PROCEDURAL MANUAL

EARLY PREGNANCY STUDY

THANK YOU FOR PARTICIPATING IN THIS IMPORTANT STUDY OF EARLY PREGNANCY.

PURPOSE OF THE STUDY

This study has several purposes:

- To evaluate the accuracy of new chemical assays of urine for the detection of very early pregnancy.

- To learn more about the early part of pregnancy, especially within the first six weeks of conception.

- To find out how soon after conception women begin to have symptoms of pregnancy.

- To provide information on how many conceptions end in delivery of a baby and how many are lost in early pregnancy.

The National Institute of Environmental Health Sciences (NIEHS) in cooperation with the National Institute of Child Health and Human Development is sponsoring the study. The principal investigator is Dr. Allen Wilcox at NIEHS, Research Triangle Park.

Survey Research Associates, also located in the Research Triangle, will be contacting volunteers and collecting the data for the study. Please call 541-7692, a local call from Chapel Hill, Durham, and Raleigh, for any questions.

PARTICIPATION

AS A PARTICIPANT, you will be asked to:

- respond to a questionnaire at the beginning and the end of the study. Survey Research Associates personnel will set up a time and location convenient to you for the confidential interviews.

- collect daily urine specimens which you will freeze. You will be paid $10 for each week you contribute urines. All needed materials will be provided for you and delivered to your home. Specimens will be picked up by study personnel every week or every other week.

- fill out a daily check-list of four pregnancy related questions on the Daily Record Card which will be provided for you each week.

STATEMENT OF CONFIDENTIALITY

All information will be kept completely confidential. You will not be identified by name and any information you provide will be combined with that from other volunteers and presented in statistical form only.

PAYMENT

Payment will be made each time the representative of Survey Research Associates comes to your home to pick up your urine samples.

BEGINNING

Active participation begins the day immediately following discontinuation of all methods of contraception. Each day thereafter, including menstruation days, the first urine of the day should be collected.

LENGTH OF STUDY

Urine specimens will be collected for 8 weeks after a missed menstrual period that is diagnosed as pregnancy or up to six months. If you become pregnant, we would like to keep in touch with you to the conclusion of your pregnancy.

COLLECTING THE SPECIMEN

We would like for you to collect the first urine of each day. It is the most importtant urine of the day for the purposes of this research. If you get up during the night it is not necessary to catch that urine. You can wait until you get up for the day. We have made every effort to consider your convenience, and will provide all the materials necessary for urine collection, and storage.

A plastic spouted beaker is provided for collection convenience. It should be rinsed carefully after each use so that there is no contamination of subsequent urines by previous specimens.

A plastic "bonnet" facilitating collectio can be provided if you prefer. It is larger and requires more storage space but some women collecting urine appreciat the convenience since it fits into the commode and can be put into place the evening before. It also has a pouring spout and should be carefully rinsed afte each use.

Each day's specimen will be stored in a small plastic bottle. This bottle should be filled to about a quarter inch from the top. (This is about 35cc.) Bottles are stored in a small box which holds a week's supply. After each collection, the specimen should be put immediately in the freezer.

A label on the lid of the plastic contain will specify the day of the week you are to use the container. Please be careful to use the container correctly labeled for that day. The label corresponds to more complete information, needed for analysis, shown on a label on the side of the container.

DAILY RECORD CARD

You will receive a Daily Record Card for each week's collection which will fit inside the box containing your bottles. The top of the card will already be filled out, showing your identification number, data form number, the week number of participation and the date of the Monday beginning that week.

Each day, at the same time you collect the first morning urine, we would like for you to answer these four questions on the lower part of the card:

> "In the past 24 hours:
>
> -Has there been unprotected intercourse?
>
> -Have you had any symptoms of pregnancy?
>
> -What number of tampons have you used?
>
> -What number of pads have you used?"

Here is an example:

The third week of Pat's urine collection begins on Monday, November 22, 1982. Early morning urine is collected. Code Y is entered in the box under M (for Monday). In the past 24 hours unprotected intercourse did occur. Code Y is entered in coresponding box under M. There were no symptoms of pregnancy. Neither tampons nor pads were used. Code 0 is entered in the three boxes.

On Tuesday, the first morning urine was missed. Later Tuesday, Pat realized that she had forgotten. She then collected a sample and noted that important fact by coding L in the box under Tu. Code 0 was entered in all four boxes for the past 24 hours as there had been no unprotected intercourse, no symptoms of pregnancy, no tampons used, and no pads used.

EXAMPLE

NIEHS EARLY PREGNANCY STUDY TELEPHONE: 541-7692

ID#: 1 - 0 2 3 Form: 0 7 V 1 Week: 0 1

Date: 1 1 (Mo.) 2 2 (Day) 8 2 (Yr.)

	M	Tu	W	Th	F	Sa	Su
urine collected? (Y=yes, 0=no, L=later void)	Y	L					
in past 24 hours: unprotctd intcs?	Y	0					
sx of pg?	0	0					
# tampons used?	0	0					
# pads used?	0	0					

Comments on back:

NOTE: You should answer the four questions for each 24 hour period even when you were not able to collect urine. Please do not go back to answer questions for previous days. Answer questions only for the current day. When the last urine of the week is collected on Sunday morning, the Daily Record Card should be transferred to the box in the freezer containing all the urines for that we The Survey Research Associates representative will pick up the Daily Record Cards with the urine specimens.

WHAT IF

-What if you miss the first morning urine? Although the first morning urine is preferable for the laboratory analysis, a urine collected anytime that day would be useful. Let us know that the specimen is not the first morning urine by recording L ("later void") on the Daily Record Card.

-What if you forget the entire day? It is important for you to make every effort to contribute a daily urine. If, however, you should miss an entire day, simply put the empty container in the carton and enter a note on the Daily Record Card. DO NOT SUBSTITUTE. Do not discontinue collection of urine. Missing a day does not disqualify your continued participation but DO NOT SUBSTITUTE urine from another day. Please answer the four questions on the Daily Record Card even if you did not collect urine that day.

-What if you go out of town? It is important to the success of the study to have as complete a set of samples from eac woman as possible. If you can manage to freeze the samples while away, we will be happy to provide a cooler and blue ice to keep it frozen while being transported. Let us know ahead of time so that we can help you in any way we can.

-What if you have a friend who is intereste in becoming a volunteer? Please have her contact us, or give us her name. We are looking for volunteers.

-What if you misplace your Daily Record Car have a defective plastic container or have any questions?
Call staff personnel at Survey Research Associates, 541-7692 any time of the day or night. If you call after office hours, please leave a message and we will call you at the beginning of the next working day. Our number is toll free from Chapel Hill, Durham and Raleigh.

NOTES AND QUESTIONS:

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