1-No; 2-Yes)
    19) PERCUSSION TENDERNESS [ ] (1-No; 2-Yes)
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20) PALPABLE LIVER [ ] (1-No; 2-Yes) IF YES, THEN 21) RECORD cm BELOW RCM (R MIDCLAVICULAR LINE) [ ]CM 22) LIVER EDGE [ ] (1-Sharp; 2-Rounded) 23) LIVER CONSISTENCY [ ] (1-Normal; 2-Abnormal) **IF ABNORMAL, THEN** (1-No; 2-Yes) 24) HARD 25) NODULAR ſ 26) PERCUSSIBLE LIVER SIZE IN R MID-CLAVICULAR LINE [ ] CM 27) **SPLEEN PALPABLE** [ ] (1-No; 2-Yes) 28) CVA TENDERNESS [ ] (1-No; 2-R; 3-L; 4-Both) 29) **BRUIT** [ ] (1-No; 2-Yes) IF YES, THEN (1-No; 2-Yes) 31) R FEMORAL [ ] 30) AORTIC [ 1 32) L FEMORAL [ 33) R CAROTID [ ] 34) L CAROTID [ ] 35) HERNIA [ ] (1-No; 2-Yes) **IF YES, THEN (1-Absent; 2-Reducible; 3-Not Reducible)** 36) UMBILICAL 37) R INGUINAL I I 1 38) L INGUINAL [ ] 39) INCISIONAL [ 1 N. (MALES ONLY) GENI TAL 1) **PUBIC HAIR** [ ] (1-Normal male pattern; 2-Decreased) 2) **PENIS** [ ] (1-Normal; 2-Abnormal) 3) DISCHARGE [ ] (1-No; 2-Yes) 4) PHIMOSIS [ ] (1-No; 2-Yes) ] ml 5) R TESTIS [ L TESTIS [ 6} ] ml

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INDICATE 1-No; 2-R; 3-L; 4-Bilateral for the following: 7) EPIDIDYMIS THICKENED/TENDER [ ] 8) VARICOCELE [ ] 9) SCROTAL MASS [ ] IF OTHER THAN 1, DESCRIBE BELOW 10} **PROSTATE** [ ] (1-Normal; 2-Abnormal) IF ABNORMAL, THEN (1-No; 2-Yes) 11) DIF ENLARGED [ ] 12) ATROPHIC [ ] 13) 14) SOFT CONSISTENCY [ ] NODULE [ 1 15) TENDER [ 1 1) RECTAL [ ] (1-Normal; 2-Abnormal) (MALES ONLY) 0. IF ABNORMAL, THEN (1-No; 2-Yes) 2) HEMORRHOIDS [ ] ANAL FISSURE [ ] 3) 4) RECTAL MASS [ ] IF YES, THEN DESCRIBE BELOW 5) ANAL SPHINCTER TONE [ ] (1-Normal; 2-Decreased 6) STOOL [ ] (1-Sample taken for occult blood testing; 2-No stool present) Ρ. EXTREMITIES 1) ABSENCE [ ] (1-No; 2-Yes) **IF YES, THEN** (1-No; 2-R; 3-L; 4-R and L) 2) FINGER [ ] 3) TOE 4) ARM [ ] 5) LEG [ ] 6) CLUBBING FINGERS [ ] (1-No; 2-Yes) 7) CLUBBING TOES [ ] (1-No; 2-Yes)

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8)	EDEMA [ ] (1-No; 2-Yes)	
	IF YES, THEN INDICATE SEVERITY (0-4)	
	9) PEDAL [ ] 10) PRETIBIAL [ ] 12) PRESACRAL [ ]	11) ANKLE [ ] 13) FACIAL [ ]
14)	ACROCYANOSIS [ ] (1-No; 2-Yes)	
15)	VARICOSE LEG VEINS [ ] (1-No; 2-R;	3-L; 4-Both)
16)	LEG VEINS INFLAMED [ ] (1-No; 2-R;	3-L; 4-Both)
17)	SOFT TISSUE MASSES OF EXTREMITIES [	] (1-No; 2-Yes)
	IF YES, DESCRIBE BELOW	

**RANGE OF MOTION** [ ] (1-Normal; 2-Decreased) 18) IF DECREASED, THEN (1-Normal; 2-Decreased) 19) R SHOULDER [ 20) L SHOULDER [ 1 ] 22) L ELBOW 24) L WRIST R ELBOW [ 21) 1 ] [ 23) R WRIST l ] 1 I ĺ 25) R HIP 26) L HIP ] ł [ 27) R KNEE I 1 28) L KNEE .] 29) R ANKLE 1 1 30) L ANKLE ĺ 1 31) STRAIGHT LEG RAISING [ ] (1-Normal; 2-Limited by back pain; 3-Limited by thigh pain; 4-Limited by muscle stiffness) 32) JOINT SWELLING [ ] (1-No; 2-Yes)

**IF YES, THEN (1-NO; 2-HARD; 3-NODULAR; 4-ERYTHEMATOUS;** 5-FLUCTUANT; 6-PAINFUL)

33)	R KNEE	[]	34)	L KNEE	[]]
35)	R ANKLE	[]]	36)	L ANKLE	( )
37)	R FINGERŚ	[]	38)	L FINGERS	[]]

Q. 1) SPINE [ ] (1-Normal; 2-Abnormal)

IF ABNORMAL, THEN (1-No; 2-Yes)

2)	SCOLIOSIS	]	]	3) KYPHOSIS [ ]
4)	DECREASED ROM	1	]	5) TENDERNESS [ ]
6)	PELVIC TILT	[	1	

R. 1) LYMPH NODES [ ] (1-Normal; 2-Abnormal)

#### IF ABNORMAL:

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RECORD SIZE OF LARGEST IF ABNORMAL, THEN DESCRIBE AS: NODE OR MASS IN CM IF TENDER FIRM FIXED CONFLUENT CONFLUENT (1-No; 2-Yes) 2) CERVICAL [ ] (1-Normal; 2-Abnormal) IF ABN: 3)[]cm 4)[] 5)[] 6)[] 7)[] 8) OCCIPITAL [ ] (1-Normal; 2-Abnormal) IF ABN: 9) [ ] cm 10) [ ] 11) [ ] 12) [ ] 13) [ ] 14) SUPRACLAVICULAR [ ] (1-Normal; 2-Abnormal) IF ABN: 15) [ ] cm 16) [ ] 17) [ ] 18) [ ] 19) [] 20) AXILLARY [ ] (1-Normal; 2-Abnormal) IF ABN: 21) [ ] cm 22) [ ] 23) [ ] 24) [ ] 25) [] 26) EPITROCHLEAR [ ] (1-Normal; 2-Abnormal) IF ABN: 27) [ ] cm 28) [ ] 29) [ ] 30) [ ] 31) [ ] 32) INGUINAL [ ] (1-Normal; 2-Abnormal) IF ABN: 33) [ ] cm 34) [ ] 35) [ ] 36) [ ] 37) [ ] 38) COMPLETION TIME [ ]

(RECORD COMMENTS TO THE DIAGNOSTICIAN ON NEXT PAGE)

39) SIGNATURE OF PHYSICIAN:

COMMENTS	TU THE	DIAGNOSTICIA	W (FREE	TEAT):
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NIOSH OCCUPATIONAL HEALTH STUDY 02/11/87

# DERMATOLOGY EXAM

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3	Ł.	PARTICIPANT ID#NAME
2	2.	DATE:3. START TIME:
4	4.	EXAMINATION STATUS: (1-COMPLETE; 2-PARTIALLY COMPLETE; 9-REFUSED)
!	5.	PHYSICIAN ID:6. PHOTOGRAPHER ID:
1	Α.	HYPERPIGMENTATION [ ] 1-ABSENT; 2-PRESENT
		1. OF SKIN (ACNE AREA ONLY) [ ] 1-ABSENT; 2-PRESENT
		a. <u>        f.          </u>
		b. <u>1       g.          </u>
		c. <u>1        </u> h. <u>1   1  </u>
		a. <u>1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1</u>
		e. <u>1. 1. 1. 1. j. L. 1. 1. 1. 1</u>
		2. OF CONJUNTIVAE [ ] 1-ABSENT; 2-PRESENT
		3. OF ORAL MUCOSA [ ] 1-ABSENT; 2-PRESENT
		4. OF NAIL BEDS [ ] 1-ABSENT; 2-PRESENT
*** ]	в.	ACNEIFORM DISEASE [ ] 1-ABSENT; 2-PRESENT
		1. ACNE VULGARIS [ ] 1-ABSENT; 2-PRESENT
		a. <u>        f.        </u>
		b. <u>        g.          </u>
		c. <u>[ ] ] ] </u> h. <u>[ ] ] ] </u>
		a. <u>                                     </u>
		e. <u>i i i j. i i i i</u>

ACNEIFORM DISEASE (CONTINUED) 2. ACNE CONGLOBATA [ ] 1-ABSENT; 2-PRESENT a. 1\_\_\_\_\_ f. 1 1 1 1 g. <u>1 1 1</u> b. <u>| | | | | |</u> c. <u>| | | | |</u> h. |\_ |\_ |\_\_| a. I. I. L. L. I. i. <u>| | | |</u> **j.** <u>1</u> <u>1</u> <u>1</u> e. <u>| | | |</u> | 3. DISSECTING CELLULITIS OF SCALP [ ] 1-ABSENT; 2-PRESENT a. <u>| | | | |</u> f. 1 1 1 b. <u>1 | |</u>1 | g. <u>1. 1. 1. 1</u> h. . . . . . c, <u>L</u> <u>L</u> <u>L</u> <u>L</u> a. <u>1 | | |</u> **i**. <u>| | | 1 | 1</u> j. <u>1. 1. 1. 1</u> e. 1 | | | | 4. HIDRADENITIS SUPPURATIVA [ ] 1-ABSENT; 2-PRESENT **f**• <u>| | 1 | 1 | 1</u> a. <u>| | | |</u> g. <u>\_\_\_\_</u> b. <u>| | | | |</u> c. [\_\_\_\_ **b**• <u>| | | | | | |</u> **i**. <u>| | |</u> a. <u>L 1 1 1</u> j. <u>1. 1. 1. 1</u> e. [ ] [ ] [ ] 5. ACNE ROSACEA [ ] 1-ABSENT; 2-PRESENT f. 1\_1\_1\_1 a. 1 1 1 1...1 9. <u>L\_l\_l\_</u> b. 1 1 1 1 ..... c. L. L. L. L. h. <u>] ] [ [ ] ]</u> **i**. <u>| | | |</u> d. 1 1 1 1 **j.** <u>1 1 1 1</u> e. <u>| | | |</u>

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# ACNEIFORM DISEASE (CONTINUED) 6. PERIORAL DERMATITIS [ ] 1-ABSENT; 2-PRESENT 7. FAVRE-RACOUCHOT DISEASE [ ] 1-ABSENT; 2-PRESENT a. <u>| | | | |</u> f. ] | | | b. 1 1 1 1 1 g. 1. 1. 1. 1 b. <u>| | | |</u> c. | | | | a. <u>1 1 1</u> 1 i. <u>1. 1. 1. 1.</u> j. \_\_\_\_ e. 1. 1. 1. 1. 1 8. CHLORACNE [ ] 1-ABSENT; 2-PRESENT a. <u>| | | | |</u> f. ] ] ] ] ] g. <u>\_\_\_\_</u>1\_\_\_\_ b. <u>| | | |</u> c. <u>| | | |</u> h. <u>| | | |</u> **i**. <u>| | | |</u> a. <u>| | | | 1</u> j. <u>| | | | |</u>| e. <u>| | | | | |</u> 9. ACNEIFORM DISEASES NOT ELSEWHERE CLASSIFIED [ 1 1-ABSENT; 2-PRESENT f. [ ] ] ] ] a. <u>| | | | |</u> g. <u>111</u> b. 1 1 1 1 c. <u>| | | | |</u> h. <u>| | | | |</u> a. <u>| | | | |</u> i. <u>| | | | |</u> e. <u>| | | | |</u> j. <u>| | | | |</u>

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\*\*\*\* C. ACNEIFORM LESIONS [ ] 1-ABSENT; 2-PRESENT (IF PRESENT, ENTER A FIVE DIGIT CODE; THE LAST DIGIT BEING THE SEVERITY INDEX) 1. OPEN COMEDONE (blackhead) 1-ABSENT: 2-PRESENT a. <u>| | | | | |</u> f. 1. 1. 1. 1. 1. g. 1 1 1 1 b. <u>| | | | | |</u> c. ] | | | | ] h. 1 1 1 1 1 a. <u>| | | | |</u> **i**. <u>| | | | |</u> e. <u>| | | | |</u> **1.** <u>1 1 1 1 1</u> 2. CLOSED COMEDONE (whitehead) (≤ 2mm) [ 1 1-ABSENT; 2-PRESENT a. <u>| | | | |</u> £. | | | | | | | g. \_\_\_\_\_ b. 1. 1. 1. 1. 1. c. \_\_\_\_\_ h. | | | | | | a. <u>| | | | |</u> i. <u>| | | | | |</u> j. <u>1. 1. 1. 1</u>. 1 e. ] \_1 1\_ 1\_ 1\_ ] 3. SMALL CYSTS (3-10mm) [ ] 1-ABSENT; 2-PRESENT a. ] \_1 \_1 \_1 \_1 f. 1 1 1 1 1 g. <u>| | | | |</u> b. 1 \_1 \_1 \_1 \_1 c. 1 1 1 1 1 h. <u>| | | | |</u> a. <u>1 1 1 1 1</u> i. <u>1.1.1.1.1</u> e. <u>| | | |</u> | ] 

## ACNEIFORM LESIONS (CONTINUED) 4. PAPULE INFLAMED (≤ 10mm) [ ] 1-ABSENT; 2-PRESENT a. <u>| | | | | |</u> f. 1 1 1 1 b. 1 1 1 1 1 g. <u>1 1 1 1 1</u> c. <u>| | | | | 1</u> h. <u>| 1 | | |</u> a. <u>1 | | | | |</u> e. <u>| | | | | |</u> 5. PUSTULES ( $\leq$ 10mm) [ ] 1-ABSENT; 2-PRESENT £. <u>| | | | |</u> g. <u>L. I. I. I</u> b. \_\_\_\_\_ c. <u>| 1 | | | |</u> h. <u>| | | | |</u> a. <u>| | | | | |</u> **i**• <u>L. L. I. I. I</u> j. <u>\_\_\_\_\_</u> e. <u>| 1\_| | | 1</u> 6. NODULES OR CYSTS, NON INFLAMED (> 10mm) [ 1 1-ABSENT: 2-PRESENT f. 1. 1. 1. 1. 1 a. <u>| | | | |</u> g. \_\_\_\_\_ b. <u>| | | | | | |</u> c. [ ] ] ] ] ] h. <u>|\_\_\_\_\_\_\_</u>\_\_\_ a. <u>\_\_\_\_\_</u> **i**• <u>| | | | | |</u> j. \_\_\_\_\_ e. <u>| | | | | | |</u>

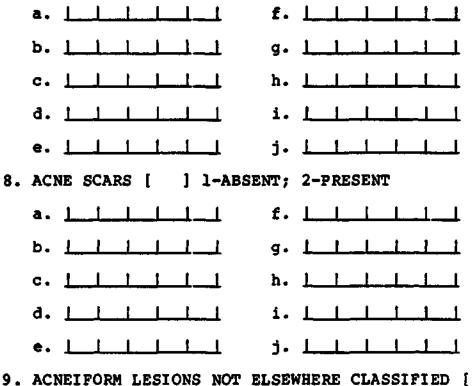
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### ACNEIFORM LESIONS (CONTINUED)

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7. NODULES OR CYSTS, INFLAMED (> 10mm) [ ]

1-ABSENT; 2-PRESENT



ERE CLASSIFIED [ ] 1-ABSENT; 2-PRESENT

a. <u>             </u>	
b. <u>1. 1. 1. 1. 1</u>	g• <u>           </u>
c. <u>           </u>	h. <u>1. 1. 1. 1. 1</u>
a. <u>           </u>	i. <u>1.  </u>
e. <u>]          </u>	j

\*\*\*\* D. LESIONS SUGGESTIVE OF PORPHYRIA CUTANEA TARDA AND LIVER DISEASE [ ] 1-ABSENT; 2-PRESENT

1. FACIAL HIRSUITISM [ ] 1-ABSENT; 2-PRESENT

IF PRESENT, PLEASE JUSTIFY UNDER "COMMENTS", SECTION D.1.

LESIONS SUGGESTIVE OF PORPHYRIA CUTANEA TARDA (CONTINUED)

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- 2. HIRSUITISM ELSEWHERE ON THE BODY SURFACE [ ] 1-ABSENT; 2-PRESENT IF PRESENT, PLEASE JUSTIFY UNDER "COMMENTS" SECTION D.1.
- 3. VESICLES, BLISTERS OR SUPERFICIAL EROSIONS ON DORSAL HANDS [ ] 1-ABSENT; 2-PRESENT
- 4. VESICLES, BLISTERS OR SUPERFICIAL EROSIONS ON SUN EXPOSED SURFACES OTHER THAN DORSAL HANDS [ ] 1-ABSENT; 2-PRESENT

5. ATROPHIC SCARS WITH MILIA ON DORSAL HANDS [ ] 1-ABSENT; 2-PRESENT

6. ATROPHIC SCARS WITHOUT MILIA ON DORSAL HANDS [ ] 1-ABSENT; 2-PRESENT

7. MOTTLED HYPERPIGMENTATION OF SUN EXPOSED AREAS [ ] 1-ABSENT; 2-PRESENT

8. SCLERODERMOID PLAQUES OF SUN EXPOSED AREAS [ ] 1-ABSENT; 2-PRESENT

9. SPIDER TELANGECTASIAS [ ] 1-ABSENT; 2-PRESENT

a.	f.	L				
ь.	g.	L	_1_	_1_	┛	⊥
c.	h.	Ł			1	
đ.	i.	L				
e.	j.	L	1			_

LESIONS SUGGESTIVE OF PORPHYRIA CUTANEA TARDA (CONTINUED)

- 10. PALMAR ERYTHEMA [ ] 1-ABSENT; 2-PRESENT
- 11. SCLERAL ICTERUS [ ] 1-ABSENT; 2-PRESENT
- 12. JAUNDICE OF SKIN [ ] 1-ABSENT; 2-PRESENT

13. PORPHYRIA CUTANEA TARDA LESIONS NOT ELSEWHERE CLASSIFIED [ ] 1-ABSENT; 2-PRESENT

a.	┶━━┶┶	f. <u>         </u>
b.		g. <u>L_l_l_l</u>
c.	i_i_i	h. <u>       </u>
đ.		· i• <u>i _ i _ i _ j _ i</u>
e.		j

IF PRESENT JUSTIFY UNDER "COMMENT" SECTION D.11.

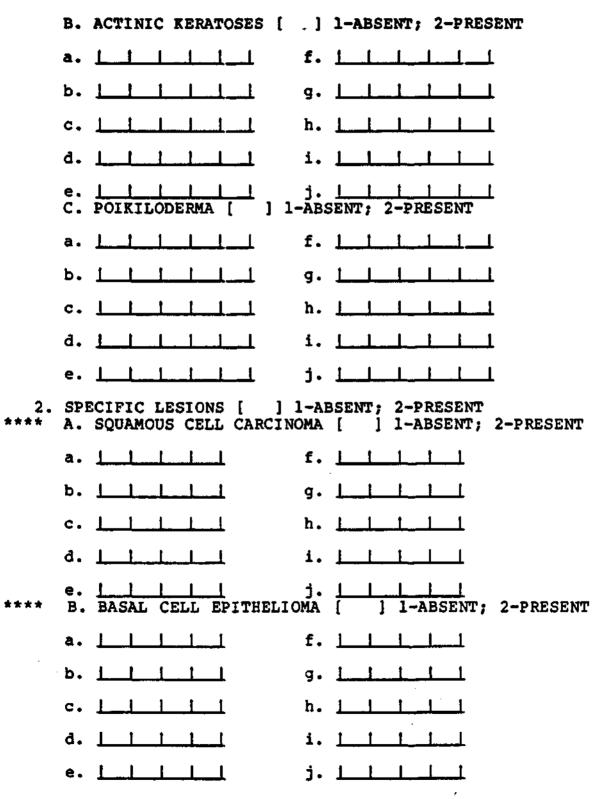
E. CUTANEOUS NEOPLASMS AND THEIR PRECURSORS [ ] 1-ABSENT; 2-PRESENT

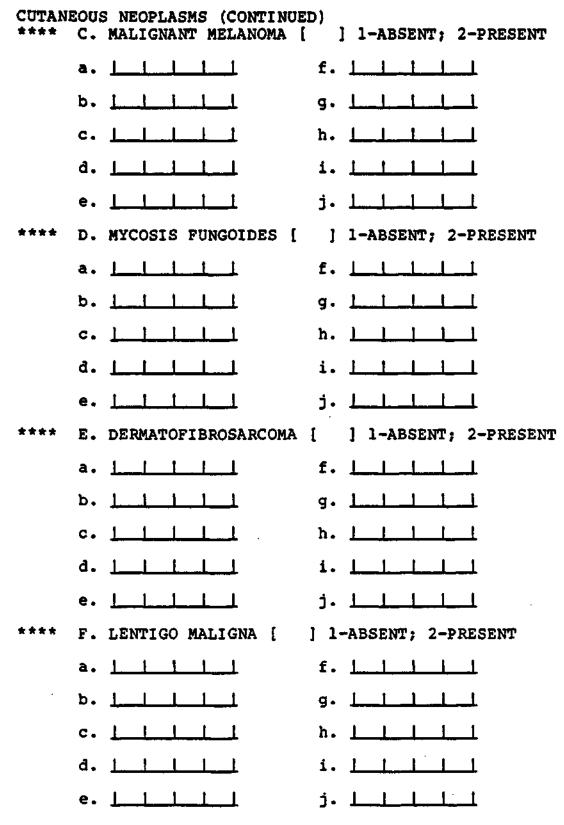
1. GENERAL ACTINIC DAMAGE [ ] 1-ABSENT; 2-PRESENT (IF PRESENT, ENTER A FIVE DIGIT CODE THE LAST DIGIT BEING THE SEVERITY INDEX)

A. SOLAR ELASTOSIS [ ] 1-ABSENT: 2-PRESENT

a. <u>       </u>	<u> </u>			1	<b>_</b>	Ŧ
Þ. <u>                                     </u>	g.		 1	1	<u> </u>	T
c	<u>1 h</u> .	1	 1	L		T
a. <u>L_1_1_</u>	<u> </u>	1	1			⊥
e. <u>       </u>						

CUTANEOUS NEOPLASMS (CONTINUED)





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	US NEOPLASMS (CONTINUE . DYSPLASTIC NEVI [	
a	• • • • • • •	£. <u>         </u>
ъ	• <u>         </u>	g, <u>1_1_1</u>
c	•	h. <u>1 1 1 1</u>
đ	• <u>         </u>	i. <u>1. 1. 1. 1</u>
e	•	j. <u> </u>
Ħ	. LEUKOPLAKIA OF ORAL (	CAVITY [ ] 1-ABSENT; 2-PRESENT
I	. MALIGNANT OR PREMALIC CLASSIFIED. [ ]	GNANT LESIONS NOT ELSEWHERE
a	$\cdot \underline{1} \underline{1} \underline{1} \underline{1} \underline{1} \underline{1}$	$f \cdot \frac{1}{1 - 1} = \frac{1}{1 - 1}$
b	• <u>• • • • • •</u>	g. <u> </u>
C	• 1	h. <u>       </u>
đ	• 1	i. <u>1. 1. 1. 1</u>
e	• 1-1-1-1	j. <u>i </u>
	INFECTIONS [ ] 1-AB: ARTS [ ] 1-ABSENT; 2-	
a		f. <u>1 1 1 1 1</u>
ъ	• 1	g. <u>1 1 1 1</u>
C	• 1 1 1 1	h. <u>1        </u>
đ	• • • • • •	i. <u> </u>
e 2. Hi a	ERPES SIMPLEX [ ] 1-4	j. <u>       </u> Absent; 2-present f. <u>         </u>
Ъ	• <u>                                      </u>	9. 1. 1. 1. 1
C	•	h. <u>1. l. l. l</u>
Đ	• <u>L. I. I. I</u>	i. <u> </u>
e	• 1	j. <u>I. I. I. I.</u>

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SKIN INFECTIONS (CONTINUED) 3. HERPES ZOSTER [ ] 1-ABSENT; 2-PRESENT a. <u>1 | 1 | 1</u> f. 1 1 1 1 g. <u>| | | |</u> b. <u>| | | | |</u> h. <u>| | | |</u> c, <u>| | | | |</u> 1. <u>1. 1. 1</u> 1 a. <u>| | | |</u> j. \_\_\_\_ 1 1 1 1 1 e. 4. MOLLUSCUM CONTAGIOSUM [ ] 1-ABSENT; 2-PRESENT a. | | | | f. 1 1 1 1 b. [ ] ] ] g. <u>1 1 1 1</u> h. <u>| | | |</u> c. <u>| | | | |</u> **i**, <u>| | |</u> d. 1 e. <u>| | |</u> | | j. <u>1...1.</u> -1 5. TINEA VERSICOLOR [ ] 1-ABSENT; 2-PRESENT f. 1 1 1 1 g. <u>L. I. I. I</u> b. <u>| | | | |</u> c. <u>L L I I</u> h. <u>| | | |</u> a. <u>1 1 1 1 1</u> i. <u>1. 1. 1</u> - 1 j. <u>| | |</u> e. 1 6. TINEA UNGUIUM [ ] 1-ABSENT; 2-PRESENT a. <u>| | | |</u> f. 1 1 1 1 **b.** [ ] [ ] ] g. <u>i\_ l</u> | | • h• <u>1 | 1 | 1</u> c. \_ \_ \_ \_ \_ \_ i. <u>| | | |</u> đ. 1 j. <u>1. 1. 1</u> e. <u>| | | |</u> |

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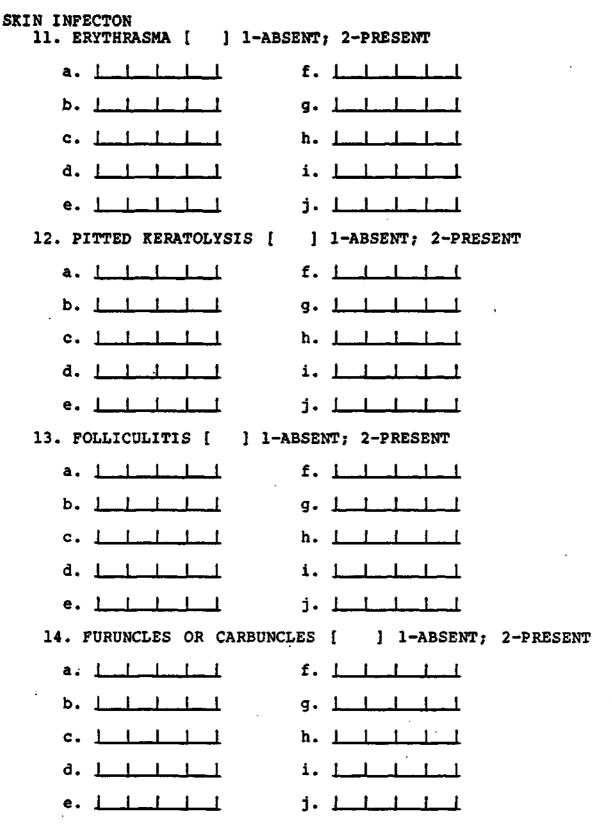
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SKIN INFECTIONS (CONTI 7. TINEA CORPORIS [	NUED) ] 1-ABSENT; 2-PRESENT
a. <u>1 1 1 1</u>	f. <u>           </u>
~ • •	g. <u>1_1_1_</u>
c. <u>         </u>	ħ₊ <u>1     1</u>
a. <u>         </u>	i. <u>         </u>
e. <u>         </u>	j. <u> </u>
8. CANDIDIASIS [	] 1-ABSENT; 2-PRESENT
a. <u>           </u>	f. <u>1. 1. 1. 1. 1</u>
b. <u>       </u>	g. <u>1 1 1 1</u>
c. <u>L_L_L_L</u>	h. <u>1.        </u>
a. 1. 1. 1. 1. 1	i. <u>1   1   1   1</u>
e.	j. <u>j. 1. 1. 1. 1</u>
	ABSENT; 2-PRESENT
	· · ·
a. <u>[</u>	f. <u>1. 1. 1.</u>
þ. <u>  1   1   1</u>	g. <u>L. I. I. I</u>
¢, <u>↓                                     </u>	h. <u>         </u>
a. <u>1      </u>	i. <u>         </u>
e. <u>           </u>	j. <u>         </u>
10. IMPETIGO [ ] 1	-ABSENT; 2-PRESENT
a. <u>         </u>	f. <u>1      </u>
Þ. <u>       </u>	g. <u>1_1_1_1</u>
c. <u>         </u>	h. <u>         </u>
a. <u>         </u>	i. <u>         </u>

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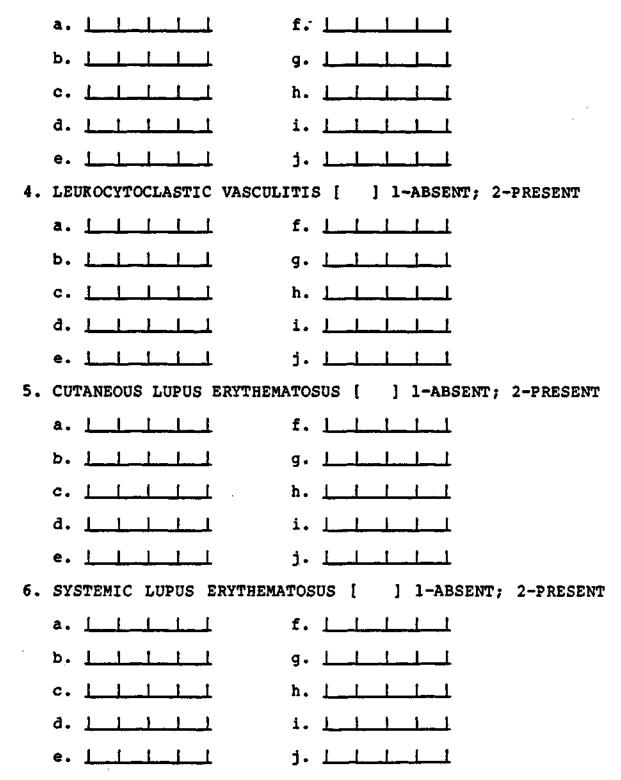
	INFECTIONS (CONTINUED) . PARONYCHIA [ ] 1-ABS	ENT; 2-PRESENT
	a. <u>         </u>	f
	b. <u>1 1 1 1</u>	g. <u>         </u>
	c. <u>L_1_1_1</u>	h. <u>1_1_1_1</u>
	a. <u>1   1   1</u>	i. <u>         </u>
16.	e. <u>         </u> SKIN INFECTIONS NOT EL	j. <u>       </u> Sewhere Classified [ ] 1-Absent; 2-Present
	a. <u>  1   1  </u>	f. []
	b. 1	g. <u>         </u>
	c. <u>         </u>	h. <u>1   1  </u>
·	a. <u>         </u>	i. <u>1      </u>
	e. <u>         </u>	j. <u>1 – I – I – I</u>
	ERGIC, AUTOIMMUNE OR IM	MUNOLOGIC DISORDERS [ ] 1-ABSENT; 2-PRESENT
		MUNOLOGIC DISORDERS [ ] 1-ABSENT; 2-PRESENT
	URTICARIA [ ] 1-ABSEN	MUNOLOGIC DISORDERS [ ] 1-ABSENT; 2-PRESENT F; 2-PRESENT
	LERGIC, AUTOIMMUNE OR IM URTICARIA [ ] 1-ABSEM a. <u>  1 1 1 1</u>	MUNOLOGIC DISORDERS [ ] 1-ABSENT; 2-PRESENT f. <u>1   1   1</u> f. <u>1   1   1</u>
	JERGIC, AUTOIMMUNE OR IM URTICARIA [ ] 1-ABSEN a. <u>1 1 1 1</u> b. <u>1 1 1 1</u>	MUNOLOGIC DISORDERS [ ] 1-ABSENT; 2-PRESENT f; 2-PRESENT f. <u>1_1_1_1</u> g. <u>1_1_1_1</u>
1.	URTICARIA [ ] 1-ABSEN a. <u>L_1_1_1</u> b. <u>L_1_1_1</u> c. <u>1_1_1_1</u>	MUNOLOGIC DISORDERS [ ]         1-ABSENT; 2-PRESENT         f; 2-PRESENT         f.         l         g.         l         h.         l
1.	JERGIC, AUTOIMMUNE OR IMI         URTICARIA [ ] 1-ABSEM         a.       1         b.       1         b.       1         b.       1         d.       1         e.       1	MUNOLOGIC DISORDERS [ ]         1-ABSENT; 2-PRESENT         f; 2-PRESENT         f         g         h         i         j
1.	JERGIC, AUTOIMMUNE OR IM   URTICARIA [ ] 1-ABSEN   a.   a.   b.   1.   b.   1.   c.   1.   d.   1.   e.   1.   1.   e.   1.   1.   I.   < td=""><td>MUNOLOGIC DISORDERS [ ]         1-ABSENT; 2-PRESENT         f.         g.         l.         h.         l.         j.         j.     </td></t<>	MUNOLOGIC DISORDERS [ ]         1-ABSENT; 2-PRESENT         f.         g.         l.         h.         l.         j.         j.
1.	JERGIC, AUTOIMMUNE OR IMI   URTICARIA [ ] 1-ABSEM   a.   b.   j.   d.   j.   e.   l.	MUNOLOGIC DISORDERS [ ]         1-ABSENT; 2-PRESENT         f.         g.         l.         l.
1.	JERGIC, AUTOIMMUNE OR IMI   URTICARIA [ ] I-ABSEM   a.   a.   b.   a.   b.   b.   b.   b.   b.	MUNOLOGIC DISORDERS [ ]         1-ABSENT; 2-PRESENT         f.         g.         l.         j.         l.         j.         l.         j.         j.

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ALLERGIC, AUTOIMMUNE OR IMMUNOLOGIC DISORDERS (CONTINUED) 3. ERYTHEMA NODOSUM [ ] 1-ABSENT; 2-PRESENT



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ALLERGIC, AUTOIMMUNE OR IMMUNOLOGIC DISORDERS (CONTINUED) 7. DERMATOMYOSITIS [ ] 1-ABSENT; 2-PRESENT

	a. <u>         </u>	f. ]		
	b. <u>1. 1. 1. 1</u>	g. <u>         </u>		
	c. <u>         </u>	h. <u>1_1_1_1</u>		
	a. <u>1_1_1_1</u>	i. <u>         </u>		
8.	e. <u>       </u> SCLERODERMA [ ] 1-ABS	j. <u>         </u> ENT; 2-PRESENT		
	a. <u>         </u>	f. 1 1 1 1		
	b. <u>1_1_1_1</u>	g. <u> </u>		
	c. <u>         </u>	h. <u>1. 1. 1. 1</u>		
	a. <u>         </u>	i. <u>       </u>		
	e. <u>         </u>	j. <u> </u>		
9.	ALOPECIA AREATA [ ] 1	-ABSENT; 2-PRESENT		
	a. <u>1_1_1_1</u>	f. <u>1   1 1 1</u>		
	Þ. <u>1 1 1 1 1</u>	g. <u>1_1_1_1</u>		
	c. <u>         </u>	h. <u>1      </u>		
	a. <u>         </u>	i. <u> </u>		
	e. <u>         </u>	j. Lada da  10.	VITILIGO [ ] 1-ABSENT	; 2-PRESENT
	a. <u>         </u>	f. <u>       </u>		
	Þ• <u>1 1 1 1 1</u>	g. <u>         </u>		
	c. <u>           </u>	h. <u>         </u>		
	a. <u>         </u>	i. <u>         </u>		
	e. <u>L L I I</u>	j. <u>1. 1. 1. 1</u>		

ALLERGIC, AUTOIMMUNE OR IMMUNOLOGIC DISORDERS (CONTINUED) 11. DERMATITIS HERPETIFORMIS [ ] 1-ABSENT; 2-PRESENT a. 1\_1\_1\_1 f. ] ] ] ] ] g. L. L. L. L b. 1 1 1 1 h. <u>| | | |</u> | c. I. I. I. I. I. a. <u>1 | | |</u> | i. <u>1\_| | |</u> e. <u>|</u> 1 1 | 1 j. 1\_\_\_ 1 12. PEMPHIGUS OR BULLOUS PEMPHIGOID [ ] 1-ABSENT; 2-PRESENT a. <u>| | | | |</u> f. \_ \_ \_ \_ \_ \_ g. <u>L\_l\_l\_l</u> b. <u>| | | | |</u> c. <u>1 1 1 1</u> h. | | | | a. 1111 i. 1. 1. 1. - 1 e. 1 1\_1\_1 **j. <u>L. I.</u> I.** 1 13. LICHEN PLANUS [ ] 1-ABSENT; 2-PRESENT f. 1 | | | a. <u>| | | |</u> b. <u>L\_1\_1\_</u> g. \_\_\_\_ c. <u>| | | |</u> h. <u>1 1 1</u> 1 i. <u>| | |</u> d. - 1 e. | | | | | 14. SARCOIDOSIS [ ] 1-ABSENT; 2-PRESENT f. ] \_ ] \_ ] a. <u>| | | | |</u> b. ]\_\_\_\_\_ g. 1\_1\_1\_ 1 h. <u>| | |</u> c. <u>| | | | |</u> 1 a. <u>\_\_\_\_</u>\_\_ i. \_\_\_\_\_ 1 e. \_ \_ \_ \_ \_ 1. <u>1. 1. 1. 1. 1</u> 

## 15. GRANULOMA ANNULARE [ ] 1-ABSENT; 2-PRESENT a. 1 1 1 1 f. 1 1 1 1 g. <u>L. I. I. I</u> b. <u>| | | | |</u> h. <u>| | |</u> | | c. <u>| | | | |</u> a. <u>L\_1\_1\_1</u> i. <u>| | | |</u> e. 1 | - 1 j. 1\_\_\_\_ t 16. ALLERGIC, AUTOIMMUNE OR IMMUNOLOGIC DISORDERS NOT ELSEWHERE CLASSIFIED [ ] 1-ABSENT; 2-PRESENT f. | | | | a. | | | | | b. 1 1 1 1 g. <u>| | | | |</u> c. \_ \_ \_ \_ \_ h. <u>| | | | |</u> a. <u>| | | |</u> | **1**• <u>| 1 | 1 | 1</u> e. <u>| | | | |</u> **j. <u>| | | | |</u>**

ALLERGIC, AUTOIMMUNE OR IMMUNOLOGIC DISORDERS (CONTINUED)

H. MISCELLANEOUS CONDITIONS [ ] 1-ABSENT; 2-PRESENT

1. PSORIASIS [ ] 1-ABSENT; 2-PRESENT

a. <u>       </u>	f
b. <u>       </u>	g. <u>L_l_l_l</u>
c. <u>         </u>	h. <u>L. I. I. I</u>
a. <u> _   _   _  </u>	i. <u>L. I. I. I</u>
e. <u>1_1_1_1</u>	j. <u>1. 1. 1</u>

MISCELLANEOUS CONDITIONS (CONTINUED)

2. SEBORRHEIC DERMATITIS [ ] 1-ABSENT; 2-PRESENT £. <u>| | | |</u> a. 1. 1. 1. 1. 1 g. <u>1 | |</u> | b. <u>| | | |</u> | c. 1\_1\_1 1 1 h. | | | | 1 a. 1.\_1 1 1 i. <u>| | |</u> 1 j. <u>1 1 1 1</u> e. 3. ATOPIC DERMATITIS [ ] 1-ABSENT; 2-PRESENT a. | | | | | g. <u>1. 1</u> 1 ь. c. \_\_\_\_ ł h. 1 1 1 1 1 1 1 1 1 1 **i**. <u>|</u> | | đ. e. 1 \_ 1 \_ 1 \_ 1 j. <u>L L 1</u> 4. DYSHIDROTIC ECZEMA [ 1 1-ABSENT; 2-PRESENT f. \_\_\_\_\_ a. 1. 1. 1. 1 g. <u>| | | |</u> **b**• 1 1 1 1 **c.** 1 1 h. ] | | | a. <u>| | | |</u> 1. <u>1. | | |</u> 1 e. 1 ŧ i. L ] 1-ABSENT; 2-PRESENT 5. NUMULAR ECZEMA [ a. 1 1 1 1 f. 1 1 1 b. <u>| | | |</u> | g. \_\_\_\_ 1 h. <u>| | |</u> c. <u>| | | |</u> - 1 1 i. <u>1\_1</u>\_1 a. <u>1 1 1 1</u> 1 j. <u>L. I. I</u> e. <u>| | | | |</u> 20

MISCELLANEOUS CONDITIONS (CONTINUED)

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6. CONTACT DERMATITIS [	] 1-ABSENT; 2-PRESENT
a. <u>         </u>	f. <u>1 1 1 1</u>
b. <u>         </u>	g. <u>L_l_l_l</u>
c. <u>         </u>	b. <u>ill</u>
đ. <u>             </u>	i. <u>L. J. J</u>
e. <u>         </u> 7. Photosensitive dermat	j. <u>       </u> ITIS [ ] <b>1-ABSENT;</b> 2-PRESENT
a. <u>         </u>	f. <u>1 1 1 1</u>
b. <u>1.1.1.1.1.1</u>	g. <u>L</u>
c. <u>1 1 1 1</u>	h. <u>       </u>
a. <u>         </u>	i. <u>1. 1. 1. 1. 1</u>
e. <u>         </u>	j. <u>1_1_1_1</u>
8. ASTEATOTIC ECZEMA OR	XEROSIS [ ] 1-ABSENT; 2-PRESENT
a. <u>         </u>	f. <u>         </u>
b. <u>         </u>	g. <u>1. 1. 1. 1</u>
¢	h. <u>1. I. I</u>
a. <u>           </u>	i. <u>i. l. l. l.  </u>
e. <u>L. I. I. I</u>	j. <u>1. 1. 1. 1</u>
9. STATIS DERMATITIS [	] 1-ABSENT; 2-PRESENT
a. <u>         </u>	£. <u>1_1_1_</u>
b. <u>1 1 1 1 1</u>	g. <u>         </u>
c. <u>         </u>	h. <u>         </u>
a. <u>i. l. l. l. l</u>	i. <u>           </u>
e. <u>         </u>	j. <u> </u>

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MISCELLANEOUS CONDITIONS (CONTINUED)

10.	PEYRONIE	'S DISEASE	I	] 1-ABSENT;	2-PRESENT

- 11. DUPUYTREN'S CONTRACTURE [ ] 1-ABSENT; 2-PRESENT
- 12. EPIDERMAL INCLUSION CYST [ ] 1-ABSENT; 2-PRESENT

a. <u>       </u>	f. <u> </u>
b. <u>         </u>	g. <u>           </u>
c. <u>i_l_l_l</u>	h. <u>1_1_1_1</u>
d. <u>L_l_l_l_l</u>	1. <u>1. 1. 1. 1. 1</u>

- 13. LIPOMA [ ] 1-ABSENT; 2-PRESENT

a. <u>         </u>	f. <u>1_1_1_1</u>
þ. <u>         </u>	g. <u>1 1 1 1</u>
c. <u>         </u>	h. <u>         </u>
a. <u>i_ i_ i_ i</u>	i. <u>         </u>
e. <u>L_l_l_l_</u>	j. <u>L. I. I. I</u>
14. DERMATOFIBROMA [	] 1-ABSENT; 2-PRESENT
a. <u>         </u>	f. <u>         </u>
b. <u>         </u>	9. <u>       </u>
c. <u>1        </u>	h. <u>         </u>
a. <u>1 1 1 1 1</u>	i. <u>       </u>
e. <u>1. 1. 1. 1</u>	j. <u>         </u>

MISCELLANEOUS CONDITIONS (CONTINUED)

- 15. MISCELLANEOUS [ ] 1-ABSENT; 2-PRESENT
  - a.
     f.

     b.
     f.

     c.
     f.

     d.
     f.

     i.
     f.

     j.
     f.
- I. PROCEDURES DONE
  - 1. FUNGAL CULTURE [ ] 1-NO; 2-YES
  - 2. KOH [ ] 1-NO; 2-YES
  - 3. WOOD'S LIGHT [ ] 1-NO; 2-YES
- J. IF REFERRAL FOR FOLLOW UP EXAMINATION OR BIOPSY IS INDICATED PLEASE RECORD UNDER APPROPRIATE "COMMENTS" SECTION.

A. HYPERPIGMENTATION:

B. ACNEIFORM DISEASE:

C. ACNEIFORM LESIONS:

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D.	LESIONS SUGGESTIVE OF PORPHYRIA CUTANEA TARDA AND LIVER
	DISEASE:
<u> </u>	
	D1. HIRSUITISM PRESENT:
	D11. PORPHYRIA CUTANEA TARDA NOT ELSEWHERE CLASSIFIED:
E.	CUTANEOUS NEOPLASMS:
<u> </u>	· · · · · · · · · · · · · · · · · · ·
<del></del>	
P	SKIN INFECTIONS:
G.	ALLERGIC, AUTOIMMUNE OR IMMUNOLOGIC DISORDERS:
_ <del></del>	
H.	MISCELLANEOUS CONDITIONS:

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COMMENTS	то	THE	DIAGNOSTICIAN:_				
	i		·· <u>·</u> ·····	. <u> </u>			
<u></u>	<b></b> . '.		· _ · · · · · · · · · · · · · · · · · ·			<u> </u>	
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SIGNATUR	e of	DR.	•	<u> </u>			

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## NEUROLOGICAL EXAMINATION

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1.	PARTICIPANT II	•• NAME
2.	EXAM DATE	3. START TIME
4.	PHYSICIAN ID	
5.	EXAM STATUS	l=complete;2=partially complete;9=refused
(1		IS ENTERED PLEASE INDICATE THE REASON (MB) IN THE APPROPRIATE "COMMENTS" SECTION.
	******7-	NOT APPLICABLE;8-DON'T KNOW;9-REPUSED*****
A:	CRANIAL NERVES	5
	RT · LT	
1)	2)	SMELL (1-Normal; 2-Abnormal)
3)	4)	VISUAL FIELD (1-Normal; 2-Abnormal) If ABNORMAL, indicate quadrant.
		5) RT
		6) LT
7)	8)	<b>OPTIC DISC</b> (1-Normal; 2-Atrophy; 3-Papilledema; 4-Other - Specify)
		9) RT
	:	LO) LT
11)	12)	PUPIL SIZE (MM)
13)	· 14)	<b>LIGHT REACTION (1-Normal; 2-Sluggish;</b> 3-None)
15)	16)	<b>PTOSIS</b> (1-Absent; 2-Partial; 3-Complete)
17)		_ OCCULAR MOBILITY (1-Normal; 2-Strabismus; 3-Dysmetria; 4-Nerve/Muscle/Gaze Paresis; 5-Other - Specify)

A:	CRANIA	AL NERVES (O	CONTINUED)
		19)	RT
		20)	LT
RT	1	LT	
21)	<b></b> .	22)	NYSTAGMUS (1-None; 2-Horizontal; 3-Vertical; 4-Rotary; 5-Other-Specify)
		23)	RT
		24)	LT
25)		JAW STREN	GTH (1-Normal; 2-Weak RT; 3-Weak LT; 4-Both Weak RT & LT; 5-Other - Specify)
		26) SPECIF	Y:
27)		JAW JERK	(1-Normal; 2-Increased)
28)		FACIAL PA	IN PERCEPTION (1-Normal; 2-Abnormal)
			If ABNORMAL, then (1-Normal; 2-Increased; 3-Decreased; 4-Absent; RT LT 5-Other - Specify)
		:	29) 30) OPTHALMIC
			31) 32) MAXILLARY
			33) 34) MANDIBULAR
	35)	SPECIFY:	
36)	- <u>-</u>	37)	CORNEAL REFLEX (1-Normal; 2-Decreased; 3-Absent; 4-Other - Specify)
		38)	RT
		39)	LT
40)		41)	<pre>FACIAL MUSCLES (1-Normal; 2-Upper Motor Neuron Weakness; 3-Lower Motor Neuron Weakness; 4-Tics; 5-Chorea; 6-Other- Specify)</pre>
	42)	SPECIFY:	

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A: CRANIAL NERVES (CONTINUED)

RT LT 43) \_\_\_\_ 44) \_\_\_\_ PALATE MOTION WITH PHONATION (1-Normal; 2-Absent; 3-Deviates Right; 4-Deviates Left; 5-Palatal Myoclonus; 6-Other-Specify) 45) SPECIFY: 46) \_\_\_\_ GAG REFLEX (1-Normal; 2-Dep. Rt; 3-Dep. Lt; 4-Both Rt & Lt; 5-Other-Specify) 47) SPECIFY: \_\_\_\_\_\_ 48) \_\_\_\_ 49) \_\_\_\_ ACCESSORY NERVES (1-Normal; 2-Weak SCM; 3-Weak Trap; 4-Both Weak; 5-Other -Specify) 50) RT\_\_\_\_\_ 51) LT\_\_\_\_\_ 52) \_\_\_\_ 53) \_\_\_\_ TONGUE HOTION (1-Normal; 2-Weakness right side of tongue; 3-Weakness left side of tonque; 4-Other - Specify) 54) RT\_\_\_\_\_ 55) LT\_\_\_\_\_ 56) \_\_\_\_\_ OTHER CRANIAL CONDITION (1-Absent; 2-Present) If PRESENT, specify. 57) SPECIFY: 

B: MUSCLE GROUP						
<pre>( 5 = nl; 4 = slight weakness; 3 = overcome gravity only; 2 = ROM w/o gravity; 1 = twitch; 0 = absent)</pre>						
RT	LT					
NECK						
1	2	FLEXORS OF HEAD				
3	4	EXTENSORS OF HEAD				
UPPER EXTRE	MITIES					
5	6	DELTOIDS				
7	8	BICEPS				
9	10	BRACHIORADIALIS				
11	12	TRICEPS				
13	14	WRIST EXTENSORS				
15	16	WRIST FLEXORS				
17	18	OPPONENS POLLICIS				
19	20	INTEROSSEI				
21	22	FINGER EXTENSORS				
LOWER EXTRE	MITIES					
23	24	PSOAS				
25	26	QUADRICEPS				
27	28	HAMSTRINGS				
29	30	DORSI/PLANTAR FLEXION FEET				
31	32	DORSI/PLANTAR FLEXION GREAT TOE				
33		l= absent; 2= present) , DESCRIBE				

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B:	MUSCLE	GROUP	(CONTI)	NUED)					
<u>.</u>	33a.		<u> </u>						
34.		F) TI	ASICULA'	TIONS ( 1. NT, DESCRI	=absent; 2 (BE	= presen	t)		
	34a.			·	• • • •			<u> </u>	
35.	-			······································					
C:	TENDON (5 = 1 = 4		s; 4 = .	increased	[wnl]; 3	= nl; 2	= dec:	rea	sed;
1.	R <b>T</b>	2	LT	BICEPS					
3.		4		QUADRI	CEPS				
5.	<del></del>	6		ACHILLI	ES				
7.	COMME	NTS		·····					<u> </u>
	SENSOR		= impai	red; 3 = 4	absent)	<u>,</u>			
TOU	CH (UPP) RT	ER EXT	REMITY) LT						
1.		2		DORSAL	DISTAL IN	DEX FING	ER		
3.	—	4	,·,·,	DORSAL	PROXIMAL	PHALANX	OF IND	EX	FINGER
5.	<u></u>	6		DORSAL	WRI ST				
7.	·	8		MID FO	REARM				
9.		10	<del></del>	BICEPS	TENDON				

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D: SENSORY (CONTINUED) TOUCH (LOWER EXTREMITY) RT LT 11.\_\_\_\_ 12.\_\_\_\_ DORSAL DISTAL GREAT TOE 13.\_\_\_\_\_ 14.\_\_\_\_ MID DORSAL FOOT 15.\_\_\_\_ 16.\_\_\_\_ ANKLE (DORSAL SURFACE) 17.\_\_\_\_\_ 18.\_\_\_\_ MID SHIN 19.\_\_\_\_\_ 20.\_\_\_\_ KNEE PIN (UPPER EXTREMITY) RT LT 21.\_\_\_\_\_ 22.\_\_\_\_ DORSAL DISTAL INDEX FINGER 23.\_\_\_\_\_24.\_\_\_\_ DORSAL PROXIMAL PHALANX OF INDEX FINGER 25.\_\_\_\_\_ 26.\_\_\_\_ DORSAL WRIST 27.\_\_\_\_\_ 28.\_\_\_\_\_ MID FOREARM 29.\_\_\_\_\_ 30.\_\_\_\_\_ **BICEPS TENDON** PIN (LOWER EXTREMITY) RT LT 32.\_\_\_\_ 31.\_\_\_\_\_ DORSAL DISTAL GREAT TOE 34.\_\_\_\_ 33.\_\_\_\_ MID DORSAL FOOT 35.\_\_\_\_\_36.\_\_\_\_ ANKLE (DORSAL SURFACE) 37.\_\_\_\_\_ 38.\_\_\_\_\_ MID SHIN 39.\_\_\_\_\_ 40.\_\_\_\_ KNEE POSITION (UPPER EXTREMITY) RT LT 41.\_\_\_\_\_ 42.\_\_\_\_ INDEX FINGER

D: SENSORY	(CONTINUED)				
POSITION (L RT	OWER EXTREMITY LT	)			
43	44	GREAT TOE			
VIBRATORY					
RT 45	LT 46	INDEX FINGER PAD			
47	48	HEAD OF RADIUS			
49	50	GREAT TOE PAD			
51	52	LATERAL MALEOLUS			
53. COMM	ents				
-	ormal; 2 = uns				
	STATION, E				
	STATION, E	YES CLOSED			
GAIT ( 1 = n	ormal; 2 = abn	ormality present)			
3	STIFF LEGG	ED			
4	ARM SWING				
5	SWAY				
6	6 BROAD BASE				
7	7 FOOT DROP				

E: STATION (	CONTINUED)
8	SUDDEN TURN ( 1= smooth; 2= unsteady; 3=falls)
9	TOE WALK (20') ( 1= maintains; 2= sinks to
10	heels; 3= can't do) HEEL WALK (20') ( 1= maintains; 2= sinks to
11	soles; 3= can't do) TANDEM WALK (20') ( 1= n1; 2= sways; 3= can't do)
12. COMMENTS	
F: COORDINAT	LON
( l= nl;	2= dysrhythmic; 3= very clumsy)
RT	LT
1	2 RAPID HAND ROTATION
3	4 INDEX FINGER TO THUMB
5	6 TOE TAPPING
G: TREMOR	
( l= nl;	2= slight tremor; 3= severe tremor)
RT	LT
1	2 HANDS AT REST
3	4 HANDS, OUTSTRETCHED
5	6 FINGER TO NOSE
7	8 HEEL TO SHIN
9. COMMENTS	

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# COMMENTS TO DIAGNOSTICIAN (FREE TEXT)

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ATTACHMENT 14

NATIONAL INSTITUTE OF OCCUPATIONAL SAFETY AND HEALTH

PROJECT TITLE: STUDY OF PERSISTENT HEALTH EFFECTS OF CHEMICAL-HERBICIDE WORKERS AND COMMUNITY RESIDENTS OF UNKNOWN EXPOSURE

MANUAL FOR ELECTROPHYSIOLOGICAL AND QUANTITATIVE SENSORY TESTING PROCEDURES

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January 14, 1987

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#### I. INTRODUCTION

Toxic abnormalities of nervous system function are usefully divided into rapidly acting, usually reversible conditions (e.g. produced by anesthesia, ethanol, narcotics, cholinesterase inhibitors, etc.) and those associated with persistent dysfunction resulting from the disruption of cellular elements. The latter group, which are the target of this study, must be further divided with regard to the cellular element involved. The most common reaction of the nervous system to exposure to exogenous neurotoxins is a distal axonopathy. This condition is characterized by distal, retrograde axonal degeneration (dying back) and is heralded by sensory loss in a stocking and glove distribution. The largest and longest axons are often initially affected and therefore the loss of vibration sense is an early and reliable clinical sign. Toxic myelinopathies (e.g. produced by hexachlorophene, acetyl ethyl tetramethylyetralin, etc.) are less common and are associated with bubbling of myelin sheaths, principally at the nodes. Myelinopathies can differentially effect PNS and CNS fibers, often result in spasticity, weakness, as well as paresthesis. Toxic neuronopathies, (e.g. produced by pyridoxine, organic and inorganic mercury compounds, arsenic. etc.) principally affecting dorsal root and autonomic ganglia, can effect distal and proximal sites simultaneously, and are characterized by sudden onset and multiple sites of dysfunction.

The pattern of neurotoxic insult, if indeed one is present, associated with low level, long term exposure to herbicides is not clearly defined. In this regard the literature contains numerous conflicting reports concerning signs, symptoms and electrophysiological correlates. The dysfunctions that have been reported tend to be relatively subtle. A screening program, such as that called for in this study, must therefore be both broad based and sensitive. A broad based approach requires assessment of multiple nerves in both the upper and lower limbs, assessment of both distal and proximal segments within individual nerves, assessment of both motor and sensory function, and assessment of both myelinated and unmyelinated fibers. The electrophysiology should include measures that are sensitive to both axonal loss (e.g. reduction in amplitude of compound action potential) and myelin loss (e.g. slowed conduction velocities, prolonged long latency responses). The sensitivity of the measures can be enhanced by rigorous quality control in all phases of testing and by careful consideration of confounding variables such as alternative causes for dysfunction (i.e. carpal tunnel syndrome).

The electrophysiological and quantitative sensory testing procedures outlined in the present document are designed to be used in concert with a clinical neurological exam to detect the presence of peripheral neuropathy. The electrophysiological measures specifically target the distal nerve segment of both the upper and lower limbs. Dysfunction in these regions is characteristic of a number of peripheral neuropathies including those associated with exposure to exogenous neurotoxins. Vibration threshold is a measure of the integrity of the distal portion of the long and large diameter axons that inervate the Pacinian and Meissner corpuscles in both hands and feet. This measure has proved a particularly sensitive index of toxic distal axonopathy. The assessment of thermal thresholds provides a measure of function within the small A-delta and unmyelinated C fibers of the peripheral nerve. Dysfunction in these fibers is prominent in peripheral neuropathies associated with diabetes, kidney failure and some neurotoxins.

#### **11. ELECTROPHYSIOLOGICAL PROCEDURES**

#### A. EQUIPMENT

Minimal requirements include:

- 1. EMG machine with the following features:
  - a. Two channel differential amplification
  - b. Averaging capability
  - c. Internal cursor for time and amplitude measurements
  - d. Stimulus isolation unit for generation of stimulus pulses

These features are found in standard electrophysiological and EMG equipment provided by the major manufactures including: Nicolet, Teca and Disa.

- 2. Digital thermometer with surface probes, accurate to 0.1  $^{\circ}$  C.
- Equipment capable of raising limb temperature 5.0 ° C. in 15 min. This can be accomplished using either a dry or wet heat blanket, or a radiant lamp.

#### B. NERVES OR END POINTS TO BE ASSESSED

All electrophysiological procedures should be performed unilaterally and on the same side for both upper and lower limbs. The <u>non-dominant</u> limb should be used unless contraindicated by localized pathology (e.g. injuries, history of entrapment, etc.).

All latencies must be measured from the onset of stimulation to the <u>onset</u> of the initial negative deflection in the evoked response (i.e. onset of depolarization). Latency measurements must be assessed using a computer cursor and must be recorded to the nearest 0.1 msec. All amplitudes must be measured from the baseline (pre-stimulus if available) to the <u>peak</u> of the negativity. Amplitude measurements must also be assessed using a computer cursor and must be recorded to the nearest 0.1 mv for motor responses and the nearest 0.1 uv for sensory responses. All distances must be measured in millimeters and recorded to the nearest 1.0 mm.

Motor nerve conduction velocity (NCV) is defined as the distance between the stimulating cathodes divided by the latency difference to the onset of the M-wave response following stimulation at a proximal and distal site. Proximal sensory NCV is defined as the distance between the stimulating cathodes divided by the latency difference to the onset of initial negative component following stimulation at a proximal and distal site. Distal sensory NCV is defined by dividing the distance between the distal stimulating cathode by the absolute latency of the initial negative component of the distal sensory response.

The following measures will be collected:

- 1. Median Sensory (antidromic)
  - a) NCV of forearm segment
  - b) NCV of distal segment (wrist to interdigital cleft)
  - c) NCV segment from palm to index finger and palm to wrist (in selected subjects)
  - d) amplitude of compound sensory response for distal stimulation
- 2. Median Motor (orthodromic)
  - a) NCV of forearm segment
  - b) M-wave amplitude for distal stimulation
- 3. Ulnar Sensory (antidromic)
  - a) NCV of distal segment (wrist to interdigital cleft)
  - b) amplitude of compound sensory response
- 4. Peroneal Motor (orthodromic)
  - a) NCV of distal segment (knee to ankle)
  - b) M-wave amplitude
  - c) absolute latency of the F-wave response for distal stimulation (fastest of at least 10 responses)
- 5. Sural Sensory (antidromic)
  - a) NCV segment from mid-calf to ankle
  - b) amplitude of compound sensory response

#### C. METHODS

l. Electrodes:

All stimulating and recording electrodes should be applied to the skin surface. Ring electrodes, which encircle the finger, are recommended for median sensory and ulnar sensory nerves.

- a) clean the skin with a suitable solvent, e.g. acetone
- b) lightly abrade the skin with electrode paste
- c) apply a conducting medium, e.g. electrode jelly, between the electrode and the skin
- 2. Skin temperature control:

Skin temperature should be maintained at 33.0  $^{\circ}$  C. for the upper limb and 32.0  $^{\circ}$  C. for the lower limb, plus or minus 1.0  $^{\circ}$  C, throughout testing. Skin temperature should be measured prior to testing at sites midway between the stimulating and recording electrodes for each limb. Temperature should be monitored and adjusted during testing using either a feedback controlled infrared radiant heater or a temperature controlled blanket wrap.

#### 3. Averaging:

All measurements should be taken from a computer averaged signal using internal cursors. This averaging technique will enhance the signal to noise ratio and facilitate accurate measurement of response onset. When measuring the M-wave response averaging 3 to 5 stimuli should be sufficient, for sensory response between 10 and 32 stimuli should be averaged.

4. Stimulation:

All testing should be done with the subject carefully isolated from ground using a professional stimulus isolation unit. Stimulus intensity varies as a function of the specific nerve and site of stimulation; the intensity should be adjusted according to the guidelines below.

5. Environment:

All testing should be done in a quiet room with the subject in a comfortable reclining position.

- 6. Specific Nerves:
  - A) Median Sensory
    - 1) Position the active ring electrode on the index finger, 1.0 cm distal to the interdigital cleft.
    - Position the reference electrode on the same index finger
       2.0 cm distal to the active lead.
    - 3) Place the ground between the active electrode and the point of stimulation.
    - 4) When stimulating at the wrist, position the stimulating cathode over the median nerve 2.0 cm proximal to the distal wrist crease. For best results, the electrodes should be positioned between the P. longus and F. carpi radialis tendons. There should be a minimal separation of 2.0 cm between the anode and cathode and the anode should be 2.0 cm further proximal than the cathode.
    - 5) When stimulating at the elbow, position the stimulating cathode over the median nerve at the elbow crease.
    - 6) Stimulus duration should be 0.2 msec.
    - 7) Stimulus intensity should be adjusted to produce a brief twitch of the abductor pollicis muscle. This should be super-maximal for the compound sensory negativity.
    - 8) Stimulus rate should be 1 per/sec.
    - 9) In subjects suspected to have carpal tunnel syndrome (ratio of distal ulnar/distal median greater than 1.25) the following additional assessments will be required: a. Distal-palmar NCV
      - i. recording electrodes remain at positions described above
      - ii. stimulating electrodes are positioned at a mid-palm site with cathode distal to the anode
      - iii. ground is positioned between the stimulating and

recording electrodes

- iv. stimulus duration is reduced to 0.1 msec and stimulus intensity remains at supramaximal levels
- b. Trans-carpal NCV
  - i. recording electrodes are positioned at the wrist with the active lead distal and the reference 2.0 cm proximal
  - ii. stimulating electrodes are positioned with the cathode at the same point as described for distalpalmar stimulation and the anode further distal
- B) Median Motor
  - 1) Position the active recording electrode over the motor endplate of the abductor pollicis brevis.
  - 2) Position the reference ring electrode on the same thumb at least 2.0 cm distal to the active lead.
  - 3) Place the ground between the distal stimulation site and the active recording lead.
  - 4) The distal and proximal stimulation sites are identical to those used for median sensory stimulation
  - 5) Stimulus duration should be 0.2 msec.
  - 6) Stimulus intensity should be supra-maximal for M-wave amplitude.
  - 7) Stimulus rate should be 1 per/sec.
- C) Ulnar Sensory
  - Position the active ring electrode around the 5th digit,
     1.0 cm distal to the interdigital cleft.
  - 2) Position the reference electrode 2.0 cm further distally on the same finger.
  - 3) Place the ground on the palm of the hand.
  - 4) Position the stimulating cathode over the flexor carpi ulnaris tendon, approximately 14.0 cm proximal to the active recording site.
  - 5) Stimulus duration should be 0.2 msec.
  - Stimulus intensity should be adjusted to elicit a supramaximal initial negative component in the compound action potential.
  - 7) Stimulus rate should be 1 per/sec.
- D) Peroneal Motor
  - 1) Place the active recording electrode over the endplate area of the extensor digitorum brevis.
  - 2) Place the reference on the lateral surface of the same foot at the base of the fifth digit.
  - 3) Place the ground on the mid-line at the level of the ankle.
  - 4) When stimulating at the ankle, position the cathode over the peroneal nerve 8.0 cm proximal to the active recording electrode.
  - 5) When stimulating at the knee, position the cathode overlying the peroneal nerve, slightly distal and lateral to the head of the fibula.
  - 6) Stimulus duration should be 0.2 msec.

- 7) Stimulus intensity should be adjusted to elicit a brief twitch of the extensor digitorum brevis and should be supra-maximal for M-wave amplitude.
- 8) Stimulus rate should be 1 per/sec.
- 9) F-wave responses should be measured with recording and stimulating electrodes in the same position as used for the M-wave, but with the stimulating leads reversed so that the anode is distal to the cathode. A minimum of 10 responses should be assessed and the shortest onset latency should be recorded.
- E) Sural Sensory
  - 1) Place the active electrode over the sural nerve at the level of the lower tip of the lateral malleolus.
  - 2) Place the reference on the lateral surface of the same foot 2.0 cm distal to the active electrode.
  - 3) Position the ground on the lower calf, between the stimulating and recording electrodes.
  - 4) Position the stimulating cathode approximately 14.0 cm proximal to the active electrode along the dorsal mid-calf.
  - 5) Stimulus duration should be 0.2 msec.
  - 6) Stimulus intensity should be supra-maximal for the sensory negativity (no muscle contraction should be visible).
  - 7) Stimulus rate should be 1 per sec.

#### D. TECHNICAL CONCERNS

To determine accurate NCV and amplitude measurements, the experimenter must be concerned with the following details:

- 1. The amplitude of all sensory and motor responses must be supramaximal. Thus, it must be determined that increasing the intensity of stimulation does not further increase the amplitude of the evoked response. Intensity <u>should</u> not be reduced to below supra-maximal levels when averaging.
- 2. The waveform must be measured using appropriate voltage and time windows. If the signal is small the gain setting should be increased so that the waveform occupies approximately 50% of the viewing window. The onset of a M-wave response should be measured using a gain setting that "clips" the peak of the M-wave.
- 3. The M-wave associated with stimulation of the proximal site should match the amplitude and waveform of that evoked by distal stimulation.
- 4. The impedance of the recording and stimulating electrodes and the location and type of ground should be selected to reduce the stimulus artifact so that a true baseline measure can be determined.
- 5. A response should be considered "absent" only after alternative

placements of the stimulating electrode have been attempted and only if there is no consistent response after averaging.

#### . E. NORMAL VALUES

1.	Median Sensory NCV (proximal) NCV (distal) peak amplitude	-	<pre>mean = 56.0 meters/sec S.D. = 3.3 meters/sec mean = 49.5 meters/sec S.D. = 4.1 meters/sec normal limit = 6.0 uV</pre>
2.	Median Motor NCV peak amplitude	-	mean = 58.8 meters/sec S.D. = 4.4 meters/sec normal limit = 4.5 mV
3.	Ulnar Sensory NCV peak amplitude	-	mean = 47.5 meters/sec S.D. = 4.1 meters/sec normal limit = 7.0 uV
4.	Peroneal Motor NCV peak amplitude F-wave latency		<pre>mean = 49.5 meters/sec S.D. = 3.9 meters/sec normal limit = 2.5 mV mean = 51.3 msec S.D. = 4.7 msec</pre>
5.	Sural Sensory NCV peak amplitude	-	mean = 43.3 meters/sec S.D. = 4.3 meters/sec normal limit = 4.0 uV

#### **III. VIBRATION THRESHOLD**

#### A. EQUIPMENT

The Vibratron II is a device developed at Albert Einstein College of Medicine in conjunction with Pfizer Inc., to quantify the ability of human subjects to detect vibratory stimuli at the distal extremes of their upper and lower limbs. The instrument is currently manufactured and distributed by Sensortek Inc., 154 Huron Ave, Clifton N.J., 07013.

The Vibratron II consists of a controller and two vibrating posts. The power supply, switches and digital meter are encased as one unit, while the vibrating rods are located in separate units with adjoining cables. Each vibrating rod protrudes through a metal case and can be contacted by either the hands or the feet. The tandem vibrating surfaces are manufactured from hardened rubber and are identical in appearance. Vibration is achieved by driving a variable voltage source. A dual position switch connected in series with the vibrating units, controls which rod vibrates, while a "dummy" switch is used to imitate the sounds and motions of switching. The amplitude of vibration is proportional to the square of the applied voltage and is continuously available on a digital display accurate to the nearest 0.1 units. A switch sets the maximal level of the vibration which ranges from 0 - 6.5 vibration units or 0 - 20 vibration units.

#### **B. TESTING PROCEDURE**

Thresholds should be measured unilaterally and on the same side for the index finger and the great toe. The side selected should be the same as that used for electrophysiological procedures.

The methodology of testing is a "two alternative forced choice procedure". For each trial the subject is <u>required</u> to determine which of the two rods is actually vibrating. The position of vibration is under experimental control, determined by a randomization sequence. The intensity sequence is similarly under the control of the experimenter and is determined by a testing algorithm (see below).

Prior to testing, all subjects should be allowed an adaptation period of approximately 10 minutes, during which they can become accommodated to room temperature. At this time each subject should be given an opportunity to become familiar with the testing apparatus and with the expected vibratory sensations. During this period, the experimenter can instruct the subject as to the appropriate length and force with which to contact the vibrating rod. An ideal duration for contact is approximately one second and the force should be the minimum necessary to detect vibration. This adaptation period will also allow the experimenter to determine the appropriate voltage level at which to begin testing. A number of vibration intensities should be set and sampled by the subject. For the initial trial, the experimenter should set the intensity at a level detectable by that subject 100% of the time. For many subjects in the 20 to 50 year age range an initial intensity setting of 6.5 units (low range) is sufficient. This level should be increased for older subjects or when testing the feet. For each trial both the intensity setting and the subject's choice should be recorded in the appropriate columns on the data sheet.

At the beginning of each testing session the subject should be issued the following instructions:

"Please press your finger lightly against each rod in sequence for approximately one second. During each trial you will be allowed to touch the rods only once. Only one of the rods will be vibrating and you must decide whether it's on the right or on the left. The task will become increasingly more difficult and I understand that you will be guessing on many of the trials."

#### C. TESTING ALGORITHM

If the subject is correct on the initial trial, the intensity should be reduced by approximately 10% for the next trial and this process should be continued until the first error. This percentage is not an exact requirement, but rather a guideline. When the subject makes his/her first error, the identical intensity should be repeated twice for a total of three trials at that level. If the position of the stimulus is correctly identified on two of the three trials, the intensity should be lowered 10%. If errors are made on two of the three trials the intensity should be raised 10%. If errors are made at two successive settings at a given level, the third stimulus is not necessary. All levels below 1.0 units should be repeated twice - even if the subject selects the correct stimulus position.

Testing is completed when the subject has made a <u>total</u> of five errors. A single error often appears early in the testing sequence. This anomalous data point is compensated for in the data analysis procedure (see below).

#### D. TECHNICAL CONCERNS

To determine accurate vibration thresholds, the experimenter must be concerned with the following details:

- The subject should be consistent in the location and duration of touch as well as in the approximate force applied to the vibrating surface. Instructions such as "please don't press so hard" can be issued during testing to insure trial-to-trial consistency.
- 2. Throughout testing, the sounds and motions associated with changing the stimulus position should be presented between each trial. For the conditions where the stimulus position remains unaltered, the "dummy" switch must be used. Both the active and "dummy" switch can be used between trials to mask the actual positioning of the stimulus.
- 3. The subject must take care not to contact the metal casing of the vibrating units during the trials.
- 4. The subject should be carefully screened from viewing the instrument settings or the data sheet.
- 5. The rods should be visually inspected prior to every test to insure that they are "free-standing" and not contacting the metal covering.
- 6. Each Vibratron II should be field calibrated every 3 months and factory calibrated at the beginning and end of the trial.
- 7. Care must be taken to start testing at a sufficiently high

stimulus intensity so as to provide a statistically valid test. A test is valid if there are a total of 18 or if there are less than 18 trials but no more than 1 error in the first eight trials. If these criteria are not met the test should be re-done beginning at a higher initial intensity.

#### E. DATA ANALYSIS PROCEDURE

The first step in calculating the vibration threshold is to select the intensity settings of the five errors and the five lowest correct scores. The highest and lowest values of the ten scores are eliminated and the mean of the remaining eight scores determine the threshold. Thresholds, measured in vibration units, can then be converted into micron values using the formula:

 $A = KX^2$ 

where A is the peak to peak amplitude in microns and K = 1/2.

#### F. NORMAL VALUES

The mean vibration threshold for the index finger in the normal population between 18 and 65 years of age is 0.7 vibration units with a standard deviation of 0.4 vibration units. The mean vibration threshold for the great toe in the same population is 1.20 vibration units with a standard deviation of 0.5 vibration units.

#### IV. THERMAL THRESHOLD

#### A. EQUIPMENT

The Sensortek Thermal Tester - NTE-2 is a device developed at Albert Einstein College of Medicine in conjunction with Pfizer Inc., to quantify the ability of human subjects to detect changes in temperature at the distal extreme of their upper and lower limbs. The instrument is currently manufactured and distributed by Sensortek Inc., 154 Huron Ave, Clifton N.J., 07013.

The PTT incorporates identical thermal plates, constructed from nickel coated copper, that can be contacted by either the hands or feet. Thermal electric cooling or heating is achieved using the Peltier effect and water profusion. Temperature can be set to within 0.1  $^{\circ}$  C. over a 40.0  $^{\circ}$  C. range and can be adjusted at a rate exceeding 1.0  $^{\circ}$  C. per/sec. During testing one plate is maintained at a level of 25.0  $^{\circ}$ C., while the temperature of the second plate is adjusted using a series of fixed step digital controls. The <u>difference</u> in temperature between the plates is continuously available on a digital display, accurate to 0.1  $^{\circ}$  C.

#### **B. TESTING PROCEDURE**

Thresholds should be measured unilaterally and on the same side for the index finger and great toe. The side selected should be the same as that used for the electrophysiological procedures.

The methodology of testing is a "two alternative forced choice procedure". For each trial the subject is <u>required</u> to determine which of the two plates is actually colder. The position of the colder plate is under experimental control, determined by a randomization sequence. The intensity sequence is similarly under the control of the experimenter and is determined by a testing algorithm (see below).

Prior to testing, all subjects should be allowed an adaptation period of approximately 10 minutes during which they can become accommodated to room temperature. At this time each subject should be given an opportunity to become familiar with the testing apparatus and with the expected thermal sensations. During this period, the experimenter can instruct the subject as to the appropriate length and force with which to contact the plates. An ideal duration for contact is approximately one second, while the force should be sufficient to blanch the nail. The adaptation period also allows the experimenter to determine the appropriate temperature difference between the plates at which to begin testing. A number of temperature differences should be set and sampled by the subject. For the initial trial, the experimenter should set the differential temperature at a level detectable by that subject 100% of the time. For many subjects in the 20 to 50 year age range an initial temperature of 10 <sup>o</sup> C. is sufficient. This level should be increased for older subjects or when testing the feet. For each trial both the temperature setting and the subject's choice should be recorded in the appropriate columns on the data sheet.

At the beginning of each testing session the subject should be issued the following instructions:

"Please press your finger against each plate in sequence for approximately one second. During each trial you will be allowed to touch the plates only once. Only one of the plates will be colder and you must decide whether it's on the right or on the left. The task will become increasingly more difficult and I understand that you will be guessing on many of the trials."

#### C. TESTING ALGORITHM

The testing algorithm is identical to that outlined for the Vibratron (see section III.C.).

D. TECHNICAL CONCERNS

To determine accurate thermal thresholds, the experimenter must be concerned with the following details:

- 1. The subject should be consistent in the location of touch and in the approximate force applied to the thermal plates. Instructions such as "please press more firmly" can be issued during testing to insure trial-to-trial consistency.
- 2. The time interval between trials should be standardized at approximately 15 seconds. It physically takes longer to set a new temperature level that requires crossing the zero point (i.e. -2.6 to +2.3) as compared with one of the same side of the zero point (i.e. -2.6 to -2.3). This factor must not be reflected in the time period between trials since it can provide a non-thermal clue.
- 3. When testing at the same level as the previous trial, the sounds and motions associated with temperature change should be faked by the experimenter.
- 4. The subject should be carefully screened from viewing the instrument settings or the data sheet.
- 5. The instrument should be factory calibrated at the beginning and end of the trial and it should be visually inspected prior to each test to insure that there is adequate water profusion and the battery charge.
- 6. The temperature of the passive plate must be maintained 25.0 ° C. using the set screw adjustment.
- 7. Care must be taken to start testing at a sufficiently high stimulus intensity so as to provide a statistically valid test. A test is valid if there are a total of 18 or if there are less than 18 trials but no more than 1 error in the first eight trials. If these criteria are not met the test should be re-done beginning at a higher initial intensity.

#### E. DATA ANALYSIS PROCEDURE

The data analysis procedure is identical to that outlined for the Vibratron (see section III. D.).

#### F. NORMAL VALUES

The mean thermal threshold for the index finger in the normal population between 18 and 65 years of age is 0.67  $^{\circ}$  C. with a standard deviation of 0.31  $^{\circ}$  C. The mean thermal threshold for the great toe in the same population is 1.01  $^{\circ}$  C. with a standard deviation of 0.61  $^{\circ}$  C.

### V. DATA INTERPRETATION

There is no pattern of electrophysiological or sensory loss that is pathognomonic for toxic neuropathy. Generally, toxins cause a distal axonopathy that may be indistinguishable from certain hereditary neuropathies as well as from the polyneuropathies associated with diabetes or kidney failure. Mononeuropathies and nerve entrapments can also be mis-identified as toxic neuropathies. The common features of the toxic distal axonopathies include: involvement of multiple nerves in the affected regions, greater dysfunction in the lower than upper limbs, greater dysfunction in the distal than proximal portions of the affected nerves, greater loss of vibration than thermal sensation, and symmetrical involvement of the limbs. While this pattern is accurate for the population it may not be characteristic for each individual. Carpal tunnel syndrome will affect the vibration scores in the hands and the distal median sensory conduction velocities but it will not affect the distal ulnar conduction velocity. Slowing in both the median and ulnar nerves is strong evidence for a true distal axonopathy.

#### VI. ADDITIONAL INFORMATION REQUIRED

The differential diagnosis of toxic neuropathy is based largely on ruling out alternative etiologies. As part of the history taken during the neurological examination the patient should list:

- A. Any previously diagnosed medical condition, i.e. diabetes
- B. Any history of familial neurological disease
- C. Any traumatic injuries to the limbs
- D. Any occupational or home exposure to chemicals
- E. Any history of alcoholism or substance abuse
- F. Any long term use of heavy equipment, i.e. jackhammer
- G. All current medication
  - A) DRUGS ASSOCIATED WITH NEUROPATHY

The following pharmaceutical agents have been associated with peripheral neuropathy:

- 1) Chloramphenicol
- 2) Cis-platinum
- 3) Clioquinol
- 4) Dapsone
- 5) Diphenylhydantoin
- 6) Disulfiram
- 7) Ethionamide
- 8) Gultethimide

- 9) Gold
  10) Hydralazine
  11) Isoniazid
  12) Metronidazole
  13) Pyridoxine
  14) Sodium Cyanate
  15) Thalidomide
  16) Vincristine

#### **Optocon Tactile Tester-Operating** manual

#### Equipment:

The Optacon Tactile Tester (OTT) measures the sensitivity of the hands and feet to tactile/vibration stimuli and was specifically designed as a screening device for the detection of the early signs of distal axonopathy. The stimulating surface consists of 144 miniature rods organized into a 24x6 matrix, with a 2.0mm horizontal and a 1.0mm vertical inter-rod spacing. Each rod protrudes through a contoured plate and contacts a discrete portion of the skin. The rods vibrate continuously at 230 Hz; the height of the rod above the plate and the amplitude of vibration are directly related to input voltage which can be continuously read on a LED display. Alternate rows vibrate in anti-phase. For threshold determinations, all rods are stimulated simultaneously which results in a spatially complex, unusual and powerful sensation for the nervous system. A prototype of the OTT has been successfully employed in field studies to detect the presence of distal axonopathy associated with exposure to toxic chemicals, alcoholism, nutritional deficiency, and diabetes.

### Procedures:

All testing should be done in a quiet environment with minimal distractions. Prior to testing, subjects should be provided with an adaptation period of between 10 and 15 minutes so they can become accommodated to room temperature. The areas to be tested should be thoroughly cleaned with a scap solution. Prior to testing, each subject should be given an apportunity to become familiar with the testing apparatus and with the expected tactile/vibration sensations. A number of intensities should be set and sampled by the subject. During this period, the experimenter could instruct the subject as to the appropriate force with which to contact the plate. Excessive force will distort the receptor surface and will dampen the mechanical movement of the rods. It is, therefore, critical that the subjects be trained to exert minimal pressure on the stimulating surface. This is best accomplished by setting a 5.0 volt intensity and encouraging the subject to experience the decreased sensation associated with increased pressure. If the wrist is properly supported, it is easy to allow your finger to just rest on the stimulating reface. Subjects will have no difficulty in accomplishing this task with minimal During testing, the subject will be required to wear active earphones proctice. which will have continuous white noise at approximately 80db SPL. White noise cassettes will be provided by Pfizer. The earphones serve the dual function of reducing ambiant room noise and masking the sounds associated with the vibration ntimuli.

The index finger of the non-dominent hand is positioned so that approximately 1.5cm<sup>2</sup> of the ventral finger pad is in contact with the stimulating urface of the OTT. The distal joint crease of the finger should be positioned verlying the outside row of rods. The non-dominent hand is selected to minimize my calluses or blisters which may be present. At the beginning of the test period, he following instructions should be issued: "You are going to receive two periods of stimulation. Each period will be marked by the presence of the light on the stimulating panel. One of those periods will be accompanied by a tactile/vibration stimulus and you must indicate whether its the first or second period. The stimulus will always be present in only one period, and you must make a decision on each trial. The task will become progessively more difficult, so please do not get discouraged. I understand you'll be apparently guessing on many of the trials."

For all trials, the stimulus intensity is set with the selection switch in the standby position. For the initial trial the experimenter should set the intensity at a level that is detectable 100% of the time. For many subjects in the 20-70 year range, an initial intensity of 6.0 volts is sufficient. This level should be increased for subjects with suspected neuropathy, for older subjects, or when testing feet. An estimate of the appropriate initial level for an individual subject can be determined during the pre-test period. For each intensity, the subject should be presented with two periods of stimulation; one with the selection switch in the real test position, and the other with the switch in the false test position.

If the subject is correct, the stimulus intensity used in the initial test should be reduced by approximately 10% for the next trial, and this process should be continued until the first error. This percentage is not an exact requirement, but rather a guideline. "When the subject makes his/her first error, repeat the same intensity for <u>two</u> additional trials. Thus a total of three trials will be presented at this intensity. If two of the three trials are judged correctly, continue to decrease the intensity differential; if two of the three are missed, increase the differential. All levels below .7 volts should be repeated twice - even if the subject is correct.

Throughout testing, the period which contains the stimulus (first vs. second resentation) should be randomized. You will be provided with a separate data heat of each subject's visit. The randomization sequence (i.e. whether the ibration is present in the first or second time period) will be predetermined and intered in the left hand columns. You will be required to enter the instrument string and the subject's choice in the middle and right hand columns. Testing is ompleted when the subject has made a total of five errors.

The procedures for determining tactile/vibration of threshold for the feet re identical to those described above with the <u>second</u> toe of one foot being placed a contact with the stimulating surface. A foot ramp will be provided by Pfizer bat will serve to support the foot and to angle the Optocon so the settings can be leved from a sitting position. A variable distance heel support will also be rovided to accommodate various feet sizes.

For accurate tactile/vibration testing, the experimenter must be concerned ith the following details:

1. The subject must be consistent in the placement of the finger with respect to the stimulating surface. There should be no movement of this finger during the testing. Instructions such as "please don't press down" can be issued during testing to insure trial to trial consistency.

Page 2

2. The time interval between trials should be standardized at approximately 10 seconds.

3. When testing the same level as the previous trials, the sounds and motions associated with intensity change should be faked by the experimenter.

4. The subject should be carefully screened from viewing the instrument setting or the data sheet. Particular attention should be paid to preventing a subject from viewing the movement of the selection switch.

#### <u>Data Analysist</u>

The first step in calculating the absolute threshold is to determine the intensity values of the five errors and the five lowest correct scores. The highest and lowest values of the ten scores are eliminated and the remaining eight scores are averaged. This procedure is designed to utilize a sufficient sample of data points and to eliminate a disproportionate contribution of a single anomolous score to the absolute threshold.

# COMPONENTS INCLUDED IN THE PFIZER THERMAL TESTER

1 Model BF5-2TC Temperature Controlled Cold/Hot Plate complete with Unit/Power Supply.

- I Extra Stage for BFS-2TC.
- 1 TH-6D Thermometer
- I Connector Cable for BF5/TH-6D
- I Tilt Stand TTS-1.
- 2 Stoge Mountings
- I PT-6 package of probes.

#### Equipment:

• The Pfizer Thermal Tester (PTT) is a device developed by Pfizer, Inc. in conjuntion with Bailey Instruments\* to quantify the ability of human subjects to detect small changes in temperature at the distal extremes of their upper and lower limbs. The instrument and testing methodology was specifically designed to monitor the integrity of small diameter neurons in a twelve-month study of the effects of oral Sorbinil compared with placebo in patients with diabetic The PTT is portable, consumes no materials, includes a fail-safe neuropathy. overheating protection mechanism and can be manufactured to either European or American electrical standards. The hardware was originially intended to prepare biological tissue for sectioning on a microtome and has been manufactured and serviced since 1969. Thermal electric cooling or heating is achieved using the "Peltier effect" combined with solid state electronics. The stimulating surface is made of molybdenum; an esoteric metal selected for its heat transfer properties. By varying direct current, temperature can be set and maintained over a 50°C range, can be changed at a rate exceeding IOC per second, and can be fine tuned to the nearest 0.1°C.

The PTT includes both an active and passive stimulating plate that are identical in appearance and are mounted on rigid support platforms. The temperature of the passive plate is determined by ambiant room temperature and the temperature of the perfusing fluid, while the active plate is under direct superimenter control. The temperature difference between the plates is continuously available to the experimenter in the form of a <u>+</u> digital readout securate to the nearest .01°C. Subjects remain unaware of the status of the plates and are asked repeatedly to compare their temperature. The absolute threshold for the detection of the colder surface is determined using a two alternative forcedshoice paradigm.

#### Procedure:

Prior to testing, all subjects should be provided with an adaptation period of petween 10 or 15 minutes during which they can become accommodated to room emperature. At the end of this period, the surface temperature of the subject's kin at the site to be tested, should be recorded by the experimenter (nearest .1°C) and noted on the data sheet. Skin temperature can be measured using the digital hermometer of the PTT in a direct mode. A thermal sensor probe will be rovided, which can plug into either the active or passive section of the hermometer.

Following the adaptation period, each subject should be given an apportunity o become familiar with the testing apparatus and with the expected thermal ensations. A number of temperatures should be set and sampled by the subject. Juring this period, the experimenter-can instruct the subject as to the appropriate angth and force of which to touch the plates. At the beginning of the test period, he following instructions should be issued:

Please press your finger against each plate in turn. Press firmly and for approximately one second at the center of each plate. One of the two plates will feel cooler and you must decide if it is the right or left plate. The plates will never be the same temperature and you must make a decision on each trial. The task will become progressively more difficult, so please do not get discouraged. I understand you will be apparently guessing on many of the trials."

for the initial trial, the experimenter should set the temperature differential at 1 level that is detectable 100% of the time. For many subjects in the 20 to 70 rear range, an initial temperature of 5.0°C is sufficient. This level should be ncreased for subjects with suspected neuropathy, for older subjects, or when esting the feet. An estimate of the appropriate initial level for an individual ubject can be determined during the pre-test period. The sign (+) of the digital eadout will inform the experimenter whether the active or passive plate is sctually cooler. The instrument setting and the subject's choice should be ecorded on the data sheet. If the subject is correct, a check, and if incorrect, a lash should be entered in the selected column. Appendix B contains a blank ecommended data sheet and a data sheet that is scored for thresholds of both ingers and toes in one subject.

If the subject is correct, the temperature differential used in the initial est should be reduced by approximately 10% for the next trial and this process hould be continued until the first error. This percentage is not an exact equirement, but rather a guideline. If the temperature differential fails below .0°C, all changes should be made in 0.1°C steps using the fine control knob. Men the subject makes his/her first error, the identical temperature should be epeated on three successive trials. If the correct position is selected on two of the three trials, the temperature is lowered. If errors are made on two of the three trials, the temperature should be raised. All levels below 0.7°C should be repeated twice - even if the subject selects the correct position.

Testing is completed when the subject has made a total of three errors. At his time, the surface temperature of the passive plate (direct reading on the ligital thermometer) should be entered on the data sheet. Throughout testing, he location of the cooler surface must be randomized across both the active and assive plates. A two-choice randomization table may be helpful in selecting the testing sequence.

For accurate thermal testing, the experimenter must be concerned with the following details:

• The subject should be consistent in the location of touch and the approximate force applied to each plate. Instructions such as "please press more firmly" can be issued during testing to insure trial to trial consistency.

2. The time interval between trials should be standardized at approximately 15 seconds. It physically takes longer to set a new temperature level that requires prossing the zero point (i.e. -2.6 to +2.3) as compared with the one on the same side of the zero point (i.e. -2.6 to -2.3). This factor must <u>not</u> be reflected in the time period between trials since it can provide a non-thermal clue.

3. When testing at the same level as the previous trial, the sounds and motions associated with temperature change should be taked by the experimenter.

The subject should be carefully screened from viewing the instrument setting  $\pi$  the data sheet.

The procedure for determining thermal threshold on the feet are identical to those described above, with the large toe on one foot being brought into contact with the plate. This can be facilitated by positioning the plates on the floor or on a slightly elevated platform (approximately 6"). If the subject experiences difficulty in making consistent contact with the stimulating surface, the experimenter should guide the toe to the appropriate target. In extreme cases, the plate may be disconnected from the support platforms, and manually held against the toe in sequence. The manual positioning of the plates can be used to test threshold in the more proximal portions of either the upper or lower limb.

### Data Analysis:

Absolute threshold - The first step in calculating the absolute threshold is to determine the temperature values of the three errors and the three lowest correct scores. The highest and lowest values of these six scores are eliminated and the mean of the remaining four scores determine the absolute thermal threshold. This procedure is designed to utilize a sufficient sample of data points and to eliminate a disproportionate contribution of a single anomalous score to the absolute threshold.

Relative threshold - A second value that can be obtained for each subject is the calculated absolute threshold expressed as a percentage of the temperature of the passive plate. Thus, an absolute threshold of 0.6°C would translate to a relative threshold of 2.4% if the passive plate had a reading of 25°C and to a value of 3.0% if the passive plate was at 20°C. Over the midrange of stimulus intensity, it has been demonstrated in the somatosensory. auditory, and visual modalities that the minimal detectable change in energy is approximately proportional to the total energy of the comparison stimulus. This is expressed at Weber's law ( 1/1=C) where I equals stimulus intensity and C is a constant that differs for each modality. Expressing thermal sensitivity as a relative threshold would be of great value in circumstances where the temperature of the passive plate could be expected to differ by a significant amount between test periods (such as the current Sorbinil study). An alternative to expressing threshold values as a percentage is to correct the absolute threshold score by a factor reflecting differences in the passive plate. In this manner temperature could continue to be expressed in degrees centigrade.

Laboratory tests will measure hepatic function (including lipid metabolism), immunologic function, hematopoetic status, selected endocrine function, urinalyses for urine sediment, for porphyrins, and for enzyme induction. Each participant will be asked to fast for at least 12 hours preceding his or her appointment for the examination. A twelve hour urine collection will be conducted during the 12 hours prior to the commencement of the examination.

Blood and urine will be collected for the following:

- A) Hepatic enzymes (gamma glutamyl transpeptidase and SGPT); alkaline phosphatase as an indicator of obstructive disease
- B) Lipid profile, including triglycerides, cholesterol, and the HDL lipoprotein fraction
- C) Complete blood count including differential and platelet estimation
- D) Tests of immunologic capability which will include total lymphocyte and white blood cell count, total T and B cell counts, counts of helper-inducer cells (T4) and suppressor-cytotoxic cells (T8), the helper-suppressor ratio, lymphocyte stimulation by Con A, phytohemagluten, pokeweed, and quantitative immunoglobulins (IgG, IgD, IgM, IgA). Delayed hypersensitivity skin testing for three common antigens (mumps, tetanus, and candida) will be performed on the evening of arrival and read at 24 and 48 hours by a trained reader.
- E) Serum levels of testosterone and gonadotropins.
- F) Thyroid screen (thyroxine, triiodothyronine, and ratio)
- G) Serum B12, folate and amylase, blood lead (potential confounders)
- H) 2,3,7,8-TCDD in serum

A relatively recent methodology for the evaluation of the body burden of 2,3,7,8-TCDD has been developed by the Center for Environmental Health at the Centers for Disease Control, and involves the measurement of the level of the dioxin in serum (Patterson et al., 1986). Current methods allow the measurement of parts per quadrillion using 50ml serum. All subjects will be screened for suitability to participate in the drawing of 105ml (seven 15ml plain clot tubes) whole blood for the purpose of evaluating 2,3,7,8-TCDD in 50ml serum. Subjects who are determined through screening to be at increased risk of adverse effects due to the additional volume of blood to be drawn, will not participate in this phase of blood testing.

Urine tests will include:

- A. A 12-hour urinary porphyrin profile, including total urinary porphyrins, distribution of uroporphyrins, coproporphyrins, and heptacarboxylic porphyrins, to be done on first morning void collected (with 5 grams sodium bicarbonate and EDTA added to the container).
- B. Urinalysis with microscopic examination (to be collected on the morning of the medical exam)
- C. Measurement of D-glucaric acid in the urine (assay using 12-hour urine collection)

-2-

#### I. Laboratory Testing: Blood and Urine

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- B) Lipid profile, including triglycerides, cholesterol, and the HDL lipoprotein fraction
- C) Complete blood count including differential and platelet estimation
- D) Tests of immunologic capability which will include total lymphocyte and white blood cell count, total T and B cell counts, counts of helper-inducer cells (T4) and suppressor-cytotoxic cells (T8), the helper-suppressor ratio, lymphocyte stimulation by Con A, phytohemagluten, pokeweed, and quantitative immunoglobulins (IgG, IgD, IgM, IgA). Delayed hypersensitivity skin testing for three common antigens (mumps, tetanus, and candida) will be performed on the evening of arrival and read at 24 and 48 hours by a trained reader.
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- A. A 12-hour urinary porphyrin profile, including total urinary porphyrins, distribution of uroporphyrins, coproporphyrins, and heptacarboxylic porphyrins, to be done on first morning void collected (with 5 grams sodium bicarbonate and EDTA added to the container).
- B. Urinalysis with microscopic examination (to be collected on the morning of the medical exam)
- C. Measurement of D-glucaric acid in the urine (assay using 12-hour urine collection)

-2-

II. Neurobehavioural and Psychological Testing

Several tests of the computer-administered Neurobehavioural Evaluation System (NES) will be included in the test battery. The majority of the tests to be used from the NES measure psychomotor skills, such as simple reaction time and psychomotor coordination.

The following tests from the NES will be administered:

Nood Scales Dynamic Continuous Performance Test Digit Span Symbol-Digit Substitution Pattern Comparison Simple Reaction Time Pattern Memory Tapping Test Vocabulary (WAIS-R)

Prior to the administration of the neurobehavioural tests, the subject will be requested to complete a NES Pre-Test Questionnaire. This questionnaire will probe for information about the subject's frame of mind at the time of the neurobehavioural evaluation and about any alcohol or medication the subject may have consumed prior to testing that might affect the test results.

-3-

Psychological testing will include the following standardly administered tests:

Symptoms Check List - 90 (SCL-90) Grooved Pegboard Word List Generation Benton Visual Retention Test (Reproduction) Similariries (Subtest of WAIS R) Trails A and B California Verbal Learning Test (CVLT) Block Design Santa Ana Dexterity Test CLVT (delay) Information Subtest of Weschsler Adult Intelligence Scale-R (WAIS-R) Beck depression Inventory Spielberger Anxiety Scale

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## NES PRE-TEST QUESTIONNAIRE

1. Exam Code

<u>/ P / T / 0 / 1 /</u>

2. Participant ID

/ / / / / / /0/

Participant Name\_\_\_\_\_

3. Date

Month	۲	/	
Day	<u> </u>	1	

Year	<u> </u>	1	

4. Interviewer ID /////

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5.	Where were you born?	<u>[_1</u>
	l = USA 2 = Other	
6.	What language do you speak at home?	<u> </u>
	l = English 2 = Other	
7.	What is you preferred hand? (For writing, throwing.)	
	l = Right 2 = Left 3 = Both	
8.	How much familiarity do you have with computers or video games?	
	1 = None 2 = Some 3 = A Lot	
9.	Do you need eyeglasses for reading?	<u>L</u> 1
	1 = Yes 2 = No	
	9a. If yes, do you have them with you today?	<u> </u>
	l = Yes 2 = No	
10.	Do you have any injuries or temporary physical ailments that might affect your performance today?	<u>[]</u>
	1 = Yes 2 = No	
11.	Do you have any worries or personal problems which might affect your performance today?	L1
•	l = Yes	

2 = No

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12.	How mu	ch sleep did you get last night?	ட
	2 = le	our usual amount ss than usual ore than usual	
13.	Which	best describes how you are feeling right now?	<u> </u>
	2 = Fr $3 = Av$ $4 = Ti$	erage	
14.		ou had any caffeine-containing coffee, tea, a in the last 24 hours?	<u> </u>
	1 = Ye 2 = No		
	14a.	If yes, how many cups did you have in the last 24 hours?	
		1 = 0-1 cup 2 = 2-3 cups 3 = 4-6 cups 4 = 7 or more cups	
	14b.	How long ago was your last cup?	<u>[]</u>
		l = within the last hour 2 = 1-3 hours ago 3 = 4 or more hours ago	
	14c.	Has your consumption of caffeine-containing beverages in the last 24 hours been:	<u> </u>
		l = your usual amount 2 = less than usual 3 = more than usual	
15.	Have y	ou smoked any cigarettes in the last 24 hours?	<u> </u>
	1 = Ye 2 = No		

15a. If yes, how long ago did you smoke your 1\_1 last cigarette? 1 = within the last hour 2 = 1-3 hours ago 3 = 4 or more hours ago How many have you smoked in the last hour? <u>[ ]</u> 15b. 1 = 0 - 12 = 2 - 33 = 4 - 64 = 7 or more 15c. Has your smoking today been: []] 1 = your usual amount  $2 = \overline{1}ess$  than usual 3 = more than usual 16. Do you ever drink alcohol-containing beverages? 1 l = Yes2 = NoIF NO, SKIP TO QUESTION #18. 16a. If yes, how often do you drink? 1 = less than once/month 2 = more than once/month but less than once/week 3 = 1-3 times/week 4 = 4-6 times/week 5 = once/day6 = 2-3 times/day 16b. When you drink, how many drinks do you average [ ] in one sitting? 1 = 1-3 drinks 2 = 4-6 drinks 3 = 7-9 drinks 4 = 10-12 drinks 5 = 13 - 15 drinks6 = more than 15

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	16c.	How often do you drink five or more drinks at one sitting?	<u> </u>
		<pre>l = never 2 = few times/year 3 = less than once/month 4 = once a month 5 = 2-3 times/month 6 = l-3 times/week 7 = 4-6 times/week 8 = daily</pre>	
17.	Have y	ou drunk any alcohol in the last 24 hours?	<u>[]</u>
	1 = Ye 2 = No		
	17a.	If yes, do you feel any effects now?	<u>[]</u>
		l = Yes 2 = No	
	17b.	How long ago was your last drink?	<u> </u>
		l = within the last hour 2 = 1-3 hours ago 3 = 4 or more hours ago	
	17c.	How many drinks did you have at that time?	ட
		1 = 0-1 2 = 2-3 3 = 4-5 4 = 6  or more	
	17å.	Has your drinking pattern today been:	<u> </u>
		1 = your usual pattern 2 = less than usual 3 = more than usual	

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18. Have you taken any drugs or medications in the Last 24 hours that affect your ability to concentrate?

 1 = Yes
 1

 2 = No
 18a. If yes, are you still feeling the effects?

 1 = Yes
 1

 2 = No
 1

 18a. If yes, are you still feeling the effects?
 1

 1 = Yes
 1

 2 = No
 1

 18b. How long ago did you take it?
 1

 1 = within the last hour
 1

 2 = 1-3 hours ago
 3 = 4 or more hours ago

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IF COMPUTER TESTS ARE <u>NOT</u> TO BE ADMINISTERED TO SUBJECT, GIVE REASON:

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