

## **SECTION 2**

### **CLINICAL CENTER GUIDELINES**

#### **INTRODUCTION**

The Women's Health Initiative (WHI) Clinical Centers (CCs) have been selected, in part, because of their experience in clinical research. These guidelines are offered to help investigators at both the Vanguard Clinical Centers (VCCs) and the New Clinical Centers (NCCs) to set up satellite or remote sites and maintain their CC operations. This section can be used as a checklist to ensure that at least the essential elements are in place. It may also be helpful for staff training.

## 2.1 Clinical Center Facilities

Adequate and appropriate facilities are important in the overall operation of the CC. Adequate facilities are also important in maintaining participant adherence.

### 2.1.1 Clinic Area

#### 2.1.1.1 Required Clinic Areas (Required)

- **Interview areas or rooms:** These should be convenient, private, attractive, and well-lit rooms or cubicles used for conducting individual interviews with the participants.
- **Classroom:** This should be a large, attractive area (comfortable for 20 people) for teaching and facilitating group sessions for the First Screening Visit (SV1) and intervention group sessions, conducting CC staff meetings, accommodating mass-mailing operations, and for use in any other activity where a large room is needed. All cooking supplies and a sink should be located either nearby or in the classroom.
- **Participant file area:** This must be a secure area. Any material that is identified with a participant's name should be locked or in a secure area when not in use to maintain confidentiality of records.
- **Medication storage area:** This should be a secure room with space for unpacking and packing shipments of medications, holding the pill scale, and storing supplies of Hormone Replacement Therapy (HRT) and Calcium/Vitamin D (CaD) medications (shelving to hold approximately 20 boxes about 1½' wide x 1' deep x 6" high). See *Section 15.2 - Medication Storage Area* for a more detailed description of the area.
- **Blood drawing area:** This should be convenient to the CC area and include a blood drawing chair, standard blood drawing equipment, and a sink in accordance with Occupational Safety and Health Administration (OSHA) requirements.
- **Blood processing area:** This should be convenient to the CC area. It must have a sink and work counter, and a refrigerated centrifuge. Access to a -70°C freezer is required to hold the sample aliquots before shipment to the specimen repository.
- **Physical measurement area:** This area should be a private area for taking height, weight, hip and waist measurements, and other physical measurements, where the participant can feel that personal information will be kept confidential. Access to a wall-mounted mirror is recommended to perform the hip and waist measurements.
- **Examination room:** This room should be set off from the other clinical areas by a door. Any windows should have blinds or curtains that can be drawn. An examination table with stirrups, at least one standing examination lamp, a stool, an overhanging equipment table, and a sink should be available in the room. Additionally, storage space in this room for gowns, sheets, gloves, specula, lubricant, and other supplies would be desirable.
- **LAN file server space:** The file server is mounted in a floor-standing cabinet and weighs about 300 lbs. The cabinet is approximately 2½' x 2½' wide and 4' tall, requiring 6" of clearance on each side when the cabinet is closed, and sufficient clearance to open and work on both front and back. It also needs 2' of air space above the cabinet. It will generate about 500 BTUs per hour, so the space must have sufficient ventilation to disperse this heat. The file server and -70°C freezer should not be located in the same area. It must be located in a secure area to avoid use by unauthorized people or accidental shut down.

#### 2.1.1.2 Recommended Clinic Areas

The following list includes additional specific areas likely to be needed at each CC to perform the activities for the WHI.

- **Accessible parking:** This is an important convenience for the participant that can improve participant adherence. The CC is encouraged to reimburse participants if free parking is not available.

- **Waiting room:** This should be a convenient and attractive area, with an adjacent reception area for appointment scheduling. The area could also be used by participants to complete any self-administered questionnaires on-site.
- **Reception desk area:** This area should be in or near the waiting room area.
- **Coffee area:** This area might include a small table, coffee pot, cups, coffee and tea supplies, and snacks for post-blood draw participants. Preferably, this area could be located near the waiting room. If the coffee and post-blood draw snacks must be kept in the waiting room, be sure that there are clear, understandable instructions posted for pre-blood draw participants to not have anything to eat or drink until after their blood has been drawn.
- **Telephone recruitment area:** This area should have a chair and small desk accommodations for telephoning and screening potential participants. It should be located in a quiet area away from the reception and waiting room areas.

## 2.1.2 Computing

### 2.1.2.1 Preparing Facilities for WHI Computing System (Required)

Clinical Centers must arrange for appropriate cabling of their facilities for local area network (LAN) access to each station. Contact the Clinical Coordinating Center (CCC) for cabling information.

### 2.1.2.2 Guidelines for Allocating Computers to Clinical Center Areas

The five personal computers (PCs) may be located throughout the CC in order to automate tasks and facilitate data management. Each CC will need to determine the most useful configuration for their CC layout. A general recommendation based on assumed tasks is provided.

**Table 2.1**  
**Suggested Personal Computer (PC) Locations**

<u># of PCs</u>	<u>Station</u>	<u>Likely Tasks</u>
1	Reception	Data Entry Office Automation
1	Interviewer	Current Medication Inventory Office Automation Data Entry Eligibility Determination Randomization
2	Data Entry	Data Entry and Scanning Eligibility Determination Randomization Database Reporting Office Automation
1	Near Study Pills	Study Pill Inventory Study Pill Dispensing Study Pill Adherence Data Entry

### 2.1.2.3 Guidelines for Data Entry Area

- **Data entry room:** The computer area should be well-lit and well-ventilated, preferably in a separate office. Since computers generate heat, they should not be in a cramped, windowless cubbyhole. Data entry preferably should not be performed in the reception area or busy office area.
- **Work space:** The table or desk that the computer is on should be large enough to accommodate a generous workspace (for forms, a copyholder, etc.).
- **Workstation:** The keyboard and monitor should be at the proper height. An operator's arms should be bent at a 90° angle when typing. If the table is too high, there are many products available that lower the keyboard. In addition, the monitor should be at eye level. If the table is too low, a stand can be used to raise the monitor or a "CRT valet" to lift the monitor totally off the desk and position it at an appropriate height. Some of these aids come with copyholders that may make data entry work easier and faster. Most computer supply companies have free trial periods for these types of equipment.
- **Ergonomic chair:** Data entry staff should have a comfortable chair. Back fatigue is a major complaint of computer users. The height should be adjustable, and the back should tilt. Before buying any furniture, if at all possible, ask staff to try it out personally since everyone's needs and preferences are different.
- **Glare-reducing screen:** Another common complaint of computer users is screen glare. There are many glare-reducing screens available that help with this problem. You can also try adjusting room lighting and positioning the screen so that it doesn't face the sun.
- **Printer table:** Laser printer control buttons should be within easy reach. There should be an adequate storage area for paper, labels and toner cartridges.
- **Computer cleaning supplies:** There are numerous cleaning products available, both for the screen and the floppy disc drives. They are a good investment, not only to increase the life of the machine, but to maintain operator comfort.
- **Personal Computer (PC) locking device:** Each PC should have a security device that locks it to the desk or table.
- **Surge protector:** Each PC should have a surge protector.

See *Vol. 5 - Data System, Section 1 - Overview* for additional guidelines.

### 2.1.3 Remote Sites

Procedures for screening visits, randomizations, and follow-up visits were initially developed with the assumption that participants would come to main (or satellite) CC sites for these visits and that CC staff would have access to WHILMA. (A satellite site is a site with access to WHILMA.) However, for those situations where screening and follow-up visits are conducted at remote sites without access to WHILMA, CCs must follow the required procedures as outlined in the WHI Manuals for all tests and data collection activities. Procedures and tests performed at remote locations must be performed in the same way as those at the main (or satellite) CC.

- The physical measurement of weight must be done using the same type of scale.
- The physical measurement of height must be done using the same type of stadiometer or the CC has completed a CCC approved reliability testing to use a portable stadiometer.
- ECGs must be done using the same MacPC.
- Functional status measurements must be done using the same type of hand-grip dynamometer.
- Blood drawing must be done with the same type of standard blood collection tubes.

- Blood and urine samples must be processed using similar equipment (i.e., refrigerated centrifuge) and following the same time limits. They must also be frozen in a -70° C freezer following the same time limits as those specified in Vol. 2, *Section 11 - Blood Collection, Processing and Shipment*.
- Pill weighing must use the same type of Ohaus scale and calibration weights.

Before conducting remote site randomizations and/or follow-up visits, CCs must develop a detailed plan of the procedures they plan to use and submit this plan to their CCC Clinic Manager (CM) liaison for review before proceeding. Clinical Centers should also submit information on remote site plans to the Project Office of the National Institutes of Health (NIH) and the appropriate Internal Review Board (IRB). The plan should include information such as:

- Name, address, and phone number of remote site.
- Distance from the main (or satellite) CC.
- Method of communication with main CC.
- How the remote site is staffed.
- Description of the facilities, including signage, parking, access to secured storage, phone and FAX, VCR, running water, dedicated or shared space, and other needed facilities.
- How participants attending the remote site can contact CC staff.
- Length of time the remote site will be used, with a statement of commitment from the remote site.
- Hours of operation.
- Type of visits that will be held at the remote site (e.g., screening visits, follow-up visits, Dietary Modification [DM] Intervention sessions).
- Equipment to be used.
- How participants attending only remote sites are identified.
- Handling of participant files and transportation of the files between the main CC and remote sites (CCs should maintain a complete participant file at the main CC).
- Procedures used to ensure timely data entry of screening and follow-up data.
- Randomization procedures used.

The plan must include procedures that ensure activities are performed by certified WHI staff. CCC Quality Assurance (QA) staff may include visits to remote sites during routine QA Visits to the main CC.

### **2.1.3.1 Remote Site Randomizations**

There are 2 options for randomizations at remote sites. The first is to complete all necessary activities at the SV3, bring the forms back to the main site at the end of the day, key-enter the information and perform the randomization. The second is to fax all completed forms to the main site during the participant visit, and randomize the participant from the main site. For each instance, HRT participants must be mailed study pills within one working day (refer to *Section 4.6.3.5 - Remote Site Randomizations* for more detailed instructions).

### **2.1.3.2 Remote Site Follow-up Visits**

Procedures and tests for follow-up visits performed at remote locations must be performed in the same way as those at the main (or satellite) CC. Conducting follow-up visits at remote site locations generally pose additional efforts by CC staff to allow for efficient data flow between the main CC and the remote site location. A CC with a remote site location should organize the activities of each to allow for accurate and timely data collection consistent with same at the main (or satellite) site. Before conducting remote site follow-up visits, CCs must develop a detailed plan of the procedures they plan to use and submit this plan to their CCC Clinic Manager (CM) liaison for review. See *Section 2.1.3 – Remote Sites* for suggested



information to be included in the plan's description. Since the dispensation of study pills is dependent on WHILMA, the procedures for how to dispense study pills in a timely manner is a challenge. Options for dispensing study pills to participants at remote site locations are described in *Section 15.4.7 – Selecting and Dispensing Study Pills for Remote Site Locations (Required)*.





**This page left blank intentionally.**

## 2.2 Services (Required)

Clinical Centers need to make arrangements for the following ongoing services:

- **Local lab analysis** of WBC, hematocrit, platelet count, and triglycerides: It may be more cost effective to order an entire CBC from a local laboratory than to order the individual hematology tests. Frequently the local laboratory will also supply the blood drawing supplies (needles, tubes, Band-Aids, etc.) at no additional cost.
- **Local reading of Pap smear and endometrial aspiration slides.**
- **Pick up or delivery service for local blood and pathological specimens:** Many local labs will provide this service.
- **Mammography and transvaginal uterine ultrasounds:** The services used for mammography and other screening procedures should be convenient for the participants. Plans for services needed for follow-up visits should be carefully worked out at each CC.
- **Dry ice:** Monthly delivery of dry ice nuggets will be needed for shipment of frozen blood/urine samples to the specimen repository.
- **Express mail:** McKesson BioServices will supply each CC with Federal Express mailers for the monthly shipment of frozen blood and urine samples (for bone densitometry sites) to the specimen repository and for overnight shipment of endometrial aspiration slides to the central pathologist.
- **Hazardous waste disposal:** Make arrangements for disposal of contaminated supplies such as blood drawing and processing waste according to OSHA and local institution regulations.
- **Autoclave services:** Make arrangements for sterilization of the endometrial aspiration equipment (e.g., tenacula) or other non-disposable supplies or provide accommodations for an autoclave on-site.
- **Emergency services:** Make arrangements for advanced cardiac life support services. Some CCs will arrange for code team services with their clinical facility. Other CCs will stipulate that Emergency Medical Systems (911) should be contacted in an emergency. Some CCs may be required by their clinical facility to maintain emergency supplies and equipment (e.g., crash cart) on-site.

## 2.3 Equipment and Supplies

### 2.3.1 Equipment and Supplies Supplied to CCs

#### 2.3.1.1 Equipment Supplied by NIH

- OHAUS electronic balance scale and 500 and 1,000 gm calibration weights.

#### 2.3.1.2 Supplies Provided by the CCC

The CCC provides each CC with the following supplies. CCs order additional numbers of items marked with an asterisk (\*) as needed using *Form 172 - Supplies Order* in *Vol. 3 - Forms* on a quarterly basis. Those items marked with 2 asterisks (\*\*) are supplied for a limited time or as appropriate.

- WHI Manuals, *Vol. 1 - 8*.
- All WHI data collection forms from the Government Printing Office (GPO). See *Vol. 3 - Forms* for a list of printed forms and *Form 170 - Forms Order* for more information about ordering forms.
- Videos.
  - WHI Consent Video.
  - HRT Consent Video (optional).
  - DM Consent Video (optional).
  - HRT Training Video: Endometrial aspiration (for clinic practitioners, not participants).
  - DM Training Video: “Keeping Track of What You Eat” (English and Spanish versions).
  - List of BSE videos CCs can order.
  - Recruitment Video.
  - Recruitment PSAs (video and audio)
- WHI slide set for professional presentations (along with paper copy).
- Printed materials.
  - Recruitment brochures (for use at CC option).\*
  - Recruitment print PSA.
  - Exercise brochure.\*
  - Newsletters.
    - CT Newsletter.
    - DM Intervention Newsletter.
  - Hormone show card (for use with *Form 43 - Hormone Use*).
  - Lipemic serum sample photographs (for use in blood processing).
  - Participant birthday cards.\*
  - USDA/DHHS Dietary Guidelines.\*
- Electronic materials. (See list in *Vol. 7 - QA, Section 2.3.3 - Electronic Files*.)
  - Model consent forms (in WORD).
  - WHI logo and catch phrase (in WORD).
  - Randomization Follow-Up Planning Spreadsheet (in Excel).

- CC Quarterly Technical Report (in Excel).
- Sample documents in *Appendix E - Model CC Printed Materials* (in WORD).
- Retention aids.
  - WHI participant folders.\*
  - WHI magnets.\*
  - WHI lapel pins.
  - WHI medication bags.\*
  - Additional incentives (a new one each year).\*
- WHI 7-day pill organizers.\*
- Breast models for breast self-exam (ordered through CCC).
- Tape measure (in centimeters).\*\*
- Dietary Assessment materials.
  - Food models (1 set).\*\*
  - Measuring cups.\*\*
  - Measuring spoons.
- DM Intervention materials.
  - Participant Manual-binder and tabs.\*
  - Participant Manual-DM Intervention session materials.\*
  - Your New Eating Style post-randomization booklet.\*
  - Fat Counter.\*
  - Food Diary.\*
  - Fat Scan.\*
  - Food models (butter pats for Session 1 demonstration).\*
  - Pocket calculator.\*

### 2.3.1.3 Supplies Provided by McKesson BioServices

- | • All HRT and CaD study pills, open-label pills, and appropriate placebos in labeled bottles. All HRT and CaD study pills come with child resistant caps (with embedded non-child resistant caps).
- The following blood and urine collection, packing, and shipping materials
  - Blood sample label sets with barcodes.
  - Urine sample label sets with barcodes (Bone Density sites only).
  - Cryogenic vials with externally threaded cap, 2 ml.
  - Freezer boxes with dividers and labels.
  - Preprinted Federal Express labels.
  - Insulated styrofoam shipping container.
  - Fiberboard shipping boxes.
  - Plastic bags, 1 quart and 1 gallon size.

- Mailing labels\*:
  - Consignee address label.
  - Black-and-white class “9” label.
  - Priority overnight label.
  - “Keep Frozen” label.
  - Diagnostic specimen label .

#### **2.3.1.4 Supplies Provided by EPICARE**

- EPICARE’s training video
- Heart Square (Heartware Inc.):\*\* (1 per CC, CCs are responsible for purchasing replacements)

#### **2.3.1.5 Supplies Provided by Businesses or Corporations**

Clinical Centers may accept (and solicit) corporate support (to provide refreshments at SV0, incentive gifts, space, or video services, for example), but such support must be provided without sponsor acknowledgment. Per the NIH Project Office, donated samples may be provided if it is made clear to the donor (preferably in writing) that acceptance of the donation does not imply NIH or WHI endorsement of the product or company, and that recipients are similarly made aware either verbally or in writing.

### **2.3.2 Equipment and Supplies CCs Must Purchase (Required)**

#### **2.3.2.1 Computer Equipment and Supplies**

- All computer equipment and supplies listed in Schedule 1A of contract.
- Laser toner cartridges.

#### **2.3.2.2 DM Intervention**

Furniture for DM Intervention group meetings:

- Tables, 36” x 72” (3-4).
- Chairs (20).
- Coffee service cart or table.

Equipment and supplies for teaching DM Intervention groups:

- Refrigerator with separate freezer section, (full size recommended) separate from refrigerator required for blood storage.
- Refrigerator thermometer.
- Coffee maker, 24-36 cup size (1).
- Electric skillet, 12” (2).
- Cooler for food transportation.
- Microwave oven (600 - 700 watt), large enough to hold one 13” x 9” Pyrex pan or stove/oven combination.
- Cart for microwave oven. (1)
- Portable easel and pads.

- Blackboard or white board.
- Erasers for chalkboard or white board.
- Dry erase markers or chalk.
- Extension cords, 12-15 feet long, heavy duty (2)
- Adapters, grounding. (2)
- Large serving platters. (2)
- Quart casserole dishes. (2)
- Baskets with liners. (4)
- Bowls with lids. (2)
- Knives. (2)
- Larger serving spoons. (2)
- Serving forks. (2)
- Cutting boards. (2)
- Server or spatula. (2)
- Pitchers, gallon or two quart sizes. (2)
- Glass Pyrex pans, 13" x 9" size. (4)
- Glass Pyrex pans, 8" square size. (2)
- Rubber scrapers. (2)
- Paper plates (8" and 4" diameter).
- Plastic silverware: knives, forks and spoons.
- Paper goods: napkins, paper towels.
- Cups, 4-6 oz. size, (hot and cold).
- Stir sticks for coffee.
- Small individual packets of sugar and non-dairy creamer.

### 2.3.2.3 Clinical Measurement

- Conventional mercury sphygmomanometer. It is advisable to have an additional conventional mercury sphygmomanometer and standard stethoscope available in the CC in case of an equipment failure.
- Standard stethoscope and ear pieces with bell (Littman is suggested); tubing to be a maximum of 14 inches long
- Blood pressure cuffs (small, regular, large, thigh)

- Foot stools (one to use during height measurements, one to assist participants onto the ECG table, and one for the Clinic Practitioner to use during pelvic exams)
- Balance Beam Scale - A Detecto Balance Beam Scale, Model #2391 or 339 is recommended. Detecto may be contacted at 1-800-641-2008. If the CC uses another type of scale, send the scale specifications, such as model name, model number, and local calibration services to the CCC. The CCC must approve any equipment substitutions (see *Vol. 2, Section 9.4.5 – Portable Scales*).
- Wall-mounted stadiometer with a perpendicular polycarbonate sliding head piece and “read-here” mark that measures from 64 to 211 centimeters (25” to 84”). The Perspective Enterprises Stature Board (#PE-WM-60-84-PC meets this requirement. Perspective Enterprises may be contacted at 1-800-323-7452. If you have alternative or modified equipment, send specifications to your CCC CM contact liaison for approval. Bone density sites should use a Harpenden stadiometer (see *Vol. 6 - DXA Quality Assurance Manual*).
- Jamar hydraulic hand dynamometer, model 1 (#PC5030J1), that registers maximum kg of force during a trial with adjustable hand grip set at the second setting. (The CCC has a dynamometer to loan out if needed.) The Dynamometer may be purchased from Samons Preston, Inc. (#5030J1) at 1-800-631-7277 or Lafayette Instrument (#700105) at 1-800-428-7545.
- Calibration weights (5- and 15-kg weights or 5- and 20-kg weights). If the weights used are not certified calibration weights, have their exact weight determined by the local Department of Weights and Measures or a certified scale technician. If kg weights cannot be located, pound weights may be substituted.
- Wide Velcro straps for calibration of dynamometer
- Standard armless, straight-backed chair (such as a plastic-molded chair) approximately 45 cm high at the front edge and 38 cm deep. The seat should not be padded and should incline no more than a few degrees from front to back. A thin strip of masking tape should be placed across the seat of the chair half-way between the front and back of the seat.
- Masking tape.
- Stopwatch.
- Sheets.
- Disposable latex gloves – various sizes.
- Disposable specula in varying sizes (metal specula may be used if autoclave services are available).
- Water-soluble lubricant, such as K-Y Jelly.
- Betadine.
- Tenacula.
- Floor-standing exam light or other light source for vaginal exam.
- Exam table with slide-out step and stirrups.
- Flexible endometrial aspiration equipment.
- Scissors to cut off tip of aspirator.
- Large Q-tips for swabbing or ring forceps and cotton balls.
- Contaminated waste bags (red bags).
- Contaminated needle container (for needles and cytobrush).
- Non-steroidal anti-inflammatory oral medication (per CC consulting gynecologist choice).
- Hurricane gel (20% benzocaine) topical anesthetic.
- Gowns.

- Wooden spatulas for Pap smear.
- Cytology brush for Pap smear.

**Some of these may be provided by the CC local lab:**

- Glass slides with frosted ends.
- Preservative for endometrial biopsy.
- Containers for endometrial biopsy.
- Pap fixative.
- Slide mailers.

#### **2.3.2.4 ECG Measurements**

- G.E. Medical Systems Information Technology (GEMSIT) (1-800-858-7044) MACPC personal cardiograph (made as joint purchase through the EPICARE or CCC) with MACPC Instruction Manual, instruction video, 12 lead ECG Acquisition Module, and Power Module supplied by GEMSIT.
- Telephone wall plug connection.
- ECG paper.
- Adult disposable electrodes (10 per participant). Economical disposable electrodes can be ordered from LecTec Corporation:

Electrode Type: Tracets MP3000.  
Address: LecTec Corporation  
10701 Red Circle Drive  
Minnetonka, MN 55343  
1-800-777-2291

- Step stool.
- Isopropyl alcohol (for skin preparation).
- 4x4 gauze pads or sandpaper wipe (for skin preparation).
- Felt tip markers and wax cosmetic pencils (light for dark skin and dark for light skin).
- Paper tape with dispenser.
- Scissors.

#### **2.3.2.5 Blood and Urine Collection, Processing, and Shipment**

The list below includes guidelines for blood collection, processing, and shipment supplies. You may choose to use a different vendor than the one recommended. Please note that blood collection supplies may now be ordered through McKesson Bioservices, as indicated.



**Blood and Urine Collection**Recommended Vendor/Part Number:

- Needles, 21 gauge, 1 to 1½” multiple sample vacutainer. Local medical supply
- 23-gauge butterfly with 12” tubing with multiple sample Luer adapter. Local medical supply
- Syringes.
- Monojet hypodermic needle (21-23 gauge, 1 ½”).
- Blood draw workstation. Recommended Baxter S9267-1
- Royal blue-stoppered serum tubes for trace elements, no additive, silicone coated, 7 ml (*Note:* 7 ml will be printed on label in red ink; be sure you use the tubes with 7 ml in red and not 7 ml in green). McKesson or BD 367737 (Baxter B2951-107, vacutainer tubes with hemoguard closure) or BD 6526 (Baxter B3007-54)
- Blue-stoppered tubes with 3.8% sodium citrate, 4.5 ml (sodium citrate 18 mg, citric acid 2.4 mg). McKesson or Monoject 340478 or Terumo Venoject T206SWY (Baxter B3048-81 or Laboratory Supply)
- Lavender-stoppered plasma tubes, with powdered EDTA (Sodium (Na<sub>2</sub>) not potassium (K<sub>3</sub>), EDTA), 10 ml. McKesson or Monoject 310745 Terumo Venoject T200SQ (Baxter B3042-54 or Laboratory Supply).
- Lavender-stoppered plasma tubes, with liquid or powdered EDTA (as preferred by local lab). Local laboratory performing tests for CC
- Vacutainer holder. Local medical supply
- Test tube racks. Local medical supply
- Alcohol swabs or cotton balls, alcohol, and alcohol dispenser or gauze swabs. Local medical supply
- Bandages (“Band-Aids”) or surgical tape. Local medical supply
- Biohazard container for needles (“sharps” container). Local medical supply
- Biohazard container for waste. Local medical supply
- Wash bottle. Local medical supply
- Lab coat. Local medical supply
- Disposable latex gloves. Local medical supply
- Chlorine bleach. Local store
- Anti-bacterial hand soap. Local store
- Aluminum foil or yellow plastic sleeves to protect the blood drawn in the royal blood collection tubes from light. Local store

**Blood and Urine Processing**Recommended Vendor/Part Number:

- Fluid-resistant lab coat. Local medical supply
- Refrigerated centrifuge with swinging buckets (able to reach relative centrifugal force of 1,300 xg). Local medical supply
- Factory certified low temperature thermometer, -90°C to +20°C or thermistor.
- Large and small test tube racks for holding vacutainer tubes and cryovials. Local medical supply
- Disposable latex gloves. Local medical supply
- Chlorine bleach. Local medical supply
- Goggles or glasses or mask with face shield or barrier shield behind which to process blood samples. Local medical supply
- Tape. Local store
- 1 ml adjustable automatic pipettor. Local medical supply
- Disposable pipette tips. Local medical supply
- 10 x 75 mm or larger test tube or 15 ml conical centrifuge tube to recentrifuge samples. Baxter C3902-4
- Sterile specimen container for collecting urine (in bone density CCs). Baxter U3031-31
- 15 ml conical centrifuge tube with lid (in bone density CCs).

**Blood and Urine Storage and Shipment**Recommended Vendor/Part Number:

- Freezer at 70°C or colder, with CO2 back-up system and temperature recorder. Local medical supply
- Factory certified low temperature thermometer, -90°C to +20°C or thermistor. EverReady thermometer ULF0105  
Telephone: (800) 453-7826
- Newspaper (for packing).
- Freezer alarm for each -70°C freezer. Rees Scientific/Informer 2400  
Telephone: (800) 327-3141
- Waterproof packing tape (strapping tape).
- Dry ice nuggets.
- Freezer gloves/vinyl or latex rubber gloves.
- Return address label (printed at CC).
- Indelible ink pen.
- Shipping tape.
- Scale for weighing shipment.

**2.3.2.6 Other Equipment and Supplies**

- Color TV and VHS VCR.

- Fax machine.
- Phone with voice mail or answering machine.
- #2 pencils for use with mark-sense forms.
- Health Education pamphlets (available if CCs choose to use them.)

The following are WHI approved pamphlets CCs can order by calling 1-800-4-CANCER. You are only allowed to place one order per brochure per month. The maximum allowable number you can order varies from brochure to brochure. The range is from 50-200.

<u>Approved Pamphlets</u>	<u>NIH Publication Number</u>
• The Pap Test: It Can Save Your Life	92-3213
• Clearing the Air: A Guide to Quitting Smoking	92-1647
• Breast Exams (Spanish): Lo Que Usted Debe Saber Sobre Los Exámenes De Los Senos	92-2000S
• Pap Test (Spanish): Hagase La Prueba Pap Hagal Hoy O Por Su Salud Y Su Familia	92-3211S
• Smoking (Spanish & English): Smoking: Facts and Quitting Tips for Hispanics	92-3405S
• Understand Breast Changes: A Health Guide for All Women (this is quite a lengthy pamphlet - it would probably be more appropriate for use in clinic waiting rooms rather than as a hand-out)	93-3536

Because pamphlets sometimes go out of print and are no longer available through the NCI, a few additional pamphlets have been added to the list. These are:

<u>Approved Pamphlets</u>	<u>NIH Publication Number</u>
• Having a Pelvic Exam and Pap Test	95-3416
• Are You Age 50 or Over? A Mammogram Could Save Your Life	94-3418
• Get a New Attitude About Cancer: A Guide For Black Americans	93-3412
<i>Designed for Spanish-speaking women:</i>	
• La Prueba Pap (Spanish Pap Test)	93-2694S
• Un Mamogram Podria Salvarle La Vida (Spanish mammogram)	94-3418S

### 2.3.3 Recommended Supplies

#### Waiting Room

- Pamphlets such as information brochures and WHI Interest Surveys.
- Phone books.

- Magazines or other WHI - appropriate reading material, e.g., travel, crafts, or sports publications. Magazines displayed in the waiting room should be neutral in content and should not contain articles promoting diet changes or hormone use.

#### Reception Area

- Shelving.
- Bulletin board.
- Calendar with dates at least six months in advance.
- Typewriter.
- Appointment book with dates at least six months in advance or access to a PC if scheduling is done via computer.
- Copier, or convenient access to one.
- Postage.
- Calculator.
- Rubber stamp with CC address.
- Shelf or hanger for coats.
- Extra pens and pencils.

#### Coffee Area

- Snacks for post blood draw participants.
- Plastic knives and spoons.
- Cups for hot and cold liquids.
- Water, coffee, decaf coffee, tea, sugar, sweetener, non-dairy creamer, stirrers.
- Coffee maker.
- Carafes for hot water, coffee and cold water.
- Napkins.
- Waste paper basket.

#### DM Intervention Sessions

- Food thermometer.
- Warming trays. (2)
- Small toaster oven. (1)
- Small tape recorder.
- Overhead projector.
- Name tags.
- Pencils and pens.
- Writing pads.
- Paper clips.
- Transparencies.

- Reference books or dietary newsletters.
- Children's toys (crayons, coloring books, reading books, etc.).

#### Clinical Measurements

- BSE video.
- Office supplies as needed.
- 1% lidocaine.
- 20-gauge spinal needles or comparable paracervical equipment of choice.
- 5-cc syringes or comparable paracervical equipment of choice.
- Sterile towels (disposable).
- Exam table paper.
- Exam table pillow.
- Paper pillow cover.
- Over-hanging equipment table.
- Resuscitation equipment (code cart).
- WD40 or comparable lubricant.
- Biohazard container for contaminated waste.
- Garbage can for paper waste.
- Silver nitrate sticks (to stop bleeding from tenacula puncture sites).
- Wall-mounted mirror.
- Dish detergent.
- Small lacrimal duct probe.

#### ECG Measurements

- Baby oil, body cream (unscented) (Use only after ECG recording if skin is irritated.)
- Dish detergent: one part detergent to 10 parts water (for cleaning Heart Square).
- Small pliers.
- Three-way adapter.
- Extension cord.
- Mattress pad.

- Towel.
- Electrodes.
- Alcohol swabs.
- Fine sandpaper wipes.

Blood Collection, Processing, and ShipmentUsual Vendor

- |   |                      |
|---|----------------------|
| • Paper towel dispenser.  | Local store          |
| • Timer.  | Local medical supply |
| • Plastic disposable transfer pipettes with bulb reservoir (5-6 per participant). | Local medical supply |
| • Applicator sticks.  | Local medical supply |
| • Wet ice.  | Local supplier       |
| • 3 ring binder for log sheets.   | Local store          |
| • First aid kit.  | Local medical supply |
| • Smelling salts/amyl nitrate poppers.  | Local medical supply |

Study Pill Storage Area:

- Table.
- Mailers - padded adhesive.
- Filament tape.
- Clerical supplies.

## 2.4 Staffing

The number of staff positions at a CC depends largely on the configuration of the CC. In general, each CC has duties that can be divided into the seven following categories: Clinical Center Management, Clerical and Support, Recruitment and Interview Activities, Data Coordination and Management, Clinical, Nutritional, and Outcomes. The general responsibilities of each category are described below. In the interests of cost containment and maximum flexibility, CCs may hire part-time staff and cross-train staff to accomplish a variety of responsibilities. Clinical Centers may also utilize students, participants, and volunteers as appropriate.

Certain guidelines must be followed when using students, volunteers, and study participants to assist with CC operations. Volunteers and students must be trained for all standardized WHI tasks that they perform (e.g., consents, data collection, or data entry.) The signing of a confidentiality statement is recommended. While the CCC strongly discourages using WHI participants as volunteers (particularly CT participants), there are no “rules” against this. However, activities performed by participants must be monitored closely. Participants must be trained and certified to perform all standardized tasks like any other staff member. Participants who assist in the CC, however, must not have access to materials, records, or lead staff support beyond what would be routine for other CT or OS participants. If the participant will be interacting with other participants she should not disclose that she is a WHI participant or has had experience with screening visits or a certain arm of the study trial. Additionally, a CT or OS participant cannot attend any DM intervention sessions.

The following tasks are not necessarily assumed by one CC staff member within an area. In fact, the key areas below include tasks that are at multiple levels of responsibility and expertise.

### 2.4.1 Clinical Center Management

#### **High level of responsibility and expertise**

- Manage CC facilities, operations, and administrative details.
- Supervise CC personnel and staffing, particularly reception and clerical staff.
- Oversee CC flow.
- Prepare administrative, budget, and progress reports as well as cost estimates, plans, and projections for future needs.
- Communicate with CC PI and serve as administrative contact person for CCC.
- Interpret and implement protocol policies and procedures.
- Participate in regular conference calls.
- Manage medication area.

#### **Moderate level of responsibility and expertise**

- Maintain documentation for all CC operations.
- Maintain updated IRB records.

### 2.4.2 Clerical and Support

#### **Moderate level of responsibility and expertise**

- Schedule outside tests.
- Schedule CC visits and provide reminders (via phone and/or mail) to participants.
- Retrieve, prepare, distribute and refile participant charts before and after CC visits.
- Maintain study manuals, including updates on the WHI Manuals.

- Serve as receptionist to people entering the CC.
- Screen CC phone calls.
- Maintain appointment calendar and logs related to CC flow.
- Maintain supplies and inventory including study forms and supplies from the CCC and study pill inventory.

**Low level of responsibility and expertise**

- File CC documents.
- Perform mass mailings for recruitment.
- Prepare participants' informational packets.
- Carry out copying and typing requests.
- Perform word processing and correspondence.

**2.4.3 Recruitment Activities****High level of responsibility and expertise**

- Plan, implement, and monitor participant recruitment and retention procedures in conjunction with scientific staff and CCC.
- Establish community contacts and resources for recruitment.
- Develop CC-specific recruitment materials.
- Participate in monthly conference calls.
- Train recruitment staff.

**Moderate level of responsibility and expertise**

- Recruit and screen participants into the study through telephone interviews with interested respondents.
- Re-establish contact with participants lost to follow-up by telephone contacts and updating personal contact information.
- Obtain informed consent.
- Explain forms.

**Low level of responsibility and expertise**

- Schedule women for their screening visits.
- Schedule participants in the CT and OS for appropriate follow-up visits.

**2.4.4 Clinical**

The licensure requirements for performing some clinical procedures depend on individual state requirements and therefore, will be CC-specific. Consult your state practice guidelines.

**High level of responsibility and expertise**

- Oversee clinical assessment and intervention operations and provide quality assurance.
- Conduct CC clinical staff meetings and provide continuing education opportunities.



- Provide consistent CC services and continuity to participants.
- Perform pelvic exams and Pap smears.
- Perform clinical breast exams.
- Perform endometrial aspirations.
- Perform transvaginal uterine ultrasound (in CCs with ultrasound equipment).
- Review and interpret screening and diagnostic reports (laboratory, ECG, mammography, Pap smear, endometrial aspiration, and transvaginal uterine ultrasound reports).
- Review laboratory and clinical results and findings with participants.
- Provide referral and follow-up.
- Provide consultation during the informed consent process.
- Counsel and evaluate participants for adverse signs and symptoms.
- Respond to participants' concerns about health and symptom management.
- Participate in appropriate conference calls and liaison with CCC.

**Moderate level of responsibility and expertise**

- Perform blood draws into appropriate specimen tubes.
- Maintain contact with participants during flow through the CC.
- Perform medication interviews.
- Perform bone densitometry (in bone density CCs: Birmingham, Tucson, Pittsburgh).
- Obtain 12-lead electrocardiogram.
- Process blood specimens: centrifuge, aliquot, label, scan labels, store (freeze) and ship to appropriate central blood repository or local lab.
- Provide breast self-examination teaching.
- Perform study pill adherence collections and dispense study pills.
- Perform cognitive assessment interview.

**Low level of responsibility and expertise**

- Measure blood pressure and resting pulse rate.
- Measure height and weight.
- Measure waist and hip circumference.
- Perform functional measurements.
- Collect urine specimens (in bone density CCs).

**2.4.5 Nutrition Interventionist****High level of responsibility and expertise**

- Oversee nutrition assessment and intervention operations and personnel.
- Provide training and quality assurance of nutrition assessment and intervention operations.
- Participate in appropriate staff group and other related conference calls.
- Provide dietary consultation during informed consent process.

- Organize scheduling for dietary intervention groups.

**Moderate level of responsibility and expertise**

- Run intervention groups.
- Provide individual counseling.
- Maintain intervention and quality assurance forms.
- Maintain participant progress notes.
- Monitor dietary changes in participants and provide feedback.
- Monitor attendance and provide make-up sessions for intervention participants.
- Respond to participants' ongoing concerns about diet, food preparation or completion of forms.

**Low level of responsibility and expertise**

- Schedule intervention groups.
- Shop and prepare foods for intervention activities.
- Assemble intervention class materials and equipment.
- Mail class reminders for intervention sessions.

**2.4.6 Dietary Assessment Staff****Moderate level of responsibility and expertise**

- Teach participants about completing dietary questionnaires (*Food Frequency*, *Four-Day Food Record*).
- Assign dates for completion of *Four-Day Food Record*.
- Review and document *Four-Day Food Record*.
- Review *Food Frequency Questionnaire* for completeness.
- Assess participant's ability to complete dietary questionnaires as a basis for determining eligibility for dietary intervention.

**2.4.7 Outcomes Specialist****High level of responsibility and expertise**

- Evaluate medical records documents to determine if they are appropriate and adequate for adjudication.
- Assemble adjudication case packets.
- Coordinate activities of staff, (e.g., data coordinator, physician adjudicator) involved in processing outcomes and maintain routine systems of communication.
- Refer questions appropriately to Clinic Practitioners (serious adverse experiences or safety issues).
- Participate in monthly conference calls.
- Review ICD-9-CM codes on hospital facesheet for outcomes of interest for WHI.

**Moderate level of responsibility and expertise**

- Ensure participant has a current Medical Records Information release signed prior to investigation of any potential outcome.
- Review medical history and update forms to identify events that indicate a possible WHI outcome.

- Review forms for completeness and check with participant to get appropriate details of medical history and health provider contacts.
- Request documents required for an outcome investigation from external sources such as a hospital, physician's office or laboratory and request additional documentation if needed.
- Route requested outcomes adjudication case packets for central adjudication.
- Monitor and track timeliness and completeness of documents requested from external sources.

**Low level of responsibility and expertise**

- Maintain participant's outcome files. This includes creating new outcome charts and filing.
- Key-enter adjudicated outcomes determination into database.
- Review list of providers maintained in the WHILMA database.

**2.4.8 Data Coordinator**High level of responsibility and expertise

- Serve as CC database and LAN manager
- Supervise data entry staff
- Monitor data flow at the clinical center
- Train other staff to use WHILMA
- Monitor eligibility
- Serve as CC unblinding officer
- Enter study drugs into WHILMA inventory

Moderate level of responsibility and expertise

- Participate in monthly conference calls
- Keep staff up-to-date on WHILMA changes
- Monitor data quality
- Train other staff on availability of and uses of WHILMA reports and CCC reports
- Enter nutrition intervention and outcomes data

Low level of responsibility and expertise

- Key-enter and scan study forms
- Run routine WHILMA reports

## 2.5 Participant Contacts

Clinical Centers should provide flexible office hours for the convenience of the participant (early mornings, weekends, and evenings). The number of weekend and evening hours may vary among CCs based on the participant population.

### 2.5.1 Participant Timeline (Required)

- **Recruitment and Prescreening:** Identifying and implementing the recruitment strategies take various lengths of time, depending on the recruitment source and the arrangements necessary to contact the potential participants. Clinical Centers will contact women who are interested and age-eligible, by telephone or mail, for a prescreening. Women eligible after the initial contact will be asked to come to an SV0 or an SV1. See Section 3 - Recruitment.
- **Pre-Screen Visit / Orientation (SV0):** This is a recommended visit for which women can be brought into the CC to learn about the WHI in a group format. Interested women may be given SV1-specific forms to complete prior to the SV1 visit.
- **First Screening Visit (SV1):** This visit is usually scheduled within two to three weeks of the initial contact. See *Section 4.1 - Screening Visits for WHI*. Allow adequate time between the initial contact or SV0 and the SV1 for the woman to receive and/or complete the mailed questionnaires.
- **Second Screening Visit (SV2):** This visit should usually be scheduled soon after the SV1, preferably within one week. Allow adequate time between SV1 and SV2 to obtain and review local laboratory results.
- **Third Screening Visit (SV3):** The SV3 should usually be scheduled within four to six weeks after the SV2, allowing sufficient time to get mammography and other results returned. However, if mammogram results are available by SV2, DM women could potentially return in as few as eight days after they complete *Form 62 - Four-Day Food Record*. For women enrolling in HRT, the minimum interval between SV2 and SV3 is 28 days to allow an adequate assessment of adherence to the enrollment period on HRT study pills.
- **Follow-Up:** Semi-annual contacts and annual visits should be scheduled so that the annual visit falls within the target window of the anniversary date of the woman's randomization into the CT. For HRT or CaD participants an early contact (six or four weeks, respectively, after randomization) is required to answer questions, evaluate safety and adherence, and respond to questions and concerns. See *Section 16 - Follow-Up Contacts*.

The time interval from SV1 to SV3 must not exceed 6 months. Women not randomized to the CT within 6 months of SV1 will be required to repeat baseline measures and forms falling outside the 6-month window. *Form 2/3 - Eligibility Screen*, *Form 11 - Consent Status*, and *Form 60 - FFQ* do not need to be repeated. (See *Section 4.5.3 - Time Limits During Screening*.)

The time window for each follow-up contact is  $\pm 2$  weeks of the target date. The target date is based on the randomization date even if a previous contact is outside the allowable window. The timing of SV3 should be scheduled to the participant's anticipated availability at that time of the year. The goal is to keep the participant on schedule as much as possible. Aim to get 90% of the contacts within  $\pm 2$  weeks of the target date and only extend the window for those participants who absolutely cannot attend follow-up visits closer to the target date.

### 2.5.2 Tasks Per Participant Contact (Required)

The forms recommended for screening contacts and required at follow-up contacts are shown in *Vol. 1, Table 1-A1.1 - Frequency of Data Collection*. Clinical Centers have the option to rearrange the activities to earlier or later screening visits to better fit the flow of the particular CC, as long as the arrangements meet the specific requirements given in *Section 4.1 - Screening Visits for WHI*. Additionally, no procedures or data collection may be done until the participant has signed the appropriate consent form.

### 2.5.3 Estimating Number of Participant Contacts

Each CC manages its own workload of recruitment, screening and follow-up contacts. The “Randomization Follow-Up Planning” spreadsheet is a tool that CCs can use to estimate the number of monthly randomizations and corresponding number of screening visits needed to meet the recruitment goals. A CC-specific Randomization Follow-Up Planning Spreadsheet has been sent via eMail from the CCC to each CC. The spreadsheet is also useful in estimating the number of follow-up visits resulting from the randomizations. In using the Randomization Follow-Up Planning Spreadsheet, you may find it helpful to initially determine the number of randomizations and enrollment visits needed to be conducted per month. Then, you can work backwards to determine the number of screening visits per month and work forward to determine the number of follow-up visits per month your CC can expect. A recent addition to the spreadsheet is a graph that plots the number of visits per month each CC can expect during the course of the study. The graph is generated by data from the spreadsheet and will reflect any changes made to the spreadsheet.

It is recommended that each CC update this spreadsheet on a regular basis (e.g., monthly) to continuously monitor your CC’s space and staffing needs. See *Figure 2.1 - Projected Number of Screening Activities, Randomizations and Follow-Up Visits Per Month* for an example of a typical spreadsheet showing the projected number of screening and follow-up visits per month at a CC. Detailed instructions on how to update and most productively use the spreadsheet can be found in the shared drive at your CC under “Reference Guidelines for Interpreting the Randomization Follow-Up Planning Spreadsheet.” Additional questions can be directed to your CCC CM liaison.



**Figure 2.1**  
**Projected Number of Screening Activities, Randomization and Follow-Up Visits Per Month**

**Error! Not a valid link.**





## 2.6 Activities Common To Participant Contacts

Each participant visit to the CC has a common flow and includes similar procedures. See *Figures 4.3, 4.5, 4.7 - Overview of SV1, SV2, and SV3*, respectively and *Section 16 - Follow-Up Contacts* for participant flow at specific visits. Activities common to CT visits include:

- Mail appointment reminders, self-administered forms and clinic location instructions one to two weeks before the scheduled visit.
- Reception.
- Review personal information.
- Review self-administered forms (by interviewer).
- Collect specimens.
- Perform clinical measurements.
- Complete visit exam.
- Dispense medications (for HRT and CaD).
- Schedule next appointment.

Activities common to Dietary Modification (DM) component visits include:

- Mail or telephone reminders.
- Reception.
- Group activity.
- Plans for next visit.

## 2.7 Clinical Center Checklists

It may be helpful initially to have checklists for routine tasks posted in the CC area. For example, ***Error! Reference source not found.*** - ***Error! Reference source not found.*** lists procedures that must be completed daily, weekly and monthly. The General Checklist identifies procedures that must be completed less frequently.

**Figure 2.2**  
**Clinical Center Checklists**

---

### Daily Checklist

1. Prepare classroom materials.
2. Stock the blood-drawing tray.
3. Send out appointment reminders for next week's appointments or call one to two days before the participant's scheduled visit.
4. Review lab results returned from local lab.
5. Review results returned from Pap smears, mammograms, endometrial aspirations, and transvaginal uterine ultrasounds.
6. Record freezer temperatures.
7. Stock clinical exam areas.
8. Prepare participants' files for next day.
9. Scan and key-enter forms from previous and current days.
10. File participants' files from previous day.
11. Arrange to autoclave used specula (if made of metal) and tenacula.
12. Calibrate participant weighing (Ohaus) scale.

---

### Weekly Checklist

1. Insert WHI Bulletins and updates in all WHI Manuals within one week of receipt from the CCC.

---

### Monthly Checklist

1. Send frozen blood samples to McKesson BioServices specimen repository.
2. Inventory CC supply of HRT and CaD study pills and order if necessary.
3. Discard returned study pills to McKesson BioServices.
4. Check stock of supplies and reorder.
5. Participate in routine conference calls (for Lead CC staff).
6. Certify internal temperatures of freezer and centrifuge with a certified thermometer.

---

### General Checklist

1. Prepare quarterly progress reports.
2. Prepare quarterly Forms Order.
3. Prepare the annual budget renewal.
4. Complete annual IRB approval.
5. QA checks and reports (see *Vol. 7 - Quality Assurance*).

## 2.8 Participant Files (Required)

Each woman coming to the CC for an SVI has a participant file labeled with the participant's WHI ID number. The participant file should contain only those materials, forms, and letters pertaining to WHI. Clinical Centers must retain records for CT and OS participants for the duration of the study.

Specific guidelines have not yet been developed to indicate the amount of time that forms should be retained after a participant has "dropped out" of the screening process (i.e., is not eligible for or declines enrollment or randomization). The number of documents that CCs can store varies depending on their facilities. However, remember that it will be common for women to be ineligible or to decline further screening and then decide to resume screening at a later date. Thus, when a participant declines further screening, it is recommended that her forms are kept reasonably accessible for at least 6 months (after which most are outdated for the purposes of screening (See *Section 4.5.3 - Time Limits During Screening*).

### 2.8.1 Release of Participant Files (Required)

No information from the participant's file should be released to anyone other than WHI personnel (e.g., your local CC and CCC personnel) or authorized FDA staff (for HRT and CaD participants) without the express written permission of the participant.

### 2.8.2 Description

The participant file should be labeled with the participant's unique WHI ID number. Use file folders that have fasteners on the side or top on both sides to secure materials in the file.

Files may be filed by participant name, but this is not recommended because records of participants with the same name may get mis-filed. A terminal-digit filing system may make handling records easier in participant file areas, particularly with a large number of records. It is best to decide on a filing system before ordering the file folders and labels.

Participant files must be kept in a secure area of the CC. The area must also be convenient and accessible to the reception or office staff.

### 2.8.3 Contents and Organization

All materials pertaining to a participant should be kept in the participant file. This includes the consent form(s), data forms, letters to and from the participant, phone contacts, letters to and from the participant's personal physician, notes about the participant and the participant's contact schedule.

The files may be organized in the following manner:

#### Left Side of File

Contact Information and Correspondence  
(most current on top)

#### Right Side of File

Exam Forms

Questionnaires (by date with most current on top)

## 2.9 Clinical Center Internal Procedure Manual

It is strongly recommended that each CC develop a CC Internal Procedure Manual that includes policies and procedures specific to the individual CC. This could include topics such as:

### Clinic Operations

- Facilities
  - Diagram of CC layout.
  - Days and routine hours of operation for your CC, including those that are designed to accommodate women unable to come at usual hours.
  - Location of WHI Manuals within the CC.
  - Location of FAX. Is it on-site or in another building?
  - Location of computers and printers. List of staff positions that have access.
- Supplies, Services, Equipment and Maintenance
  - Inventory and location of CC equipment. Indicate those items that are WHI-specific or dedicated.
  - Inventory of CC supplies, forms and medications.
  - Vendors and services: List of vendors for CC operations, materials and services (e.g., dry ice, hazardous waste disposal, etc.), clinical procedures materials, including examination room and lab supplies. Indicate turn-around time and minimum stock for each. See *Section **Error! Reference source not found.** - **Error! Reference source not found.*** and *Section **Error! Reference source not found.** - **Error! Reference source not found.***.
  - Maintenance resources: Include those services used for maintenance, calibration of equipment and general housekeeping. Specify name and phone number for freezer and computer maintenance and emergencies.
  - Procedure for cleaning instruments, gowns and protective cover-wear per OSHA requirements, if disposables are not used.
- Staffing (see *Section **Error! Reference source not found.** - **Error! Reference source not found.***)
  - Organization chart of CC.
  - Directory of all CC staff (including PI and Co-PIs) including location and phone numbers.
  - Job descriptions for all WHI positions.
  - Description of staffing back-up plans and personnel.

### Clinic Safety and Emergency Procedures

- Plans for fire, earthquake, or other disaster occurrences, including emergency phone numbers and contacts.
- Clinical Center procedure for medical emergencies. Include copy of Incident Report Form.
- Unblinding procedure, including name and phone number of unblinding officer. Means of contact should also be included, whether by phone, pager, etc., and off hour coverage plans.
- Safety protocol for lab accident (including accidental needle puncture, and biohazardous or chemical spill). Include copy of Incident Report Form if different than above.
- After-hours contact schedule and phone numbers.

**Recruitment**

- Copies of all recruitment materials, including letters, bus routes, maps, information materials, interest surveys, newsletters, etc. Include all recruitment plans, calendars of recruitment activities, and strategies, and any other additional scripts if used.
- Timetable of recruitment material distribution.
- Outline of SV0 activities if SV0 is utilized.
- Systems for reviewing and responding to monthly recruitment reports sent by CCC.

**Clinical Procedures**

- Laboratory
  - Phlebotomy and processing procedures for CC: Internal QA system for monitoring blood drawing, urine collection and processing and shipping of specimens.
  - Local lab: Accreditation, list of tests utilized, normal value range for each test.
  - Local lab and central lab tracking procedures: Tracking of all lab results, logging system utilized. Tracking of specimen shipments.
  - Any Clinical Center-specific lab alert values beyond those in *Vol. 1, Protocol, Section 5.5 - Notifications*.
  - System for communicating results to primary care providers and participants.
- Mammography
  - List of ACR-accredited facilities in the area.
  - Result notification system and communication to primary care providers and participants.
- DM Materials Storage
  - Location of materials.
  - System for organizing, identifying and inventorying supplies.
- DM Participant Education Materials
  - Copies of all materials created by the CC that are given to DM participants.
- DM Group Formation
  - Procedures for assigning participants to DM groups including:
    1. Waiting list.
    2. Telephone log.
    3. Prioritizing participants not assigned to a group > 8 weeks postrandomization.
    4. Maintaining contacts with women waiting for groups.
  - Procedures for non-computerized group formation, if applicable.
- DM Group Scheduling
  - Procedures for scheduling DM groups.
  - Procedures for scheduling DM Group Nutritionists.
  - Procedures for contingency plans if Group Nutritionist and/or classroom are not available.

- DM Review and Assessment
  - Description of system for reminding participants of regularly scheduled monthly/quarterly sessions (e.g., postcards, letters, buddy systems, phone tree).
- DM Observation
  - Description of system used to document and follow-up issues identified via *Form 305 - Nutrition Intervention Checklist*.
  - Description of system used for coordinating facilitator observations including:
    1. Scheduling observations.
    2. Scheduling post-observation conferences.
    3. Scheduling Action Plan follow-up.
    4. Storage of completed observation forms (*Forms 70, 71 and 72*).

**Data Management**

- Policies and Procedures for:
  - Maintaining log of approved changes/additions to WHI computing system.
  - Maintaining log of computer problems and inquiries.
  - Disposing (shredding) of unneeded confidential documents.
  - Backing up local workstation drives.

## 2.10 Emergency Procedures

Each CC should have specific procedures outlined for handling emergency situations. All emergency procedures described below are guidelines. Specific procedures can be developed at CC option. Specific requirements and strict step-wise instructions for emergencies can be fully documented in the CC Procedure Manual. Refer to *Section 15.6 - Study Pill Adherence Monitoring (Required)* for guidelines on handling situations related to study pill overdose.

### 2.10.1 Telephone Procedures

If a caller feels her situation is an emergency, some “on-the-spot” evaluation may be needed. If the situation clearly is not an emergency, the caller should be reassured and calmed. If the caller can be calmed, advice can then be given or the call transferred to a Clinic Practitioner or the Clinic Manager. If the caller cannot be subdued or if the situation may be deemed an emergency, the procedures outlined below should be followed.

- Inform Clinic Manager of existence of phone emergency.
- Have participant file pulled.
- Record the participant’s full and correct phone number.
- Record the name of the caller if other than the participant.
- Record the address of the caller; include a cross street if possible.
- Find out if there is anyone else in the house who may assist them.
- If necessary, have someone in the CC call the local emergency number, such as “911.” Keep the caller on the line until help arrives.
- Give the Emergency Medical System the CC phone number. Ask where you can call to get further information about the caller’s status or condition.
- Record the encounter on the narrative sheet in the participant’s file. Additionally, keep a record of emergencies in a separate file in the CC. Note on the record the participant’s name, the staff member who assisted the caller, the date and time of the call, a summary of the problem, actions taken and a summary of the result.

### 2.10.2 Clinical Center Emergencies

- Involving a participant:

In possible emergency situations, it is better to be overly cautious than not cautious enough. If the participant is injured or unable to leave the CC due to illness, call a person listed on the Contact Information. If a contact person cannot be located, a staff member of the CC should make every reasonable effort to get the participant to medical care. If hospitalization seems necessary, contact an ambulance or call 911 for transportation. Record the emergency and disposition in the participant’s file (e.g., on an Incident Report Form) and make a copy for a separate file in the clinical area.

- Involving a staff member:

Follow recommendations of the Health and Safety Division of your institution. Clinical Center staff should be familiar with these guidelines and copies of the guidelines should be readily available.

Notify your Clinic Manager and PI when any emergency situation occurs.

### **2.10.3 After-Hours Procedures (Required)**

Each CC should establish procedures by which a participant can contact CC personnel when the CC is closed. For example, a recording at the CC can direct the caller to an emergency number or the CC phone can be transferred to a person able to handle possible emergencies.

Clinical Centers are required to have a freezer alarm system that notifies designated staff if there is an after-hours freezer failure. See *Section 2.3.2.5* and *Vol. 2, Section 11 - Blood and Urine Collection, Processing and Shipment* for further details.



## 2.11 Interviewer Procedures

This section contains general procedures for research project interviewing of study participants. The guidelines describe the interview function and interviewing techniques, but they are intended neither as specific instructions for completing forms nor as detailed directions for conducting visits. Those instructions and directions are found in *Vol. 3 - Forms*.

These guidelines are described to assist WHI interviewers as they perform their duties in the context of participant contact. They apply to all WHI staff members eliciting information from participants.

### 2.11.1 Overview

As an interviewer, you are the participant's link with WHI. While you do not act alone in establishing a relationship with the participant, an unpleasant interview experience could tip the balance for a participant who is beginning to lose interest or is contemplating withdrawal.

Although in many ways the CC resembles a medical setting, it is not a medical care facility. The following characteristics distinguish WHI CCs from medical care facilities:

- WHI is a research project, and personnel who staff the CCs are part of a research team.
- Research project interviewers are not caregivers, helpers or advisors beyond the scope of the protocol.
- Individuals who take part in the study are *participants*, not patients; they join and remain voluntarily.
- Participants contribute to the content of scientific knowledge without gaining much for themselves.
- The CC does not bill participants for routine study visits.

Within the WHI research setting, you collect data on forms in three ways:

- Conduct in-person interviews to question participants for information or to verify observations with forms such as *Form 43 - Hormone Use*.
- Conduct telephone interviews using forms such as *Form 3 - Eligibility Phone Screen*.
- Review or preview participant self-administered forms with participants and summarize data items using forms such as *Form 30 - Medical History Questionnaire*.

### 2.11.2 Research Project Interviewing

For successful interviewing, you should have broad knowledge of the research project interview task as well as the forms and their completion. Your knowledge base should include the following:

- *Nature of research interviewing:* An interview is a social interaction designed to exchange information between a questioner and a respondent. The quality of the information exchanged depends upon the skill of the interviewer in handling that relationship.
- *Scope of research interviewing:* The research project interviewer collects data that will answer research questions.

The *research* interview contains elements that separate it from other kinds of interviewing. Strictly speaking, the research interview has the practical, utilitarian goal of data collection. In WHI, research project interviewers must combine the utilitarian objective with a more social objective of participant retention.

The retention objective is an important one, and social interaction should be a part of every interview. But it is also important that the interview not drift into lengthy conversation. Conversation of a general nature for the purpose of participant bonding should be confined to a few minutes at the beginning and the end of participant visits or phone calls.

- *Significance of research interviewing:* The research project is dependent upon the reliability and validity of the data collected by its interviewers. Bias in interviewing can compromise data.

The interviewer reduces the chance of bias by presenting neutral reactions to all answers and by maintaining a brisk, regular pace of question delivery. Regardless of how carefully worded the questions and how neutrally presented, research interviews are subject to bias from two sources: interviewer delivery and participant responses. It is the interviewer's job to minimize bias from either source.

Interviewers can introduce bias into survey results by interpreting answers, favoring one answer over another, treating some questions as sensitive, reacting to liked or disliked participant characteristics, or using slanted probes or positive or negative filler words. To avoid these potential sources of bias, interviewers must perfect both neutral delivery and neutral response.

Participants can bias their responses by trying to answer questions when they simply don't know the answers. Even when the participant knows the answers, she doesn't always give them truthfully. What's more, she often doesn't realize that she's not being truthful. The participant may bias her response unconsciously by slanting answers to make herself feel better, giving responses she thinks her friends would, or providing answers she thinks the interviewer expects. The interviewer overcomes participants' emotional, unconscious bias tendencies by presenting questions at a regular pace and by maintaining neutrality.

### 2.11.3 Interviewer Roles (Required)

Although the ultimate goal of the research project interview is standardized and reliable data collection, the interviewer also plays an important role as the human conduit of information from participants to the database. The way the interviewer conducts the interviews both facilitates and standardizes the gathering of the data.

The following are some of the important roles of the interviewer:

#### **Manage the Interview**

- Control and focus the interview without dominating either the exchange or the participant. Your job is to get information, not to show what you know. The participant's answers to the questions are important. You convey that importance by your professional demeanor, by maintaining control of the situation, and by focusing on the content of the interview.
- Be politely firm and businesslike; timidity signals lack of confidence. If you communicate insecurity or hesitancy to participants, some of them will take advantage and assume a power position, others will feel sympathetic and assume a "mother" position. In either case, the participant's responses could be biased. The participant assuming the power position could distort strong opinions to keep the position; the mothering participant could try to make the interviewer's job easier by answering obligingly.
- Dress for a supporting, not a starring, role in the survey scenario. Neatness and professionalism are the rule. Clinical Centers may want to provide dress codes.

#### **Collect Data**

- Understand the purpose and meaning of the data items on the forms. If you don't, ask your supervisor for clarification.
- Take no personal stake in the content of the interview. Make sure your opinions and behavior neither add to nor subtract from the research intention of any items in the forms.

#### **Assess Symptoms**

- See information on symptom assessment in the explanation of *Form 10 - HRT Management and Safety Interview* and *Form 17 - CaD Management and Safety Interview* in *Vol. 3 - Forms*.

**Encourage Participation and Adherence**

- Send the participant away with an overall feeling of well-being. The goal is to make the participant's CC encounters pleasant enough to be worth repeating.
- Be friendly but not chummy. Use a manner of speaking that is natural to you. If your usual manner is too casual, then with your supervisor's help, develop a firmness and modularity in this role that is genuine.
- Approach the interview with pleasure and assume the participant will do the same. Most people like being asked about themselves and their well-being; you are giving participants an opportunity to express themselves.
- Keep contact notes on personal conversation for use by the next interviewer. Record participant information that another interviewer might reasonably be expected to know, not gossip kinds of information.
- Review contact notes before each new contact. Be careful when using comments recorded by another interviewer. There is a difference between "remembering" a participant and "talking about" a participant, which may be interpreted as a breach of confidentiality.

**Present Incentives and Rewards**

- Project sincerity and enthusiasm when you present participant incentives or awards. Without words you can announce a shift in mood from data collection to a presentation context by shifting your physical position toward the participant (see "Use Body Language" under *Section **Error! Reference source not found.** - Error! Reference source not found.* below).

**Recruit New Participants**

- Encourage respondents to join and remain in the study, but don't oversell or coerce. Many people will agree to participate to end a phone call and then never return materials or show up for appointments.
- Leave the door open for participants who are reluctant to participate in the study so that you can make another try at a later time.
- Emphasize the contribution that a participant alone can make if you suspect that other persons in the household are influencing the respondent's decision about enrolling.

**Clarify the Nature of the Research Setting**

- Make sure participants know that although in many ways the CC resembles a medical clinic, it is not a medical care facility, and you as an interviewer are not a caregiver, helper, or advisor.
- Give participants information about your role as an interviewer by making the following points:
  - 1) That you are a research project interviewer, not a source of primary care.
  - 2) That you are not in a position to diagnose or refer them to someone other than their primary care provider for further medical care.

The following is a sample explanation you can give to a participant:

*"Because this is a research study, there are some similarities between our Clinical Center and your physician's office. This can create some confusion about what to expect when you come to visit us.*

*"We want you to know that we are not your primary care providers. While we perform some of the same procedures as your physician, we do not collect complete information on your health. Your family physician or primary care provider knows you best and can provide you with complete medical care or refer you to other physicians or specialists.*

*“We are concerned about you and your health, however, so we offer the following:*

- *We will refer you to your family physician or primary care provider if we find something that we feel you should know about or should check more thoroughly.*
- *In the waiting room we have available pamphlets and reading materials on programs for quitting smoking, lowering your cholesterol, etc. Please feel free to take these with you.”*

(Note: When presenting participants with abnormal blood results or other clinical problems, choose your wording carefully. Do not unnecessarily alarm the participants. Do not diagnose the problem or recommend further tests be performed. Refer the participants to their physicians.)

### **Represent the Clinical Center and WHI**

- Always be polite. Remember, you represent the CC and your co-workers.
- Call participants by name to make the experience at the CC more personal. Always use titles (Ms., Mrs.) and last names unless the participant requests otherwise.
- Impart to the participants respect for the confidentiality of the information they provide by focusing your attention on them alone. Do not let the interview be interrupted by co-workers in a casual manner.

The telephone interviewer who conducts the initial screening phone call has an important responsibility for WHI. In most instances, the telephone interviewer's ability to develop and maintain a positive rapport with the participant influences initial recruitment, the quality of the data obtained, and the willingness of the participant to remain in the study for the duration. It is important that all interviewers maintain a professional and friendly manner at every contact with the participant.

## **2.11.4 Interview Guidelines**

The research interview is a structured conversation designed to exchange information between a questioner and a respondent. The structure is provided by questions and scripts. The quality of the information exchanged depends upon the skill of the interviewer in handling that relationship. The following are some techniques to keep in mind as you conduct your interviews.

### **2.11.4.1 Interview Techniques (Required)**

#### **Use the Setting**

- Use the setting to your advantage. The CC provides waiting rooms and office space for WHI interviews. The setting accomplishes two important things: it gives a professional impression and it puts the participants at ease.
- Insist on the privacy of the interview, except for observation by WHI personnel. Observers should not intrude into the interview.
- Ask family members to wait in the waiting room during the question and answer periods of the interview, even if you have allowed them to be present during the introductory parts of the interviews.

#### **Prepare for Each Interview**

- Prepare for the interview before you bring the participant in so that you can focus all of your attention on the participant. See preparation details for each contact in *Section 4 - Screening* and *Section 16 - Follow-Up Contacts*.
- Review the contact notes in the chart before beginning each contact.
- Make sure you have all the forms and materials necessary to complete the interview.
- Make sure no other participant's information is on the desk.

- Avoid interviewing someone you know. If you see the name of a friend or acquaintance among the participants, tell your supervisor.

**Know the Forms Thoroughly**

- Follow all instructions and suggested scripts contained on the form itself and in instructions in *Vol. 3 - Forms*. Following or not following the instructions, scripts or recommended remarks makes the difference between consistent and inconsistent data.
- Study the questions and data items on the forms so that you understand what they mean. Become familiar enough with them so that you can *ask* the questions instead of *reading* them, but don't try to ask questions from memory alone. Use the form as a reference at all times.
- Practice parts of the interviews that seem awkward or unnatural to you until you can ask the questions in a natural manner.
- Review the instructions for each form regularly. Do not rely solely on memory for detailed instructions on form use.
- Use the scripted parts of the interview as they are written. Discuss with your supervisor the content and flow of recommended remarks, especially when in doubt about appropriate procedures to follow in unusual situations. (Referral of specific problems to the CCC is the responsibility of the supervisor.)
- Use the response categories that are given. Probe for specificity if necessary (see "Probe Carefully" below).
- Avoid as much as possible using the "other" or "don't know" category.
- Never assume you know what the participant means. Probe for clarity if necessary (see "Probe Carefully" below).
- Record open-ended answers verbatim.
- Record your comments in brackets on the form if you have strong impressions about a participant's answer. Indicate the question you are referring to, and make your comments as clear and concise as possible.

**Maintain Professional Contact**

- Treat every participant with graciousness and respect; treat none as a buddy.
- Do not give personal opinions on any study matters and do not give advice on personal matters even if you are asked.

**Set the Appropriate Pace**

- Use a brisk, businesslike pace, but don't rush the participant or show impatience.
- Vary from your established pace on cues from the participant. If the participant shows frustration or lack of understanding, then slow down. If the participant shows annoyance or jumps in with answers to anticipated questions, then speed up. But do not skip questions.

**Maintain a Neutral Tone**

- Speak distinctly, without unusual inflection that could draw undue attention to part of a question.
- Do not place emphasis on specific response alternatives.

**Maintain a Neutral Response**

- Record information faithfully regardless of whether you think it's good, bad, boring, or exciting.

- Keep your reactions to yourself, no matter what you may think of an individual or the feelings expressed. Practice *not feeling* a reaction; school yourself out of emotional attachment to the information you hear.
- Inspire confidence by your detachment so that participants feel comfortable giving you the unvarnished truth.
- Do not indicate surprise, pleasure, approval, or disapproval of any answer by word or action. Do not smile, grimace, gasp, laugh, frown, agree, or disagree. Even a slight intake of breath or a raised eyebrow may indicate to a participant that you are reacting to an answer. Project smooth, gracious acceptance of information, no matter how outrageous the content.
- Repeat the question exactly as it is written if the participant misunderstands a word or a question and asks for clarification. Do not define words, interpret questions, or suggest answers. See “Lack of Understanding or Recall” in *Section **Error! Reference source not found.** - Error! Reference source not found.* below for how to respond if a participant does not understand a question.

### **Deliver the Questions Thoughtfully**

- Make your delivery smooth, natural, and enthusiastic. Avoid sounding like a robot.
- Sound fresh for everyone. You may ask the same questions a dozen times in a day, but participants hear them only once in their interview.
- Use the questions, scripts, or recommended remarks as they are written, without apology.
- Emphasize that there are no right or wrong answers; the only thing that matters is the truth from the participant.
- Do not try to justify questions or to defend a line of inquiry; you are asking questions that have been asked of many other participants.
- Keep the questions in the order they’re written and maintain the flow of the visit.
- Record open-ended answers in the exact words the participant uses.
- Tell your supervisor if you find a problem with the wording of a question.

### **Probe Carefully**

Probing is a critical technique to master, as it is easy to fall prey to directing responses or altering the meaning of a question. Probes must be as uniform as possible within and among clinics.

- Use probes to elicit answers to either closed-ended or open-ended questions.
- If you feel a participant has provided an inappropriate response or doesn’t understand the question, first try repeating the question and the response categories verbatim.
- Probe by asking sufficient supplemental questions to get the participant’s answers in full but not so many that you don’t get the truth.
- Avoid asking leading questions when probing and do not suggest an answer.
- Do not insert your own ideas of what the participant might be saying. Do not agree or disagree with an answer.

#### **Probing for answers to closed-ended questions:**

In closed-ended questions, the need for probing arises when the participant gives an answer that is not included in the response categories.

Example:

The question, “Have you felt so down in the dumps that nothing could cheer you up?” (on *Form 37 - Thoughts and Feelings*) asks the participant about general depression.

In reviewing the form with the participant you find that answer blank. You read the instructions and the question, and the participant says, “Well, everybody has those feelings sometimes.”

Repeat the response categories, “Would you say you were down or depressed: Not at all, A little, Enough to bother you, Quite a bit, Very much so, or Extremely so?”

Participant: “Well, I was blue for a day or two.”

Ask the participant to choose the category that fits best and repeat the categories.

#### Probing for answers to open-ended questions:

In open-ended questions two problems call for probing: the need to *clarify* a response and the need to *get additional information* in a response.

The following are examples of neutral probes to *clarify*:

*What do you mean by that?*

*Why do you say that?*

*In what way was it a problem?*

*Could you rephrase that?*

The following are some examples of neutral probes to get *additional information*:

*Are there other (repeat the phrase from the question)?*

*How else would you describe (repeat the phrase from the question)?*

*What else (repeat the phrase from the question)?*

See instructions for using *Form 3 - Eligibility Phone Screen* in *Vol. 3 - Forms* for extensive descriptions and examples of probing.

#### **Control Silence**

- Use silence at the right moment to show your patience while waiting for the participant to formulate an answer, but do not leave the silence too long or it will threaten the participant. In role playing with other interviewers, experiment with pauses to discover your own reactions to silences.

#### **Use Body Language**

- Use the setting, your posture, and your gestures to convey the feeling you wish to project to best control the interview. If you sit with a desk between you and the participant, you project formality and assume a certain amount of authority. For less formality and authority, move your chair around the desk so that you are face-to-face with the participant.
- Lean forward slightly to communicate sincerity or to focus or refocus the participant’s attention on you and your questions.
- Keeping your eyes on the form with your pencil poised to write when asking questions tells the participant you are not just making conversation. Try the technique with an inattentive participant. However, be careful to convey individual interest in the participant (not just the data collection.)

### 2.11.4.2 Special Situations (Required)

In conducting interviews on a daily basis with numerous participants, you will encounter special situations. They will be easier to deal with if you have thought about them ahead of time.

The following are some of the special situations you might encounter with WHI participants.

#### **Emotion**

- Be prepared for unusual circumstances. Talking about cancer or heart disease can arouse emotion in many people. Participants who have recently lost loved ones, especially to one of these illnesses, may become upset with some questions.
- Remain calm but not distant or cold; let the emotion run its course. Have tissues available. Often participants who have experienced losses express strong motivation to continue with the project to contribute to the disease prevention effort.
- Stop the interview if a participant is clearly unable to finish the visit. Offer a quiet place; get a supervisor or manager to help. If you cannot reschedule immediately, be sure to arrange to call the participant within a few days — just to make sure everything is all right and to try to reschedule the visit.

#### **Strong Objections to Questions**

- Assume the burden of communication; take the blame for misunderstandings. If a participant fails to grasp the meaning of a question, admit that perhaps you didn't deliver it clearly and repeat the question. Do not allow the participant to feel that the questions are too difficult for her to answer.
- If the participant is angry, reluctant or impatient about a single question or a series of related questions, cite "the office" or the "researcher." Blame the project for objectionable material, not the participant for being objectionable.
- Respond in a non-defensive tone as though you have heard the objection before. Don't delay the interview any more than necessary; move on to the next question. If the participant pursues the objection, remind the participant that although the researcher had a purpose in including the question in the interview, the participant doesn't have to answer the question.
- If a participant hesitates or refuses to answer, repeat the question. Say, "Let me go over that again. If you don't want to answer, that's your choice; but my instructions are to ask each of the questions." Add that the participant's feelings or opinions about the question are important. If the participant still refuses, accept the refusal graciously and go on to the next question.

#### **Impatience With the Length of the Interview**

- If a participant is anxious to finish the interview and says so, say, "I need only a few more minutes of your time. Your answers are important to us, and we'd like to have all of them."

#### **Curiosity About the Research**

- Be ready with standard replies for people who want to know more about the research. The *Questions and Answers for CC Staff* in Section G.1 may help.
- Do not get involved in long explanations of the project, the forms, the research methods, or the outcomes of the study. Be sure to use standard responses.
- Invite participants to talk to your supervisor or Clinic Manager if they wish to carry a discussion further.



### **Second Guessing Purposes of Questions**

- Do not invent your own explanations when participants want you to tell them why certain questions are included in the interview. For participants who persist, tell them that the researcher had a purpose for the question and that you must ask all the questions as they are written.
- Invite participants to talk to your supervisor or Clinic Manager if they wish to carry a discussion further.

### **Advancing Age**

- Gauge your pace according to the needs of the participant. Some older participants may require a slower delivery; others may be insulted by it. (See *Section 20.2.1 - Older Women* for more detailed suggestions on working with older participants in the research setting.)

### **Hard of Hearing**

- For participants who might rely on lip-reading, make sure your face is clearly visible and not obscured by hair, glare, or shadows.
- Slow down for participants with hearing problems and speak in lower-pitched (more bass-pitched, not soft-spoken or high-pitched) tones.
- If you need to increase the volume, move closer to the participant to avoid shouting. Female interviewers often increase their pitch when they speak louder which makes hearing more difficult for many participants who hear lower-pitched tones better. The participant may also turn her “good” ear toward you. Take this cue to speak clearly and distinctly toward that side.

### **Lack of Understanding or Recall**

- Take responsibility for making questions understandable. Do not make participants feel that it’s their fault if they don’t understand a question.
- Take away the burden of not remembering: participants shouldn’t feel ashamed by lack of recall. If a participant doesn’t remember a date, lead a discussion back through some prominent seasons or events, repeating the phrase of the question as you go.
- Repeat the question at least once for the participant who does not understand the question. Repeat it twice if the participant has patience for it. After that, record whatever answer the participant offers and go on. Don’t risk annoying the participant for the sake of an answer to a single question.
- If a participant asks what a word means, use only the definitions provided on the forms and in the instructions. If there are none, say “Whatever the word means to you.” In some instances, you may also emphasize again that the researchers are interested in the participant’s feelings and that you “can’t really answer for” the participant or “put words in her mouth.”

### **Wandering, Extra Talking**

- Focus the participant’s attention on the questions, while always being polite. Respond to attempts at idle conversation, no matter how interesting, with brief answers, then return to the form. For example, say, “That’s very interesting...now, what would you say about (the question)?” Participants will get the message that you’re not going to engage in extraneous conversation (see “Use Body Language” under *Section 2.11.4.1-Interview Techniques* above).

#### **2.11.4.3 Guidelines for Suicidal Ideation (Required)**

Since distress can vary in severity, so the response by WHI staff must vary. Below you will find suggestions on how to handle three different levels of severity. As state laws governing how to respond to suicidal

individuals may vary, each WHI PI should consult with a mental health professional to determine the best actions to take when severe distress or suicidality is detected.

It is recommended that each site determine those staff who have the level of comfort and sufficient experience to proceed with the assessment described in Level 1 below. Those staff who feel a participant may be seriously distressed but do not feel comfortable with addressing this with the participant, should ask the designated staff who can comfortably proceed to complete the interaction with the participant. The PI at the site should be made aware immediately of any participant with serious emotional distress symptoms, especially suicidal thoughts.

### **Level 1: Significant symptoms of distress (e.g., depression)**

Clinic staff who identify significant distress should:

1. Seek further information through paraphrasing to clarify the significance of her distress (I hear you saying . . . Did you say . . . etc). If in doing so the participant does not express suicidal thoughts, proceed with the steps 2-5 below. If she does express suicidal thoughts proceed to Level 2.
2. Recommend to the participant that she consult with her primary care physician who can evaluate and treat her or refer her for specialty care.
3. Request and document in writing (i.e, put in participant's file) permission from participant to follow-up with her within a few days.
4. Notify the responsible WHI clinician or the lead practitioner at the site.
5. Call participant within a couple of days for follow-up.

### **Level 2: Significant symptoms of distress (e.g., depression) with statement such as "life is not worth living, I wish I were dead."**

Clinic staff should refer participant to the responsible WHI clinician (e.g. Clinic Practitioner, PI) for further evaluation. The responsible WHI clinician should assess suicidal intent through direct questioning.

1. If the participant's distress is so bad that she is planning to hurt herself then go to Level 3. If the participant denies that she is planning to hurt or kill herself, proceed through steps 2-6 below.
2. Encourage her to consult her personal physician immediately and offer assistance with that communication (e.g., let her use clinic phone).
3. Request and document in writing her permission to contact a family member. Call family member and inform him/her of the situation. Repeat your recommendation to contact her personal physician as soon as possible.
4. Request and document in writing her permission to contact her personal physician. Call her physician and inform him/her of participant's status.
5. Request permission from participant to follow-up with her within a few days.
6. Call participant within a couple of days for follow-up and notify PI.

### **Level 3: Significant symptoms of depression with statements indicating suicidal intent**

State laws vary regarding the responsibility a staff person has if a participant were suicidal. Therefore, each site should develop a set of guidelines that are consistent with state law. It is recommended that each PI consult with a mental health professional to develop them.

Generally, clinic staff should:

1. Inform the participant of the importance of preventing her from hurting herself. Request and document in writing her permission to contact a family member, friend or family physician. If the participant refuses to tell her family/doctor, inform her that you are obligated to do so.
2. Call family member and/or physician and inform him/her fully. Ask family member to come to clinic site and accompany her to her personal physician's office, local emergency room or community mental health clinic. If no family member is available, accompany her to one of these treatment sites.
3. Develop a policy consistent with state and local laws regarding the CC's responsibility to treat suicide intent. Clinics should consult with a mental health professional (i.e. psychiatrist, psychologist).

#### **2.11.4.4 Guidelines for Domestic Violence (DV)**

In the course of interacting with WHI participants, staff will encounter women who disclose or have evidence that they are in a situation involving domestic violence (DV). Since the level of risk may vary, the response by WHI staff can be flexible. State laws may have mandatory requirements governing how to respond to DV. Each CC therefore needs to ascertain any such jurisdictional reporting requirements and apply these within the suggested guidelines that follow. Each CC will also need to identify the staff member, best suited by experience and comfort level, who should interact with the participant regarding DV, and determine how the staff member receiving the original report should respond.

While many staff members may know information about DV, it is frequently difficult to know what words can be used. For this reason specific scripts for assessing the participants status are included within the algorithm below. The purpose is to provide timely, emotionally sensitive support to women who reveal that they are currently or were recently in an unsafe, abusive relationship.

##### **Background**

There are many factors that contribute to the difficulty staff have in discussing issues related to DV with study participants. Some of these factors may be:

- a. the issue of DV is stigmatized in our society and therefore an uncomfortable subject;
- b. staff members may have personal experiences with DV by having witnessed violence in their family or personally being a survivor of DV;
- c. the WHI study does not have DV as an outcome, and staff may not have been trained in appropriate assessment and brief intervention for women in situations involving DV.

Always discuss issues of DV in a private setting. Self-disclosure of domestic violence may involve a lot of risk-taking for the woman. This is especially true if the woman has never previously shared this information.

While some women may voluntarily self-disclose currently being in a relationship involving DV, many women will not self-disclose information due to many reasons, including fear of retaliation, low self-esteem, shame/embarrassment, isolation, a perception that the staff is not supportive of issues of DV, and lack of trust in the staff (fear that they will be reported).

##### **Assure confidentiality of her answers.**

"Your answers to the questions on these forms are confidential. We will not share this information with anyone," (add "within limits of the law" where there are mandatory state or local laws regarding reporting of DV).

It is suggested that CCs provide resource cards in places accessible to participants such as the women's restroom. These small resource cards can be privately accessed by women and are also an explicit message to participants that the CC considers DV an important women's issue. Posters in exam rooms or restrooms addressing support for abused women may help to communicate to women that your CC and WHI is concerned about DV.

**General Preparation for DV**

- Compile a list of DV resources for your clinic.
- Perform in-service training for clinic staff.
- Establish liaison with community resources.

**Algorithm for Assessment and Resource/Referral Support:**

1. WHI participants may disclose that they are in relationships involving DV through their responses to questions on WHI forms (see below) or by mentioning this during a visit.

*Form 37 – Thoughts and Feelings* (Ver. 4), Item 97 – “Were you physically abused by being hit, slapped, pushed, shoved, punched or threatened with a weapon by a family member or a close friend?”

*Form 37 – Thoughts and Feelings* (Ver. 4), Item 98 – “Were you verbally abused by being made fun of, severely criticized, told you were a stupid or worthless person, or threatened with harm to yourself, your possessions, or your pets, by a family member or close friend?”

**Or**

*Form 38 – Daily Life* (Ver. 5), Item 52 – “Were you physically abused by being hit, slapped, pushed, shoved, punched or threatened with a weapon by a family member or a close friend?”

*Form 38 – Daily Life* (Ver. 5), Item 53 – “Were you verbally abused by being made fun of, severely criticized, told you were a stupid or worthless person, or threatened with harm to yourself, your possessions, or your pets, by a family member or close friend?”

Participant answers “**Yes**” to any of the above questions.

Staff response: “I noticed that you answered “yes” to this question about physical (or verbal) abuse and it upsets me. We ask these questions on WHI forms because violence in the home is a significant health risk for women that the study is concerned about. I appreciate your honesty in answering these questions.”

Follow with brief assessment of:

- a. The safety of the woman’s current situation. “Was the abuse that you said upsets you something that is happening in your relationship or your home right now?” “Do you feel safe going home tonight, or do you have a friend’s house or would you like the name of a shelter that you might go to?”  
  
If there is current danger and the woman does not want to go to a friend’s house or a shelter, ask “Are there guns, weapons, or knives in your house?” If yes, “Where could you take these so you would be safer?”
  - b. Her readiness to seek help, “You don’t deserve to be in a situation where you are afraid of being hurt. Here is a list of community resources, supportive counselors, and of safe places for you to stay. Do you think that you might be interested in talking to one of these resource people now or in the future?” If the participant does not want the list, then mention, “If at any time you need the phone numbers, we have cards in the ladies room that you can take privately if you wish.”
2. WHI participants may present with physical evidence or abuse (e.g., bruises, healing abrasions/lacerations, any type of injury). In these instances, designated staff should establish whether or not these signs are due to DV, and if so should assess the severity of the situation in a similar fashion as described in a and b above, including compliance with state requirements.

For participants who show no evidence of physical abuse and answer “**No**” to the previously identified questions about DV, resource support cards should be provided in the restrooms.

**Resources:**

K. Furniss. "Domestic Violence: What Nurses Need to Know."

Kaiser Permanente NW. "Domestic Violence Diagnosis & Assessment."

C.P. Mouton, S. Rovi, K. Furniss, N.L. Lasser. "The Associations between Health Status and Domestic Violence in Older Women: Results of a Pilot Study."

## Section 2 Clinical Center Guidelines

### Table of Contents

Contents	Page
<b>Introduction .....</b>	<b>2-1</b>
<b>2.1 Clinical Center Facilities .....</b>	<b>2-2</b>
2.1.1 Clinic Area .....	2-2
Required Clinic Areas (Required) .....	2-2
Recommended Clinic Areas .....	2-2
2.1.2 Computing .....	2-3
Preparing Facilities for WHI Computing System (Required) .....	2-3
Guidelines for Allocating Computers to Clinical Center Areas .....	2-3
2Guidelines for Data Entry Area .....	2-4
2.1.3 Remote Sites .....	2-4
Remote Site Randomizations .....	2-5
Remote Site Follow-up Visits .....	2-5
<b>2.2 Services (Required).....</b>	<b>2-6</b>
<b>2.3 Equipment and Supplies .....</b>	<b>2-7</b>
2.3.1 Equipment and Supplies Supplied to CCs .....	2-7
Equipment Supplied by NIH.....	2-7
Supplies Provided by the CCC.....	2-7
Supplies Provided by McKesson BioServices .....	2-8
Supplies Provided by EPICARE.....	2-9
Supplies Provided by Businesses or Corporations .....	2-9
2.3.2 Equipment and Supplies CCs Must Purchase (Required).....	2-9
Computer Equipment and Supplies .....	2-9
DM Intervention.....	2-9
Clinical Measurement .....	2-10
ECG Measurements .....	2-12
Blood and Urine Collection, Processing, and Shipment.....	<b>Error! Bookmark not defined.</b>
Other Equipment and Supplies .....	2-14
2.3.3 Recommended Supplies .....	2-15
<b>2.4 Staffing.....</b>	<b>2-19</b>
2.4.1 Clinical Center Management.....	2-19
2.4.2 Clerical and Support.....	2-19
2.4.3 Recruitment Activities .....	2-20
2.4.4 Clinical.....	2-20
2.4.5 Nutrition Interventionist .....	2-21
2.4.6 Dietary Assessment Staff .....	2-22
2.4.7 Outcomes Specialist.....	2-22
2.4.8 Data Coordinator.....	2-23
<b>2.5 Participant Contacts .....</b>	<b>2-24</b>
2.5.1 Participant Timeline (Required).....	2-24
2.5.2 Tasks Per Participant Contact (Required).....	2-24
2.5.3 Estimating Number of Participant Contacts .....	2-25

<b>2.6</b>	<b>Activities Common To Participant Contacts .....</b>	<b>2-27</b>
<b>2.7</b>	<b>Clinical Center Checklists .....</b>	<b>2-28</b>
<b>2.8</b>	<b>Participant Files (Required).....</b>	<b>2-29</b>
2.8.1	Release of Participant Files (Required) .....	2-29
2.8.2	Description .....	2-29
2.8.3	Contents and Organization .....	2-29
<b>2.9</b>	<b>Clinical Center Internal Procedure Manual .....</b>	<b>2-30</b>
<b>2.10</b>	<b>Emergency Procedures .....</b>	<b>2-33</b>
2.10.1	Telephone Procedures .....	2-33
2.10.2	Clinical Center Emergencies .....	2-33
2.10.3	After-Hours Procedures (Required) .....	2-34
<b>2.11</b>	<b>Interviewer Procedures .....</b>	<b>2-35</b>
2.11.1	Overview.....	2-35
2.11.2	Research Project Interviewing.....	2-35
2.11.3	Interviewer Roles (Required).....	2-36
2.11.4	Interview Guidelines       2-38	
	Interview Techniques (Required) .....	2-38
	Special Situations (Required) .....	2-42
	Guidelines for Suicidal Ideation (Required).....	2-43
	Guidelines for Domestic Violence (DV).....	2-45

## Figures

2.1	Projected Number of Screening Activities, Randomization and Follow-Up Visits Per Month.....	2-26
2.2	Clinical Center Checklists .....	2-28

## Tables

2.1	Suggested Personal Computer (PC) Locations .....	2-3
-----	--	-----