Women's Health Initiative

Manuals

Volume 3: Forms

Version - July 8, 1994

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> Supported by: NIH # NO1-WH-2-2110

R:\DOC\MAN\CUR\VOL3\Vol 3, 0 - FORMS TOC and Introduction 07/08/94

REVISION HISTORY

Date 07-30-93 07-08-94 **Revision** First printing Second printing

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NUMERICAL LIST OF FORMS (ENGLISH AND SPANISH)

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NUMERICAL LIST OF FORMS - ENGLISH

Form#	For m Name	Bulletin Number	Current Version #	Date of Form	Printed by GPO	Copy at CC	Date at CC
1	Recruitment Activity Summary Discontinued 6/95				—		—
2	Eligibility Screen (Self-Administered) Discontinued 12/98	88			—		—
3	Eligibility Phone Screen Discontinued 12/98	88			—		—
4	HRT Washout Discontinued 12/98	88		_	—		—
5	Interviewer Assessment of Eligibility Discontinued 9/94	19		—	—		—
6	Final Eligibility Assessment Discontinued 12/98	88		—	—		—
7	Participation Status Discard Ver. 2 and previous versions	91	V3.0	2/14/00	Х		2/00
8	Enrollment/Randomization Log		V1.0	7/30/93		Х	8/93
10	HRT Management and Safety Interview May use Ver. 7.1 (w/labels) until supply depleates	109 103	V7.2 V7.1	6/23/03 4/09/02	X		6/03
10A	HRT Mgmt and Safety Interview-Self Administered May use Ver. 7.0 (w/labels) until supply depleates	109 101	V7.2 V7.0	6/23/03 11/15/01	X		6/03
11 *	Consent Status Discontinued 9/04	110		_	—		—
16	CaD Eligibility Review Discontinued 12/00	91		_	—		—
17	CaD Management and Safety Interview Discard Ver. 4.0 and previous versions	101	V5.0	11/15/01	X		11/01
17A	CaD Mgmt and Safety Interview-Self Administered Discard Ver. 4.0 and previous versions	101	V5.0	11/15/01	X		11/01
20	Personal Information Discontinued 12/98.	88		_	—		—
22	Participant Transfer Form Moved to Outlook Public Folders Discard Ver. 3.1 and previous versions	101	V3.2	11/09/01		Х	11/01
23	Search to Locate Participant Discard Ver. 1	91	V2.0	2/14/00		Х	2/00
24	Retention Worksheet Discard Ver 3.0	109	V3.1	2/4/03	X		2/03
25	Participant Treatment Assignment: E-Alone Discard Ver. 1 (Estrogen Plus Progestin)	110 106	V1.1 V1.0	3/1/04 7/8/02	X		3/04
28	Participant Treatment Assignment: CaD	111	V1.0	10/1/04	Х		9/04
30 *	Medical History Questionnaire Discontinued 12/98	88		—			—
31 *	Reproductive History Questionnaire Discontinued 12/98	88					

32	*	Family History Questionnaire Discontinued 12/98	88			
* De	note	es marksense scannable form				

Form#	Form Name	Bulletin	Current	Date of	Printed	Copy at	Date at
		Number	Version	Form	by	CC	CC
			#		GPO		
33 *	Medical History Update	109	V5.3	5/30/03	Х	_	6/03
	May use Ver. 5.2		V5.2	11/15/02			11/02
	Discard Ver. 5.1 and previous versions						
33D	Medical History Update (Detail)	96	V4.0	01/15/01	Х	_	1/01
	Discard Ver 3.2 and previous versions	93	V3.2	02/14/00			5/00
34 *	Personal Habits Questionnaire	88	—	—			
	Discontinued 12/98						
35 *	Personal Habits Update	109	V1.2	5/30/03	Х		6/03
	May use Ver. 1.1	88	V1.1	11/15/98			11/98
	Discard Ver. 1.0						
36	Daily Life	7	—	—	—	—	—
	Discontinued 12/94						
37 *	Thoughts and Feelings	111	V6.0	10/1/04	Х		9/04
	Discard Ver. 5 and all previous versions	88	V5.0				
38 *	Daily Life	109	V6.2	5/30/03	Х		6/03
	May use Ver. 6.1	88	V6.1	11/15/98			11/98
	Discard Ver. 6 and all previous versions						
39 *	Cognitive Assessment	107	2.0	03/01/01	Х		11/02
	Discard Ver. 1.3 and previous versions	88					
39B *	Cognitive Assessment	109	V2.1	11/14/03	Х		11/03
	(Use during 2004)	98	V2.0	3/01/01			2/01
	May use Ver. 2.0 for AVs						
40	Addendum to Medical History Update	103	V1.0	4/15/02	Х		4/02
41	Addendum to Personal Information	109	V1.1	8/20/03	Х		8/03
	Discard Ver. 1.0	107	V1.0	11/15/02			11/02
42	Observational Study Questionnaire	88	_	_		_	
	Discontinued 12/98						
43	Hormone Use	88			_	_	
	Discontinued 12/98						
44	Current Medications (Backup)	98	V4.0	5/01/01	Х		4/01
	Discard Ver. 3 and previous versions						
45	Current Supplements (Backup)	41	V2.0	7/19/95	Х		7/95
	Discard Ver. 1.2 and previous versions						
48 *	OS Follow-up Questionnaire	88	—	—			—
	Discontinued 3/01						
49	Estrogen Plus Progestin Survey	107	V1.0	3/14/03	Х		3/03
50	On-Study Bleeding	37			_		
	Discontinued 6-95						
51	HRT Diary	19			I —		—
	Discontinued 9-94						
53 *	HRT Calendar	88	V1.1	11/15/98	Х		11/98
	Discard Ver. 1.0						
54	Change of Medications	85	V3.0	3/1/98	Х		3/98
	Must use Ver. 3 if starting cyclic CEE/MPA or	80	V2.0	3/5/97			3/97
	open label MPA 5mg.						
	May use Ver. 2 otherwise.						
	Discard Ver 1						
55	Estrogen Alone Survey	111	V2.0	10/1/04	X		9/04
	Discard Ver. 1	110	V1.0	1/5/04			

* Denotes marksense scannable form

Form#	For m Name	Bulletin Number	Current Version Number	Date of Form	Printed by GPO	Copy at CC	Date at CC
60 *	Food Frequency Questionnaire	109	V1.6	5/30/03	Х		6/03
	May use Ver. 1.5	88	V1.5	11/15/98			11/98
	Discard Ver 1.4 and previous versions						
60A *	Food Frequency Questionnaire	88	V1.5	11/15/98	Х		11/98
	(for Asian Population)	83	V1.2	6/15/97			6/97
	May use Ver. 1.2						
	Discard Ver. 1.1 and previous version						
61	How to fill out the Food Questionnaire	37	V2.2	6/1/95	Х		6/95
	May use Ver. 2.1	24	V2.1	12/1/94			12/94
	Discard Ver 2 and previous version						
62	Four-Day Food Record		V2.1	9/11/95	Х		12/95
	May use Ver. 2	19	V2.0	7/8/94			9/94
	Discard Ver. 1.1 and previous version			6/1 5 /0 5			-
63	Session Data Sheet	83	V5.0	6/15/97		Х	7/97
<i>c</i> 1	Discard Ver. 4 and all previous versions	100	X 74.1	11/14/02	37		11/02
64	Individual Data Sheet	109	V4.1	11/14/03	Х		11/03
65	May use Ver. 4.0	91	V4.0	9/15/99		V	11/99
65	DM Intervention Group Status Change Discard Ver. 1	61	V2.0	3/15/96		Х	4/96
66	DM Intervention Peer Group Meeting	53	V1.0	10/18/95		Х	10/95
67	TMC Phone Call	98	V1.0	01/15/01		Х	1/01
68	Food Record Inquiry Form Discard Ver. 1	19	V2.0	7/8/94		Х	9/94
69	Keeping Track of What You Eat Discard Ver. 1	19	V2.0	7/8/94	Х		9/94
70	Facilitator Feedback Form – Participant	81	V1.2	4/18/97		Х	4/97
	May use Ver. 1.1	19	V1.1	7/8/94			9/94
	Discard Ver. 1						
71	Facilitator Feedback Form – Nutritionist Discontinued 08/01	100					
72	Summary and Action Plan	81	V1.1	4/18/97		Х	4/97
	May use Ver. 1		V1.0	7/30/93			8/93
73 *	Personalized Evaluation of Fat Intake Self- Assessment Questionnaire	108	V2.0	9/1/03	Х		9/03
	May use Ver. 1.0	104	V1.0	4/15/02			4/02
80	Physical Measurements	91	V2.1	02/14/00	Х		5/00
	May use Ver. 2.0	19	V2.0	7/8/94			
	Discard previous versions						
81	Pelvic Exam	91	V6.1	2/14/00	Х		5/00
	Discard Ver.6 and previous versions						
82	Endometrial Aspiration	91	V2.0	7/08/94	Х		9/94
	Discard Ver. 1.1 and previous versions						
83	Transvaginal Uterine Ultrasound Discard Ver. 1.1 and previous versions	19	V2.0	7/8/94	Х		9/94
84	Clinical Breast Exam Discard Ver. 3.1 and previous version	90	V4.0	9/15/99	Х		11/99
85	Mammogram	84	V3.1	12/15/97	Х		12/97
	May use Ver. 3	29	V3.0	2/17/95			2/95
	Discard Ver 2 and previous version						

* Denotes mark sense scannable for m

Form#	ŧ	For m Name	Bulletin Number	Current Version Number	Date Of Form	Printed by GPO	Copy at CC	Date at CC
86		ECG Discard Ver. 1	19	V2.0	7/8/94	Х		9/94
87		Bone Density Scan Discard Ver. 1.1 and previous version	24	V2.0	12/1/94	X		12/94
88		Oophorectomy Discontinued 2/94	7		—			
89		Breast Follow-Up Discontinued 7/97	82		—			
90		Functional Status	19	V1.0	7/8/94	Х		9/94
91		ECGLog	19	V1.0	7/8/94		Х	9/94
92		Pap Smear Discard Ver. 1	96 29	V2.0 V1.0	01/15/01 2/17/95	Х		1/01 2/95
100		Blood Collection and Processing Discard Ver. 1.4 and all previous versions	82	V1.5	7/1/97	X		7/97
101		Urine Collection and Processing Discard Ver. 1	19	V2.0	7/8/94	X		9/94
104		Frozen Specimen Shipment Discontinued 4/97	81		—			—
111		Extension (Non-HT) Consent Status	111	V1.0	10/1/04	Х		9/04
112		Extension (HT) Consent Status	111	V1.0	10/1/04	Х		9/04
113		Supplemental Consent Status	111	V1.0	10/1/04	Х		9/04
114		WHI Genetic Studies Consent Status	111	V1.0	10/1/04		Х	9/04
143	*	OS Follow-Up Questionnaire (OS Year 3) Discontinued 11/03	109					
144	*	OS Follow-Up Questionnaire (OS Year 4) Discontinued 11/03	109		—			
145	*	OS Follow-Up Questionnaire (OS Year 5)	90	V1.0	7/1/99	Х		7/99
146	*	OS Follow-Up Questionnaire (OS Year 6)	95	V1.0	7/14/00	Х		11/00
147	*	OS Follow-Up Questionnaire (OS Year 7)	106	V1.1	11/01/02	Х		10/02
148	*	OS Follow-Up Questionnaire (OS Year 8)	105	V1.0	7/15/02	Х		6/02
149	*	Supplement to OS Follow-up Questionnaire	110	V1.0	4/1/04	Х		4/04
170		Forms Order	—	Sample	Changes Quarterly			_
171		Inquiry Form	19	V1.2	7/8/94		Х	—
172		Supplies Order	—	Sample	Changes Quarterly	—		—
955		Enrollment HRT Dispensing (Backup)	19	V1.1	7/8/94		Х	

* Denotes mark sense scannable form

NUMERICAL LIST OF FORMS - SPANISH

Form#	Form Name	English Bulletin Number	Spanish Bulletin Number	Current Ver.#	Date of Form	Printed by GPO	Copy at CC	Date at C
28	Eligibility Screen (Self-Administered) Discontinued 12/98	88	_			_		—
3S	Eligibility Phone Screen Discontinued 12/98	88		—		—		_
4S	HRT Washout Discontinued 12/98	88						
5S	Interviewer Assessment of Eligibility Discontinued 9-94	19		—	—	—		—
10S	HRT Management and Safety Interview Use Ver. 7.1 (w/labels) until supply depleat	109 101		V7.2 V7.0	11/14/03 11/15/01	Х		6/03
10AS	HRT Management and Safety Interview Use Ver. 7.0 (w/labels) until supply depleated	109 101		V7.2 V7.0	11/14/03 11/15/01	Х		6/03
16S	CaD Eligibility Review Discontinued 12/00	84						
17S	CaD Management and Safety Interview Discard Ver. 4.1 and previous versions	101	99	V5.0	11/15/01	Х		11/01
17AS	CaD Management and Safety Interview Discard Ver. 4.0 and previous versions	101		V5.0	11/15/01	Х		11/01
20S	Personal Information Discontinued 12/98	88						
25S	Participant Treatment Assignment: E-Alone Discard Ver. 1 (Estrogen Plus Progestin)	110		V1.1	3/1/04	Х		3/04
28S	Participant Treatment Assignment: CaD	111		V1.0	10/1/04	Х		9/04
30S	Medical History Questionnaire Discontinued 12/98	88	—	—				
31S	Reproductive History Questionnaire Discontinued 12/98	88						
32S	Family History Questionnaire Discontinued 12/98	88	—	—		—		_
33S *	Medical History Update May use Ver. 5.2 Discard Ver. 5.1 and previous versions	109		V5.3 V5.2	5/30/03 11/15/02	Х		5/03 11/02
33DS	Medical History Update (Detail) Discard all previous versions	96	99	V4.0	1/15/01	Х		1/01
34S	Personal Habits Questionnaire Discontinued 12/98	88						
35S *	Personal Habits Update Discard Ver. 1	88	89	V1.1	11/15/98	Х		11/98
36S	Daily Life Discontinued 12/94	7						
37S	Thoughts and Feelings Discard Ver. 5 and previous versions	111 88		V6.0	10/1/04	Х		9/04
38S	Daily Life Discard Ver. 6.0 and previous versions	86		V6.1	11/01/01	X		11/01

* Denotes marksense scannable form

Form#	For m Name	English Bulletin Number	Spanish Bulletin Number	Current Ver.#	Date of Form	Printed by GPO	Copy at CC	Date at C
39S	Cognitive Assessment (Use during 2003)	107 88	89	2.0	01/01/03	X		11/02
	Discard Ver 1.3	00						
39BS	Cognitive Assessment (Use during 2004) Discard Ver. 1.1	98	99	V2.0	3/01/01	Х		02/01
40S *	Addendum to Medical History Update	103	_	V1.0	4/15/02	Х		4/02
41S	Addendum to Personal Information May use Ver. 1.0	109 107		V1.1 V1.0	8/20/03 11/15/02	Х		8/03 11/02
428	Observational Study Discontinued 12/98	88						
43S	Hormone Use Discontinued 12/98	88		—		—		
48S *	OS Follow-up Questionnaire Discontinued 3/01	88	89					
49S	Estrogen Plus Progestin Survey	107		V1.0	3/14/03	Х		3/03
51S	HRT Diary Discontinued 7/95		—	—	—	—	—	
53S	HRT Calendar	19	35	V1.0	7/8/94	Х		4/95
55S	Estrogen Alone Survey Discard Ver. 1 and pervious versions	111 110		V2.0 V1.0	10/1/04 1/5/04	Х		9/04
60S *	Food Frequency Questionnaire	109	_	V106	11/14/03	Х		11/03
	May use Ver. 1.5 Discard Ver. 1.4 and previous versions	88	89	V1.5	11/15/98			11/98
61S	How to Fill Out the Food Questionnaire	37	89	V2.2	6/1/95	Х		6/95
	May use Ver. 2.1 Discard Ver. 2 and previous version	24	35	V2.1	12/1/94			12/94
62S	Four-Day Food Record	_	89	V2.1	9/11/95	Х		12/95
	May use Ver. 2 Discard Ver. 1	19	35	V2.0	7/8/94			9/94
69S	Keeping Track of What You Eat Discard Ver 1	19	35	V2.0	7/8/94	Х		9/94
70S	Facilitator Feedback Form – Participant	81	89	V1.2	7/8/94		X	4/97
	May use Ver. 1.1 Discard Ver 1	19	35	V1.1	7/8/94			9/94
73S *	Personalized Evaluation of Fat Intake Self- Assessment Questionnaire	108		V2.0	9/1/03	Х		9/03
	May use Ver. 1.0	104		V1.0	4/15/02			4/02
143S *	OS Follow-Up Questionnaire (OS Yr 3) Discontinued 11/03	109		—	—			
144S *	OS Follow-Up Questionnaire (OS Yr 4) Discontinued 11/03	109		—	—	—	—	—
145S *	OS Follow-Up Questionnaire (OS Yr 5)	90	92	V1.0	7/1/99	Х		7/99
146S *	OS Follow-Up Questionnaire (OS Yr 6)	95	99	V1.0	11/15/00	X		11/00
147S *	OS Follow-Up Questionnaire (OS Yr 7)	106		V1.1	11/01/02	X		10/02
149S *	Supplement to OS Follow-up Quesitonnaire	110		V1.0	4/1/04	X	<u> </u>	4/04

* Denotes mark sense scannable form

WHI Manuals Volume 3

Forms

A. INTRODUCTION

1. Volume 3 - Forms

The purpose of *WHI Manuals*, *Vol. 3* is to:

- provide a record of each WHI form,
- document the purpose of each form,
- document when each form is to be used,
- provide detailed instructions for completing each form.

Each WHI form has a unique number as indicated in the Table of Contents. The forms are organized sequentially by number in this manual. In general, forms are grouped by type (for example, forms numbered 1-11 are screening forms).

The Table of Contents also indicates if you will receive copies of the forms from the Government Printing Office (GPO) or if you need to make copies of the form at your Clinical Center (CC). In general, forms that you use in large quantities and all the mark-sense forms are printed by the GPO and shipped to your CC quarterly. (See *Form 170 - Forms Order* for more information about shipping schedule.) One to two page forms you use less frequently are copied at the CC. To make copies at your CC, use the current version of the form in this manual.

General information on completing and editing forms is provided in *Vol. 2 - Procedures, Section 18 - Data Management*. Additional information on mark-sense forms is found in *Vol. 5 - Data System*. The Data System Manual also provides detailed information on scanning and key-entry of WHI forms.

2. WHI Manuals

The design and implementation of the WHI, as captured in the study Protocol, policies, procedures, interventions, and data collection instruments are described in the WHI Manuals. The primary function of these manuals is to provide common training and reference materials across all participating WHI organizations as a way of assuring the quality of the study. Each operational unit is responsible for developing its own manual describing the policies and procedures specific to that unit.

The WHI Manuals are contained in several volumes. The allocation of topics to volumes was based on the WHI staff members who would most use the various sections.

Volume 1 - Study Protocol and Policy: This manual contains the Protocol for the Clinical Trial (CT) and Observational Study (OS), the committee structure and the policies governing the scientific conduct of the study. As this is a document written for and by WHI Investigators, procedural aspects of the study that are performed by Investigators (e.g., outcomes classification) are included in this manual.

Volume 2 - Procedures: This manual describes all CC procedures and guidelines for operations other than Nutrition Intervention. As the primary CC training and reference source, this manual serves as the standard by which CC operations are assessed.

Volume 3 - Forms: All standardized study forms are displayed in the Forms Manual in numerical order. Accompanying each form is a detailed set of instructions describing who completes the form, when and how each data item should be coded, and what should happen to the form when completed.

Volume 4 - Dietary Modification Intervention: The Nutrition Intervention Manual consists of two parts: the Nutritionists' materials and the Intervention participants' materials. The Nutritionists' materials describe the procedures for carrying out the intervention sessions for the Dietary Modification (DM) component. The participants' materials contain information pertinent to each intervention session.

Volume 5 - Data System: This is a user's manual for the WHI computing system. Information is provided on the general hardware and software used as well as the specific WHI database.

Volume 6 - DXA Quality Assurance Manual for Hologic QDR-2000 Bone Densitometer: This is a user's manual for the WHI Bone Density CCs. This manual is intended as a supplement to the Hologic User's Manual.

Volume 7 - Quality Assurance Manual: This Manual provides procedures and checklists for CC QA Activities.

Volume 8 - Outcomes: This Manual provides procedures and forms for outcome ascertainment and adjudication.

B. HOW TO USE THIS MANUAL

Vol. 3 - Forms contains forms number 1-199. The forms are sorted by number in each part. Tabs are numbered in groups of 10 (e.g., 1, 10, 20, etc.).

To locate a particular form, consult the numerical list in the Table of Contents or the alphabetical list in Part D below. Turn to the appropriate numbered tab. For easy reference, the header of each page of the instructions indicates the form number and the form version number.

This manual provides the following items for each form:

- A copy of the form.
- A cover sheet detailing:
 - the form version number and date,
 - a brief description of the form,
 - when to use the form,
 - purpose of the form, and
 - general step-by step instructions for handling the form.
- An item-by-item description and instructions for each data item on the form.

When you receive updates to the Forms Manual, follow the instructions for inserting and replacing forms and instructions in the manual. When you replace a form and corresponding instructions, keep a copy of the replaced or discontinued form for reference. You may occasionally need to refer back to older versions of forms or discontinued forms when you review previous participant forms. The Table of Contents includes discontinued forms and gives discontinued dates.

Section E - Form Version History lists all forms and gives a version history for each form.

C. COMMON DATA ITEMS

The following items appear on most forms. This section gives codes and general coding guidelines and are not repeated for each form.

- 1. CC Number
- 2. Participant ID Number
- 3. Dates
- 4. Employee ID
- 5. Contact Type
- 6. Visit Type
- 7. Text Fields

1. CC Number

The Clinical Coordinating Center (CCC) assigns a unique 2-digit code number to each CC, and each CC remote site.

1.1 Sorted by ID Number

ID - CC Short Name	ID - CC Short Name
11 - BETTENDO	48 - WORCESTR
12 - BIRMING	49 - NY-CITY
13 - BOWMAN	50 - COLUMBUS
14 - BRIGHAM	51 - MEDLAN
15 - BUFFALO	53 - OAKLAND
16 - CHICAGO	54 - JACKSONV
17 - CHUVISTA	55 - TORRANCE
18 - SEATTLE	56 - MADISON
19 - ATLANTA	57 - STONYBRK
20 - EVANSTON	58 - CHAPHILL
21 - IOWACITY	59 - CHI-COOK
22 - LAJOLLA	60 - CHI-RUSH
23 - PAWTUCK	61 - CINCINNA
24 - MEMPHIS	62 - DETROIT
25 - MINNEAPO	63 - IRVINE
26 - NEWARK	64 - MIAMI
27 - PHOENIX	65 - NEVADA
28 - PITTSBUR	66 - PORTLAND
29 - TUCSON	67 - SANANTON
30 - UCDAVIS	68 - LA
42 - STANFORD	69 - FALL RIVER
43 - MILWAUKE	70 - MEM SAT
44 - GWU-DC	71 - RRC
45 - HONOLULU	72 - NEW BRUNSWICK
46 - GAINESVI	73 - DESMOINE
47 - HOUSTON	

CC Short Name - ID	CC Short Name - ID
ATLANTA - 19	LAJOLLA - 22
BETTENDO - 11	MADISON - 56
BIRMING - 12	MEDLAN - 51
BOWMAN - 14	MEM SAT - 70
BRIGHAM - 14	MEMPHIS - 24
BUFFALO - 15	MIAMI - 64
CHAPHILL - 58	MILWAUKE - 43
CHI-COOK - 59	MINNEAPO - 25
CHI-RUSH - 60	NEVADA - 65
CHICAGO - 16	NEWARK - 26
CHUVISTA - 17	NEWBRUNSWICK - 72
CINCINNA - 61	NY-CITY - 49
COLUMBUS - 50	OAKLAND - 53
DESMOINES - 73	PAWTUCK - 23
DETROIT - 62	PHOENIX - 27
EVANSTON - 20	PITTSBURGH - 28
FALL RIVER -69	PORTLAND - 66
GAINESVI - 46	RRC -71
GWU-DC - 44	SANANTON - 67
HONOLULU - 45	SEATTLE - 18
HOUSTON - 47	STANFORD - 42
IOWACITY - 21	STONYBRK - 57
IRVINE - 63	TORRANCE - 55
JACKSONV - 54	TUCSON - 29
LA - 68	UCDAVIS - 30
	WORCESTR - 48

The participant ID number is a unique, 8-digit number which identifies each woman entered into the WHI database. Clinical Centers assign the number to a woman when they first enter her name into the WHI database. See *WHI Manuals, Vol. 5 - Data System, Section 5 - Member Entry Screen* for a description of when and how to assign the number.

The format of the participant ID number is <u>CC 99999</u> - <u>A</u>

where "CC" is the 2-digit CC number of CC that first enters the woman into the database and assigns the participant ID number; "99 999" a 5-digit number, and "A" is a one-digit character.

A date is required at the beginning of each form (usually the date of contact such as date of the exam, follow-up, or event).

When recording dates, always write them in MM-DD-YY format where MM is the 2-digit month (e.g., enter 05 for May), DD is the 2digit day, and YY is the 2-digit year (e.g., 97 for 1997). Some dates require only month and year. Enter them as MM-YY. For dates that require only year, enter them as YY.

On the paper forms, this is shown as:



As an example, June 22, 1997 would be filled in:

0 6 -2 2 -9 7

Codes for dates are:

Month	Day	Year
01 - January	01	Last two digits of the year
02 - February	02	
03 - March		93
04 - April		
05 - May	30	98
06 - June	31	99
07 - July		00
08 - August		01
09 - September		etc.
10 - October		
11 - November		
12 - December		

4. Employee ID The WHI employee ID number is a 5-digit number assigned to each CC staff member. The first 2 digits are the employee's CC number and the last 3 digits represent a number unique to each CC staff member at one CC. You use only the last 3 digits on most forms. See *Vol. 5 - Data System, Section 2.2. - Managing WHI Database User Accounts* for a description of when and how to assign the number.

- **5. Contact Type** Contact type is required at the beginning of most forms. You use it to indicate the type of contact you had when you completed the particular form.
 - 1 Phone
 - 2 Mail
 - 3 Visit
 - 8 Other

Mark "1 - Phone" if you completed the form based on a phone contact. This occurs when you call the participant or the participant calls the CC.

Mark "2 - Mail" if you receive information about the participant in the mail. Examples of mail contact include when 1) the participant mails a questionnaire or medication bottle to the CC and 2) you mail a medication bottle to the participant.

Mark "3 - Visit" if you receive the information on the form during a visit with the participant.

Mark "8 - Other" if none of the above contacts apply.

- 6. Visit Type Visit type is required at the beginning of most forms. Indicate the type of contact for which the participant or the CC staff are completing the form, even if the contact is not at the scheduled contact. For example, if the participant forgets to bring the FFQ to SV1 and mails it to the CC the next week, mark "1 Screening Visit" and indicate "1" for the number of screening contact.
 - 1 Screening Contact
 - 2 Semi-Annual Contact
 - 3 Annual Contact
 - 4 Non-Routine Contact
 - 5 4-week CaD Phone Call (Form 17)
 - 6 6-week HRT Phone Call (Form 10)
 - 7 DM Intervention Session (used on Form 64 Intervention Contact Record)

Indicate the visit type as follows:

- For screening contacts, indicate the number of screening contact types as:
 - 0 for SV0
 - 1 for SV1
 - 2 for SV2
 - 3 for SV3
- For semi-annual contacts, indicate the number of the contact by indicating the year of the contact as follows:
 - 01 for semi-annual contacts 6 months following randomization,
 - 02 for semi-annual contacts 18 months following randomization,

03 - for semi-annual contacts 30 months following randomization, etc.

- For annual contacts, indicate the number of the contact by indicating the year of the contact as follows:
 01 for annual contacts 12 months following randomization,
 - 02 for annual contacts 24 months following randomization, 03 - for annual contacts 36 months following randomization, etc.
- 7. Text Fields Many forms contain text fields. The most common text fields are 1) names, 2) addresses, and 3) specify fields for questions answered "Other, specify."

Key-enter all text fields in upper/lower case format. Pay particular attention to the proper capitalization of participant's names and addressees. The text may be used to generate address labels. Use all upper case only for those fields that usually require all upper case letters (for example, the 2-letter state abbreviation).

8. Spanish Translation The self-administered and interviewer-administered forms have both an English and Spanish version. Both the English and Spanish versions of the forms have the same form number, with the Spanish version differentiated with an "S" after the form number.

Both the English and Spanish versions of the forms are key-entered into the same data entry screen. The key-entry screens for these forms contain a data item at the end of the screen in which to indicate if the form is in English or Spanish.

- If the form is an English version that you key-enter, you can leave the item blank or key-enter "1 English."
- If the form is a Spanish version, you must key-enter "2 Spanish."

You do not need to answer this question for scanned forms (for example, English and Spanish *Form 60 - FFQ*). Scanning the form will automatically tell WHILMA which version of the form you are using.

D. ALPHABETICAL LIST OF FORMS

Form Name	Form #
Blood Collection and Processing	100
Bone Density Scan	87
Breast Follow-Up	89
CaD Eligibility Review	16
Change in Medications	54
Clinical Breast Exam	84
Cognitive Assessment (Not included)	39
Consent Status	11
Contact Search to Locate Participant (Not included)	23
Current Medications (Backup)	44
Current Supplements (Backup)	45
Daily Life	38
Daily Life (1) (Discontinued 2-94)	36
DM Intervention Group Status Change	65
ECG	86
ECG Log	91
Eligibility Phone Screen	3
Eligibility Screen (Self-Administered)	2
Endometrial Aspiration	82
Enrollment HRT Dispensing (Backup)	955
Enrollment/Randomization Log	8
Facilitator Feedback Form - Nutritionist	71
Facilitator Feedback Form - Participant	70
Family History Questionnaire	32
Final Eligibility Assessment	6
Food Frequency Questionnaire	60
Food Record Inquiry Form	68
Forms Order	170
Four-Day Food Record	62 104
Frozen Specimen Shipment Functional Status	104 90
Functional Status	90
Hormone Use	43
How to Fill Out the Food Questionnaire	61 53
HRT Calendar HRT Diary (Discontinued 9-94)	53 51
HRT Management and Safety Interview	51 10
HRT Washout	4
Individual Data Sheet	64

Inquiry Form	171
Interviewer Assessment of Eligibility (Discontinued 9-94)	5
Keeping Track of What You Eat	69
Mammogram	85
Medical History Questionnaire	30
Medical History Update	33
OS Follow-up Questionnaire (Not included)	48
Observational Study Questionnaire	42
On-Study Bleeding (Discontinued 6-95)	50
Oophorectomy (Discontinued 2-94)	88
Pap Smear	92
Participation Status	7
Pelvic Exam	81
Personal Habits Questionnaire	34
Personal Information	20
Physical Measurements	80
Recruitment Activity Summary	1
Reproductive History Questionnaire	31
Retention Worksheet (Not included)	24
Session Data Sheet	63
Summary and Action Plan	72
Supplies Order	172
Thoughts and Feelings	37
Transvaginal Uterine Ultrasound	83
Urine Collection and Processing	101

E. FORM VERSION HISTORY

[To follow.]