Reproductive History Form Instructions RHX Version C, 12/01/95 QxQ Date 02/23/2001

I. GENERAL INSTRUCTIONS

The Reproductive History Form (RHX) is completed during the female participant's baseline clinic visit. The interviewer must be certified and should have a working knowledge of the data entry procedures for the electronic version from and the document titled "General Instructions for Completing Paper Forms" prior to completing this form. ID Number, Contact Year, and Name should be completed as described in that document.

The purpose of the RHX is to obtain baseline information on the female participants' menstrual history and pregnancy, gynecologic surgery or radiation therapy, and use of supplemental female hormones for reasons other than birth control (estrogen hormone replacement therapy). The exact wording and order of the questions should be followed to ensure standardization. Items should not be skipped unless indicated by the skip pattern instructions. Because there are many skip patterns, the interviewer should be very familiar with the flow of the survey to insure smooth administration with a conversational tone. Items in BRACKETS and/or CAPITAL LETTERS are instructions to the interviewer and are not read to the participant.

READ THE ITEMS CLEARLY USING THE EXACT WORDING ON THE FORM. The introductory and transitional scripts may deviate from the prototypes provided, but must include the same information.

Some participants may view this material as very sensitive. The interviewer should be aware of the sensitive nature of the information and make the participant feel comfortable. If required, the interviewer should explain that these are characteristics that sometimes can explain the development of heart disease. Beyond this, however, no specific information should be mentioned to the participant.

II. SPECIFIC INSTRUCTIONS

A. Menstrual History and Pregnancies

1. The exact age in years should be reported. If the participant reports the time in school grades, probe for years. A "best estimate" is acceptable if the interviewer feels confident that a thoughtful estimate is provided. If the participant is unsure of at what age her first menstrual period occurred, probe by asking about possible other associated life events which she

may recall more clearly. If she still does not know, draw 2 horizontal lines through the boxes.

If the participant says that she has never menstruated, enter "0" and skip to Item 12.

- Include pregnancies resulting in miscarriage and abortion. If the participant was uncertain of a pregnancy, do not include it in the total. If not known, draw 2 horizontal lines through the boxes.
- 3. If not known, draw 2 horizontal lines through the boxes.
- 4. Even if the participant has had only one menstrual period in the past 2 years, or reports any bleeding in the past 2 years, enter "Yes." Consider regular bleeding induced by hormone medication as a menstrual period.
- 5. If the participant can not remember when she had her last menstrual period, draw 2 horizontal lines through the boxes.
- 6. Read the Item and the response categories after handing the Response Card to the participant. The overall intent of this question is to identify the reason for the above reported menstrual periods or bleeding during the last 2 years; a narrower objective is to identify the cause of periods/bleeding in women who are postmenopausal.

Response Categories for Item 6

Natural periods	Cyclic vaginal bleeding wo	men experience
-----------------	----------------------------	----------------

when pre- or peri-menopausal.

Hormone Only Use of hormone replacement treatment during

menopause or peri-menopause (i.e., not hormones for the purpose of contraception) which can result in cyclic and non-cyclic uterine

bleeding.

Illness Cancer, infections, miscarriage, etc. can cause

non-cyclic uterine bleeding.

Other Conditions other than natural periods, hormone

use or illnesses can cause vaginal bleeding,

and should be coded as other.

Don't Know Unexplained vaginal bleeding due to an

unknown cause is coded as "Don't Know."

If more than one response category is applicable, ask the participant to select the one which explains the cause of the majority of her periods or bleeding during the last two years.

A response of ILLNESS, OTHER or DON'T KNOW will be discussed with the participant during the medical data review.

- 7. This item determines the number of periods missed over the last 2 years. If the participant has not missed any periods over the last 2 years, enter '00' and skip to Item 11. If not known, draw 2 horizontal lines through the boxes.
- 8. If the term "menopause" is not immediately understood, ask: "Have your periods stopped for at least 6 months?" If the participant hesitates or is unsure, record "unknown" as her response and skip to Item 11. If she reports with certainty that she has not reached menopause, enter "NO" and skip to Item 12.
- 9. If not known, draw two horizontal lines through the boxes. A logical inconsistency among the previous responses is acceptable here; for instance, if a participant has indicated that she has reached menopause (YES to Item 8) but she has also reported menstrual periods or bleeding within the last 6 months (Items 4, 5 or 7). There could be reasons for these "inconsistencies" which are not explored in the interview, such as irregular menses or symptoms associated with the peri-menopausal stage.
- 10. If the participant reports that she had already reached menopause before she had gynecological surgery, record the response as "natural."
- 11. If the participant is unsure of having hot flashes and asks for clarification, define a hot flash as "an intense sensation of warmth or feeling flushed all over, lasting anywhere from a few seconds to a few minutes."

B. Birth Control Pills

12. Only include birth control pills used for family planning purposes. Birth control pills used exclusively for non-family planning purposes should be noted in Section C (Hormone Use).

If the participant only reports ever taking <u>one</u> complete birth control pill cycle (21 or 28 day) in her lifetime, record "Yes." If the participant never completed even 1 (21 or 28 day) birth control pill cycle, record "No." (Consider a complete "mini-pill" regimen the same as a birth control pill cycle.)

- 13. If the participant has started taking birth control pills several times, record the age of the first time. If not known, draw 2 horizontal lines through the boxes.
- 14. "Current" refers to the time of the interview. If "Yes," go to Item 16.
- 15. Record the age when birth control pills were stopped for the <u>last</u> time. If not known, draw 2 horizontal lines through the boxes.

Note: A participant using 21-day cycle birth control pills might answer "No" to Item 14 if she is currently menstruating and not "currently taking" a daily pill for that week. Probe for this situation if the participant hesitates or acts surprised when you ask Item 15.

16. Enter the total number of years of usage. If the participant has used the birth control pill more than once, enter the total number of years used, not counting the intervening periods of non-use. This requires all the time intervals of usage to be summed and then the total rounded off to the nearest year. Round partial year amount of 1 to 6 full months up. (Example: If 2 years, 6 1/2 months is the total reported, record this as "3 years.") If the total "years" of usage is less than 6 full months, enter "00." (Example: If 5 1/2 months, record "00;" if 6 1/2 months, record "01"). If not known, draw 2 horizontal lines through the boxes.

C. Hormone Use

17, 24, 30, & 36. Hormonal creams do not apply. Birth control pills prescribed for therapeutic indications other than family planning should be included in this section (e.g., for control of symptoms of a painful pelvic condition called "endometriosis," for control of too frequent or too irregular menstrual periods). If the participant only reports having taken at least one complete cycle (21 or 28 day), record "YES." (Consider a complete "mini-pill" regimen the same as a cycle.) If the participant has not completed even one (21 or 28 day) cycle, record "NO." If the response is NO or UNKNOWN, go to Item 42.

NOTE: Items 18-41 record information on a maximum of four different hormone preparations, starting with the most recent one. Information on the first hormone is recorded in Items 18-23; information on the second in Items 24-29; information on the third in Items 30-35; information on the fourth in Items 36-41. Combination hormone preparations should be entered as one hormone with a "/" between the separate doses for the two hormones. For example:



0	.6	2	5	/	2	.5
---	----	---	---	---	---	----

18, 24, 30, & 36. Transcribe the name of the hormone. Print clearly. If the name is not known, draw two horizontal lines here and through the boxes for medication code, but attempt to complete the remaining questions.

When a hormone(s) is reported in Item 18a(litemes 24b, 30b, 36b), look it up in the List of Gonadal-Hormones at the end of these instructions. This list provides the location of the picture of the drug in the Physician's Desk Reference (PDR), its MEDISPAN drug code, its trade and generic names and the possible concentrations. If the participant has the hormone with her, use the label on the bottle in conjunction with the list to determine and record the correct concentration (Items 18b, 24c and 36b). If the label is not informative or if the participant has no bottle or pills, use the PDR picture to help determine the name and concentration. Enter leading zeros if necessary so the response is right justified. All valid concentrations are provided on the list. Most hormones have multiple concentrations listed; pick the correct one. If the hormone is not on the list or cannot be found in the PDR, set the status field to Q (questionable).

Record the 6-digit medication code number (Items 18d, 24e, 30e and 36e) of the hormone just recorded. If using a paper form, this item may be temporarily skipped and completed later. In selecting the MEDISPAN code for a preparation with multiple hormones, identify the code based on the FULL NAME OF THE PRODUCT, not just the first hormone.

- 19, 25, 31 & 37. If the participant started taking the specified hormone more than once, enter the age of the first time. If not known, draw two horizontal lines through the boxes.
- 20, 26, 32 & 38. "Current" means either in a cycle at the time of the interview or between cycles, or currently in a program of female hormone shots or implants. If the response is YES, go to Item 22, 28, 34, 40).
- 21, 27, 33 & 39. Enter the age at which she <u>last</u> stopped taking the specified hormone. If not known, draw two horizontal lines through the boxes.
- 22, 28, 34 & 40. Add together all the years and months during which the specified hormone was used. If the participant's response sums to a total greater than the total number of years and

remind the participant that "we are looking for the length of time that you have ever used the hormone." If the participant has used the hormone more than once, enter the total number of months or years used, <u>not</u> counting the intervening periods of non-use. This requires summing all the time intervals of usage.

- 23, 29, 35 & 41. Enter the usual or most representative figure if it has varied over time. If not known, draw 2 horizontal lines through the boxes.
- 24 29. These items are repeats of Items 18-23 for a second female hormone. If more than two hormones were used in the interim between the third and fourth examination, only record the two which were most recent. This should not be confused with a single hormone preparation that consists of two hormones. If the participant only took one hormone, leave Item 24 blank and go to Item 42.
- 30 35. These items are repeats of Items 18-23 for a third female hormone. If more than two hormones were used in the interim between the third and fourth examination, only record the two which were most recent. This should not be confused with a single hormone preparation that consists of two hormones. If the participant only took one hormone, leave Item 30 blank and go to Item 42.
- 36 41. These items are repeats of Items 18-23 for a fourth female hormone. If more than two hormones were used in the interim between the third and fourth examination, only record the two which were most recent. This should not be confused with a single hormone preparation that consists of two hormones. If the participant only took one hormone, leave Item 36 blank and go to Item 42.

D. Gynecologic Surgery

42 -43. If the participant is unsure, probe by suggesting that the uterus is also called the womb, and that in some places this is called a "female operation." It may be necessary in some cases to clarify that surgery to "tack-up the bladder" is different operation that does not involve the uterus nor ovaries. It may also be necessary to suggest that the ovaries may be referred to as "egg sacs." If YES, enter Y and continue to the next question. If NO or UNKNOWN, go to Item 47.

If necessary, suggest that the uterus is also called the womb.

44. Enter the age at which the uterus was removed. If not known, draw 2 horizontal lines through the boxes.

The interviewer should probe to determine whether only one or both ovaries were removed. Also note that with a vaginal hysterectomy (when the uterus is removed through the vagina and no abdominal incision is made), the ovaries are <u>not</u> removed.

Note: "Half" an ovary should be recorded as <u>no</u> ovary removed. If the response is NO or UNKNOWN, go to Item 35.

46. If more than one operation was performed, record the age of the most recent one. If not known, draw two horizontal lines through the boxes.

E. Administrative Information

- 47. Enter the date on which the participant was seen in the clinic.
- 48. Record "C" if the form was completed on the computerized data entry system, or "P" if the paper form was used. If the form was completed partially on paper and partially on the computer, code as "Paper Form."
- 49. Enter the 3 digit JHS code for the person at the clinic completing this form in the boxes provided.