APPENDIX C

TRAINING QA CHECKLISTS

Form #	Form Name	Ver. #	Date
511	Initial Consent Checklist	V1	04/18/97
512	HRT Consent Checklist	V1	04/18/97
513	DM Consent Checklist	V1	04/18/97
514	OS Consent Checklist	V1	04/18/97
515	CaD Consent Checklist	V1	04/18/97
516	DM/HRT Eligibility and Randomization Checklist	V1	04/18/97
517	CaD Eligibility and Randomization Checklist	V1	04/18/97
518	OS Eligibility and Enrollment Checklist	V1	04/18/97
519	Participant Status and Retention **[To Follow.]**	—	—
530	Study Medication Handling Checklist	V1	04/18/97
531	Study Medication Dispensing Checklist	V1	04/18/97
532	Study Medication Adherence Collection Checklist	V1	04/18/97
533	Data Entry for Study Medication Selection and Adherence Collection Checklist	V1	04/18/97
534	HRT and CaD Management and Safety Interview Checklist	V1	04/18/97
535	Unblinding Checklist	V1	04/18/97
540	Pathology Lab Review Checklist	V1	04/18/97
541	ECG Checklist	V1	04/18/97
542	Breast Exam Checklist	V1	04/18/97
543	Pelvic Exam and Pap Smear Checklist	V1	04/18/97
544	Endometrial Aspiration Checklist	V1	04/18/97
550	Blood Drawing and Urine Collection Checklist	V1	04/18/97
551	Blood and Urine Processing Checklist	V1	04/18/97
552	Blood and Urine Shipment Checklist	V1	04/18/97
553	Anthropometric Measurements Checklist	V1	04/18/97
554	Pulse and Blood Pressure Checklist	V1	04/18/97
555	Functional Status Measurements Checklist	V1	04/18/97
560	DM Intervention Checklist (consolidated 560A, 560B, and 560C)	V3	08/15/01
561	DM Session Observation Checklist	V2	08/15/01
562	DM Eligibility Checklist	V1	04/18/97
563	DM Post-Randomization Interview Checklist	V1	04/18/97
564	Dietary Assessment QA Checklist (consolidated 564A, 564B, and 564C)	V3	08/15/01
565	Food Frequency Questionnaire Checklist	V2	08/15/01
566	Food Record Instruction Checklist	V1	04/18/97
567	Food Record Documentation Checklist	V1	04/18/97
570	Outcomes Ascertainment Checklist	V1	04/18/97
580	Data Entry and Scanning Checklist	V1	04/18/97
581	Participant Files Checklist	V1	04/18/97

Clinical Center	___ ___	_____
Person being observed	___ ___ ___	_____
Person documenting observation	___ ___ ___	_____
Date of observation	___ ___-___ ___-___ ___	(M/D/Y)
Type of observation	___ CC QA	___ CCC QA

Time Start: _____

	Yes	No	N/A	Not Obs	See Comment
GENERAL					
Greets participant and introduces self.	___	___	___	___	___
Offers consent video for viewing.	___	___	___	___	___
Gives participant sufficient time to read the consent (if not read at home).	___	___	___	___	___
Provides an overview of the study (i.e., purpose, reason for study).	___	___	___	___	___
Covers the following key points:					
• Participation is voluntary and you may withdraw at any time.	___	___	___	___	___
• If you drop out, no one can take your place.	___	___	___	___	___
• Information is confidential, no identifying information will be released.	___	___	___	___	___
• Follow-up continues for the remainder of the study.	___	___	___	___	___
DESCRIBES SV1 ACTIVITIES					
Medications and supplements.	___	___	___	___	___
Hormone interview.	___	___	___	___	___
Physical measurements and blood draw.	___	___	___	___	___
Explains risks associated with procedures (blood draw and physical measurements).	___	___	___	___	___
Some women (over 65) may have their physical strength tested.	___	___	___	___	___
INTERVIEWING PROCESS					
Allows ample time to discuss the consent form and answers questions in a private area.	___	___	___	___	___
Uses easy-to-understand language, avoids jargon.	___	___	___	___	___
Does not rush or coerce participant to sign.	___	___	___	___	___
Reminds participant to call CC with questions or concerns.	___	___	___	___	___
Encourages questions and discussion; asks open-ended questions to assess participant's understanding.	___	___	___	___	___
Gives participant a copy of consent form after signing.	___	___	___	___	___

Clinical Center	___ ___	_____
Person being observed	___ ___	_____
Person documenting observation	___ ___ ___	_____
Date of observation	___ ___-___ ___-___ ___ (M/D/Y)	
Type of observation	___ CC QA ___ CCC QA	

Time Start: _____

	Yes	No	N/A	Not Obs	See Comment
GENERAL					
Greets participant and introduces self.	___	___	___	___	___
Offers HRT video for viewing (optional). Provides handout showing inaccuracies of the video.	___	___	___	___	___
Gives participant sufficient time to read the consent (if not read at home)	___	___	___	___	___
Provides an overview of the study (i.e., purpose, reason for study).	___	___	___	___	___
Covers the following key points:					
• Participation is voluntary and you may withdraw at any time.	___	___	___	___	___
• If you drop out, no one can take your place.	___	___	___	___	___
• Information is confidential, no identifying information will be released.	___	___	___	___	___
• The study pills (Premarin or Premarin plus Cycrin) are female hormones that are not experimental and have been used for many years by millions of women.	___	___	___	___	___
• Participants are randomized to a placebo (inactive) or active hormone group, and this is done by computer.	___	___	___	___	___
• Placement into a group is by chance (done by computer). Neither WHI clinic staff nor you will know which group you are in.	___	___	___	___	___
• You must be willing to be in either group.	___	___	___	___	___
DESCRIBES HRT EXPECTATIONS					
Take pills daily.	___	___	___	___	___
Inform CC staff of any bleeding or symptoms.	___	___	___	___	___
Come to the clinic every six months initially.	___	___	___	___	___
A 9-year commitment of yearly exams that will include mammogram, CBE, ECG, and physical measures. In addition, for some women exams will include pelvic exams and blood draws, and may also include functional and cognitive testing and endometrial aspirations.	___	___	___	___	___

	Yes	No	N/A	Not Obs	See Comment
INTERVIEWING PROCESS:					
Allows ample time to discuss the consent form and answers questions in a private areas.	___	___	___	___	___
Uses easy-to-understand language, avoids jargon.	___	___	___	___	___
Does not rush or coerce participant to sign.	___	___	___	___	___
Reminds participant to call the CC with questions or concerns.	___	___	___	___	___
Gives participant copy of consent form after signing.	___	___	___	___	___
Encourages questions and discussion; asks open-ended questions to assess participant understanding.	___	___	___	___	___
FORM 11 - CONSENT STATUS REVIEW					
Completes *Form 11 - Consent Status* appropriately.	___	___	___	___	___
Records encounter data correctly - participant name/ID, date, employee ID, contact and visit type.	___	___	___	___	___

Time End: _____ **Total Time:** _____

COMMENTS:

Clinical Center	___ ___	_____
Person being observed	___ ___ ___	_____
Person documenting observation	___ ___ ___	_____
Date of observation	___ ___-___ ___-___ ___(M/D/Y)	
Type of observation	___ CC QA	___ CCC QA

Time Start: _____

	Yes	No	N/A	Comments
1. Person being observed is appropriately certified to conduct Informed DM Consent.				
Describes Informed DM Consent				
2. Participation is voluntary and participants may drop out at any time.				
3. If participant drops out, no one can take her place.				
4. Information is confidential. Only group information released.				
5. No known risks of dietary changes.				
6. Describes risks of clinical procedures.				
Describes DM Randomization				
7. Group assignment by chance.				
8. Woman cannot choose group assignment, must be willing to be in either group.				
9. Reinforces the importance of both groups to the study.				

	Yes	No	N/A	Comments
20. Occasionally keep records of foods you eat (occasional FFQ, potential 4DFR and/or 24-Hour Recall).				
Interviewing Process				
21. Establishes rapport with participant.				
22. Good eye contact, pleasant voice.				
23. Encourages questions.				
24. Language is easy to understand, avoids jargon.				
25. Uses consistent terminology to describe Comparison and Dietary Change groups.				
26. Clarifies participants questions when necessary.				
27. Participant is allowed sufficient time to discuss the consent form and not rushed or coerced to sign.				
28. Reminds participant to call CC with questions or concerns.				
29. Thanks the participant.				
30. Consent form is reviewed and discussed in a private and comfortable area.				
31. Completes *Form 11 - Consent Status* accurately.				
32. Consent is signed before any CT-specific activities performed.				

Time End: _____ **Total Time:_____**

Clinical Center	___ ___	_____
Person being observed	___ ___ ___	_____
Person documenting observation	___ ___ ___	_____
Date of observation	___ ___-___ ___-___ ___(M/D/Y)	
Type of observation	___ CC QA	___ CCC QA

Time Start: _____

	Yes	No	N/A	Not Obs.	See Comment
GENERAL					
Greets participant and introduces self.	___	___	___	___	___
Gives participant sufficient time to read the consent (if not read at home).	___	___	___	___	___
Provides an overview of the study (i.e., purpose, reason for study).					
Covers the following key points:					
• Participation is voluntary and you may withdraw at any time.	___	___	___	___	___
• If you drop out, no one can take your place.	___	___	___	___	___
• Information is confidential, no identifying information will be released.	___	___	___	___	___
• Follow-up continues for the remainder of the study.	___	___	___	___	___
Explains risks associated with procedures (blood draw and physical measurements).	___	___	___	___	___
DESCRIBES FOLLOW-UP CONTACTS					
Health update questionnaires to be completed and mailed back to the clinic each year.	___	___	___	___	___
Keep clinic informed of any changes in address.					
Return to clinic in 3 years for procedures and measurements (repeat baseline clinical measurements).	___	___	___	___	___
INTERVIEWING PROCESS					
Allows ample time to discuss the consent form and answer questions in a private area.	___	___	___	___	___
Uses easy to understand language, avoids jargon.	___	___	___	___	___
Does not rush or coerce participant to sign.	___	___	___	___	___
Reminds participant to call CC with questions or concerns.	___	___	___	___	___
Encourages questions and discussion; asks open-ended questions to assess participant understanding.	___	___	___	___	___
Gives participant a copy of consent form after signing.	___	___	___	___	___

Clinical Center	___ ___ _____
Person being observed	___ ___ ___ _____
Person documenting observation	___ ___ ___ _____
Date of observation	___ ___-___ ___-___ ___ (M/D/Y)
Type of observation	___ CC QA ____ CCC QA

Time Start: _____

	Yes	No	N/A	Not Obs.	See Comment
GENERAL					
Sends participant consent form and appropriate information to read before the visit.	____	____	____	____	____
Gives the participant sufficient time to read the consent (if not read at home).					
Provides an overview of the study (i.e., purpose, reason for study).	____	____	____	____	____
Covers the following key points:					
• Participation is voluntary and you may withdraw at any time.	____	____	____	____	____
• If you drop out, no one can take your place.	____	____	____	____	____
• Information is confidential, no identifying information will be released.	____	____	____	____	____
• Does not affect participation in DM or HRT.	____	____	____	____	____
• Participants are randomized to a placebo (inactive) or active calcium and vitamin D group, and this is done by computer.	____	____	____	____	____
• Placement into a group is by chance (done by computer). Neither WHI staff nor you will know which group you are in.	____	____	____	____	____
• You must be willing to be in either group.	____	____	____	____	____
DESCRIBES CaD EXPECTATIONS					
Must limit Vitamin D intake to < 600 IUs; may continue to take own calcium supplements.	____	____	____	____	____
Take one pill twice a day.	____	____	____	____	____
Offers taste test.	____	____	____	____	____
A 8-year commitment of taking one pill twice a day in addition to other WHI commitments.	____	____	____	____	____
Explains visit/contact schedule (very similar to CT component she's in.)	____	____	____	____	____

Form 516 - DM/HRT Eligibility and Randomization Checklist

Clinical Center	___ ___	_____
Person being observed	___ ___ ___	_____
Person documenting observation	___ ___ ___	_____
Date of observation	___ ___-___ ___-___ ___ (M/D/Y)	
Type of observation	___ CC QA ___ CCC QA	

	Yes	No	N/A	Not Obs.	See Comment
PREPARATION					
Verifies that baseline forms are complete before randomization.	___	___	___	___	___
Reviews *Form 2/3* for items needing staff assessment (before SV3).	___	___	___	___	___
FINAL ELIGIBILITY ASSESSMENT					
Completes and key-enters *Form 6 - Final Eligibility Assessment* just before randomization (form may be initiated and partly completed at an earlier visit).	___	___	___	___	___
• Completes depression, drug and alcohol use on *Form 6* appropriately or refers to CP for further evaluation.	___	___	___	___	___
• Completes staff assessment items on *Form 6* for each study component. "Ineligible" marked *only* if participant is not already ineligible for that study component for some other reason.	___	___	___	___	___
• Marks CP Evaluation items on *Form 6* only if override is necessary and appropriate (DM/HRT).	___	___	___	___	___
Updates Current Medications at SV3.	___	___	___	___	___
Reviews *Form 2/3* with participant on day of randomization (SV3).	___	___	___	___	___
• Uses procedures and script in *Form 2/3* instructions.	___	___	___	___	___
• Marks that review was done on *Form 6*. (Marks "1 - Yes" only after review of form with participant is complete.)	___	___	___	___	___
Completes pre-randomization discussion of requirements for participation.	___	___	___	___	___
If participant is <u>not</u> eligible:					
• Prints eligibility report (optional).	___	___	___	___	___
• Notifies responsible CC staff (CP or nutritionist).	___	___	___	___	___
• Notes reason(s) for ineligibility in participant file.	___	___	___	___	___

Clinical Center	___ ___	_____
Person being observed	___ ___ ___	_____
Person documenting observation	___ ___ ___	_____
Date of observation	___ ___-___ ___-___ ___ (M/D/Y)	
Type of observation	___ CC QA ___ CCC QA	

	Yes	No	N/A	Not Obs.	See Comment
FINAL ELIGIBILITY ASSESSMENT					
Completes *Form 16 - Calcium/Vitamin D Eligibility Assessment* just before randomization.	___	___	___	___	___
• Completes interview portion of the form.	___	___	___	___	___
• Completes staff assessment items.	___	___	___	___	___
Completes pre-randomization discussion of requirements for participation and CaD taste test.	___	___	___	___	___
If participant is not eligible:					
• Prints eligibility report (optional).	___	___	___	___	___
• Notifies responsible CC staff person (CP, CM, or designee).	___	___	___	___	___
• Notes reason(s) for ineligibility in participant file.	___	___	___	___	___
RANDOMIZATION					
Performs randomization within a 4-week window on either side of the appropriate target annual visit date.	___	___	___	___	___
Performs randomization out of view of participant.	___	___	___	___	___
Updates *Form 8 - Randomization Log* immediately after randomization.	___	___	___	___	___
If participant is randomized:					
• Prints Member Study Status Report (optional).	___	___	___	___	___
• Files copy in participant file.	___	___	___	___	___
FORM 16 REVIEW					
Records encounter data correctly - participant name/ID, date, employee ID, contact and visit type.	___	___	___	___	___

COMMENTS:

_____

_____

Clinical Center	___ ___	_____
Person being observed	___ ___ ___	_____
Person documenting observation	___ ___ ___	_____
Date of observation	___ ___-___ ___-___ ___ (M/D/Y)	
Type of observation	___ CC QA ___ CCC QA	

	Yes	No	N/A	Not Obs.	See Comment
FINAL ELIGIBILITY ASSESSMENT					
Reviews and updates, required forms (if appropriate) by staff before enrollment (including *Form 2/3*).	___	___	___	___	___
Completes and key-enters *Form 6 - Final Eligibility Assessment* before enrollment.	___	___	___	___	___
If participant is <u>not</u> eligible:					
• Prints eligibility report (optional).	___	___	___	___	___
• Notifies responsible CC staff person (CP, CM, or designee).	___	___	___	___	___
• Notes reason(s) for ineligibility in participant file	___	___	___	___	___
OS ENROLLMENT					
Performs enrollment as soon as possible after all required documents received (e.g., within 1-2 days).	___	___	___	___	___
Performs enrollment out of view of participant.	___	___	___	___	___
Updates *Form 8 - Enrollment/Randomization Log* immediately after enrollment.	___	___	___	___	___
If participant <u>is</u> eligible and enrolled:					
• Prints Participant Contact Schedule (optional):	___	___	___	___	___
• Files copy in participant file.	___	___	___	___	___
• Gives copy to participant.	___	___	___	___	___
• Prints Member Study Status Report and (optional).	___	___	___	___	___
• Files copy in participant file.	___	___	___	___	___
FORM 6 REVIEW					
Records encounter data correctly - participant name/ID, date, employee ID, contact type and visit type.	___	___	___	___	___

Clinical Center	___ ___	_____
Person being observed	___ ___ ___	_____
Person documenting observation	___ ___ ___	_____
Date of observation	___ ___-___ ___-___ ___ (M/D/Y)	
Type of observation	___ CC QA	___ CCC QA

[to follow]

Clinical Center	___ ___	_____
Person being observed	___ ___ ___	_____
Person documenting observation	___ ___ ___	_____
Date of observation	___ ___-___ ___-___ ___ (M/D/Y)	
Type of observation	___ CC QA ___ CCC QA	

	Yes	No	N/A	Not Obs.	See Comment
STORAGE AREA					
Secured storage area (locked during non-business hours).	___	___	___	___	___
Area large enough to store boxes for each type of study pills.	___	___	___	___	___
Separate box or other container for HRT and CaD available for discarded study pills.	___	___	___	___	___
STUDY PILLS					
At least one carton of each study pill type in inventory.	___	___	___	___	___
Stores study pill boxes so box labels visible.	___	___	___	___	___
Bottle mailing cartons or envelopes available.	___	___	___	___	___
Records receipt of study pill shipments using Medication Inventory function in WHILMA.	___	___	___	___	___
Confirms receipt of each shipment by e-mail, phone or fax to McKesson.	___	___	___	___	___
Uses scan gun to enter box numbers.	___	___	___	___	___
Ships returned study pills to McKesson or disposes of locally using institutionally-approved procedures.	___	___	___	___	___
Study pill inventory matches current Drug Inventory report from WHILMA.	___	___	___	___	___
No outdated open-label study pill in inventory.	___	___	___	___	___

COMMENTS:

_____

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_____

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_____

Clinical Center	___ ___	_____
Person being observed	___ ___ ___	_____
Person documenting observation	___ ___ ___	_____
Date of observation	___ ___-___ ___-___ ___ (M/D/Y)	
Type of observation	___ CC QA ___ CCC QA	

	Yes	No	N/A	Not Obs	See Comment
DISPENSING STUDY PILLS (ENROLLMENT and OPEN - LABEL HRT; BLINDED HRT and CaD)					
Offers participant a non-child-resistant cap:	___	___	___	___	___
• If "yes":					
• Participant signs statement. (One time only.)	___	___	___	___	___
• Files statement in participant file. (One time only.)	___	___	___	___	___
Gives participant supporting materials as needed.	___	___	___	___	___
• Enrollment/HRT study pills:					
• 7-day pill organizer	___	___	___	___	___
• HRT Handbook	___	___	___	___	___
• HRT Calendar (during 1st year only)	___	___	___	___	___
• Open-label HRT pills:					
• Gives instructions in writing	___	___	___	___	___
• Completes *Form 54 - Change of Medications*	___	___	___	___	___
• CaD:					
• Offers choice of chewable or swallowable pills (when available)	___	___	___	___	___
• 7-day pill organizer	___	___	___	___	___
• CaD Study pill instructions	___	___	___	___	___
Verifies bottle is labeled with participant name and ID number before giving to participant.	___	___	___	___	___
Gives hints on pill-taking, such as how to remember to take pills and where to store them.	___	___	___	___	___
Reminds participant to return all bottles to CC.	___	___	___	___	___

COMMENTS:

_____

_____

_____

Clinical Center	___ ___	_____
Person being observed	___ ___ ___	_____
Person documenting observation	___ ___ ___	_____
Date of observation	___ ___-___ ___-___ ___ (M/D/Y)	
Type of observation	___ CC QA ___ CCC QA	

	Yes	No	N/A	Not Obs	See Comment
Bottle Collection and Weighing					
Prints dispensation report from WHILMA (optional).	___	___	___	___	___
• Files copy in participant file.	___	___	___	___	___
Pill-weighing scale is properly calibrated each day.	___	___	___	___	___
Weighs HRT (enrollment, blinded HRT study, and open-label) pills in scoop, after taring scale to zero.	___	___	___	___	___
Weighs CaD pills in bottle, with cap.	___	___	___	___	___
Weighs pills out of sight of participant.	___	___	___	___	___
Does not reveal pill weight or adherence percentage to participant.	___	___	___	___	___
• Collects an "estimated" pill count if participant has not physically returned the pill bottle.	___	___	___	___	___
• If participant has not returned bottles, reminds participant to return bottles at her next visit or gives mailer to participant to mail bottle.	___	___	___	___	___
Enters pill adherence rate on *Form 10 - HRT Management and Safety Interview* or *Form 17 - CaD Management and Safety Interview*.	___	___	___	___	___
Places returned HRT and CaD pills in corresponding discard box.	___	___	___	___	___
Removes or blacks out participant name on returned bottles before discarding.	___	___	___	___	___

COMMENTS:

Form 533 - Data Entry for Study Medication Selection and Adherence Collection Checklist

Clinical Center ___ ___ _____

Person being observed ___ ___ ___ _____

Person documenting observation ___ ___ ___ _____

Date of observation ___ ___-___ ___-___ ___ (M/D/Y)

Type of observation ___ CC QA ___ CCC QA

	Yes	No	N/A	Not Obs.	See Comment
HRT ENROLLMENT PILLS SELECTION					
Conducts bottle selection at SV2 (not in advance), unless medication is mailed to participant.	___	___	___	___	___
Conducts bottle selection on only one PC at a time.	___	___	___	___	___
Enters enrollment selection directly into WHILMA, or	___	___	___	___	___
Enters selection information on *Form 955* at time of selection.	___	___	___	___	___
Enters contact date in WHILMA or records current date on *Form 955*.	___	___	___	___	___
Changes "Run-in attempt #" field in WHILMA to "2" *only if* the selection is a second enrollment attempt (i.e., participant failed an initial enrollment).	___	___	___	___	___
Follows procedure:					
• Selects bottle from enrollment box.	___	___	___	___	___
• Scans bottle label in WHILMA.	___	___	___	___	___
• Scans participant ID label.	___	___	___	___	___
• Verifies that transaction is accepted by WHILMA and committed.	___	___	___	___	___
• Places participant label on bottle.	___	___	___	___	___
Completes WHILMA selection for one participant (including giving the bottle(s) to her) before beginning another bottle selection.	___	___	___	___	___
ADHERENCE DATA ENTRY					
Obtains weight (or estimated count) of remaining pills from appropriate staff person.	___	___	___	___	___
Enters correct contact date for adherence in WHILMA:					
• Uses current date if adherence is collected at visit.	___	___	___	___	___
• Uses date of phone call if participant calls to report she has run out of pills.	___	___	___	___	___

Form 534 - HRT and CaD Management and Safety Interview Checklist

Clinical Center	___ ___ _____
Person being observed	___ ___ ___ _____
Person documenting observation	___ ___ ___ _____
Date of observation	___ ___ - ___ ___ - ___ ___ (M/D/Y)
Type of observation	___ CC QA ___ CCC QA

	Yes	No	N/A	Not Obs	See Comment
PREPARATION					
Participant's file is available for quick referencing.	___	___	___	___	___
Reviews participant's file for pertinent information, such as hysterectomy status.	___	___	___	___	___
Correctly weighs pills and enters data into WHILMA to ascertain adherence (See checklists 532 and 533).	___	___	___	___	___
INTERVIEW					
Interviewer is polite, pleasant, and supportive.	___	___	___	___	___
Reads text (*Form 10 - HRT Management and Safety Interview* and/or *Form 17-CaD Management Safety Interview*) and asks questions with minimal variation from the script.	___	___	___	___	___
Helps participant clarify pill-taking behavior and provides suggestions for improvement.	___	___	___	___	___
Marks appropriate boxes on forms.	___	___	___	___	___
Updates address and phone number (at follow-up visits).	___	___	___	___	___
Allows participant to ask questions.	___	___	___	___	___
Reminds participant with uterus in first year of study to complete (*Form 53 - HRT Calendar* and bring it to next visit.	___	___	___	___	___
Acknowledges participant efforts in the study and offers supportive statements.	___	___	___	___	___
Reminds participant of next appointment date.	___	___	___	___	___
FOLLOW-UP					
Documents symptoms, safety issues or worries concerning participant and refers appropriately to CP for evaluation.	___	___	___	___	___
Correctly identifies participants who qualify for the Intensive Adherence Program (IAP) or may benefit from the IAP and refers them to appropriate CC staff.	___	___	___	___	___
Arranges for future contact attempts if current attempts to reach participant are unsuccessful.	___	___	___	___	___

Clinical Center	___ ___	_____
Person being observed	___ ___ ___	_____
Person documenting observation	___ ___ ___	_____
Date of observation	___ ___-___ ___-___ ___ (M/D/Y)	
Type of observation	___ CC QA ___ CCC QA	

	Yes	No	N/A	Not Obs	See Comment
UNBLINDING ACTIVITIES					
Informs and obtains approval of Consulting Gynecologist or PI for unblinding. (Clinic Practitioner may transmit request to Unblinding Officer.)	___	___	___	___	___
Ensures unblinding occurs only for participant safety or management of adverse effects:	___	___	___	___	___
• When step-down management of symptoms not tolerated.	___	___	___	___	___
• Heavy bleeding within first six months post-randomization.	___	___	___	___	___
• Any bleeding after first six months post-randomization.	___	___	___	___	___
• When requested by primary MD after full explanation of purpose for double-blind.	___	___	___	___	___
Ensures unblinding result is released to Consulting Gynecologist and Unblinding Officer only.	___	___	___	___	___
Ensures participant is not informed of her treatment arm, unless necessary.	___	___	___	___	___
Documents in the participant's file only that the unblinding occurred, not the treatment arm.	___	___	___	___	___
Ensures that results of any unblindings are separate from participant file and are not known to any CPs.	___	___	___	___	___
CONSULTING GYNECOLOGIST (CG) COMMUNICATIONS					
Ensures CG access to unblinding protocols and algorithms.	___	___	___	___	___
Ensures CG is not involved with adjudication of outcomes.	___	___	___	___	___
UNBLINDING OFFICER (UO) COMMUNICATIONS					
Ensures UO is not involved in the adjudication of outcomes.	___	___	___	___	___
Provides UO with answers to WHILMA unblinding questions (UO doesn't determine answers).	___	___	___	___	___
Contacts the CCC to unblind if CC UO not available.	___	___	___	___	___
Ensures that employee ID entered in the Unblinding screen is that of staff member requesting unblinding (CP or CG).	___	___	___	___	___

Clinical Center ___ ___ _____

Person being observed ___ ___ ___ _____

Person documenting observation ___ ___ ___ _____

Date of observation ___ ___-___ ___-___ ___ (M/D/Y)

Type of observation ___ CC QA ___ CCC QA

	Blood Work (Form 100)			Pelvic (Form 81)			EA (Form 82)			TVUU (Form 83)			Mammogram (Form 85)			Pap (Form 92)		
	Yes	No	N/A	Yes	No	N/A	Yes	No	N/A	Yes	No	N/A	Yes	No	N/A	Yes	No	N/A
1. Takes appropriate action based on results.																		
2. Completes form appropriately.																		
• Checks participant name on both form and lab results.																		
• Records results on form.																		
• Records staff ID and date on form.																		
3. Attaches appropriate report to form and files in chart.																		
4. Tracks unreturned reports and follows up in a timely manner.																		

Blood Work (Form 100)

Clinical Center ___ ___ _____

Person being observed ___ ___ ___ _____

Person documenting observation ___ ___ ___ _____

Date of observation ___ ___-___ ___-___ ___ (M/D/Y)

Type of observation ___ CC QA ___ CCC QA

	Yes	No	N/A	Not Obs	See Comment
PREPARATION					
MAC PC has adequate memory for day's recordings.	___	___	___	___	___
Supplies for day's ECG set out.** (See list of necessary supplies on page 3).	___	___	___	___	___
Bed is wide enough to support participant's arms (or compensatory measures taken.)	___	___	___	___	___
Provides appropriate explanations.	___	___	___	___	___
Assists participant onto table and supports her as she reclines.	___	___	___	___	___
ELECTRODE PLACEMENT (ARMS AND LEGS)					
Locates electrode sites properly on legs and arms.	___	___	___	___	___
Prepares skin by rubbing approximately 10 times with alcohol swab.	___	___	___	___	___
Marks proper electrode sites.	___	___	___	___	___
Applies electrodes with contact side facing toward head, in order of participant's RL, RA, LL, LA.	___	___	___	___	___
ELECTRODE LOCATION AND PLACEMENT (CHEST)					
Identifies sternal landmarks (manubrium with sternal notch, sternal angle and second rib.)	___	___	___	___	___
Locates and marks **V1** at right sternal border of 4th intercostal space.	___	___	___	___	___
Locates and marks **V2** at same level at left sternal border.	___	___	___	___	___
Marks a cross on midsternal line between V1 and V2.	___	___	___	___	___
Locates and marks **E** on midsternal line horizontal to intersection of 5th intercostal space and medclavicular line.	___	___	___	___	___
Marks **V6** at intersection of midaxillary line and horizontal plane of E.	___	___	___	___	___

	Yes	No	N/A	Not Obs	See Comment
CLEAN-UP					
Removes electrodes gently, cleans skin as needed, and covers participant as soon as possible.	___	___	___	___	___
Asks participant about feeling dizzy after sitting up and takes appropriate actions.	___	___	___	___	___
Assists participant safely down off bed.	___	___	___	___	___

FORM 91 - ECG LOG AND MACPC ENTRY REVIEW:					
Enters the following information onto log:					
• Date of Record	___	___	___	___	___
• First four letters of last name	___	___	___	___	___
• First Name	___	___	___	___	___
• First seven digits of participant ID number	___	___	___	___	___
• Last digit of participant ID number	___	___	___	___	___
• Correct code for baseline or follow-up record	___	___	___	___	___
• WHI Staff ID number	___	___	___	___	___
• Participant age	___	___	___	___	___
• E value	___	___	___	___	___
• V6 measurement	___	___	___	___	___
MACPC key-entry: Enters the following data into correct fields:					
• First four letters of last name in "last name" field	___	___	___	___	___
• First seven digits of participant ID number in "patient ID #" field	___	___	___	___	___
• Last digit of participant ID number in "first name" field					
• Baseline or follow-up year code in "location number" field	___	___	___	___	___
• Staff ID number in "room number" field	___	___	___	___	___
• Age in "age" field	___	___	___	___	___
• E value in "height" field	___	___	___	___	___
• V6 measurement in "weight field"	___	___	___	___	___

Clinical Center	___ ___ _____
Person being observed	___ ___ ___ _____
Person documenting observation	___ ___ ___ _____
Date of observation	___ ___-___ ___-___ ___ (M/D/Y)
Type of observation	___ CC QA

	Yes	No	N/A	Not Obs.	See Comment
CLINICAL BREAST EXAM (CBE)					
Provides explanation of CBE to participant in a reassuring manner.	___	___	___	___	___
Inspects breasts while participant is in a sitting position, then with arms over head, then with hands pressed against hips, then leaning forward.	___	___	___	___	___
Performs axillary exam on both sides.	___	___	___	___	___
Palpates each breast systematically in all four quadrants with participant lying down and arm under head.	___	___	___	___	___
Provides feedback from exam to participant.	___	___	___	___	___
BREAST SELF EXAM (BSE)					
Provides explanation of purpose and timing of BSE.	___	___	___	___	___
Provides opportunity for participant to demonstrate BSE.	___	___	___	___	___
OPTIONAL					
Provides a brief explanation of anatomy, topography, and normal variability of breast tissue.	___	___	___	___	___
Provides video for viewing.	___	___	___	___	___
Demonstrates on breast model with participant and provides opportunity for participant to practice on the nodule-simulated model.	___	___	___	___	___
Provides time for participant to ask questions.	___	___	___	___	___
Teaches and watches participant perform BSE of both breasts and axilla.	___	___	___	___	___

FORM 84 - CLINICAL BREAST EXAM REVIEW					
Records encounter data correctly: participant name / ID, date, employee ID, contact type, visit type.	___	___	___	___	___
Records summary data of CBE appropriately.	___	___	___	___	___

Clinical Center	___ ___	_____
Person being observed	___ ___ ___	_____
Person documenting observation	___ ___ ___	_____
Date of observation	___ ___-___ ___-___ ___ (M/D/Y)	
Type of observation	___ CC QA	

	Yes	No	N/A	Not Obs.	See Comment
PELVIC EXAM					
Escort is present, if appropriate.	___	___	___	___	___
Provides full explanation of procedure in a reassuring manner.	___	___	___	___	___
Ensures comfortable and correct positioning of participant.	___	___	___	___	___
Performs external inspection of vulva and perineum.	___	___	___	___	___
Repeats external inspection while participant performs valsalva maneuver.	___	___	___	___	___
Gently inserts appropriately sized warmed speculum using lubrication.	___	___	___	___	___
PAP SMEAR					
Slides properly labeled including participant name and ID# prior to exam.					
Uses spatula first, then cytobrush, or spatula alone if there is no cervix.	___	___	___	___	___
Uses proper fixative.	___	___	___	___	___
Gently removes speculum.	___	___	___	___	___
Disposes of speculum and Pap tools properly.	___	___	___	___	___
BIMANUAL EXAM					
Performs bimanual exam with warm lubricating jelly, palpating pelvic organs (uterus, tubes, ovaries) for shape, consistency, position, pain, masses, size.	___	___	___	___	___
Performs bimanual exam for descensus during valsalva maneuver.	___	___	___	___	___
Performs recto-vaginal exam if indicated for retroverted uterus.	___	___	___	___	___
FORM 81 - PELVIC EXAM AND FORM 92 - PAP SMEAR REVIEW					
Records encounter data correctly: participant name / ID, date, employee ID, contact type, visit type.	___	___	___	___	___
Records exam data appropriately.	___	___	___	___	___

Clinical Center	___ ___	_____
Person being observed	___ ___ ___	_____
Person documenting observation	___ ___ ___	_____
Date of observation	___ ___-___ ___-___ ___ (M/D/Y)	
Type of observation	___ CC QA	

	Yes	No	N/A	Not Obs.	See Comment
PARTICIPANT SAFETY AND COMFORT					
Escort is present, if appropriate.	___	___	___	___	___
Gives full explanation of procedure in a reassuring manner.	___	___	___	___	___
Screens for allergies and contraindications to medications.	___	___	___	___	___
Provides for premedications with nonsteroidal anti-inflammatory drug if needed and not contraindicated at clinic discretion.	___	___	___	___	___
Uses local anesthesia as needed at clinic discretion.	___	___	___	___	___
• Follows procedure guidelines for paracervical anesthesia (i.e., 1+ cc of 1% lidocaine at 4- and 8- o'clock positions of cervical mucosa, with more added as needed at 2- and 11-o'clock positions; and/or benzocaine 20% gel applied topically to cervix)	___	___	___	___	___
ENDOMETRIAL ASPIRATION					
Uses tenaculum and/or small lacrimal probe or dilator as needed for stenotic os.	___	___	___	___	___
Uses aseptic technique with flexible sampler.	___	___	___	___	___
Notes uterine depth.	___	___	___	___	___
Notes amount of endometrial cavity fluid, if any.	___	___	___	___	___
Makes multiple full rotations for collection.	___	___	___	___	___
Assures that participant can sit up after procedure and is comfortable.	___	___	___	___	___
Reviews instructions for post-endometrial aspiration care with participant.	___	___	___	___	___
Uses proper specimen preparation and labeling.	___	___	___	___	___
Arranges for follow-up aspiration or transvaginal ultrasound if unable to enter uterus in two attempts (one by MD).	___	___	___	___	___
FORM 82 - ENDOMETRIAL ASPIRATION REVIEW					
Records encounter data correctly: participant name / ID, date, employee ID, contact type, visit type.	___	___	___	___	___
Records exam data appropriately.	___	___	___	___	___

Clinical Center	___ ___	_____
Person being observed	___ ___	_____
Person documenting observation	___ ___	_____
Date of observation	___ ___-___ ___-___ ___ (M/D/Y)	
Type of observation	___ CC QA ___ CCC QA	

	Yes	No	N/A	Not Obs	See Comment
GENERAL					
Uses universal precautions for drawing blood.	___	___	___	___	___
• Wears disposable plastic latex gloves.	___	___	___	___	___
• Washes hands (before and after blood draw).	___	___	___	___	___
• Wears lab coat.	___	___	___	___	___
Uses appropriate blood draw chair (no wheels) to draw blood.	___	___	___	___	___
Maintains an adequate inventory of blood processing supplies.	___	___	___	___	___
• Ensures dates on blood collection tubes have not expired.	___	___	___	___	___
BLOOD DRAWING PREPERATION					
Confirms the participant has signed the Initial Consent.	___	___	___	___	___
Explains the blood draw procedure to the participant, as detailed in the Initial Consent.	___	___	___	___	___
Labels *Form 100* with participant's name/ID number.	___	___	___	___	___
Reviews type of sample to draw in the Blood Request portion of *Form 100.*	___	___	___	___	___
Clips set of blood sample labels to *Form 100.*	___	___	___	___	___
Verifies identifying information on *Form 100.*	___	___	___	___	___
Asks the participant the three questions on *Form 100* about fasting, physical exercise, and aspirin/anti-inflammatory agents.	___	___	___	___	___
Asks the participant if she bleeds easily or faints during a blood draw. If yes, follows appropriate procedures.	___	___	___	___	___
Arranges set of blood collection tubes in a test tube rack.	___	___	___	___	___
BLOOD DRAWING TECHNIQUE					
Wraps tourniquet about three to four inches above venipuncture site.	___	___	___	___	___
Leaves tourniquet on participant's arm no longer than one minute at a time.	___	___	___	___	___
Time left on arm: _____					

Clinical Center	___ ___	_____
Person being observed	___ ___	_____
Person documenting observation	___ ___	_____
Date of observation	___ ___-___ ___-___ ___ (M/D/Y)	
Type of observation	___ CC QA	___ CCC QA

	Yes	No	N/A	Not Obs	See Comment
EQUIPMENT/SUPPLIES					
Equips blood processing area with appropriate equipment/supplies:					
• Has small refrigerator, –70°C freezer, refrigerated centrifuge, sufficient counter space, certified thermometer, and sink with running water.	___	___	___	___	___
• Maintains an adequate inventory of blood processing supplies.	___	___	___	___	___
SAFETY PROCEDURES					
Processes blood in accordance with OSHA guidelines:					
• Wears goggles with side protection and a face mask (or uses a barrier shield).	___	___	___	___	___
• Wears lab coat and latex gloves.	___	___	___	___	___
• Does not store food or drink in refrigerator, freezer, or cupboards used for blood/urine equipment storage.	___	___	___	___	___
• Does not eat or drink in the processing area.	___	___	___	___	___
• Disposes of blood/urine collection tubes, stoppers, and pipette tips in a labeled biohazard discard box.	___	___	___	___	___
• Protects participant from processing area (e.g., possible splashes).	___	___	___	___	___
PREPARATION (BLOOD)					
• Is familiar with guidelines for blood processing (Vol. 2, Section 11, Figure 11.3).	___	___	___	___	___
Royal blue tubes (3):					
• Protects from natural and fluorescent white light.	___	___	___	___	___
• Stands 30 minutes to 45 minutes at room temperature for clot to form.	___	___	___	___	___
All tubes except CBC:					
• Stands no longer than 1 hour at room temperature without refrigeration or placing in an ice bath.	___	___	___	___	___

	Yes	No	N/A	Not Obs	See Comment
PREPERATION (URINE)					
Is familiar with guidelines for urine processing. (Vol. 2, Section 11.6 - Urine Processing)	___	___	___	___	___
Processes urine sample within 30 minutes of reciept.	___	___	___	___	___
Refrigerates if urine samples not processed immediately.	___	___	___	___	___
Labels centrifuge tube with urine sample number.	___	___	___	___	___
Transfers 10 ml of urine sample into centrifuge tube.	___	___	___	___	___
CENTRIFUGATION (URINE)					
Centrifuges for 10 minutes at 1,300 xg.	___	___	___	___	___
PROCESSING (URINE)					
Labels cryovials with urine bar code labels.	___	___	___	___	___
Pipettes 1.8 ml of urine to cyrovials #17, #18, and #19.	___	___	___	___	___
Checks each cyrovial to ensure correct labeling.	___	___	___	___	___
Screws caps tightly on each cyrovial.	___	___	___	___	___
Disposes of urine and collection materials in accordance with institutional guidelines.	___	___	___	___	___
FREEZING AND STORING CRYOVIALS (BLOOD / URINE)					
Places cryovials in freezer boxes, double checking cyrovials marked on *Form 100 - Blood Collection and Processing* and *Form 101 - Urine Collection and Processing*.	___	___	___	___	___
Places freezer boxes in –70°C freezer within specified times.	___	___	___	___	___
• Places storage boxes in a –20°C freezer post aliquoting if –70°C freezer not available; transfers to –70°C freezer within 2 days (48 hours post aliquoting).	___	___	___	___	___
FORM 100 - BLOOD COLLECTION AND PROCESSING **FORM 101 - URINE COLLECTION AND PROCESSING**					
Records encounter data correctly - participant name/ID, date, employee ID, contact and visit type.	___	___	___	___	___
Completes Blood/Urine Processing portion of *Form 100 / 101*	___	___	___	___	___
• Completes times on form as blood/urine is processed	___	___	___	___	___
• Marks cryovials processed on *Form 100/101* after processing.	___	___	___	___	___

COMMENTS:

Clinical Center ___ ___ _____

Person being observed ___ ___ _____

Person documenting observation ___ ___ _____

Date of observation ___ ___-___ ___-___ ___ (M/D/Y)

Type of observation ___ CC QA ___ CCC QA

	Yes	No	N/A	Not Obs	See Comment
PREPARATION					
Freezes samples at least two hours before packing them for shipment.	___	___	___	___	___
Completes Notification of WHI Shipment form.	___	___	___	___	___
Sends frozen samples to McKesson at least once per month.	___	___	___	___	___
Sends shipment on Mon.-Wed., excluding the day before a holiday.	___	___	___	___	___
Includes in the blood shipment to McKesson all aliquots for the blood samples recorded on *Form 100 - Blood Collection and Processing* and *Form 101 - Urine Collection.*	___	___	___	___	___
PROCESS					
Places freezer boxes in plastic bags.	___	___	___	___	___
• Labels freezer boxes with CC ID number, frozen shipment number, and box sequence number. (Optional)	___	___	___	___	___
Uses 10-12 lbs. of dry ice for layering on bottom, middle, and top of shipping container.	___	___	___	___	___
Stuffs newspaper in empty spaces in shipping container.	___	___	___	___	___
Includes Notification of WHI Shipment form.	___	___	___	___	___
Tapes seams of shipping container with waterproof tape.	___	___	___	___	___
Seals shipping fiberboard box with strapping tape.	___	___	___	___	___
Attaches shipment labels to shipping box.	___	___	___	___	___
Completes and attaches airbill holder to the front of shipping box.	___	___	___	___	___
Writes weight of ice in pounds (or kilograms as requested on label) on black and white class "9" label.	___	___	___	___	___
Notifies McKesson of pending shipment via e-mail or phone.	___	___	___	___	___
Includes airbill number.	___	___	___	___	___
Places shipping box in freezer if pickup is over 3 hours.	___	___	___	___	___
Maintains log of shipment numbers.	___	___	___	___	___

COMMENTS:

_____

_____

Clinical Center	___ ___	_____
Person being observed	___ ___	_____
Person documenting observation	___ ___	_____
Date of observation	___ ___-___ ___-___ ___ (M/D/Y)	
Type of observation	___ CC QA	___ CCC QA

	Yes	No	N/A	Not Obs	See Comment
PREPARATION					
Ensures equipment is available for physical measurements (scale, stadiometer, tape measure).	___	___	___	___	___
Balance-beam scale on a level, hard surface.	___	___	___	___	___
Wall-mounted stadiometer on a level, hard surface.	___	___	___	___	___
Ensures participant is wearing only light clothing (no heavy jackets or sweaters, pockets emptied).	___	___	___	___	___
Instructs participant to remove shoes.	___	___	___	___	___
Explains each procedure before it is performed.	___	___	___	___	___
HEIGHT MEASUREMENT					
Instructs participant to stand erect, back against stadiometer, eyes straight ahead, heels together, with weight equally distributed across both feet.	___	___	___	___	___
Brings carpenter square down slowly and firmly on top of head.	___	___	___	___	___
Reads measurement at end of maximum inspiration.	___	___	___	___	___
Takes measurement at eye level. (Uses foot stool, if necessary.)	___	___	___	___	___
Informs participant of measurement in feet and inches.	___	___	___	___	___
WEIGHT MEASUREMENT					
Balances the scale to zero before participant steps on scale.	___	___	___	___	___
Instructs participant to stand in the middle of the platform on the scale.	___	___	___	___	___
Adjusts counter weights until balance-beam is evenly balanced.	___	___	___	___	___
Informs participant of weight in pounds.	___	___	___	___	___
PREPARATION FOR WAIST AND HIP MEASUREMENT					
Asks participant to remove outer layer of clothing, and ensures privacy. Only non-binding undergarments are worn.	___	___	___	___	___
Verifies participant is standing erect, weight on both feet, arms at side and feet together.	___	___	___	___	___

Clinical Center ___ ___ _____

Person being observed ___ ___ _____

Person documenting observation ___ ___ _____

Date of observation ___ ___-___ ___-___ ___ (M/D/Y)

Type of observation ___ CC QA ___ CCC QA

	Yes	No	N/A	Not Obs	See Comment
PREPARATION					
Ensures equipment is available for resting pulse and blood pressure measurements (watch with second hand, tape measure, mercury sphygmomanometer, blood pressure cuffs in various sizes, stethoscope).	___	___	___	___	___
Area is free of excessive noise and activity.	___	___	___	___	___
Performs measures before potentially stressful procedures (e.g., blood draw, clinical measurements) or at least 30 min. after.	___	___	___	___	___
Performs 30 minutes after blood draw in opposite arm if measures not done before blood draw.	___	___	___	___	___
Explains procedure.	___	___	___	___	___
Measures arm for correct cuff size.	___	___	___	___	___
Instructs participant on correct posture (back supported, feet flat on floor) and correct positioning of arm (rest elbow and forearm on table or arm rest).	___	___	___	___	___
Allows participant to rest for full 5 minutes before obtaining measurements.	___	___	___	___	___
RESTING PULSE					
Palpates radial pulse with index and middle fingers.	___	___	___	___	___
Zeroes stop watch.	___	___	___	___	___
Counts pulse for 30 seconds.	___	___	___	___	___
Informs participant of pulse rate.	___	___	___	___	___
Advises and refers participant to CP if heart rate > 130 or < 40 beats/minute.	___	___	___	___	___
BLOOD PRESSURE					
Positions cuff appropriately with the inflatable bag centered over the brachial artery and the lower border above the antecubital crease.	___	___	___	___	___
Checks that manometer starts at zero.	___	___	___	___	___
Determines palpated systolic pressure (by inflating cuff and palpating pulse).	___	___	___	___	___
Deflates cuff quickly and completely.	___	___	___	___	___
Waits 30 seconds before taking the first measurement.	___	___	___	___	___
Applies the bell of the stethoscope over the brachial artery with light pressure (just below but not touching cuff or tubing).	___	___	___	___	___

Clinical Center	___ ___	_____
Person being observed	___ ___	_____
Person documenting observation	___ ___	_____
Date of observation	___ ___-___ ___-___ ___ (M/D/Y)	
Type of observation	___ CC QA ___ CCC QA	

	Yes	No	N/A	Not Obs	See Comment
PREPARATION					
Person observed is certified for task.	___	___	___	___	___
Ensures equipment is set up for functional status measurements (dynamometer, chair, stopwatch, marked gait course).	___	___	___	___	___
Ensures participant is wearing light clothing and comfortable shoes.	___	___	___	___	___
GRIP STRENGTH					
Ensures dynamometer is at second setting and dial is at zero.	___	___	___	___	___
Explains and demonstrates procedure. Instructs participant to:	___	___	___	___	___
• Flex arm 90° at elbow with forearm parallel to floor.	___	___	___	___	___
• Squeeze while lowering hand on 3-second count.	___	___	___	___	___
Determines dominant side correctly:	___	___	___	___	___
• Asks participant if she has any pain or an injury in either hand.	___	___	___	___	___
Has participant practice by doing one sub-maximal trial.	___	___	___	___	___
Performs two trials on the same side.	___	___	___	___	___
• Coaches participant to squeeze as hard as she can.	___	___	___	___	___
Resets dial to zero after each trial.	___	___	___	___	___
CHAIR STAND					
Uses standard height chair without arms; hard seat is taped appropriately.	___	___	___	___	___
Explains and demonstrates procedure. Instructs participant to:	___	___	___	___	___
• Sit with feet flat on floor and arms folded across chest.	___	___	___	___	___
• Stand once (if participant unable to stand without using arms, procedure is ended).	___	___	___	___	___

Clinical Center	___ ___ _____
Person being observed	___ ___ ___ _____
Person documenting observation	___ ___ ___ _____
Date of observation	___ ___ - ___ ___ - ___ ___ (M/D/Y)
Type of observation	___ CC QA ___ CCC QA

	Yes	No	N/A	Comments
Food Tasting				
1. Adequate equipment:				
• Refrigerator.				
• Freezer.				
• Stove.				
• Oven.				
• Microwave.				
• Sink with hot water.				
• Hot/cold serving equipment.				
• Preparation tools.				
2. Adequate space to store and prepare food.				
3. Sanitary food storage: • Cold food stored at <40° Fahrenheit.				
Group Meeting Room				
4. Appropriate size (for groups of 8-15).				
5. Adequate furniture.				
6. Comfortable: • Lighting. • Temperature.				

	Yes	No	N/A	Comments
16. Local training of DM Intervention staff completed as outlined on *Form 461 – DM Intervention Certification Request.*				
DM Intervention Staff Meetings				
17. Weekly or bi-weekly meetings held.				
18. Behavioral scientist participates regularly in staff meetings (as possible) to assist with challenging issues.				
Promoting Group Participation				
19. Maintenance sessions scheduled throughout the quarter to provide opportunities for participants to make up missed sessions as guests at another group.				
20. Participants reminded about upcoming sessions. • Describe system.				
21. Participants contacted after every missed session. • Describe system.				
22. Participants completing make-up activities for missed sessions. • Describe system.				
23. Self-monitoring tools collected, reviewed, and returned to participants before or at the next session.				

	Yes	No	N/A	Comments
• Performance Monitoring Committee (PMC) Report. • DM Adherence Analyses.				
30. Progress Notes: • Adequate for each DM participant. • Binder for each DM group kept separate from general files.				
31. Participants having "Interrupted DM Intervention" identified and followed as specified in *Vol. 2, Section 6.*				
32. *Form 7 – Participant Status* used appropriately to indicate Intervention Status. Participants who have refused all contact with DM staff: • Marked "Stop Intervention" on *Form 7 – Participant Status.* • Not assigned to a dietary group.				
QA Observations				
33. *Form 560 – DM Intervention Checklist* completed annually.				
34. DM Intervention Observation Schedule for each Group Nutritionist.				
35. Observe and provide feedback to each Group Nutritionist: • During training. • During first month facilitating Dietary Change group. • At least annually.				
36. *Form 561* completed and stored.				

Clinical Center	___ ___ _____
Person being observed	___ ___ _____
Person documenting observation	___ ___ _____
Date of observation	___ ___-___ ___-___ ___ (M/D/Y)
Type of observation	___ CC QA ___ CCC QA

Session Foundation & Framework:
The principles of group facilitation and adult learning provide the foundation for WHI DM Intervention sessions. The session framework provides a structure for delivering sessions using these principles. The Nutritionist uses these principles within the session framework to foster program participation and adherence to the WHI DM Intervention goals.

Session Observations:
The observer's primary role is to look for the use of group facilitation and adult learning principles within the session framework to foster program participation and adherence to the WHI DM Intervention goals.

Session: ____ Number attending: ____

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Group Facilitation & Adult Learning Principles					
1. Room arrangement fosters group discussion.	❑	❑	❑	❑	❑
Example: _____					
2. Assesses the group interest in topic.	❑	❑	❑	❑	❑
Example: _____					
3. Assesses group knowledge and experience.	❑	❑	❑	❑	❑
Example: _____					
4. Makes discussions and activities relevant to group members' life experiences.	❑	❑	❑	❑	❑
Example: _____					
5. Limits lecture and avoids scripts.	❑	❑	❑	❑	❑
Example: _____					

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
16. Encourages group members to support each other.	❑	❑	❑	❑	❑

Example: _____

Communication & Enhancing Motivation

17. Asks permission before providing information/giving advice.	❑	❑	❑	❑	❑

Example: _____

18. Provides choice/options.	❑	❑	❑	❑	❑

Example: _____

19. Explains materials and responds to questions clearly.	❑	❑	❑	❑	❑

Example: _____

20. Uses open-ended questions throughout.	❑	❑	❑	❑	❑

Example: _____

21. Demonstrates reflective listening throughout.	❑	❑	❑	❑	❑

Example: _____

22. Periodically uses affirmations.	❑	❑	❑	❑	❑

Example: _____

23. Periodically summarizes group discussion.	❑	❑	❑	❑	❑

Example: _____

24. Explores pros and cons (ambivalence), if applicable.	❑	❑	❑	❑	❑

Example: _____

Providing Feedback to Group Facilitator

1. Ask facilitator to share her overall impression of how the session went.
2. Provide your overall impression of how the session went.

   Example: _____

3. Ask facilitator to share her impression of what went well.
4. Provide specific examples to illustrate strengths. (At least 3)

   Example: _____

   _____

   _____

5. Ask facilitator to share her impression of what was challenging or what she might like to improve.
6. Provide specific examples of areas that could be improved. (No more than 3)

   Example: _____

   _____

   _____

7. Ask for input from facilitator regarding feedback. (What do you think? Is there anything you would like to add?)

Comments:

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Clinical Center	___ ___ _____
Person being observed	___ ___ ___ _____
Person documenting observation	___ ___ ___ _____
Date of observation	___ ___-___ ___-___ ___ (M/D/Y)
Type of observation	___ CC QA ___ CCC QA

Time Start: _____

	Yes	No	N/A	Comments
1. Person being observed is appropriately certified to conduct DM Eligibility assessment.				
Review DM Adherence Related Issues				
2. Reviews motivation for joining DM.				
3. Clarifies that DM is not a weight loss program.				
4. Reviews history of weight cycling.				
5. Reviews 4DFR:				
5.1 Looks for unusual eating patterns.				
5.2 Estimates daily servings of fruits/vegetables and grains.				
5.3 Assesses 4DFR completeness:				
- minimum 3 days				
- legible				
- food descriptions complete				
- serving sizes reasonably estimated				

	Yes	No	N/A	Comments
Review DM Comparison Group Expectations				
14. Eat what you normally do, no changes required, do not meet with nutritionist.				
Review DM Dietary Change Group Expectations				
15. Change eating patterns to greatly decrease fat and increase fruits/vegetables/grains.				
16. Schedule and length of group sessions - 1 year and maintenance.				
17. Availability to attend group sessions.				
- Flexibility to attend group sessions.				
- Availability during first year.				
- Plans for extended traveling.				
- Transportation available and distance to travel to CC.				
18. Willingness to attend group sessions.				
18.1 Willingness to make up missed group sessions.				
Review DM Randomization				
19. Determines participant's willingness to be randomized into either group.				
20. Appropriately screens participants.				

Form 563 - DM Post-Randomization Interview Checklist

Clinical Center ___ ___ _____

Person being observed ___ ___ ___ _____

Person documenting observation ___ ___ ___ _____

Date of observation ___ ___-___ ___-___ ___ (M/D/Y)

Type of observation ___ CC QA ___ CCC QA

Time Start: _____

	Yes	No	N/A	Comments
1. Person being observed is appropriately certified to conduct DM Post-Randomization Interview.				
Introduction				
2. Welcomes participant to the Dietary study.				
3. Gives baseline Welcome Packet to participant and briefly reviews contents with participant.				
4. Appropriate materials included in the baseline Welcome Packet.				
If Randomized to Dietary Change Group				
5. Presents randomization assignment without personal bias.				
6. Tells participant to not reveal her randomization assignment to clinic staff unless asked.				
7. Describes next phase of participation.				
8. Reviews participant availability (day/eves) for DM sessions.				
9. Assigns participant to DM group or adds to DM waiting list.				

Form 564 - Dietary Assessment QA Checklist

Clinical Center	___ ___ _____
Person being observed	___ ___ ___ _____
Person documenting observation	___ ___ ___ _____
Date of observation	___ ___-___ ___-___ ___ (M/D/Y)
Type of observation	___ CC QA ___ CCC QA

	Yes	No	N/A	Comments
WHI Manuals				
1. Complete and up-to-date.				
2. Easily accessible for staff certified for FFQ activities. Specify Volumes: _____				
3. Describe system used to distribute study information/updates (e.g., WHI Manual Bulletins, Inquiry Reporting System (IRS) etc.) to staff certified for FFQ.				
4. Locally developed participant materials submitted to Participant Material Review Mailbox in Outlook prior to use with participants. Refer to *Vol. 1 – Study Policies, Section 3.8 – Participant Materials.*				
Training and Certification of FFQ Staff				
5. Local training of FFQ staff completed as outlined on *Form 465 – Food Frequency Questionnaire Certification* (including annual re-certification).				
6. *Form 565 – Food Frequency Questionnaire Checklist* completed for all staff certified for FFQ: • At training. • Within two months after certification.				
7. Describe system used to monitor the quality of FFQ review for annual re-certification:				
FFQ Review				
8. Describe system to ensure FFQ administered in standardized way, consistent with baseline administration.				

Form 565 - Food Frequency Questionnaire Checklist

Clinical Center	___ ___ _____
Person being observed	___ ___ ___ _____
Person documenting observation	___ ___ ___ _____
Date of observation	___ ___-___ ___-___ ___ (M/D/Y)
Type of observation	___ CC QA ___ CCC QA

	Yes	No	N/A	Comments
1. Person being observed is appropriately certified to administer and/or edit the FFQ.				
2. Administers FFQ in a standardized way, consistent with baseline procedures.				
FFQ Administration (Required only for CCs that administer the FFQ in the clinic - group or individual instruction.)				
3. Follows procedures specified in the WHI Manuals (*Vol. 3, Form 60*) to introduce the FFQ to the participant.				
4. Reviews *Form 61 – How to Complete the Food Questionnaire.*				
5. Locally developed materials, in addition to *Form 61 – How to Complete the Food Questionnaire*, submitted to Participant Material Review mailbox in Outlook prior to use with participants. Refer to *Vol. 1 - Study Policies, Section 3.8 - Participant Materials.*				
6. Answers participant questions in a non-leading manner.				
Pre-Scan Edit (Includes cursory review.)				
7. Follows procedures specified in the WHI Manuals (*Vol. 3, Form 60* and *Vol. 2, Section 10*).				
8. Reviews the front page (shaded area) for accuracy and completion of data specified.				

Form 566 - Food Record Instruction Checklist

Clinical Center	___ ___ _____
Person being observed	___ ___ ___ _____
Person documenting observation	___ ___ ___ _____
Date of observation	___ ___-___ ___-___ ___ (M/D/Y)
Type of observation	___ CC QA ___ CCC QA

Time Start: _____

	Yes	No	N/A	Comments
Preparation				
1. Person being observed is appropriately certified to perform Food Record Instruction.				
2. Instruction conducted in a private and comfortable area.				
3. Participant's take-home packets available.				
4. VCR equipment set up and ready for use.				
5. Food models and calendar available.				
Instructional Process				
6. Shows WHI instructional video "Keeping Track of What You Eat."				
7. Distributes the 4DFR and "Keeping Track of What You Eat" to participants.				
8. Answers participant questions clearly.				
9. Has participants write a practice (sample) meal and reviews it for adequacy of completion.				

Form 567 - Food Record Documentation Checklist

Clinical Center	___ ___ _____
Person being observed	___ ___ ___ _____
Person documenting observation	___ ___ ___ _____
Date of observation	___ ___ - ___ ___ - ___ ___ (M/D/Y)
Type of observation	___ CC QA ___ CCC QA

Time Start: _____

	Yes	No	N/A	Comments
Documentation of 4DFR				
1. Person being observed is appropriately certified to perform 4DFR documentation.				
2. 4DFR is documented in a private and comfortable area.				
3. Reviews Vitamin and Mineral Supplements (pg. 4) for completeness: 3.1. "Yes" Box checked and remainder of page completed if participant took a supplement. 3.2. Supplements recorded on the days taken in the daily record. 3.3. "No" Box checked if the participant did not take a supplement.				
4. Reviews General Questions (pg. 5) for completeness: 4.1. Verifies (writes NA and initials) those items that the participant does not use. 4.2. Information is complete for each item listed.				
5. Uses the WHI 4DFR Documentation Checklist and obtains the designated information for each food item listed.				
6. Obtains complete food descriptions including brand names when appropriate.				

	Yes	No	N/A	Comments
Interviewing Process				
17. Establishes rapport with the participant.				
18. Good eye contact, pleasant voice.				
19. Encourages questions.				
20. Allows adequate time for participant to respond.				
21. Clarifies participants responses when necessary.				
22. Asks open-ended, non-leading questions.				
23. Remains neutral in questions and responses.				
24. Rephrases questions if the participant does not appear to understand the question.				
25. Records participant's responses accurately.				
26. Uses food models and ruler appropriately.				
27. Thanks the participant and reaffirms her importance to the study.				
Administrative Procedures				
28. Uses a different colored pen than the participant.				

Clinical Center	___ ___	_____
Person being observed	___ ___	_____
Person documenting observation	___ ___	_____
Date of observation	___ ___-___ ___-___ ___ (M/D/Y)	
Type of observation	___ CC QA ___ CCC QA	

	Yes	No	N/A	Not Obs	See Comment
FORMS COMPLETION					
Reviews forms for completeness.	___	___	___	___	___
Demonstrates familiarity with forms [33/33D; 120 - 131].	___	___	___	___	___
Identify appropriate details of medical history and health provider contacts that need clarification.	___	___	___	___	___
Fills in blanks or documents why not answered.	___	___	___	___	___
Makes corrections appropriately.	___	___	___	___	___
Refers questions appropriately to Clinic Practitioner. (SAE or safety issues)	___	___	___	___	___
ASCERTAINMENT PROCEDURES					
Knows what answers necessitate outcomes investigation.	___	___	___	___	___
Requests general medical release from participant. (Recommend multiple copies be obtained.)	___	___	___	___	___
Runs the outcomes analysis program in WHILMA to identify the type of outcome that has occurred. [DC]	___	___	___	___	___
Generates the request for Medical Records Information report. [DC]	___	___	___	___	___
Identifies all of the document source(s), such as hospital, physician's office, or other facility recorded on *Form 33/33D*.	___	___	___	___	___
Requests all the documents required for each identified outcome.	___	___	___	___	___
Follows up on outstanding documentation request.	___	___	___	___	___
Receives requested documents:					
• Matches the documents with the document types that were requested.	___	___	___	___	___
• Compares documents received to study identifying data to assure accurate identification of participant.	___	___	___	___	___
• Reviews documentation for legibility. (Re-request if necessary.)	___	___	___	___	___

Clinical Center	___ ___	_____
Person being observed	___ ___	_____
Person documenting observation	___ ___	_____
Date of observation	___ ___-___ ___-___ ___ (M/D/Y)	
Type of observation	___ CC QA	___ CCC QA

	Yes	No	N/A	Not Obs	See Comment
DATA ENTRY WORK AREA					
Keeps forms with participant file during entry process (except mark-sense forms and/or lab forms waiting for results).	___	___	___	___	___
Maintains clearly labeled areas in data entry work station for:	___	___	___	___	___
• Files or forms needing to be reviewed.	___	___	___	___	___
• Files or forms ready to be key-entered or scanned.	___	___	___	___	___
• Files or forms ready to be refiled in participant file area.	___	___	___	___	___
Stores files in the appropriate location according to their stage in the data entry process.	___	___	___	___	___
FILE PROCESSING					
Maintains efficient and organized method of routing files and forms with data problems to appropriate clinical staff for resolution and then back to data entry.	___	___	___	___	___
Resolves data problems before key-entering or scanning form.	___	___	___	___	___
Does not re-scan FFQs after an encounter is created.	___	___	___	___	___
Runs eligibility determination on all participants after each screening visit.	___	___	___	___	___
Enters at least 80% of all self-administered forms within two weeks of receipt (from Timeliness Report).	___	___	___	___	___
KEY ENTRY					
Enters common data items (encounter information) correctly from form.	___	___	___	___	___
Marks first page of form with initials to indicate form is key-entered.	___	___	___	___	___

Form 581 - Participant Files Checklist

Clinical Center ___ ___ _____

Person being observed ___ ___ ___ _____

Person documenting observation ___ ___ ___ _____

Date of observation ___ ___-___ ___-___ ___ (M/D/Y)

Type of observation ___ CC QA ___ CCC QA

	Yes	No	N/A	Not Obs	See Comment
STORAGE OF PARTICIPANT FILES					
File room and files easily accessible to CC staff.	___	___	___	___	___
File room and files secure from non-WHI staff.	___	___	___	___	___
File room neat and organized.	___	___	___	___	___
Participant files easy to locate by CC staff.	___	___	___	___	___
Participant files confined to only a few locations within CC.	___	___	___	___	___
Outguides used to indicate location of files missing from file room.	___	___	___	___	___
Describe filing system used (numerical, terminal digit, alphabetical). _____					
Describe system for filing eligible and non-eligible participants. _____					
LOOSE SHEETS (Forms temporarily stored outside participant file.)	___	___	___	___	___
Stored in accessible, logical, and secure manner.	___	___	___	___	___
Loose forms not left where participants can view them.	___	___	___	___	___
System in place to locate specific forms that are missing from the participant's file.	___	___	___	___	___
STORAGE OF OTHER FORMS (e.g., DM Intervention or Outcomes forms.)					
Stored in secure and logical manner.	___	___	___	___	___
Can be accessed only by authorized staff	___	___	___	___	___
Boxes or other storage media for archived forms are clearly labeled to identify contents.	___	___	___	___	___
CC has system for quickly locating and retrieving a participant's stored forms.	___	___	___	___	___

Clinical Center	___ ___ _____
Participant ID	___ ___-___ ___ ___ ___ ___-___
Person documenting observation	___ ___ ___ _____
Date of observation	___ ___-___ ___-___ ___ (M/D/Y)
Type of observation	___ CC QA ___ CCC QA

Study Component(s): **HRT** _____ **DM** _____ **CaD** _____ **OS** _____

	Yes	No	N/A	No Obs.	See Comment
FORMS REVIEW					
Correct participant name and ID number on first page of every form.	____	____	____	____	____
All forms in file belong to correct participant	____	____	____	____	____
Corrections made appropriately (e.g., neatly crossed out, initialed, and dated).	____	____	____	____	____
Form 11 contact date matches date corresponding consent form was signed.	____	____	____	____	____
Specimen/test results in file. Dates transcribed and results abstracted properly onto:					
• *Form 81 - Pelvic Exam*	____	____	____	____	____
• *Form 82 - End. Aspiration*	____	____	____	____	____
• *Form 83 - TVUU*	____	____	____	____	____
• *Form 84 - CBE*	____	____	____	____	____
• *Form 85 - Mammogram*	____	____	____	____	____
• *Form 89 - Breast Follow-Up*	____	____	____	____	____
• *Form 92 - Pap Smear*	____	____	____	____	____
• *Form 100 - Blood Collection and Processing*	____	____	____	____	____
Follow-up of abnormal lab/test results documented appropriately.	____	____	____	____	____

FILE REVIEW					
In-person and phone contacts with participants are documented in contact notes or on forms.	____	____	____	____	____
Treatment and referrals documented in contact notes.	____	____	____	____	____
DM Progress Notes completed with sufficient frequency and detail.	____	____	____	____	____

Form 583 - Participant File Audit - On Site Checklist

Clinical Center ___ ___ _____

Person being observed ___ ___ ___ _____

Person documenting observation ___ ___ ___ _____

Date of observation ___ ___-___ ___-___ ___ (M/D/Y)

Type of observation ☐ CC QA ☐ CCC QA

Study Component(s) **DM** ____ **HRT** ____ **CaD** ____ **OS** ____

	Yes	No	N/A	Not Obs	See Comment
FILE REVIEW					
Appropriate forms present for study component(s).	____	____	____	____	____
All forms in file belong to the correct participant.	____	____	____	____	____
Forms are filed in systematized order. (If CC has a documented order that forms are filed in the file, obtain a copy.)	____	____	____	____	____
Specimen reports attached to appropriate forms (e.g., blood, mammogram, Pap, endometrial aspiration, etc.)	____	____	____	____	____
Files/forms do not contain definitive unblinding information (e.g., DM treatment assignment blacked out; DM intervention forms filed elsewhere; HRT unblinding not revealed).	____	____	____	____	____
Contact notes in file.	____	____	____	____	____
DM progress notes stored in file.	____	____	____	____	____
DM Intervention progress notes stored in file.	____	____	____	____	____
Outcomes documents kept separate from main participant file.	____	____	____	____	____
FORMS REVIEW					
Correct participant name and ID number (using barcode label) on first page of every form, including lab results.	____	____	____	____	____
Contact dates, screening visit type and number, and employee ID completed correctly.	____	____	____	____	____
Corrections made appropriately (e.g., neatly crossed out, initialed and dated).	____	____	____	____	____
Ink used on non-mark-sense forms.	____	____	____	____	____
Consent forms present and complete for relevant study components.	____	____	____	____	____
Form 11 contact date matches date corresponding consent form signed.	____	____	____	____	____
Date of consent precedes date of appropriate procedures.	____	____	____	____	____

COMMENTS:

_____

_____

Form 590 - Interviewing and Forms Checklist

Clinical Center	___ ___	_____
Person being observed	___ ___	_____
Person documenting observation	___ ___	_____
Date of observation	___ ___-___ ___-___ ___ (M/D/Y)	
Type of observation	___ CC QA ___CCC QA	

	Yes	No	N/A	Not Obs	See Comment
PREPARATION					
Prepares for interview by ensuring appropriate supplies and forms are available.	____	____	____	____	____
Conducts interview in an organized, neat and preferably private area.	____	____	____	____	____
INTERVIEW					
Appears familiar with forms used.	____	____	____	____	____
Follows appropriate script.	____	____	____	____	____
Keeps interview on track by presenting questions at a brisk, regular pace.	____	____	____	____	____
Speaks clearly, and uses appropriate inflection when speaking.	____	____	____	____	____
Maintains eye contact.	____	____	____	____	____
Uses easy-to-understand language and avoids jargon.	____	____	____	____	____
Encourages discussion; asks open-ended questions.	____	____	____	____	____
Probes for information appropriately.	____	____	____	____	____
Listens carefully to participant's questions and concerns.	____	____	____	____	____
Establishes rapport with participant.	____	____	____	____	____
Reduces the chance of bias by maintaining a neutral attitude.	____	____	____	____	____
Documents relevant information in contact notes.	____	____	____	____	____
FORM REVIEW					
Assures that correct participant ID barcode is affixed to front of form.	____	____	____	____	____
Records encounter data correctly: date, employee ID, contact and visit type.	____	____	____	____	____
Completes appropriate form(s) at time of interview.	____	____	____	____	____
Reviews interview forms for completeness.	____	____	____	____	____
Reviews self-administered forms for general completeness of all pages.	____	____	____	____	____

Clinical Center	___ ___	_____
Person being observed	___ ___	_____
Person documenting observation	___ ___	_____
Date of observation	___ ___-___ ___-___ ___ (M/D/Y)	
Type of observation	___ CC QA ___ CCC QA	

Time Start: _____ **SV#**_____

	Yes	No	N/A	Not Obs	See Comment
FILE PREPARATION					
Reviews file before visit. Ensures file contains all forms needed for visit.	____	____	____	____	____
Lab results (blood, Pap, mammogram, etc.) available in participant's file.	____	____	____	____	____
Signed General Medical Release form in participant file or blank form included.	____	____	____	____	____
Barcode labels available.	____	____	____	____	____
Results of recent database eligibility determination in file.	____	____	____	____	____
SCREENING VISIT ACTIVITIES					
Starts visit activities within 10 minutes of participant's arrival.	____	____	____	____	____
Explains flow of visit to participant.	____	____	____	____	____
Ensures participant has signed appropriate consent form before performing any procedures.	____	____	____	____	____
Reviews self-administered forms for completeness.	____	____	____	____	____
Reviews any abnormal test results and makes appropriate referral.	____	____	____	____	____
Provides appropriate materials, handouts, etc.	____	____	____	____	____
Provides appropriate study forms to be completed.	____	____	____	____	____
EXIT INTERVIEW					
Reviews CC screening visit checklist (optional); confirms all necessary tasks are completed.	____	____	____	____	____
Discusses future involvement with WHI and what to expect at next visit or contact.	____	____	____	____	____
Schedules next CC visit.	____	____	____	____	____
Participant visit flows smoothly. (Participant not left alone for long periods of time; transitions between procedures are smooth and efficient.)	____	____	____	____	____

Time End: _____ **Total Time of Visit:** _____

Clinical Center	___ ___	_____
Person being observed	___ ___ ___	_____
Person documenting observation	___ ___ ___	_____
Date of observation	___ ___-___ ___-___ ___ (M/D/Y)	
Type of observation	___ CC QA ___ CCC QA	

Semi-Annual Visit #_____ **Annual Visit #_____**

Time Start: _____ DM_____ HRT_____ CaD_____ OS_____

	Yes	No	N/A	Not Obs	See Comment
FILE PREPARATION					
Reviews file before visit. Ensures file contains all forms needed for visit.	____	____	____	____	____
Lab results (blood, Pap, mammogram, etc.) available in participant's file.	____	____	____	____	____
Barcode labels available.	____	____	____	____	____
FOLLOW-UP VISIT ACTIVITIES					
Conducts follow-up visit within target window (± 2 weeks from target date).	____	____	____	____	____
Starts visit activities within 10 minutes of participant's arrival.	____	____	____	____	____
Explains flow of visit to participant.	____	____	____	____	____
Reviews self-administered forms for completeness.	____	____	____	____	____
Obtains signature on new General Medical Release form(s).	____	____	____	____	____
Lab results available provided to participant and/or PCP. Makes referral for abnormals.	____	____	____	____	____
Provides appropriate materials, handouts, etc.	____	____	____	____	____
EXIT INTERVIEW					
Reviews CC visit checklist (optional) and visit plan; confirms all necessary tasks are completed.	____	____	____	____	____
Discusses future involvement with WHI and what to expect at next visit or contact.	____	____	____	____	____
Schedules next CC visit.	____	____	____	____	____
Participant visit flows smoothly. (Participant not left alone for long periods of time; transitions between procedures are smooth and efficient.)	____	____	____	____	____

Time End:_____ **Total Time of Visit:_____**

Clinical Center	___ ___	_____
Person being observed	___ ___ ___	_____
Person documenting observation	___ ___ ___	_____
Date of observation	___ ___-___ ___-___ ___ (M/D/Y)	
Type of observation	___ CC QA ___ CCC QA	

	Yes	No	N/A	Not Obs	See Comment
TRACKING MAIL CONTACTS (1-4)					
Records promptly receipt of OS forms returned by mail.	___	___	___	___	___
Key enters promptly address changes provided by Post Office resulting from Contacts 1-4.	___	___	___	___	___
TRACKING TELEPHONE CONTACTS (5-7)					
Makes telephone Contacts 5-7 within defined timeframe.	___	___	___	___	___
Promptly key enters address changes provided by respondent during Contact 5.	___	___	___	___	___
Promptly mails new packet of forms if address correction is indicated during telephone Contact 5.	___	___	___	___	___
Promptly records completion of forms administered by phone to indicate that further contact is unnecessary.	___	___	___	___	___
Completes suggested minimum number of attempted contacts before moving on to next Contact level.	___	___	___	___	___
INTERVIEWING PROCESS					
Prepares for interview by determining which Contact (5, 6, or 7) is to be made.	___	___	___	___	___
Uses form appropriate to Contact level:					
• Contact 5: *Form 33, Form 48*	___	___	___	___	___
• Contact 6: *Form 33, Form 48*	___	___	___	___	___
• Contact 7: *Form 40*	___	___	___	___	___
Obtains verbal consent to do interview.	___	___	___	___	___
Follows suggested script appropriate to Contact level (5, 6, or 7).	___	___	___	___	___