REPRODUCTIVE HISTORY FORM

A. REPRODUCTIVE HISTORY

1. Did the participant have menstrual periods within 2 years prior to her last visit? [See PIN sheet] ...... Yes Y No N

   Go to Item 10, Screen 2

2. Have you had any menstrual periods or bleeding during the last 2 years? ...... Yes Y No N

   Go to Item 6

3. In what month and year was your last menstrual period or bleeding?

   [ ] [ ] month

   [ ] year

4. Was this a natural period, or was it due to the use of hormones, or to some other cause? [HAND RESPONSE CARD TO PARTICIPANT AND READ EACH RESPONSE CATEGORY.]

   Natural periods N
   Hormones Only H
   Illness I
   Other O
   Don't Know D

5. In the past 2 years, how many periods did you miss? [If "000" go to item 9]

   [ ] [ ]

6. Have you reached menopause? ........... Yes Y No N

   Go to Item 10, Screen 2

   Unknown U

7. At approximately what age did menopause begin? 
   
8. Was your menopause natural or the result of surgery or radiation?
   
   Natural N
   Surgery S
   Radiation R
   Unknown U

9. Are you having hot flashes? Yes Y
   No N

10. Since your last ARIC visit on (date) have you taken or used any female hormone pills, skin patches, shots, or implants? Yes Y

   Go to Item 35, Screen 7
   No N
   Unknown U

   "Please give me the names of all female hormones you have used since that exam, starting with any you may be taking currently or with the most recent one. Please exclude hormone creams."

11. Name 1:
   a. _______________________________________________________

   Concentration (mg or mcg units):
   b. _______________________________________________________

   first hormone

12. Code 1: __________________________

13. At what age did you start taking this hormone for the first time? 

14. Are you currently taking this hormone? Yes Y
   No N

   Go to Item 16

15. At what age did you stop taking this hormone?

16. For how long altogether since your last ARIC exam have you used this hormone?
   a. ____________ years
   b. ____________ months

17.a. Do(Did) you take this hormone by mouth? Yes Y

   Go to Item 18, Screen 4
   No N

   b. How many days do(did) you take this hormone in a 4 week period?

REPRODUCTIVE HISTORY FORM (RHKB screen 4 of 8)

17.c. On a typical day when you took this hormone, how many pills did you take? per day

Go to Item 23, Screen 5

18. How did/do you use this hormone?
[READ EACH RESPONSE]

Patch P
Go to Item 20

Shot S
Go to Item 21

Implant I

19. On a typical day when you have a patch on, how many do you use?

Go to Item 23, Screen 5

20. How often do you receive your shot?

a. per
b. Month

Go to Item 23, Screen 5

21. Where is your implant placed?
[READ EACH RESPONSE]

Upper Arm A
Uterus (womb) W
Other O

REPRODUCTIVE HISTORY FORM (RHKB screen 5 of 8)

22. On a typical day when you have your implant in place, how many do you have in place? ...

23. Have you taken a second female hormone since your last ARIC visit? Yes Y No N

Go to Item 35, Screen 7

24. Code 2:

25. At what age did you start taking this hormone for the first time?

26. Are you currently taking this hormone? Yes Y No N

Go to Item 28,

27. At what age did you stop taking this hormone?

28. For how long altogether since your last ARIC exam have you used this hormone?

a. years
b. months

Concentration (mg or mcg units):

a. 

b. first hormone
29.a. Do(did) you take this hormone by mouth?
   - Yes Y
   - No N
   Go to Item 30

   b. How many days do(did) you take this hormone in a 4 week period?
   - [ ] days

   c. On a typical day when you take(took) this hormone, how many pills do(did) you take?
   - [ ] per day
   Go to Item 35, Screen 7

30. How did/do you use this hormone?
   (READ EACH RESPONSE)
   - Patch P
   - Shot S
   - Implant I
   Go to Item 32

31. On a typical day when you have(had) a patch on, how many do(did) you use?
   - [ ] Go to Item 35, Screen 7

32. How often do(did) you receive your shot?
   a. [ ] per
   b. Month M
   Other O
   Go to Item 35, Screen 7

33. Where is(was) your implant placed?
   (READ EACH RESPONSE)
   - Upper Arm A
   - Uterus (womb) W
   - Other O
   Go to Item 32

34. On a typical day when you have(had) your implant in place, how many do(did) you have in place? ................
   [ ]

35. Did participant have a partial or total hysterectomy or oophorectomy at the time of her last visit? ....... Yes Y
   [See PIN sheet]
   - No N
   Go to Item 37

36. At your last visit on (date), you reported prior surgery to have your uterus or ovaries removed. Have you had additional surgery on your uterus or ovaries?
   - Yes Y
   Go to Item 38
   - No N
   Go to Item 42, Screen 8

37. Have you had surgery to have your uterus or ovaries removed? (That is, a partial or total hysterectomy or oophorectomy.) ........................ Yes Y
   - No N
   Go to Item 42, Screen 8
   Unknown U
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<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td><strong>38. Has your uterus (womb) been removed?</strong></td>
<td>Yes</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td><strong>39. How old were you when this operation was performed?</strong></td>
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<td><strong>40. Have you had either one or both ovaries removed?</strong></td>
<td>Yes, one</td>
<td>O</td>
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<td></td>
<td>Yes, both</td>
<td>B</td>
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<tr>
<td><strong>41. How old were you when this operation was performed?</strong></td>
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<td><strong>42. Date of data collection:</strong></td>
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<tr>
<td></td>
<td>month</td>
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<td>year</td>
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<td><strong>43. Method of data collection:</strong></td>
<td>Computer</td>
<td>C</td>
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<td>Paper form</td>
<td>P</td>
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<td><strong>44. Code number of person completing this form:</strong></td>
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**Reproductive History Form (RHXB screen 8 of 8)**

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INSTRUCTIONS FOR THE REPRODUCTIVE HISTORY FORM
RHX, VERSION B, 03/11/93
PREPARED 09/23/93

This form updates some aspects of the reproductive history of female participants since Visit 2. The exact wording and order of the questions should be followed to ensure standardization. Questions 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. Interviewers are certified in general clinic interviewing and familiar with the ARIC data entry system (DES) and the "General Instructions for Completing Paper Forms" (in case the computer is down) prior to administering this form. Items in BRACKETS and/or CAPITAL LETTERS are instructions to the interviewer and are not read to the participant.

COMPLETE THE HEADER (paper form) by applying a long participant ID label and entering the participant’s Name. READ THE QUESTIONS 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.

READ INTRODUCTORY SCRIPT

"These questions update information you provided us about your reproductive history since your last ARIC visit. Some of the questions need a direct answer from you and some require you to choose an answer from a series of responses. I will let you know which type of response is necessary for each question."

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.

A. Reproductive History

1. DO NOT READ THE QUESTION, CHECK THE ARIC PARTICIPANT INFORMATION (PIN) SHEET to determine whether the participant had menstrual periods within 2 years prior to Visit 2. If YES or UNKNOWN, go to Item 2. If NO, go to Item 10.

2. 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. If the participant reports that she has not had any menstrual
periods during the past 2 years, skip to Item 6 to determine whether the participant has reached menopause.

3. If the participant cannot remember when she had her last menstrual period, draw 2 horizontal lines through the boxes.

4. Read the question 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. "Natural periods" refer to cyclic bleeding women experience when pre- or peri-menopausal. "Hormone use" refers to the use of hormone replacement treatment during menopause or peri-menopause (not hormones for the purpose of contraception) and can result in cyclic and non-cyclic uterine bleeding. Some "illnesses" (cancer, infections, miscarriage, etc.) can cause non-cyclic uterine bleeding. "Other" conditions can cause bleeding, and should be coded as '0'. If more than one response category was 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.

5. This question 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 9. If not known, draw 2 horizontal lines through the boxes.

6. 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 question 10. If she reports with certainty that she has not reached menopause, enter "NO" and skip to question 10.

7. If the term "menopause" is not immediately understood, the age at which menopause began should be defined as the age at which "periods had stopped for at least 6 months". 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 6) but she has also reported menstrual periods or bleeding within the last 6 months (Items 2, 3 or 5). 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.

8. If the participant reports that she had already reached menopause before she had gynecological surgery, record the response as "natural".

9. If the participant is unsure of having hot flashes, suggest that a hot flash is "an intense sensation of warmth or feeling flushed all over, lasting anywhere from a few seconds to a few minutes".

10. 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) since Visit 2, record "YES." (Consider a complete "mini-pill" regimen the same as a cycle.) If the participant hasn’t completed even one (21 or 28 day) cycle, record "NO." If the response is NO or UNSURE, go to Item 35.

NOTE: Items 11-24 record information on a maximum of two different hormone preparations, starting with the most recent one. Information on the first hormone is recorded in Items 11-22; information on the second in Items 23-34. If more than two hormones were used in the interim between the second and third examination, only record the two which were most recent. This should not be confused with a single hormone preparation that consists of two hormones.

11 & 23. 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 11.a (Item 23.a), 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 Physicians 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 11.b and 23.b). 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. In Visit 3 (in contrast to Visit 2), **only** the concentration of the **first** hormone in the preparation is recorded on the form. If the hormone is not on the list or cannot be found in the PDR, set the status field to Q (questionable).

12 & 24. Record the 6-digit medication code number 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.

13 & 25. 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.

14 & 26. "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 16 (28).

15 & 27. Enter the age at which she last stopped taking the specified hormone. If not known, draw two horizontal lines through the boxes.

16 & 28. Add together all the years and months since the last ARIC visit during which the specified hormone was used. If the participant’s response sums to a total greater than the total number of years and months since the Visit 2 exam, remind the participant that "we are looking for the length of time that you have used the hormone since your exam at Visit 2." If the participant has used the hormone more than once, enter the total number of months or years used, **not** counting the intervening periods of non-use. This requires summing all the time intervals of usage.

17-22 & 29-34. These items have been added to Visit 3 to document more fully use of exogenous hormone(s) between the two ARIC exams. There are four separate sets of questions to describe the four ways the female hormone could be taken: pills, patches, shots (injections) and implants. Only one set can be filled out for each drug. The questions are worded either in the present or past tense.

Choose the proper tense, based on the information from Item 14 (26), and use it consistently through the set of questions.

17 & 29. Items 17a-c cover female hormones taken by mouth (i.e, pills). If the hormone was not taken by mouth, record NO go to Item 18. If YES, determine how many days in a 4 week period the pills were prescribed to be taken (Item 17b) and...
how many pills were taken on a typical day (Item 17c). If the response to Item 17b is greater than 28, tell your participant that we are defining a ‘4 week period’ as 28 days, and then reask the question. If the response to Item 17c is ‘½ a pill’ (e.g., a 10 mg pill split in half), enter ‘0’ per day. The number of pills taken each day can be calculated from the name and concentration listed in items 11a and 11b during analysis. Repeat the sequence for the second hormone (if more than one was taken), beginning with Item 29.

18 & 30. Determine how the hormone was administered. Follow the skip patterns.

19 & 31. Select the appropriate tense, based on Item 14(26). Multiple patches can be worn simultaneously. If a different number of patches were worn at different times, determine and record the number of patches currently (or most recently) in place. Then go to Item 23.

20 & 32. Record the number of injections (Item 20a) in a specific time period (Item 20b). For example, 2 shots per month:

\[
\begin{align*}
20.a. & \quad \text{per} \\
\text{b. Time} & \quad \text{Week} \quad W \\
& \quad \text{Month} \quad M \\
& \quad \text{Other} \quad O
\end{align*}
\]

Then go to Item 23 or 35, respectively.

21 & 33. Select the appropriate tense, based on Item 14(26). Determine where the implant was placed and follow the skip rules. If the participant had more than one implant in place since Visit 2, determine the location of the current (or most recent) implant.

22 & 34. Record the number of implants in place at the above location.

23-34. These items are repeats of Items 11-22 for a second female hormone. If more than two hormones were used in the interim between the second and third 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 23 blank and go to Item 35.

35. DO NOT READ THIS QUESTION TO THE PARTICIPANT. CHECK THE VISIT 2 INFORMATION SHEET (PIN) to determine whether the participant reported having had a partial or total hysterectomy or an oophorectomy at Visit 2. If YES, enter Y and continue to the
next question. If NO or UNSURE, go to Item 37. If no Visit 2 PIN sheet is not available, enter UNSURE and go to Item 37.

36. A positive response to Item 35 does not rule out the possibility of additional gynecologic surgery since the last ARIC visit. This question documents additional surgery which may have been done on the uterus or ovaries. If no additional surgery was performed, go to Item 42; otherwise, skip to Item 38.

37. 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 a different operation that does not involve the uterus or ovaries. If NO or UNSURE, go to Item 42.

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

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

40. 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 not removed.

Note: "Half" an ovary should be recorded as no ovary removed. If the response is NO or UNSURE, go to Item 42.

41. 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.

B. Administration

42. Enter the date on which the participant was seen in the clinic. Code in numbers using leading zeroes where necessary to fill all boxes. For example, May 3, 1993, would be entered as:

```
0 5 1 0 3 1 9 3
month day year
```

43. 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."

44. The person at the clinic who has completed this form must enter his/her code number in the boxes provided.