1 3 4 5 6 7 8 ID# FORM 0 5 V 1 Card 01 9-10

EARLY PREGNANCY STUDY

HUSBAND'S QUESTIONNAIRE

Thank you very much for completing this questionnaire. All information you provide is entirely confidential and will be used only for group statistics. Your name will not be associated with your information.

INSTRUCTIONS: STATEMENTS IN ALL CAPITAL LETTERS ARE INSTRUCTIONS TO YOU. Please use pencil to record your answers and do not skip any question unless instructed to do so. If your answer does not fit one of the responses provided, feel free to write in your answer. With careful reading of instructions, it takes ten to fifteen minutes to complete the questionnaire properly.

1 3 4 5 6 7 8 1 1D# O 5 V 1

GO TO SECTION D

Card 04 9-10

#### MEDICATIONS SUPPLEMENT

### HUSBAND'S QUESTIONNAIRE

ENTER RESPONSES TO C2 THRU C6 ON MEDICATION TABLE BELOW. Please list the names of all these medication on the table below and answer C2. C3-C6 for each medication listed. SPECIFY BRAND NAME FOR ASPIRIN AND OTHER ANALGESICS. C3. What was your usual dosage for (MEDICATION NAMED)? C4. How often did you take this medication? C5. Is this a prescription medication? C6. How many days or weeks did you take this medication during the last 13 weeks? C5 PRESCRIPTION? C6 TIME TAKEN C4 SCHEDULE C2 MEDICATION NAME C3 DOSAGE 22-23 15-18 11-14 (1)YES DAYS OFFICE CODE X DAY OFFICE CODE 24-25 X WEEK (2)NO WEEKS 37-38 30-33 26-29 X DAY (1) YES DAYS OFFICE CODE OFFICE CODE 39-40 X WEEK (2)NO WEEKS 52-53 41-44 45-48 X DAY DAYS OFFICE CODE OFFICE CODE (1)YES 54-55 X WEEK (2)NO WEEKS 67-68 56-59 60-63 (1)YES OFFICE CODE OFFICE CODE X DAY DAYS 69-70 X WEEK (2)NO WEEKS 82-83 75-78 71-74 DAYS X DAY (1)YES OFFICE CODE OFFICE CODE 84-85 X WEEK (2)NO WEEKS 97-98 86-89 90-93 DAYS X DAY (1)YES OFFICE CODE OFFICE CODE 99-100 (2)NO WEEKS X WEEK

### SECTION A - TOBACCO HISTORY

A1.	Have you ever smoked a total of 100 cigarettes in your lifetime?	
	(1) YES	11
	(2) NO GO TO A7	11
A2.	At what age did you start smoking cigarettes? DO NOT INCLUDE "EXPERIMENTAL" SMOKING BUT RECORD THE AGE AT WHICH YOU STARTED SMOKING ON A REGULAR BASIS.	
	AGE	12-13
АЗ.	Are you currently smoking? CURRENT SMOKING REFERS TO SMOKING DURING THE LAST TWO WEEKS.	
	(1) YES GO TO A5	14
	(2) NO	-
A4.	How old were you when you stopped smoking?	
	AGE	15-16
A5.	Altogether, how many years have you smoked, subtracting out times when you were not smoking?	
	YEARS	17-18
A6.	On an average day, how many cigarettes a day do/did you smoke? (20 CIGARETTES TO A PACK)	
	CIGS	19-20
A7.	Did you smoke any marijuana during the last three months?	
	(1) YES	21
	(2) NO GO TO A9	* 1

A8.	How many times did you smoke marijuana during the last three month	s?
	# TIMES	22-23
A9.	Did your mother smoke cigarettes when she was pregnant with you? DK IS OUR ABBREVIATION FOR "DON'T KNOW."	
	(1) YES	
	(2) NO	24
	(8) DK	
A10.	When you were younger than 10 years old, did your mother smoke in your home on a regular basis?	
	(1) YES	
	(2) NO	25
A11.	When you were younger than 10 years old, did your father smoke in your home on a regular basis?	
	(1) YES	
	(2) NO	26
A12.	When you were younger than 10 years old, did anyone else in your household smoke on a regular basis?	
	(1) YES	
	(2) NO	27

### SECTION B - BEVERAGE INFORMATION

PLEASE	USE	THE	SPACE	BELOW	EACH	QUESTION	FOR	ANY	COMMENTS	OR	MATH	RELATED	TO
THAT QI													

THAT	QUESTIO	N.	
81.	How man	y cups of brewed caffeinated coffee did you drink in the nth?	
			28-30
B2.	How many last mor	y cups of instant caffeinated coffee did you drink in the nth?	
			31-33
В3.	How many drink ir	y cups or glasses of hot or iced <u>non-herbal</u> tea did you the last month?	
			34-36
B4.	How many month?	/ 12 oz. bottles or cans of beer did you drink in the last	
			37-39
85.	How many	4 oz. glasses of wine did you drink in the last month?	
			40-42
B6.	month?	$1\frac{1}{2}$ oz. shots of hard liquor did you drink in the last Include mixed drinks and count Martinis, Black Russians, 2 drinks since they have double the amount of alcohol.	
			43-45
B7.	How many the last	servings of the following soft drinks did you drink in month?	
	COLAS:	Coke, Diet Coke, Tab, Pepsi, Diet Pepsi, Pepsi Light, Shasta Cola, Diet Shasta, Chek Cola.	46-48
	OTHERS:	Dr. Pepper, Sugar Free Dr. Pepper, Mello Yello, Mountain Dew, Sun Drop, Cheerwine, Barq's Root	
		Beer, Barq's Sugar Free Root Beer.	49-51

# PLEASE READ THIS PAGE CAREFULLY BEFORE GOING TO THE NEXT PAGE AND REFER TO THIS PAGE AS YOU COMPLETE THE MEDICATIONS TABLE.

In this section, we want to obtain information on all medications you have taken during the past  $\underline{\text{three}}$  months (13 weeks). This page provides you with information on how to fill out the table. Please enter your information on the table on the next page.

C2. Please list the names of all these medications on the medication table and answer C3-C6 for each medication listed. SPECIFY BRAND NAME FOR ASPIRIN AND OTHER ANALGESICS.

If you do not know the exact name of the medication, record the type of medication such as antibiotic, cough syrup, etc. USE THE MEDICATIONS SUPPLEMENT IF YOU USED MORE THAN FOUR MEDICATIONS. BE SURE NOT TO WRITE IN THE OFFICE CODE BOXES.

C3. What was your usual dosage for (MEDICATION NAMED)?

The dosage refers to the amount of medication you take each time you use the medication. Dosages are commonly expressed as milligrams (mgs), capsules, pills, tablets, tablespoons, teaspoons, ounces, injections or cubic centimeters (cc). Be sure to record the amount and type of dosage such as 2 tablets, 250 mgs or 1 tablespoon. You may use standard abbreviations in recording. Whenever possible, record the more precise measure such as two 500 mg tablets instead of two tablets.

C4. How often did you take this medication?

Record <u>either</u> the number of times a day <u>or</u> the number of times a week you took the medication. If the schedule for taking the medication is so variable that you cannot record a usual schedule, make notes in the comments section of the page and explain the situation. If you do make notes, be sure to indicate which medication the note refers to.

C5. Is this a prescription medication?

A prescribed medication refers to a medication filled by a pharmacist according to a physician's prescription. It does not refer to an over-the-counter medication that your doctor may have told you to take.

#### EXAMPLE

	C2 MEDICATION NAME	C 3 DOS AGE	C4 SCHEDULE	C5 PRESCRIPTION?	C6 TIME TAKEN
	OFFICE CODE	OFFICE CODE	I X DAY	(1)YES	DAYS
1	One a day Strengard	1 Tablet	X WEEK	(2)NO _/_	_/3 WEEKS
0	OFFICE CODE		女  X DAY	(1)YES/_	_/O DAYS
2	Polyeillin	capsule	X WEEK	(2)NO	WEEKS

- John takes One-A-Day Stressgard at breakfast every day. Therefore he took 1 tablet 1 time a day for 13 weeks (there are approximately 13 weeks in this three-month period).
- 2. John had bronchitis and took 250 mg polycillin capsules  $4 \times a$  day for 10 days according to his doctor's prescription.

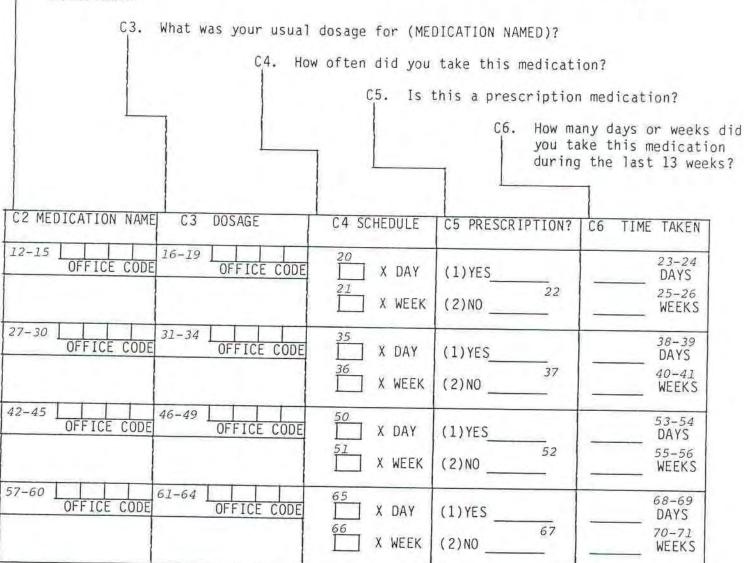
11

C1. Have you taken any prescription or non-prescription medications, including aspirin, digestive aids and vitamins during the past THREE months (13 weeks)?

(1) YES\_\_\_\_ COMPLETE C2-C6
(2) NO GO TO SECTION D

ENTER RESPONSES TO C2 THRU C6 ON MEDICATION TABLE BELOW.

C2. Please list the names of all these medications on the table below and answer C3-C6 for each medication listed. SPECIFY BRAND NAME FOR ASPIRIN AND OTHER ANALGESICS.



COMMENTS:

SECTION	D	-	BACKGROUND	QUESTIONS
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. What is the highest grade in school or year in college that you comple ${\tt YEARS\ ELEMENTARY\ SCHOOL}\_$	
	eted?
YEARS HIGH SCHOOL	-
YEARS COLLEGE OF	FFICE
	CODE
2. How many years of vocational or technical training have you had? THIS DOES NOT INCLUDE TRAINING FOR HIGH SCHOOL, COLLEGE OR GRADUATE SCHOOL CREDIT.	/E ARS
. Are you currently employed?	
(1) YES	
(2) NOGO TO DO	6
OFFICE What is the name of the company or organization you work for and what dompany make or do?	
CIRCLE CODE FOR WHOLESALE, RETAIL OR OTHER:	
CIRCLE CODE FOR WHOLESALE, RETAIL OR OTHER:  W R O SKIP TO D9.	CODE
W R O SKIP TO D9.  THROUGH D8 ARE FOR CURRENTLY UNEMPLOYED ONLY	CODE
W R O SKIP TO D9.  THROUGH D8 ARE FOR CURRENTLY UNEMPLOYED ONLY	CODE
W R O SKIP TO D9.  THROUGH D8 ARE FOR CURRENTLY UNEMPLOYED ONLY Have you ever been employed?	
W R O SKIP TO D9.  THROUGH D8 ARE FOR CURRENTLY UNEMPLOYED ONLY Have you ever been employed?  (1) YES	į.
W R O SKIP TO D9.  THROUGH D8 ARE FOR CURRENTLY UNEMPLOYED ONLY Have you ever been employed?  (1) YES  (2) NOGO TO D9  Please describe your most recent job, including your complete job title	

		OFFICE CO	DDE
CIRCLE CODE FOR WHOLESALE,	RETAIL, OR OTHER: W	R O	JUL
Which of these categories b	est describes your race	?	
	(1) AMERICAN IND	IAN OR ALASKAN NATIVE	
		IFIC ISLANDER	
	(3) BLACK, NOT O	F HISPANIC ORIGIN	
	(4) HISPANIC		
	(5) WHITE, NOT O	F HISPANIC ORIGIN	
	(6) OTHER (SPECI	FY)	
Were you born in the United	States?	(1) YESGO TO	D13
		(2) NO	
In what country were you bor	n?		
			ICE DE
In what year did you first e	enter the U. S.?	YE	AR
On what date was this questi	onnaire completed?	MONTH DAY Y	EAR

THANK YOU VERY MUCH FOR COMPLETING THIS QUESTIONNAIRE. YOUR SRA REPRESENTATIVE WILL PICK IT UP WHEN SHE VISITS YOUR WIFE NEXT WEEK.

If you would like to review a summary of the study, please turn the page for a copy of the text of the consent form.

## CONSENT TO PARTICIPATE IN THE EARLY PREGNANCY STUDY

The National Institute of Environmental Health Sciences is conducting a study of early pregnancy, in which you are invited to participate. The data is being collected by Survey Research Associates, Inc., a firm which specializes in health studies. In this study, urine samples from women who may be pregnant will be analyzed using newly-developed and very sensitive assays for pregnancy hormone. Two assays for human chorionic gonadotropin (hCG) and one for luteinizing hormone (LH) will be used on each specimen. This study will provide information about the usefullness of these new tests, and will also provide some information about the events of early pregnancy. For example, this study may detect conceptions that are lost before a woman realizes she is pregnant. Eventually, this project may result in improved tests for pregnancy diagnosis, and may lead to a better understanding of factors that promote a healthy pregnancy.

Participants are being asked to do the following:

- Respond to a questionnaire at the beginning and the end of the study. These questionnaires are completely confidential. They include questions on menstrual history, use of birth control, drugs and medications, and behavior related to pregnancy.
- Collect daily urine specimens which they will freeze for 1-2 weeks, at which time the specimens will be picked up by study personnel. Urine will be collected for up to six months or 8 weeks after a missed menstrual period that is diagnosed as pregnancy.
- 3. Fill out a daily check-list of four pregnancy-related questions.

Participants will be paid \$10 a week for the collection and storage of these urine specimens.

The hCG assays that will be used in this study are still in the experimental stage, and in most cases will not be performed until you have completed your participation in the study. Therefore, this study will not provide you with diagnosis of your own pregnancy. You will have to obtain pregnancy diagnosis and prenatal care in the usual way. If you become pregnant in the course of this study, the investigators would like to keep in touch with you to the conclusion of your pregnancy. However, you are free to withdraw from participation in the study at any time, before or after you become pregnant.

The results of your tests will be combined with data collected from other women in order to do statistical analysis. All information in this study is completely confidential and information with your name will be stored in locked files. Although your personal test results will not be accessible by themselves you are entitled to data describing the whole study after data collection has been completed.

If you have any questions in the course of the study that cannot be adequately answered by study personnel, you are invited to directly contact the Principle Investigator, Dr. Allen J. Wilcox, of the National Institute of Environmental Health Sciences, at 541-3445.