



**Longitudinal Menopause Status and HT Use
Created Variables dataset**

Baseline through Visit 15

CODEBOOK

ARCHIVED DATASET 2019

PAGE INTENTIONALLY BLANK

DOCUMENTATION FOR THE SWAN LONGITUDINAL MENOPAUSAL STATUS DATASET

This dataset contains created variables related to menopause status and hormone therapy (HT) use. It is a longitudinal dataset, meaning that it contains multiple rows of data per ID. Specifically, each participant may contribute up to 16 lines of data (corresponding to baseline through visit 15 annual interview data).

Differences from the prior release of the Menopause Status archive dataset (nialmst2018):

- Visit 15 was added
- Only two women from Visit 16 who were still menstruating were added to this dataset.

Who is included in the public use dataset:

The dataset contains information for the 3,302 women from the seven clinical sites participating in the SWAN longitudinal study. The sites include Boston, MA, Pittsburgh, PA, Oakland and Los Angeles, CA, Detroit, MI, Chicago, IL, and Newark, NJ.

How this codebook is constructed:

This documentation section contains in depth explanation of the Final Menstrual Period (FMPDAY) and Hormone Therapy (HT) use. A list describing the variables used to create these variables is also provided, along with an interview questionnaire on which many of the variables are based. Note that none of those variables are available in this dataset (they can be retrieved from each visit's dataset).

The assigned participant ID has been replaced with a randomly generated ARCHID in order to protect participant privacy. The *baseline* interview date is denoted as day 0 and is used as the basis for all other dates. A variable describing the race/ethnicity of participants (RACE) and study site (SITE) were added from the Screener dataset.

Missing data coding:

Original missing codes (-1: not applicable, -7: refused, -8: don't know, -9: missing) have been recoded to SAS missing codes (.B: not applicable, .D: refused, .C: don't know, and .A: missing).

NOTE: Please be aware that there was for the Newark, NJ women a gap of 2-3 visits between Visits 06 and 09. This might affect the accuracy of the created variables.

Variables included in the dataset

Variable	Meaning and some description	Codes
ARCHID	Participant ID	
VISIT	Study visit	'00'= Baseline to '16'= Visit 16
AGE	Age at Visit	
RACE	Race/Ethnicity	1= Black 2= Chinese/Chinese American 3= Japanese/Japanese American 4= White Non-Hispanic 5= Hispanic
SITE	Study site	11= Detroit, MI 12= Boston, MA 13= Chicago, IL 14= Oakland, CA 15= Los Angeles, CA 16= Newark, NJ 17= Pittsburgh, PA
INTDAY	Annual interview completion day	Day
LMPDAY	Last reported bleeding day at each visit.	Day
HRMUSER	Whether or not the participant reports HT use since last visit, including birth control.	0 = No 1 = Yes
MSTATUS	<p>Menopause status – is determined from questions on bleeding patterns, current hormone use, pregnancy, breastfeeding, hysterectomy, and oophorectomy.</p> <p>This variable distinguishes whether women have gone through menopause naturally (MSTATUS=2, natural post) or had it surgically induced by having both ovaries removed (bilateral salpingo oophorectomy or BSO, where MSTATUS=1, post by BSO). Hysterectomy without BSO prior to an observed natural post is coded to 8 (unknown due to hysterectomy) since bleeding status cannot be determined due to menstruation ceasing. Note, unilateral oophorectomy alone can still allow for determination of status by bleeding patterns, so no special coding is necessary.</p> <p>Menopause status is compared across visits, and no women were allowed to move backwards in status (e.g. early peri at Visit 08 could not be pre at Visit 09)</p> <p><u>Post by BSO</u> - women with both ovaries removed (Bilateral Salpingo Oophorectomy or BSO) prior to natural post menopause</p> <p><u>Natural Post</u> - women who had no bleeding in the 12 months prior to the visit</p> <p><u>Late Perimenopause</u> - women who had bleeding in the last 12 months prior to her visit but no bleeding in the past three months</p> <p><u>Early Perimenopause</u> - women who had bleeding in the last three months but who said their menstrual periods had become farther apart, closer together, more variable, or more regular</p> <p><u>Premenopausal</u> - women who reported bleeding in the past three months and who responded that their menstrual periods had stayed the same since their last visit</p> <p><u>Pregnant/breastfeeding</u> – women who reported a pregnancy since the last visit or are currently breastfeeding</p> <p><u>Unknown due to HT use</u> - pre- and perimenopausal women using hormones, including birth control pills, estrogen, and progestin, patches and a few vaginal hormones (for a full list, please refer to the section labelled 'List of drugs that determine Hormone Therapy')</p> <p><u>Unknown due to hysterectomy</u> – women who reported hysterectomy without BSO prior to natural post</p>	<p>1 = Post by BSO (Bilateral Salpingo Oophorectomy)</p> <p>2 = Natural Post</p> <p>3 = Late Peri</p> <p>4 = Early Peri</p> <p>5 = Pre</p> <p>6 = Pregnant/ breastfeeding</p> <p>7 = Unknown due to HT use</p> <p>8 = Unknown due to hysterectomy</p>

Variable	Meaning and some description	Codes
FMPDAY	<p>DESCRIPTION OF HOW FMPDAY COMPUTED:</p> <p>The final menstrual period day (FMPDAY) is only available for women who are classified as having made a ‘clean’ (not using HT) transition to post menopause.</p> <p>FMPDAY is calculated when a woman who is not taking hormone therapy has surpassed 12 months past the last remembered menstrual bleeding (LMPDAY). In most cases, the reported FMPDAY was taken from the variable LMPDAY for the visit immediately prior to the first visit that the participant was classified as post-menopausal.</p> <p>In a small number of cases, the participant reported bleeding since her last study visit, but provided a last bleeding date that was more than 12 months prior to the current visit date. In these cases, the FMPDAY is the LMPDAY reported at that visit (rather than at the prior visit).</p> <p>In addition, there were some cases, at the late peri visit immediately prior to the first post visit, where the participant reported no bleeding since her previous study visit. We then consult the LMPDAY reported at that previous visit, and assuming that all other data is correct, this day is then the participant’s FMPDAY.</p>	Days
AGEFMP	The participant’s age at their FMPDAY (either computed or imputed)	Day
HTVNUMS	<p>The cumulative number of visits that the participant has reported HT use, including birth control.</p> <p>This variable was created as the summation of the variable HRMUSER in the annual Interview dataset from Visit 01 to Visit 15. Note that the variable is not reset each time that a participant stops and then restarts HT use.</p> <p>V14 Note: Visit 14 is INCLUDED in this cumulative HT use variable if there was enough information to set HRMUSER for Visit 14.</p>	Integer: 0 ~ 15

Note: FMPDAY and AGEFMP do not time vary. All the other variables are given by ID and visit.

Hormone Therapy (HT) Use and Cohort Eligibility

Eligibility criteria for the study required that participants were not using HT in the months preceding study screening and the Baseline Interview. Specifically, participants who:

- a) reported any HT use in the three months prior to study screening or
- b) reported any HT use in the month prior to the Baseline Interview

were deemed ineligible for the longitudinal cohort *with the exception of three women who were discovered later on to have HT use reported in the ‘Other Rx Med’ category, and three more who were identified when the HRMUSER was expanded to include antineoplastics.*

By virtue of the eligibility criteria, all cohort participants will have a response of “No” to the Screener question: “In the past 3 months, have you taken any female hormones, including birth control pills?” and the baseline question pertaining to hormone use in the past month with the exception of the six mentioned in the above paragraph (in italics).

Some women reported having used HT more than three months prior to study screening. Data on “ever” HT use (including birth control pills) prior to SWAN is available on both the Screener and the Baseline Interview.

HT Use Data: Annual Follow-Ups

The main source of information regarding HT use in SWAN is the Annual Interview (visits 01-14) or the Rx/OTC/Vitamin/Supplement Medication Form (visits 12 and 13 and 15). At all follow-up visits participants are asked about their use of each type of HT: estrogen pills, estrogen by injection or patch, progestin pills, combination estrogen/progestin, birth control pills, and later on expanded to include other hormones that impact menstrual bleeding such as Selective Estrogen Receptor Modulators (SERMS), antineoplastic drugs with hormonal action, GNRH receptor analogues, and gonadotropins.

At each follow-up visit, a participant is classified as a “hormone user”, in the variable *HRMUSER*, if she responds ‘yes’ to having taken at least one type of hormone since her last study visit.

HT Use Variables and Menopausal Status Classification

1. Variables identifying hormone users:

- *HRMUSER* indicates participants who, since their last study visit, report having taken at least one of: estrogen pills, estrogen by injection or patch, progestin pills, combination estrogen/progestin, birth control pills, Selective Estrogen Receptor Modulators (SERMS), antineoplastic drugs with hormonal action, GNRH receptor analogues, or gonadotropins.
- *HRMUSER* does not indicate whether or not the participant has reported use at any prior visits.
- Menopause status *MSTATUS=7* (undetermined due to HT use) is NOT the same as *HRMUSER=1* (yes).

2. The current menopause status classification algorithm and HT use

- Participants who have had surgical menopause by bilateral salpingo oophorectomy, or BSO (*MSTATUS=1*) will be classified as *MSTATUS=1* at all future visits. This assignment is made irrespective of whether or not they report HT use at the time of, or following their surgery.
- Once assigned as post, a participant will remain post, unless she has surgery. The assignment of post is made irrespective of whether or not the participant reports any HT use. This has several implications:
 - a) HT users who have previously been classified as post will continue to be classified as post. They should be identified using *HRMUSER*.
 - b) Some women will report HT use at the first visit at which they are classified as post. In these cases, the post classification should be treated with caution, since the lack of bleeding (resulting in the post classification) could be associated with the reported HT use, and is not necessarily indicative of a 'true' change to post menopause. In addition, future status classifications (all of which will be post, unless the participant has surgery) should be viewed with some caution, due to the 'can't go backwards' in status rule.
- Participants with *MSTATUS=7* are only a subset of those who report hormone use. Hormone users should be identified using *HRMUSER*, not *MSTATUS=7*.
- With the exception of *MSTATUS=1* (post by BSO), and the application of the 'can't go backwards in status' rule (for example, a woman classified as late perimenopausal at visit 07 cannot be classified as early peri or premenopausal at visit 08), status classifications at each visit are made according to information provided at that visit. Specifically, the assignment of *MSTATUS=7* (undetermined due to HT use) is made solely based on reported bleeding and reported HT use since the last study visit. If a participant was classified as *MSTATUS=7* at her previous visit, but reports no HT use at the current visit, then her menopause status assignment at that visit will be based solely on bleeding information provided at that visit. The algorithm does not take into consideration the possible effects of prior hormone use on future status classifications. Therefore, the status classification assigned at visits following reported HT use (and particularly at the first visit following reported HT use) should be treated with caution. These assignments are possibly being affected by residual effects of the HT use.

List of drugs that determine Hormone Therapy (HRMUSER=1 specifically)

ACTIVELLA
ALESSE
ALORA TRANSDERMAL
ALTAVERA
ALYACEN
AMETHIA
AMETHYST
ANASTROZOLE
ANGELIQ
APRI
ARANELLE
ARIMIDEX
AROMASIN
ASHLYNA
AVIANE
AYGESTIN
AZURETTE
BALZIVA
BEKYREE
BEYAZ
BI-ESTROGEN/PROMETRIUM
BIO-IDENTICAL ESTROGEN + TESTOSTERONE SUBDERMAL PELLETT
BLISOVI
BREVICON
CAMRESE
CAMRESE LO
CENESTIN
CLIMARA PRO TRANSDERMAL
CLIMARA TRANSDERMAL
CLOMID
COMBIPATCH
CONJUGATED ESTROGENS/ MEDROXYPROGESTERONE
CRYSSELLE
CYCLAFEM
CYCLESSA
CYCRIN
DASETTA
DAYSEE
DEMULEN
DEPO-PROVERA INJECTION
DESOGEN
DIVIGEL TOPICAL
ELINEST
EMOQUETTE
ENPRESSE
ENSKYCE

ESCLIM TRANSDERMAL
ESTERIFIED ESTROGENS
ESTRACE (Not vaginal/topical)
ESTRADERM M TRANSDERMAL
ESTRADERM TRANSDERMAL
ESTRADIOL (Not vaginal/topical)
ESTRADIOL TRANSDERMAL
ESTRADIOL/NORETHINDRONE
ESTRADIOL/NORGESTIMATE
ESTRATAB
ESTRATEST
ESTRATEST HS
ESTRIOL/ESTRADIOL/ESTRONE TRANSDERMAL
ESTROGEL TOPICAL
ESTROGEN (Not vaginal/topical)
ESTROGEN INJECTION
ESTROGEN TRANSDERMAL
ESTROGEN/PROGESTIN
ESTROGENS CONJUGATED
ESTROGENS CONJUGATED/ MEDROXYPROGESTERONE
ESTROPIPATE
ESTROSTEP
ESTROSTEP FE
ETHINYL ESTRADIOL/NORETHINDRONE
EVISTA
EXEMESTANE
FARESTON
FEMARA
FEMCON FE
FEMHRT
FEMPATCH TRANSDERMAL
FEMRING VAGINAL RING
FERTINEX
FYAVOLV
GENERESS
GIANVI
GILDAGIA
GILDESS
GONAL-F
HCG
HCG SUBLINGUAL
HMG/PROGESTERONE
HUMAN CHORIONIC GONADOTROPIN
INTROVALE
JINTELI
JOLESSA

JUNEL
KAITLIB
KARIVA
KLIOGEST
KURVELO
LARIN FE
LASOFOXIFENE
LEENA
LESSINA
LETROZOLE
LEUPROLIDE
LEVLEN
LEVLITE
LEVONEST
LEVORA
LO LOESTRIN FE
LO/OVRAL
LOESTRIN
LOESTRIN FE
LOMEDIA
LOW-OGESTREL
LORYNA
LOSEASONIQUE
LUPRON
LUPRON DEPOT
LUTERA
LYBREL
MARLISSA
MEDROXYPROGESTERONE
MEGACE
MEGESTROL
MENEST
MENOSTAR TRANSDERMAL
MICROGESTIN
MICROGESTIN FE
MICRONOR
MIMVEY
MINASTRIN
MINI-PILL
MIRCETTE
MIRENA
MODICON
MONONESSA
MYZILRA
NECON
NIKKI
NOLADEN FORTE

NOLVADEX
NORDETTE
NORETHINDRONE
NORETHINDRONE ACETATE/ETHINYL
NORGESTREL
NORTREL
NUVARING VAGINAL RING
NORINYL
OCELLA
OGEN
OGESTREL
ORESTRALYN
ORSYTHIA
ORTHO EVRA TRANSDERMAL
ORTHO-CYCLEN
ORTHO-CYCLEN 28
ORTHO-EST
ORTHO-NOVUM
ORTHO-NOVUM 1/50
ORTHO-PREFEST
ORTHO-TRICYCLEN
OVCON
OVRAL
OVRETTE
PHILITH

PIMTREA
PIRMELLA
PORTIA
PREFEST
PREMARIN (Not vaginal/topical)
PREMPHASE
PREMPRO
PREVIFEM
PROFASI
PROGESTERONE MICRONIZED
PROGESTERONE SR
PROGESTERONE (Not vaginal/topical)
PROMETRIUM
PROVERA
QUARTETTE
QUASENSE
RALOXIFENE
RECLIPSEN
SEASONALE
SEASONIQUE
SETLAKIN
SOPHIA-A (Japan V04 only)
SRONYX
SYEDA
SYNAREL NASALSPRAY

SYNTEST DS
TARINA
TAMOXIFEN
TRI-ESTARYLLA
TRI-LINYAH
TRI-LEGEST
TRINESSA
TRIPHASIL
TRI-PREVIFEM
TRIVORA
VESTURA
VIORELE
VIVELLE DOT TRANSDERMAL
VIVELLE TRANSDERMAL
VYFEMIA
WERA
XULANE
YASMIN
YAZ
ZOLADEX
ZARAH
ZENCHENT
ZEOSA
ZOVIA

SECTION V: Copy of the Data Collection Forms

VISITS 00 – 10 Questions B12-B17 shown below are taken from an Interview Visit for creating the hormone use variables

VISITS 00 – 13 Questions D4-D5 and E1-E4, and E6 were used in the creation of the variable MSTATUS. These same questions have been asked at all follow-up visits.

NOTE: THESE QUESTIONS AT EACH VISIT ARE WHAT THE CREATED ARE BASED ON, THEY ARE NOT PROVIDED IN THIS DATASET. FOR MORE DETAILED INFORMATION, REFER TO EACH VISIT DATASET.

		a. What is the name of the medication?		b. Have you been taking it during the past month?		c. INTERVIEWER CHECK: MEDICATION VERIFIED FROM CONTAINER LABEL?		
		HORMONE QUESTIONS B12-17:						
		Since your last study visit, have you taken....						
		NO	YES	NO	YES	NO	YES	
B12.	Birth Control pills? #BCP1 #BCP2	1 (B13)	2	#BCPEN1, #BCPMED1	1	2	1	2
		1	2	#BCPEN2, #BCPMED2	1	#BCPTW1 2 #BCPTW2	1	#BCPVER1 2 #BCPVER2
B13.	Estrogen pills (such as Premarin, Estrace, Ogen, etc)? #ESTROG1 #ESTROG2	1 (B14)	2	#ESTREN1, #ESTRMD1	1	2	1	2
		1	2	#ESTREN2, #ESTRMD2	1	#ESTRTW1 2 #ESTRTW2	1	#ESTRVR1 2 #ESTRVR2
B14.	Estrogen by injection or patch (such as Estraderm)? #ESTRNJ1 #ESTRNJ2	1	2	#EINJEN1, #EINJMD1	1	2	1	2
		1	2	#EINJEN2, #EINJMD2	1	#EINJTW1 2 #EINJTW2	1	#EINJVR1 2 #EINJVR2
B15.	Combination estrogen/progestin (such as Premphase or Prempro)? #COMBIN1 #COMBIN2	1	2	#COMBEN1, #COMBMD1	1	2	1	2
		1	2	#COMBEN2, #COMBMD2	1	#COMBTW1 2 #COMBTW2	1	#COMBVR1 2 #COMBVR2
B16.	Progestin pills (such as Provera)? #PROGES1 #PROGES2	1 (B17)	2	#PROGEN1, #PROGMD1	1	2	1	2
		1	2	#PROGEN2, #PROGMD2	1	#PROGTW1 2 #PROGTW2	1	#PROGVR1 2 #PROGVR2

- a. What is the name of the medication? b. Have you been taking it during the past month? c. INTERVIEWER CHECK: MEDICATION VERIFIED FROM CONTAINER LABEL?

Since your last study visit, have you taken..

	NO	YES		NO	YES	NO	YES
B17. Any other <u>prescription hormones</u> that I haven't asked you about, for example vaginal rings (such as Femring), progestin injections (such as Depo-Provera), estrogen/testosterone combinations (such as Estratest), or vaginal creams?	1 #OHRM_1	2 #OHRMED1		1 #OHRMMO1	2	1 #OHRMVR1	2
	1 #OHRM_2	2 #OHRMED2		1 #OHRMMO2	2	1 #OHRMVR2	2
	1 #OHRM_3	2 #OHRMED3		1 #OHRMMO3	2	1 #OHRMVR3	2
	1 #OHRM_4	2 #OHRMED4		1 #OHRMMO4	2	1 #OHRMVR4	2

Since your last study visit, have you had any of the following surgeries or procedures?	NO	YES	DON'T KNOW
D4. Hysterectomy (an operation to remove your uterus or womb)?	1 (D5)	2	-8 (D5)
a. When was this performed? [PROMPT FOR YEAR EVEN IF MONTH IS UNKNOWN. ENTER -9 IF MONTH IS UNKNOWN.] #HYSTERE <div style="display: flex; align-items: center; gap: 10px;"> <div style="border: 1px solid black; padding: 5px; display: inline-block;"> M M </div> / <div style="border: 1px solid black; padding: 5px; display: inline-block;"> Y Y Y Y </div> </div> #HYSTERMO #HYSTERYR #HYSTDAT			

IF HYSTERECTOMY, COMPLETE "HYSTERECTOMY PARTICIPANT FORM" AT END OF INTERVIEW.

D5. Did you have one or both ovaries removed (an oophorectomy)?	1 (D6)	2	-8 (D6)
#OOPHORE a. Was one ovary removed or were both ovaries removed? ONE OVARY REMOVED 1 BOTH OVARIES REMOVED 2 DON'T KNOW -8 #ONEOVAR			

Now I would like to ask you about your menstrual periods.

E1. Did you have any menstrual bleeding since your last study visit? #BLEEDNG
 NO 1 (E6)
 YES 2

E2. Did you have any menstrual bleeding in the last 3 months? #BLD3MON
 NO 1
 YES 2

E3. What was the date that you started your most recent menstrual bleeding? [PROMPT FOR MONTH AND YEAR, EVEN IF DAY IS UNKNOWN. ENTER -8 FOR DAY FIELD IF UNKNOWN

		/			/				
M	M		D	D		Y	Y	Y	Y

#BLEEMO #BLEEDAY #BLEEYR] #LMPDAY

For the next two questions, I would like to ask you to think about your periods since your last study visit, during times when you were not using birth control pills or other hormone medications.

E4. Which of the following best describes your menstrual periods since your last study visit? Have they:
 [HAND RESPONDENT CARD "E"] #DESCPER
 Become farther apart? 1
 Become closer together? 2
 Occurred at more variable intervals? 3
 Stayed the same? 4
 Become more regular? 5
 DON'T KNOW -8
 NOT APPLICABLE -1 (E6)

E6. Since your last study visit, have you been pregnant? Please include live births, stillbirths, abortions, miscarriages, tubal or ectopic pregnancies. #PRGNANT
 NO 1 (F1)
 YES 2

VISIT 11

Questions B11-B16 shown below are taken from the **interim contact Visit 11 Interview** for creating the hormone use variable.

Please note that interim contact visit 11 asked the questions in a more abbreviated manner, so the code used is provided in this documentation separately.

Since your last study visit, did you take...		a. Have you taken this medication?			b. If yes, have you been taking it during the past month?	
		NO	YES		NO	YES
B11. Birth Control pills?	#BCP111	1 (B12)	2	→	1	#BCPMO111 2
B12. Estrogen pills (such as Premarin, Estrace, Ogen, etc)?	#ESTROG111	1 (B13)	2	→	1	#ESTRMO111 2
B13. Estrogen by injection or patch (such as Estraderm)?	#ESTRNJ111	1 (B14)	2	→	1	#EINJMO111 2
B14. Combination estrogen/progestin (such as Premphase or Prempro)?	#COMBIN111	1 (B15)	2	→	1	#COMBMO111 2
B15. Progestin pills (such as Provera)?	#PROGES111	1 (B16)	2	→	1	#PROGMO111 2
B16. Any other <u>prescription hormones</u> , for example vaginal rings (such as Femring), progestin injections (such as Depo-Provera), estrogen/testosterone combinations (such as Estratest), or vaginal creams	#OHRM_111	1 (C1)	2	→	1	#OHRMMO111 2

VISITS 12 – 13 and 15

Questions B14-B19 shown below, and Section C and D from the medication form are taken from the **Visit 12 Interview (these questions apply to Visit 13 and Visit 15 also)**

RX/OTC/VITAMIN/SUPPLEMENT MEDICATION FORM

INTERVIEWER-ADMINISTERED ANNUAL FOLLOW-UP FORM

Study of Women’s Health Across the Nation

ABBREVIATED HERE TO INCLUDE ONLY PERTINENT QUESTIONS:

Since your last study visit...		NO	YES	DON'T KNOW
B14.	Birth Control pills? #BCP112	1	2	-8
B15.	Estrogen pills (such as Premarin, Estrace, Ogen, etc)? #ESTROG112	1	2	-8
B16.	Estrogen by injection or patch (such as Estraderm)? #ESTRNJ112	1	2	-8
B17.	Combination estrogen/progestin (such as Premphase or Prempro)? #COMBIN112	1	2	-8
B18.	Progestin pills (such as Provera)? #PROGES112	1	2	-8
B19.	Any other <u>prescription hormones</u> that I haven’t asked you about, for example vaginal rings (such as Femring), progestin injections (such as Depo-Provera), estrogen/testosterone combinations (such as Estratest), or vaginal creams? #OHRM_112	1	2	-8

IF PARTICIPANT REPORTED TAKING ANY HORMONES SINCE HER LAST STUDY VISIT (THAT IS, “YES” TO ANY OF B14 - 19), ASK B22, OTHERWISE GO TO Q B23 ON PAGE 4.)

B22. **Since your last study visit**, were you taking some hormones and then stopped taking them? **#STOPHOR12**

NO..... 1 (B23, PAGE 4)
 YES..... 2

B22.1 In what month and year did you last take hormones? **#HORMMO12 / #HORMYR12 #HORMDAT12**

<table border="1"> <tr> <td style="width: 20px; height: 20px; text-align: center;">M</td> <td style="width: 20px; height: 20px; text-align: center;">M</td> </tr> </table>	M	M	/	<table border="1"> <tr> <td style="width: 20px; height: 20px; text-align: center;">Y</td> </tr> </table>	Y	Y	Y	Y
M	M							
Y	Y	Y	Y					

[PROMPT FOR YEAR EVEN IF MONTH IS UNKNOWN. ENTER -8 IF MONTH IS UNKNOWN.]

RX/OTC/VITAMIN/SUPPLEMENT MEDICATION FORM

INTERVIEWER-ADMINISTERED ANNUAL FOLLOW-UP FORM

Study of Women’s Health Across the Nation

ABBREVIATED HERE TO INCLUDE ONLY PERTINENT QUESTIONS:

SECTION B. RX/OTC MEDICATIONS SINCE LAST STUDY VISIT

We last interviewed you on _____[DATE]. We would like to ask you questions about what’s happened to you since then.

I would like to begin the interview by asking you some questions about prescribed and over - the - counter (OTC) medications.

I will start by asking about any pills or medicines, including patches, suppositories, injections, creams and ointments which are prescribed by your doctor or other health care provider that you have taken since your last study visit.

Since your last study visit...		NO	YES	DON'T KNOW
B14.	Birth Control pills? #BCP1	1	2	-8
B15.	Estrogen pills (such as Premarin, Estrace, Ogen, etc)? #ESTROGN1	1	2	-8
B16.	Estrogen by injection or patch (such as Estraderm)? #ESTRINJ1	1	2	-8
B17.	Combination estrogen/progestin (such as Premphase or Prempro)? #COMBEST1	1	2	-8
B18.	Progestin pills (such as Provera)? #PROGEST1	1	2	-8
B19.	Any other <u>prescription hormones</u> that I haven’t asked you about, for example vaginal rings (such as Femring), progestin injections (such as Depo-Provera), estrogen/testosterone combinations (such as Estratest), or vaginal creams? #OHRM_1	1	2	-8

IF RESPONDENT HAS TAKEN ANY HORMONES (IF YES TO ANY OF B15 - 19) ASK B20, OTHERWISE GO TO Q B22.

B20. Were you using any prescription medications containing estrogen or progestin **at the time of your last study visit?** #ESTLASTV

- NO1 (B21)
- YES2 (B22)
- DON'T KNOW-8 (B21)

IF PARTICIPANT REPORTED TAKING ANY HORMONES SINCE HER LAST STUDY VISIT (THAT IS, “YES” TO ANY OF B15 - 19), ASK B22, OTHERWISE GO TO Q B23 ON PAGE 4.)

B22. **Since your last study visit**, were you taking some hormones and then stopped taking them? **#STOPHORM**

NO..... 1 **(B23, PAGE 4)**
YES.....2

B22.1 In what month and year did you last take hormones? **#HORMMO / #HORMYR**

M	M	/	Y	Y	Y	Y
---	---	---	---	---	---	---

[PROMPT FOR YEAR EVEN IF MONTH IS UNKNOWN. ENTER -8 IF MONTH IS UNKNOWN.]

B23. **Since your last study visit**, did you take any medications that are administered **only once or twice per year**? (CIRCLE ONE.) **#MEDSONCE**

NO 1
YES.....2

B24. **In the past three months**, have you used any prescription or over the counter medications including supplements, vitamins, pain medications, laxatives, cold medications, cough medications, stomach medications, and ointments or salves? (CIRCLE ONE.) **#RXOTC3MO**

NO 1
YES.....2

IF PARTICIPANT REPORTED “YES” to B23 or B24,

- **RECORD ALL RX and SELECTED NON-RX MEDICATIONS (Page 8) ON “RX/SELECTED Non-Rx Medication Data Collection Sheet” (SECTION C)**
- **RECORD ALL OTHER OTC/VITAMINS/SUPPLEMENTS PRODUCTS ON “Over-the-Counter (OTC) / VITAMIN/Dietary SUPPLEMENT (Non Prescription) Products Data Collection Sheet” (SECTION D)**

B22. You reported taking hormones. Have you taken any hormones in the past month? #MONHORM

NO..... 1
 YES..... 2 (B23, PAGE 4)

B22.1. In what month and year did you last take hormones?

#HORMMO / #HORMYR

M	M	/	Y	Y	Y	Y	

[PROMPT FOR YEAR EVEN IF MONTH IS UNKNOWN. ENTER -8 IF MONTH IS UNKNOWN]

Bleed Form

We last interviewed you on _____ [DATE]. According to our study records, you were not yet postmenopausal (by that, we mean that you had not yet gone 12 months without bleeding). The next questions are about your menstrual periods since _____ [DATE].

Now I would like to ask you about your menstrual periods.

B1. Did you have any menstrual bleeding since _____ [DATE]? #BLEEDNG

NO..... 1 (END)
 YES..... 2

B2. Did you have any menstrual bleeding in the last 3 months? #BLD3MON

NO..... 1
 YES..... 2

B3. What was the date that you started your most recent menstrual bleeding? [PROMPT FOR MONTH AND YEAR, EVEN IF DAY IS UNKNOWN. ENTER -8 FOR DAY FIELD IF UNKNOWN.]

M	M	/	D	D	/	Y	Y

#BLEEMO #BLEEDAY #BLEEYR LMPDAY

For the next two questions, I would like to ask you to think about your periods since _____ [DATE], during times when you were not using birth control pills or other hormone medications.

B4. Which of the following best describes your menstrual periods since _____ [DATE]?
 Have they... [HAND RESPONDENT CARD "H."] #DESCPER

Become farther apart? 1
 Become closer together? 2
 Occurred at more variable intervals? 3
 Stayed the same? 4
 Become more regular? 5
 DON'T KNOW -8
 NOT APPLICABLE..... -1 (END)

B5. A menstrual cycle is the period of time from the beginning of bleeding from one menstrual period to the beginning of bleeding of the next menstrual period. Since your last study visit, what was the usual length of your menstrual cycles? #LENGCYC

LESS THAN 24 DAYS..... 1
 24-35 DAYS..... 2
 MORE THAN 35 DAYS 3
 TOO VARIABLE OR IRREGULAR TO SAY 4
 DON'T KNOW -8

SECTION C. SWAN RX/selected Non-Rx Medication Data Collection Sheet

#_#MEDNUM_	<u>Medication Details</u>				<u>V12-13 only</u> Dose – Quantity (how many times taken/time unit)	<u>V12-13 only</u> Dose – Duration (for how long)
Medication Name	Route*	Dosage Form**	Strength	Strength Unit	#	#
#MEDNAME	#MEDROA	#DOSEFORM <u>V12-13 only</u>	#MEDSTREN	#MEDUNIT	#FREQNUM	#DURNUM
					#FREQTIME D W M Y Other, specify: #FREQTIMS	D W M Y O NA #DURTIME
Collect at time of blood draw						
RX Status: 1 Written Rx 2 OTC/self 3 OTC/doctor Other_____4 (V15 only) -8 Unknown #RXSTATUS	PRN? No 1 Yes 2 #PRN	Verified by container? No 1 Yes 2 #MEDVCONT	Currently using medication? No 1 Yes 2 New since interview.....3 (V15 only) #MEDCURR	Taken within 24 hours of blood draw? No.....1 Yes.....2 No Blood Draw3 #MED24HR		

VISIT 14

Questions C2-C3 shown below are taken from the **interim contact Visit 14 Interview** for creating the MSTATUS variable. These questions are asked in a more abbreviated manner than prior follow-up visits. Questions not asked by Los Angeles (site 15) are indicated in **green**. Note: Los Angeles participants were asked the hysterectomy and oophorectomy questions on the bleeding pattern form only (next page), and not on the interim form.

C2. **Since your last study visit**, have you had a hysterectomy (an operation to remove your uterus or womb)? (CIRCLE ONE RESPONSE.) **#HYSTERE14** (Los Angeles asked on bleeding pattern form)

- No 1 (GO TO C3)
- Yes..... 2
- Don't Know-8 (GO TO C3)

C2a. **If YES**, please give date of the hysterectomy: (CHECK BOX IF DATE UNKNOWN.)

#HYSTERMO
M M

#HYSTERYR
Y Y Y Y

#HYSTDAT14
Don't Know (-8)

C3. **Since your last study visit**, did you have one or both ovaries removed (an oophorectomy)? (CIRCLE ONE RESPONSE.)

#OOPHORE14(Los Angeles asked on bleeding pattern form)

- No 1 (GO TO C4)
- Yes..... 2
- Don't Know-8 (GO TO C4)

C3a. Was one ovary removed or were both ovaries removed? **#ONEOVAR14**

- One Ovary Removed..... 1
- Both Ovaries Removed 2
- Don't Know -8

Note: The time frame of the 'past two weeks' differs from what was asked at other visits (since your last study visit).

Los Angeles did collect hormone use since your last study visit using five hormone questions. (see below)

The following question about hormone therapy refers to the past two weeks.

F1. **During the past 2 weeks**, have you used prescription hormone therapy (such as, estrogen, estrogen/progesterone pill or patch)? (CIRCLE ONE RESPONSE.)

#RXHRT2W14

- No 1 (END)
- Yes..... 2

Questions B1-B5 were taken from the **interim contact Visit 14 Bleeding Pattern form**.

At your last SWAN visit (_____), according to our study records, you were not yet postmenopausal (by that, we mean that you had not yet gone 12 months without bleeding). We would like to update your menopause stage by asking you a familiar series of questions about your bleeding patterns. The next questions are about your menstrual periods since your last study visit.

B1. Please enter today's date: #INTDATE

M	M	/	D	D	/	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---	---

B2. Did you have any menstrual bleeding **since your last study visit?** (CIRCLE ONE RESPONSE.) #BLEEDNG14

No.....1 (END FORM)
 Yes2

B3. Did you have any menstrual bleeding **in the last 3 months?** (CIRCLE ONE RESPONSE.) #BLD3MON14

No.....1
 Yes2

B4. What was the date that you started your most recent menstrual bleeding?

M	M	/	D	D	/	Y	Y	Y	Y
#BLEEMO14			#BLEEDAY14			#BLEEYR14			

[IF YOU DO NOT KNOW THE EXACT DAY, ENTER THE MONTH AND YEAR.]

LMPDAY

For the next two questions, we would like to ask you to think about your periods since your last study visit, during times when you were not using birth control pills or other hormone medications.

B5. Which of the following best describes your menstrual periods **since your last study visit?** Have they: #DESCPER14
 (CIRCLE ONE RESPONSE.)

Become farther apart?1
 Become closer together?2
 Occurred at more variable intervals?3
 Stayed the same?4
 Become more regular?5
 Don't Know8
 Not Applicable-1 (END)

VISIT 14 HORMONE QUESTIONS ASKED BY LOS ANGELES

SECOND GROUP OF QUESTIONS: THE TIME FRAME IS SINCE YOUR LAST SWAN STUDY VISIT

Your last SWAN study visit was on _____. We would like to ask you questions about what's happened to you since then.

Medication use

These questions ask about medications which are prescribed by your doctor or other healthcare provider that you have taken since your last study visit. (CIRCLE ONE NUMBER ON EACH LINE.)

<u>Since your last study visit</u> , have you taken....		NO	YES	DON'T KNOW
D1.	Birth Control pills? #BCP114	1	2	-8
D2.	Estrogen pills (such as Premarin, Estrace, Ogen, etc)? #ESTROG114	1	2	-8
D3.	Estrogen by injection or patch (such as Estraderm)? #ESTRNJ114	1	2	-8
D4.	Combination estrogen/progestin (such as Premphase or Prempro)? #COMBIN114	1	2	-8
D5.	Progestin pills (such as Provera)? #PROGES114	1	2	-8
D6.	Any other <u>prescription hormones</u> that I haven't asked you about, for example vaginal rings (such as Femring), progestin injections (such as Depo-Provera), estrogen/testosterone combinations (such as Estratest), or vaginal creams? #OHRM114	1	2	-8