SECTION 3

RECRUITMENT

INTRODUCTION

Recruitment in clinical trials is difficult, usually more so than anticipated. Because study power calculations assume an even flow of randomization throughout the designated recruitment period, careful plans must be devised so that goals can be met in a timely fashion. All the Clinical Centers (CC) made those careful plans. The following is a general list of guidelines to consider to help meet the participant goals for recruitment in the Clinical Trials (CT) and Observational Study (OS).

- Recruitment should start promptly on the targeted date.
- Multiple and varied recruitment strategies are advisable at each site.
- One individual (recruitment coordinator) at each CC site should have overall responsibility for recruitment and be provided sufficient staff.
- Recruitment staffs should have trial-wide networking, including meetings and conference calls.
- Staff turnover should be anticipated, and backup personnel should be trained in advance.
- Staff trained for diverse populations and ethnic matching of staff and screenees can enhance recruitment.
- Recruitment and CC sites should be physically accessible to participants in terms of location, parking, and transportation.
- Clinical Centers should establish accurate systems to monitor their own recruitment progress.
- The medical and lay communities should be well informed about the study before the onset of recruitment.
- Local medical associations and hospital staff members should be contacted by the Principal Investigator at each CC.
- Special-interest groups should receive presentations in appropriate language from the recruitment staff.
- Since the study involves older adults, public relations campaigns should provide a positive image of aging

This section describes **guidelines and recommendations** for recruitment and initial screening of potential participants. Although the procedure for recruitment is more flexible than the procedures for screening, follow-up, and intervention, all plans for recruitment must be described by the CC and submitted to Clinical Coordinating Center (CCC). The process is described below.

3.1. Overview

Recruitment of study participants begins with a plan for the identification of sources of potential participants. The recruitment process begins when the potential participant is invited to express interest in participation, and ends when she comes to the CC for Screening Visit 1 (SV1).

The purpose of recruitment is to:

- Identify groups of potential study participants.
- Introduce the study to potential participants who express preliminary interest.
- Identify potentially eligible women for in-depth eligibility assessment.

The tasks involved in recruitment are:

- Prepare a CC-specific recruitment plan (see *Section 3.2. –Recruitment Plan*).
- Incorporate use of study-wide materials (see *Section 3.3. - Study-Wide Recruitment Efforts*).
- Conduct initial mailings (see *Section 3.4. – Solicitation of Participants).*
- Conduct screening telephone calls (see *Section 3.5. - Screening Contact*).
- Send the screening packets to eligible women (see *Section 3.6 – Mailing Initial Baseline Forms*).

Clinical Centers are encouraged to identify methods for increasing the efficiency of recruitment and screening. Some CCs will substitute in-person contacts for mailings and telephone calls to enhance their ability to reach certain populations. The data collection requirements remain the same, regardless of the mode of contact. The general guidelines for interviewer-administered questionnaires (*Section 2.11. – Interviewer Procedures*) should be followed when providing assistance to women completing self-administered forms.

Each CC will recruit a portion of the 63,000 CT participants in the Dietary Modification (DM) component and in the Hormone Replacement Therapy (HRT) components over a 3-year period. An additional 100,000 are to be enrolled in the OS component.

3.1.1. Clinical Coordinating Center Role in Recruitment

The CCC is responsible for monitoring, fostering, and encouraging the recruitment effort, and for providing accurate and timely information on the number of participants screened and randomized at each CC. The CCC distributes monthly recruitment activity reports to all participating CCs and the National Institutes of Health (NIH). The reports contain information on all aspects of recruitment, including: yields from each stage of the screening process, actual vs. goal achievements in screening and randomization, etc. These reports serve two purposes: 1) to inspire supportive and constructive collaboration among CCs, and 2) to alert the NIH to study-wide or CC-specific problems early enough to take corrective action.

The CCC Recruitment Coordinator serves as the key contact person for the Recruitment Coordinators at the CCs. The CCC Recruitment Coordinator reviews the CCs' recruitment materials and methods for procedural effectiveness and scientific integrity, passes information and concerns between the scientists and the CC Recruitment Coordinators, keeps the CCs informed of national recruitment efforts, participates in recruitment associated conference calls, provides support in the use of the recruitment database, generates recruitment reports, and trains CC Recruitment Coordinators at central training sessions.

3.1.2. Recruitment Coordinator

Clinical Center Recruitment Coordinators are members of the regional Recruitment and Retention Staff Groups that meet via conference call monthly or as needed during the recruitment period to review progress in recruitment and share experience and expertise. The purpose of these calls is to provide collaboration and

develop camaraderie among recruitment staff. *See Vol. 1 – Study Protocol and Policies, Section 2 – Protocol, Section 10 – Study Organizations*.

3.1.3. Recruitment Activities Data Collection (Required)

To capture information on the efforts of the CCs to identify women who might be potentially eligible and interested in participating in the study, the CCC provides *Form 1 - Recruitment Activity Summary*. This form is intended to collect data on the number of mailings, advertisements, news articles, public service announcements, presentations, etc., that a CC does during a 1-month period. The CCs complete and submit the form to the CCC on the first working day of the month for the previous 1-month period. One of the requirements of the form is that the CC attach any recruitment materials developed during the reporting period (for example, press releases, public service announcements, newspaper articles and advertisements, posters, cards and other marketing tools). The CCC keeps these materials in a library of study-wide and CC-specific recruitment materials.

3.1.4. System for Addressing Problems in Recruitment

It is essential that recruitment for the study be completed in a timely manner. Monthly recruitment reports distributed by the CCC are reviewed and addressed by PIs, staff groups, subcommittees, CCC, or the NIH Project Office. See *Vol. 1 – Study Protocol and Policies, Section 2 – Protocol, Section 10 – Study Organization*. Questions about protocol and procedures may be directed to the CCC via the Inquiry Reporting System (IRS). (See *Section 1.4.2 – Methods of Communication* and *Form 171 – Inquiry Form*.)

3.1.5. Guidelines for Developing Recruitment Materials

The following guidelines should be considered when preparing all recruitment material. They include suggestions about content, visual design, writing style, printing and mailing. These guidelines will be used by the CCC when reviewing recruitment materials developed by individual CCs.

Content

- Be brief. Include only what the reader needs to decide to contact you. Ask yourself, "Would I really read this after a busy day?"
- Put the most important points first and last. Use a logical sequence for the rest.
- Keep language appropriate at about a 6^{th} grade level.
- Do not make false claims or promises (for example, do not include: "By participating in the study you will lose weight, live longer," etc.).
- On brochures or letters with an enclosure card or tear off, consider the need for confidentiality. Do not ask for personal information.
- Do not discriminate. The contents of materials you send to a particular group should be the same as that given to other groups, although the style may differ.
- Pilot test developed materials. Show the materials to age-eligible women not connected with research for only a few seconds, then ask, "What would you say this is all about, in your own words?" Then ask them to read it over more slowly and tell you what it is about. Revise materials if necessary and then retest.
- Include: "funded by the National Institutes of Health."

Visual Design

- Make sure that the visuals draw the eye to the two or three key points.
- Consider inclusion of your own institutional seal for credibility.

- Include the study logo and catch phrase on all recruitment pieces, including posters.
- Include lots of white space in the margins and between blocks of text.
- Use illustrations (simple line drawings are best) to reinforce information and direct the eye to the key points.
- Show the material for a few seconds to some age-eligible women not connected with research and ask them what they notice first, what they remember, what they should do, etc.

Writing Style

- Use a simple and relaxed conversational style. Don't be afraid to use the word "you." Ask yourself, "Would I talk like this to my grandmother?"
- Avoid large blocks of text. Break information into bulleted lists whenever possible. Ask yourself, "Can I scan this in a few seconds and find what I need?"
- Use the active voice. State subject and verb directly instead of describing object as acted upon by an unstated subject. For example, use "You will receive these benefits" rather than "Benefits provided include." Be direct and personal.
- Use short and simple words (for example, "assigned by chance" rather than "randomized"; "handouts about" rather than "handouts pertaining to").
- Use short and simple sentences with as few qualifying phrases as possible. The best structure is: subject, verb, object. Limit each sentence to one idea.

Printing

- Prepare camera-ready (not Xerox) copies for the printer.
- Print on at least a 60-pound paper if double sided. Self-mailers are often printed on 65-pound paper.
- Letters must be on your institutional, a referring agency's institutional, or WHI letterhead with an official signature and timely date.
- Color of type print and paper should be consistent with and complement those agreed upon for the study. Black print on white or yellow is the easiest to read.
- Type style and size for the text should be consistent and should be 12 point or larger. Do not use script or sans serif fonts. These fonts don't have the squiggles on the ends of the lines and therefore make letter recognition harder.
- Do not use all capital letters, even in titles or headings. Capital letters are more difficult to read and recall. Use larger and bolder print instead.

Mailing

- Type or handwrite addresses on mailing envelopes. Participants may respond positively to handwritten envelopes but time and cost factors may prohibit this strategy. Postal regulations state that one may handwrite the name and address when using bulk mailing, but anything else handwritten on the envelope is considered a message and is prohibited.
- Do not knowingly mail to the same individual more than three times.

3.1.6. Participant Material Review Recommendations and Guidelines

Participant materials are written materials given to women at any time during screening or participation in WHI. CCs should submit participant materials to their local CC's IRB and the CCC for review and approval. When submitting materials to the CCC, please indicate when and how the materials are to be used. Materials such as print adds or PSAs are not considered participant materials and do not need to be reviewed.

During CCC review of participant material, we have identified some common themes in these materials that are summarized here. Basic recommendations for preparing participant materials are contained in *WHI Manual Volume 2, Procedures, Section 3.1.5. – Guidelines for Developing Recruitment Materials*.

Nutrition Materials:

Articles, handouts, newsletters, and posters containing information on nutrition are not allowed for distribution to potential participants. This information can influence and/or contaminate women who may join the Dietary Modification part of the study. Although it is understood that nutritional information is widely available to the general public, the study cannot be directly responsible for distributing such materials.

HRT/Clinical Materials:

News or scientific material concerning menopause and/or hormone replacement therapy (HRT) should not center on its benefits or risks, but rather on the need for further research to answer the questions raised by HRT usage. Articles which promote HRT or alarm women may serve to discourage them from volunteering or continuing their participation in the WHI. This is because they can develop feelings of either needing to take "real" hormones (not potentially be randomized to a placebo), or making sure that they avoid hormones.

Terms:

Some terms and facts have been revised and/or corrected, based on recent committee decisions or procedural clarifications. Some of the revisions/corrections to keep in mind are listed below.

Commonly Used Terminology of Fact:	**Correct Terminology of Fact:**
avoid exercise for 8 hours before	avoid exercise for 12 hours before
Dietary Change Program	Dietary Program
Dietary Intervention Group	Dietary Change Group
Food Frequency Questionnaire	Food Questionnaire
low-fat diet	low fat, high fruit, vegetable, and grain dietary pattern
practice pills	study pills
run-in period	enrollment period
study hormone medications	study pills
the largest study ever on women's health	one of the largest studied ever on women's
Usual Diet Group or Dietary Control	Dietary Comparison Group

Phrases:

To avoid giving an incorrect impression of the study or of a woman's participation in the study, some conditional phrases are recommended.

Unconditional phrase:	**Conditional phrase:**
study is looking at how to improve	study is looking at ways to improve
will answer questions about	may help answer questions about
will improve your health	may improve your health
you will receive	you may receive

Readability:

The reading level of participant materials is very important. It may not be widely known that to follow the instructions on an aspirin label requires a 10th grade reading level while one if four American adults reads at a 5th grade level or below. Also, the grade level achieved in school is not a measure of an individual's reading skills. You can use Microsoft *Word*™ to evaluate a document using he Tools menu and selecting Grammar. Several suggestions for improving a document's readability are listed below.

- **Use the active voice where ever possible:** State the subject and verb directly instead of describing an object as acted on by an unstated subject. Speak directly to the participant. The passive voice often makes your writing less clear because it often leaves out who will do the action.

  Active voice: We will give you the test results.

  At this visit, we will tell you more about the study.

  Please do not eat for 12 hours.

  Passive voice: Test results will be given to you.

  At the visit, women are told more about the study.

  Women are asked not to eat for 12 hours.

- **Use shorter sentences and words:** Participant material is made more readable by using shorter sentences and simpler words, less wordy phrases and more positive wording. Many people have a hard time following the key point in a long sentence, particularly if it has a lot of clauses. Ideally, sentence length will vary so the reader won't find the material monotonous. An average readable sentence length in American English is 17-23 words. If your sentence is over 25 words, your writing may be difficult to read. A long word has three or more syllables.

  Shorter sentence: Studies will help decide how best to prevent these diseases. (10 words)

  Longer sentence: As a result, recommendations for successful prevention and treatment of these diseases cannot be made with confidence, due to the lack of adequate clinical testing. (25 words)

  Shorter word: about

  Longer word: approximately

- **Use simple phrases:** Use a simple and relaxed conversational style.

  Simple phrase: Women can be part of the answer.

  Wordy phrase: Women now have the opportunity to be part of the answer.

- **Use positive wording:**

  Positive wording: Please do not exercise.

  Negative wording: You will not be able to exercise.

- **Minimize medical jargon and avoid technical terms:** When medical jargon is necessary, define the medical term immediately after it appears in the sentence.

- **Words:** Some words commonly used in WHI are not familiar to the lay public or have negative connotations. Therefore we suggest using simpler substitute words when preparing participant materials. A list of recommended words is given below.

Commonly Used Words:	**Recommended Substitute Words:**
approximately	about
assistance	help
cardiovascular disease	heart disease
clarify	make clear
compensate/reimburse	pay
concerning	about
conclusion	end
consult the map	use the map
currently	now
diseased afflicting women	diseases in women
dispense	give
do not hesitate to call	fell free, please call
e.g.	for example
eligible	if you can join
endometrial aspiration	test of the lining of the uterus or womb
experiment	study
exposed/exposure	worked with/lived with
i.e.	that is
immediate	right away
impact	make a difference, effect
in order to	to
in the absence of	without
intervention/treatment group	women in the Dietary Change group/getting active pills
medication	study pills or pill bottles

Commonly Used Words:	Recommended Substitute Words:
myself	me
notify you	let you know
osteoporosis	osteoporosis (weak or brittle bones)
participate in	join or take part in
pelvic exam	female or internal exam
placebo	inactive pills
postmenopausal	change of life
prior to	before
procedures	tests, exams, activities
provided	given
randomized	group is chosen by chance
remain	live or stay
require	ask, need
research	study (some ethnic groups think of experiment or exploitation when they hear the word research)
reside	live
select	choose
similar	like
study arm/component	study part/programs
subjects	participants, women
submitted	given
trial	study
uterus	womb
voicemail	a recording machine

Formatting:

- **Use 12-point Serif fonts:** Participant material is more readable if a ≥ 12-point font is used (the font used here is 12 points). The ideal font size for older populations is 13 or 14. Do not use `script`, or sans serif fonts. Sans-serif fonts don't have the squiggles (serif) on the ends of the lines that make the letter recognition easier. Serif type is the most familiar style (this type is Times New Roman) and the easiest to read. Mixing several types styles on the same page may also be confusing.
- **Use upper and lower case:** Use upper and lower case letters even in titles and headings. CAPITAL LETTERS are more difficult to read and recall. Use larger or **bolder** print or underlining instead.
- **Preserve white space:** Do not crowd too much information on a page. During screening, you have three screening visits and several months to convey the complex information regarding the Women's Health Initiative to the potential participant.

3.2. Recruitment Plan (Required)

Each CC prepares a detailed recruitment plan following guidelines provided by CCC. This includes a complete calendar of all events related to recruitment activities with specific attention to the initiation of recruitment strategies and their subsequent regular, periodic evaluation. Mass mailing drop-dates, media coverage, and community events that the CC is participating in or presentation to lay and professional groups, etc. are noted on the calendar. The calendar can be used to evaluate the effectiveness of past strategies and to plan future ones. In the case of media coverage or publicity the CC can plan for an increase in public response.

Peer review of each CC's plan will be carried out by other RCs at training workshops. The CCC will retain a copy of all recruitment plans. Subsequent updates will be submitted to the CCC at six month intervals.

Each of the CC plans should contain the following information:

- A description of the primary and backup catchment areas (in grant application).
- Census or other data on the target population (women between 50 and 79 years old).
- A description of specific recruitment approaches that will be used and in what order.
- Estimates of yields from the specific approaches based on past experience.

Each plan should describe backup strategies that can be quickly employed if the primary strategies result in a less than expected yield. A minimum of three months and up to six months may pass before the results of a newly implemented strategy is evident. Most CCs use an integrated approach to recruitment, employing most, if not all of the following approaches discussed below simultaneously.

3.2.1. Targeted Mass Mailings

All CCs are encouraged to employ a major direct mail campaign, involving tens of thousands of mailings to women in the target age group. Age-eligible women can be identified through a variety of sources: motor vehicle registration lists; drivers' license lists; Health Maintenance Organization (HMO) membership databases; voter registration tapes; Medicare enrollee lists; health insurers' lists; commercial mailing list brokers, etc. These sources usually include name, address, age, and gender. In addition to these general sources of age-eligible women, many CCs have identified several other enriched sources of participants. These include databases containing some clinical information as well as general demographics, such as breast cancer screening clinic patients or screenees or participants in previous clinical trials. The above described mailing lists are invaluable resources.

Previous experience suggests that second and even third mailings using the same list can increase the yield slightly. Because most mailings from the CCs use bulk rate (third class) it may take at least a week for the Postal Service to deliver, and another week for the reply card to be returned. Therefore repeat mailings should be spaced at least three or four weeks apart.

Another approach is to repeat mailings according to response. If the response is low from a specific age-group or zip code, remail at a different time of year. For the older age group, choose good weather and moderate temperatures. Exclude the holiday seasons from mailings. If the response is good to the first mailing, remail at the same time of year on a yearly basis. Those not able to consider participating when you first mail may be available the next year. If the remailing is done from the CC rather than an HMO or other organization, a cover letter should mention that you have sent them information previously. Also, mention of recruitment statistics may spur some women to respond. For example, “In the past year, 500 women have enrolled in the Women’s Health Initiative…”.

To facilitate formation of intervention groups for the DM component, it may be preferable to target mailings within geographic areas or zip codes.

Mailings usually consist of a letter inviting women who are age eligible to return a form or postcard indicating their potential interest. Include a brochure describing the study (see *Section 3.3.3. – WHI Recruitment Brochure*) with a postage-paid return envelope or postcard. An interested woman can either call or mail in her response.

3.2.1.1. Identification of Sources of Names

Each CC identifies potential participants through various referral sources. The nature of these sources depends on the target population of the CC. The procedure for identifying potential participants varies by referral source and CC.

In each case, negotiations are made with the individual sources. Some sources provide mailing labels, while others require the CC to furnish recruiting materials for mailing by the source.

It is best to target groups with whom you already have a relationship and to maintain visibility with them. It is important to establish ongoing relationships with the agencies that have agreed to cooperate.

Do not assume that the negotiations will be completed quickly. Experience suggests that some negotiations may take months to finalize. Thus you will need to develop these relationships many months in advance of planned initial mailings to avoid delays in the recruitment schedule.

Monitor the success of various recruitment strategies and referral sources. This information is used to streamline the process and troubleshoot recruiting problems for all CCs. To monitor recruitment, assign a 3-digit number to each different referral source and different recruitment strategy you use. For example, brochures handed out at health fairs, presentations, or to individuals to pass out to their friends and co-workers would be three different referral source codes. Assign two referral source codes to a source to which you do two mailings, one for the first mailings and a different number for the second mailings. For example, a CC doing second mailings would assign the following referral source numbers:

101 Organization A - first mailing

102 Organization A - second mailing

201 Organization B - first mailing

202 Organization B - second mailing

Monitoring the return and eligibility rates of these sources can guide you in future recruitment plans. Clinical Centers can monitor this in several ways: add a referral source code (RSC) in the recruitment database (RDB) available through the CC; use a user-defined field in the WHILMA database, or on *Form 2/3 – Eligibility Screen*.

3.2.1.2. Using Sources for Preliminary Screening

The screening of potential participants begins with the initial identification of individuals. Because of the time and cost spent in screening potential study participants, the referral sources should know and publicize only <u>limited</u> eligibility criteria.

Give out only the following eligibility criteria to individuals not associated with this study.

- The participant must be aged 50–79.
- The participant must be female.
- The participant must be postmenopausal.
- The participant must be able to attend regular CC visits.

The ability to assist with this limited eligibility review varies from source to source, depending on its available information. Usually, screening at the source level is limited to screening lists for age-eligible women. It is best to begin with sources that have the largest numbers of potentially eligible individuals.

3.2.2. Priming the Community

All CCs should identify techniques to be employed before embarking on recruitment, including informing the medical community, the community-at-large, and the special communities providing services to older adults, special populations and/or women. Clinical Centers can mail letters to physicians and medical societies in the local area describing the study, requesting referrals and giving assurances that the goals of the study do not conflict with or supplant the primary care physician (*see Figure E.1.1. – Model Letter to Community Health Care Providers and Physicians*). The lay community can be informed through general press releases (see *Figure E.1.3. – Model National Press Release*) in the local print and visual media or radio and TV talk shows featuring interviews with study investigators, public service announcements (PSAs) on TV or radio, and feature articles in specialty magazines, newspapers, newsletters, etc., targeting older women. Good rapport with the community is essential to successful recruitment.

3.2.3. Mass Media

Recruitment can be planned and promoted through various marketing and publicity strategies. These methods vary between CCs.

The CCC can provide the CCs and their institutional public relations personnel with sample press releases or CCs can prepare their own (see *Section 3.1.5. – Guidelines for Developing Recruitment Materials*).. The material released should be fairly specific for the population of interest. Send a copy of all publicity materials to the CCC Recruitment Coordinator for inclusion in the recruitment materials library. The CCC RC will review these materials using the same guidelines.

Clinical Centers must be prepared to handle, by letter or telephone, the response from the public immediately after the media publicity goes out, including national publicity (for example, NIH announcement of new CCs). A contact phone number is essential. If an answering machine is used, let participants know so they won't expect an immediate response and can feel comfortable leaving a message. Press releases should not be sent out until the CC is organized to handle the response. Responses to media messages will vary. Plan to do press releases based on human interest and pubic events (for example, the opening of CCs, Mother's Day, etc.). Be certain the press release contains some new information. Don't be too optimistic that the responses will continue for long. It is surprising how quickly the calls stop after a newspaper article or PSA has run. Plan to do another release in a few weeks.

All CCs should plan to use the media, such as local television news spots, newspaper feature articles, etc., for informing the community and for requesting volunteers for the study. For CCs that are especially successful using mass media as a recruitment tool, this may be the source of most of their participants. For most, it will more likely be an adjunct to a primary strategy of mass mailings. The media messages should communicate that the volunteers must be generally healthy women aged 50–79. The effective coordinated use of mass media along with mass mailings can result in dramatic increases in response.

CCs using sequential geographic recruitment strategies to facilitate DM group formation may not want to use mass media as a primary recruitment tool or may need to modify their responses to call-ins generated from publicity.

3.2.4. Community Activities

Clinical Centers can participate at health fairs, blood pressure screenings, or other women's events such as "Race for the Cure," to pass out brochures and be seen by the community. You can identify the organizations, agencies, and group residences that have older women as their clientele and make arrangements to address these groups and solicit participation.

3.2.5. Medical Records

Some CCs will screen medical records as a backup strategy. From medical records it is possible to identify potential participants who meet basic eligibility requirements. Once potential participants are identified in this way, it is most effective to have the invitation for screening come from the personal physician. For example, a CC might plan to give brochures and invitations to all age-eligible women attending a large radiology group practice. Specific medical record review is very labor intensive.

3.3. Study-Wide Recruitment Efforts

Although the individual CCs bear the responsibility of recruiting participants for their CC, study-wide efforts using the same or slightly modified recruitment and orientation materials at each CC can enhance visibility and bonding with the national study. For example, when all CCs begin recruiting, there will be a national public awareness and recruitment campaign using appropriate materials, national television shows, magazines and public service announcements (PSAs) with prominent spokespersons. The CCC will coordinate this campaign with a public relations firm and input from the Recruitment and Retention Staff groups, WHI committee structure, and the NIH Project Office.

3.3.1. Video Tapes

The WHI will produce at least four videos. One video will provide a brief (10-15 minutes) overview of the study to be used either for recruitment, at the time of screening, or during a group orientation meeting or community presentation. One video will be used for initial consent. Two videos discuss the risks and benefits of being in the CT and will be used as part of the informed consent process for DM and HRT.

3.3.2. WHI Logo and Catch Phrase

The study is so long that family and community support will be invaluable in the long run to keep women in the study and participating fully. Community recognition and support will also encourage women to participate until the end of the study. To generate this family and community support there must be wide recognition of the study and respect for those who are participating.

The WHI logo was designed as a visual strategy to generate recognition of the Women's Health Initiative among the general public and women in particular. It emphasizes that the study group is women. The catch phrase "Be part of he answer" emphasizes that women have a chance to participate in the study of women's health. See *Figure 3.1. – WHI Logo and Catch Phrase*. You can obtain an electronic copy of the logo from the CCC. The logo is an elegant, stylized depiction of mature women. The study colors are attractive and eye catching; blue (Pantone 287) and purple (Pantone 252). The colors are used effectively in a bleeding pattern on the study-wide brochure and medicine bags.

- Posters sporting the WHI logo and catch phrase can be used at health fairs and presentations, worksites and clinics, clubs, markets, libraries, and pharmacies to name only a few possibilities.
- Study materials should display the logo and can use the catch phrase on stationery, brochures, CC interest questionnaires, appointment reminder cards, birthday cards, note cards and invitations to participate.
- Recruitment and retention incentive gifts should display the logo and catch phrase on items such as pins, pot holders, memo pads, photo pins, or tote bags.

3.3.3. WHI Recruitment Brochure

A study-wide brochure has been developed for the WHI to be used by all CCs in their mailings or presentations. CCs can mail the brochure separately or include it in a mailing with a cover letter and interest survey. Brochures are printed with the same information for all CCs but with CC-specific information on one panel and on a tear-off, postage-paid return postcard. The brochure asks and answers general questions about the study and lists the CC's address and phone number. On the postcard, the woman is asked to provide her full name, current address, home and work phone numbers and to check how she heard about the study. The CC can write a referral source code on the postcard to aid in identifying the source to which the woman responded. The brochures are printed by the Government Printing Office (GPO). Clinical Centers order them quarterly through the CCC. See *Figure 3.2. – WHI Recruitment Brochure*.

If CCs choose to develop their own promotional brochure, it should conform to the criterion in *Section 3.1.5. – Guidelines for Developing Recruitment Materials*.

3.3.4. Slide Presentation

The Publications and Presentations Subcommittee of WHI has developed slides for professional presentations that are produced and distributed to all CCs. They should be reviewed and updated periodically. The slides vary in degree of complexity and detail. Individual CCs can therefore tailor the slide set used for presentations to physician groups, grand rounds, or other professional groups These slides may have limited usefulness for older laywomen. Additional slides are being created for lay presentations. Paper versions of these slides will also be provided if CCs want to make overhead transparencies.

3.3.5. Press Releases

Figure E.1.3. – Model National Press Release shows a sample press release that can be used as a model. See *Section 3.2.3. – Mass Media*, paragraph 3 regarding use of and response to press releases.

3.3.6. Public Service Announcements (PSAs)

PSAs should address the importance of WHI because many health concerns of women have been neglected by researchers in the past. Include that there is now an opportunity for women to "be part of the answer" in women's health. Present the choice to take action for the benefit of future generations of women. The benefit to an individual woman's health through screening and monitoring at no cost can be stated. Some PSAs could address ethnic barriers to health care and research studies. The special needs of diversity in literacy levels, ethnic backgrounds and culture also need to be taken into account.

Two examples of 30-second PSAs are:

> "Heart disease, cancer, and thinning bones are diseases that kill or disable a growing number of women each year. You can be a vital part of a nationwide study to determine ways to prevent these illnesses. Help launch a new era in women's health by participating in the Women's Health Initiative. If you are 50 to 79 years of age, you can make a difference, not only for women's health today, but that of future generations as well. Start your journey to a long life with a healthy heart and spirit. To register, call your toll-free line at…"
>
> "Heart disease is the number one killer of women in the United States. Breast cancer will affect one in every nine women. Weakening bones disable nearly 30% of women over age 75. You can help change these staggering statistics by joining one of the largest health studies ever conducted. (Local CC) is leading the way in the Women's Health Initiative – a nationwide study of factors that affect women's health. If you are 50 to 79 years of age and want to lay the foundation for women's health today and that of future generations, call our toll-free line at…"

3.3.7. Spokespersons

National and local spokespersons to spearhead PSAs on radio and TV could reach different populations through different media. Spokespersons of diverse ethnic backgrounds and ages are essential to appeal to different women. It will be critical to have spokeswomen who are recognizable to a broad range of American women. Possible candidates may be drawn from the following sectors:

- Celebrities
- Politicians
- Writers and journalists
- WHI PAC (Women's Health Initiative Program Advisory Committee)

3.3.8. Television

Television can be used most effectively to make the WHI well known to women and the public in general. WHI can be featured on local women's health programs. Talk shows might feature WHI when discussing women's health issues. Talk shows on Spanish networks can be especially effective for recruitment of Hispanic women. The under representation of minority women in many important research studies could be one topic that illustrates the special nature of the WHI.

3.3.9. Print Media

Magazines and Newsletters

- A number of national magazines identified to target for WHI articles are: TV Guide, Family Circle, Readers Digest, Redbook, Woman's Day, Ladies Home Journal, Working Women, American Health, People, Newsweek, Time, Vanity Fair, Ms., AARP Newsletter, HMO magazines and newsletters, employee trade magazines, etc.
- Press releases, could be sent to identified publications and writers.
- Clinical Centers should alert the CCC to any proposed national coverage so that all CCs can be alerted and prepare for the publicity.

Newsprint

- Prepare press releases and/or press conferences throughout the year and for Mother's Day, emphasizing that participation in WHI is a lifelong gift from mothers to their daughters' and granddaughters' future health.
- Identify newspapers with wide circulation in your area.
- Identify interest angles specific to each newspaper. Human interest articles featuring disease detection during screening or mother/daughter participants, for example, would stimulate interest. The angles should be attention getting and readership appropriate.
- Prepare news releases targeting various interest areas, for example, lack of women in research, lack of minorities in research, human interest, etc.
- Write a letter to health editors (or science, food, or lifestyle editors) with a news release. Follow up with a call to the health editor within one week.

Columnists

- Freelance writers and syndicates columnists who write regularly for local newspapers or magazines should be identified and contacted to encourage them to explore WHI issues as potentials subject matter.
- Get samples of columns from each paper to model news releases.
- Develop an angle(s).
- Write a letter to each columnist. Follow up with a call within one week.
- Establish a mechanism to tabulate and distribute on a monthly basis all written national promotion pieces.

3.3.10. Recruitment Video

Plans are underway to produce a WHI recruitment video as an upbeat marketing tool for use at community presentations and initial screening visits.

Some important themes are:

- Reasons for importance of WHI.
- Lack of research data on women.
- Benefits of participation.
- Components of the clinical trial.
- Women of different ethnic backgrounds and economic status in the video.

3.3.11. Timeline

Clinical Centers should develop and finalize a timeline of specific recruitment efforts 8-12 weeks before projected implementation dates for events such as those listed below.

- Holidays like Mother's Day (May)
- Special women's events such as National Breast Cancer Awareness Month (October), American Heart Month (February), or The Susan G. Komen Breast Cancer Foundation's Race for the Cure (all months of the year in different cities)
- Spring and fall, which are optimal recruitment months

For example, development should begin in February for April/May activities and in July for September/October activities.

3.4. Solicitation of Participants

Potential participants may be solicited using various strategies. One strategy is mass mailings using voter registration lists, Department of Motor Vehicles (DMV) lists, Health Care Finance Administration (HCFA, Medicare) lists, HMO lists, etc. Another strategy is participation in community activities like health fairs, civic celebrations, clinic openings, open houses, etc. Another valuable strategy is to employ local media in the form of PSAs for television and radio, participation in health programming, principal invegtigator interview, news stories and paid advertisements. All of these strategies may be used simultaneously in order to reach a wide and varied population.

3.4.1. Mass Mailings

The initial contact with a potential participant is usually a mailing that includes an introductory letter and the recruitment brochure with a return postcard, interest survey or prescreen. Send a draft of the introductory letter to the CCC for review and placement in the study-wide and CC-specific recruitment materials library. Follow *Section 3.1.5. – Guidelines for Developing Recruitment Materials*.

- Initial contact letter (see *Figure E.2.1. – Model Initial Contact Letter*): typically a 1-page letter that includes:

  a) A statement of introduction from the referring agency, if applicable.

  b) A statement that participation in the study is completely voluntary and does not affect the individual's relationship with the referring agency.

  c) A brief description of the study.

  d) An explanation of the enclosed prescreen or interest survey, if included.

  e) A statement requesting the individual to complete and return the interest survey, prescreen or postcard or call the CC.

  f) A statement thanking the individual for completing and returning the prescreen or postcard and stating that eligible participants will be contacted by the CC.

The letter is usually printed on the referring agency's or WHI stationery and mailed in a corresponding agency envelope. Some CCs may mail directly.

- Recruitment Brochure

  See *Section 3.3.3. – WHI Recruitment Brochure* and *Figure 3.2. – WHI Recruitment Brochure*.

- Prescreen

  Clinical Centers may choose to include a brief prescreen (see *Figure E.2.3. – Model Prescreen*) with the letter rather than a brochure with return postcard. If a brochure is also included, remove the return postcard to avoid the women responding twice. The CC is responsible for preparing its own prescreen with the recruitment source identified on the prescreen. The prescreen can include questions about the woman’s age, availability for CC visits over the next three years, and other broad eligibility questions (for example, current hormone use, cancer history, heart attack or stroke in the past six months, menopausal status). Initial eligibility and interest can be assessed quickly using a prescreen.

- Interest Survey

  An interest survey (see *Figure E.2.2. – Model Interest Survey*) may be included with the initial contact letter in addition to a brochure. In this case, a return postage-paid envelope is also included. The interest survey is a first step to determine if the woman is interested in participating and whether further contact should be made. It establishes the best time to follow-up with phone contact and is a preliminary screen for age and gender.

- Return Envelope

  The return envelope is a postage-paid business reply envelope addressed to the CC for returning the prescreen or interest survey. The return envelope is not necessary if the brochure with return postcard is used.

3.4.1.1. Preparation of Initial Contact Mailing

Mailings can be prepared in several ways. Small mailings (1–2,000) can be prepared at the CC. Large mailings (2,000 or more) can be prepared efficiently and economically at the CC only if the referring agency provides the names on diskettes or if the CC has access to other needed facilities, such as computer equipment and tape drives. If these facilities are not available, CCs can use local printing agencies to assist in preparing mass mailings.

3.4.1.2. Duplicates

Women may receive initial contact letters from more than one source agency. This can occur when the individual is on the mailing list of several referral agencies. For example, an individual may be recruited from a breast cancer screening clinic as well as a list of Medicare enrollees. Removal of duplicate names is often not possible because: 1) confidentiality requirements of some agencies do not allow the CC to have access to the names of individuals on the mailing lists; and 2) time and costs for removing duplicate names on accessible lists are prohibitive. In addition, experience has shown that individuals may respond negatively to letters from one agency but be willing to participate when contacted by a different agency or after learning that friends have participated.

3.4.1.3. Responses

Clinical Centers must anticipate that not all the addresses used for the mailings are correct or current. The percentage of out-of-date or incorrect addresses varies depending on the referring agency and date the addresses were prepared. Clinical Centers should advise the referring agencies that returns can be expected. They man be willing to attempt to contact these individuals.

3.4.1.4. Anticipated Return Rate

The anticipated rate of return varies by referring agency. Pilot studies for WHI suggest that between 5% and 30% of women will respond to the initial mailing. A proportion of these responses may be refusals. It is important to keep track of the rate of return by referring agency. (See *Section 3.2.1.1. – Identification of Source of Names*.)

If an individual calls the CC rather than returning the postcard or prescreen, CCs may complete the prescreen over the phone or conduct the screening contact on *Form 3 – Eligibility Phone Screen*.

3.4.1.5. Processing Responses

- Stamp the date on each response as it is received.
- Review the name and address on the postcard, interest survey or prescreen for completeness and readability. Occasionally, the name and address may be incomplete or unclear on the interest survey or prescreen while it is legible on the return envelope. In such cases, transcribe the information from the envelope to the interest survey or prescreen before discarding the envelope.
- If applicable, review the prescreens for potential eligibility and any comments regarding participation. The goal at this point is to eliminate from further screening any individuals who are clearly uninterested or ineligible. All other respondents should be considered potentially eligible.
- Sort the prescreens into the following three categories:

- Ineligible due to age or other information provided. Indicate on the form that the participant is ineligible. File all ineligible responses for future reference.
- Possibly eligible for the CT; screening phone call required.

  Add the woman's name to the list of women to be called, including best time of day to call. Proceed to preparation for Screening Contact. See *Section 3.5. - Screening Contact.*
- Possibly eligible at future date. This includes individuals who:

  a. Are too young now, but will be age-eligible before your recruitment phase ends.

  b. Are not immediately available to come to CC visits, but will be during the recruitment period.

Indicate on the form when the individual may be eligible in the future. File the form by date of possible eligibility with other prescreens of individuals who are possibly eligible at a future date. Review this file on a monthly basis and proceed to the screening contact preparations for those individuals who reach the recorded date.

3.4.2. Mass Media

Recruitment through mass media will be used by many CCs, either alone or in conjunction with mailing strategies. Depending on the emphasis, CCs need to adapt the steps and allocation of resources in the recruitment process to handle the uneven load.

The simplest approach to incorporating mass media campaigns into recruitment is to consider each media release and its subsequent response as an additional source of names. Responses to each campaign can then be monitored and evaluated for efficiency and success in reaching target populations.

For call-in responses, the CC may choose to have a recording describe general aspects of the study and request that the caller leave her name and phone number if she is still interested. An interviewer would then call the woman back and proceed with the screening interview. See *Section 3.5. - Screening Contact*. Alternatively, if CCs have staff available, a trained interviewer can take the call and complete the screening interview.

3.4.3. Community Activities

Clinical Centers that choose to use community activities such as presentations to particular groups, hosting booths at health fairs, etc., also need to plan well ahead for varying levels of activities. The different forums require the CC to determine to what extent recruitment and prescreening can be completed in a single encounter. In some circumstances it may only be feasible to provide the WHI Recruitment Brochure and an opportunity for the woman to express her interest. In other settings it may be reasonable to complete the screening interview (*Form 2/3 – Eligibility Screen*) and *Form 60 – Food Frequency Questionnaire (FFQ)* and determine initial eligibility for HRT and DM. This contact is referred to as Screening Visit Zero or SV0. It is the responsibility of the CC to determine the feasibility of completing the recruitment and prescreening activities in the various settings. The documentation of these efforts can be managed using the same system for identifying sources of names and number of responses.

3.5. Screening Contact (Required)

The WHI requires the collection of screening data using either an interview-administered (*Form 3 - Eligibility Phone Screen)* or a self-administered format (*Form 2 - Eligibility Screen*). These forms contain the same data items but the format is changed to make it suitable for the two methods of data collection. Clinical Centers may use a prescreen (as described in *Section 3.4.1. – Mass Mailings*) but must complete *Form 2/3 – Eligibility Screen* to continue screening the participant further.

A screening contact is completed on all women who return a prescreen, postcard, interest survey, or otherwise express interest and who initially meet the study eligibility criteria. Women may be recruited in such ways that this contact is done in person or by mail. Clinical Centers choosing to have the form completed by the participant will use *Form 2 – Eligibility Screen*. For example, Some women may be recruited through community organizations. Such women may be initially screened at an organization meeting. If women do not have telephones and are randomized/enrolled, careful planning must be done to ensure adequate follow-up. The self-administered versions of the screening questionnaire (*Form 2 – Eligibility Screen*) can be used for these settings. All interview-administered eligibility screens will be completed using *Form 3 – Eligibility Phone Screen*.

This section focuses on the screening telephone interview (*Form 3 – Eligibility Phone Screen*). The estimated time to complete the screening phone call is 15 minutes.

3.5.1. Purpose

The purpose of the screening contact is to:

- Explain the purpose and the requirements of the CT to those participants who responded to the initial contact letter by returning the prescreen, interest survey or postcard, or who called the CC to express interest.
- Ask the woman specific questions related to the eligibility criteria for CT participation in general and HRT and DM specifically.
- Schedule an appointment for SV0 or SV1.

3.5.2. Phone Procedures

Usually, CCs should complete the screening contact within three weeks of the return of the prescreen, interest survey, postcard, or phone contact to the CC. Attach a *Form 3 – Eligibility Phone Screen* to each prescreen, interest survey, postcard, or phone response you have sorted into the category “Possibly Eligible.”

Prepare to do several phone calls in any one session. You may find that using a telephone headset is less tiring than using a standard telephone handset when doing many calls. Frequently, you will not be able to complete all the contacts you set out to do. The individual may not be home or the phone may be busy. A grid for recording the date and time of all phone attempts is on *Form 3 - Eligibility Phone Screen*. If you are unable to complete a phone call at a particular time and day, try calling at other times and days.

3.5.2.1. Role of Phone Interview

The telephone interviewer plays a critical role in the collection of information for the WHI study. In most instances, she (or he) is the woman’s first “live” contact with WHI and sets the tone for the entire study. The interviewer's ability to develop and maintain a positive rapport with the woman influences initial recruitment, the quality of the data obtained, and the willingness of the woman to remain in the study for the duration. It is important that you always maintain a professional and friendly manner at every contact with the woman.

3.5.2.2. Eligibility Phone Screen Script

Refer to the scripts provided with the form instructions for *Form 3 – Eligibility Phone Screen* (see *Vol. 3 – Forms, Form 3 – Eligibility Phone Screen* Instructions, Part D – Scripts). The scripts have sufficient detail to explain the study and screen out those women who are unlikely to take part in the study or who would be eliminated because of specific exclusion criteria. Interviewers should try to follow the suggested scripts but modification due to individual CC screening design and clinic flow is appropriate. Interviewers may answer general questions but should refer women to the CC staff during SV1 for additional questions.

3.5.2.3. Determine Preliminary Eligibility

See scripts in *Form 3 – Eligibility Phone Screen* Instructions, Part D – Scripts. If eligible, schedule an initial screening appointment. Not that usually a woman must be eligible for at least on CT component to be scheduled for an SV1. If a CC needs additional women to meet their OS goals, women eligible for OS but not CT may be invited to SV1.

3.5.2.4. Edit the Eligibility Phone Screen

It is critical that *Form 3 - Eligibility Phone Screen* is carefully reviewed immediately following the interview. Quickly check the entire form, making sure that each answer is fully recorded. Edit the interview form as if no future opportunity will be available to clarify a response.

In completing the encounter, the woman's initial eligibility for the CT can be determined. Some specific eligibility criteria, such as participation in other studies, may require further investigation. Update this information and indicate any change in the margin area of the form. Initial any changes in the margin area. Complete all of these items before sending the form to data entry.

3.5.2.5. Process the Eligibility Phone Screen

Sort the completed *Form 3 – Eligibility Phone Screen* forms into the following categories:

- Possibly Eligible: First screening visit scheduled.
- Ineligible. Indicate in the comments area on the form that the woman is ineligible was why and the date of recontact if planned.

Send the forms in all three categories to data entry. Priority for key-entry should be given to the "Possibly Eligible" category first, and then "Ineligible." For women to be contacted at a later date, the interviewer should keep the forms filed according to month or year of planned recontact. On each *Form 2/3 – Eligibility Screen*, enter the name and contact information of the woman, if not previously entered. Scan the *Form 2/3 – Eligibility Screen* (key-enter the Spanish version) and run an eligibility determination for both HRT and DM. (See *Vol. 5 – Data System, Section 7 – Data Entry* for details.)

If the woman has been scheduled for an SV1 and later, the database determines that the woman is ineligible for both components, indicate this change on the form and return the form to the interviewer. The interviewer will then call the woman and cancel her CC visit. This should happen infrequently.

If the database indicates that more information is needed to determine the woman's eligibility for either HRT or DM, schedule an SV0 or SV1, depending on your CC's procedures. If a visit has not been scheduled, indicate the need for an SV0/SV1 on the form and return the form to the interviewer for visit scheduling. Label a temporary folder with each eligible woman's full name. File the interest survey prescreen or postcard and *Form 2/3 – Eligibility Screen* in the temporary folder.

If the database indicates that a woman is ineligible for either HRT or DM, review the reason for exclusion to determine whether this is a temporary or permanent exclusion. See *Section 4.5.4.2. – Ineligible on Form 2/3 – Eligibility Screen* for list of criteria for which you may rescreen.

File the participant's forms according to month and year to re-contact. Forms for women who are permanently excluded should be filed by ID number or alphabetically.

3.5.3. Eligibility Screens Administered Other than by Phone

Clinical Centers need to adapt the approach for telephone screening above to group or individual SV0 settings. The script that accompanies *Form 3 – Eligibility Phone Screen* serves as a model for determining what information should be provided to women in these settings. If the screening activities are conducted in a visit format, other steps, such as completion of other forms (e.g. the *FFQ*) may be carried out at the same SV0 encounter.

Form 2 – Eligibility Screen may be mailed to potential participants. If *Form 2* is mailed include the instruction sheet "How to Fill Out Form 2 – Eligibility Screen", *Figure E.2.4.*, in the packet. Generally, the women will have responded to an initial contact letter by returning a postcard or interest survey or contacted the CC by phone in response to news or publicity. *Form 2 – Eligibility Screen* and *Form 20 – Personal Information* can be mailed together to establish initial eligibility and gather contact information. Clinical Centers may want to include the *FFQ* in this packet to further establish eligibility for DM, improve the yield of SV1 and increase the efficiency of the screening process. A letter of explanation and instruction should accompany he forms along with a #2 pencil and postage-paid return envelope. A special warning against folding the mark-sense version of forms should be stressed. When these forms are received by the CC, the forms should be scanned (and key-entered) so that an eligibility determination an be run. If the woman is eligible, she should be scheduled for an SV1.

3.6. Mailing Initial Baseline Forms

After completing a *Form 3 – Eligibility Phone Screen* or receiving a *Form 2 – Eligibility Screen* and determining that the woman is interested and eligible, CCs may choose to mail the *FFQ* and *Form 20 – Personal Information* to her, if they have not already been completed.

3.6.1. Initial Baseline Forms

Mail the following baseline forms:

- *Form 60 – FFQ*

  The *FFQ* is used as a screening tool to disqualify those women consuming <32% of their kilocalories as fat from the DM component, but must be completed by all women at baseline.

- *Form 20 – Personal Information*

- Other Baseline Forms

  At CC discretion, *Form 30 – Medical History, Form 31 – Reproductive History, Form 32 – Family History*, and *Form 34 – Personal Habits*, or some subset of these, may also be given to the woman to complete before SV1. For CC hosting group SV0s, it may simplify data flow and tracking to administer these baseline forms at one time. For other CCs that have not yet had a face-to-face encounter with the woman, it may be desirable to postpone this data collection until the woman is more heavily committed to the study and has had a chance to develop some rapport with staff. *Form 37 – Thoughts and Feelings* contains sensitive questions and should not be distributed until rapport is established.

3.6.2. Procedures for Mailing and Processing Initial Baseline Forms

Include the following in the packet of materials in a large outgoing envelope:

- Cover letter of welcome.
- *Form 20 – Personal Information*
- *Form 60 – FFQ*
- *From 61 – How to Fill Out the Food Questionnaire*
- A general instruction sheet for completing forms.
- One #2 pencil.
- A large return-addressed envelope with postage prepaid, if you choose to ask the woman to return the *FFQ* to the CC by mail for evaluation of dietary eligibility before SV1.

If an appointment for SV0 or SV1 has already been made include:

- Appointment reminder.
- Map and directions to the CC.
- Information about parking.

Label the packets. Mailing labels may be generated for mailing the packet to the identified group of participants who are interested and eligible for study participation. (To reduce the chance of having the wrong participant label on forms, it is recommended that the participant barcode ID labels **not be attached** to forms until they are returned.)

Mail the baseline forms packet to women who are eligible and interested as determined by completion of *Form 2/3 – Eligibility Screen*. Mail the packet immediately after the telephone contact. Because the *FFQ* is scannable and must not be folded, large envelopes are needed so it can be kept flat.

Process returned questionnaires. Open each returned questionnaire packet as it is received. Stamp the date received on it. Pull the woman's temporary folder. Place a participant barcode label on each form where indicated.

Review each form for completeness and readability. Review the *FFQ* according to the procedures of *Section 10.2.3.2. - Pre-Scan Edit*. Scan the form into the database. Run an eligibility determination for both HRT and DM. If CCs choose to ask women to return the *FFQ*s to the CC by mail before scheduling an SV1, the eligibility determination for DM should be made before scheduling the visit. CCs may thereby reduce the number of CC visits scheduled for women ineligible for the DM. If the woman is ineligible for **both** the CT components indicate this in her temporary folder. At CC discretion, contact the woman by phone or send her a letter of regret thanking her for her time thus far and indicating that she may be eligible for the OS if she is interested. If more information is needed to determine eligibility for **either** CT component, contact the woman and schedule an SV1.

If a CC has an abundance of women eligible and willing to proceed with SV1, give priority to those willing and eligible for both HRT and DM. In planning the study, certain assumptions were made about the overlap between these components. To maintain the desired efficiency in operations and cost, it is important to recruit for this overlap as often as possible. Experience gained early in the recruitment process will help determine if there are other ways to facilitate the overlap.

Proceed with preparation for SV1 as described in *Section 4.2.3. - Preparation for SV1*.

3.7. Visit (SV0) (Not Required)

The purpose of SV0 is to provide a clear explanation of WHI, to determine preliminary eligibility, and to schedule and SV1.

The SV0 can be designed for a variety of uses. It can be used for orientation and baseline screening for potential participants or, for example, streamlines for women interested in HRT and needing a hormone wash-out. SV0 groups can average from 10 to 40 or more women depending on the SV0 design or staff and facilities available. An SV0 can be held at the CC or in the community. Some community organizations, such as churches or women's groups, etc., will sponsor SV0s at their facilities. See *Table 3.1. – Possible Pre-SV1 Recruitment Contacts* for SV0 options used at various CCs. Two possible SV0scenarios are described below.

Scenario 1:

The baseline screening type SV0 begins with staff and potential participant introduction. Women enjoy learning about each other during this time and can share reasons why they are interested in the study. Next is an informational presentation that can include an orientation video or a verbal overview of WHI, including a description of study components and the commitment requirements of each component. A question-and-answer period follows the informational presentation to create a less formal atmosphere and to make sure the women fully understand the study. The first half of the SV0 ends with the completion of *Form 2 – Eligibility Screen* which the staff review on the spot to determine completeness and preliminary eligibility. The first part generally takes about one hour.

After a refreshment break, the second hour begins with completion of the Initial Informed Consent form. If the woman signs it, she is given a copy to keep. Women are also encouraged to take the consent form home to read at their leisure and return at the SV1. The *FFQ* can follow the consent. As the *FFQ*s are completed, staff members review them for completeness and clarify any omissions or mistakes immediately. The *FFQ*s can be scanned at this time if the scanner is available to determine DM eligibility and guide subsequent screening activities. However, scanning immediately can be very time consuming depending on the number of women present and the number of staff available. You may need to postpone review of the *FFQ*s to the next day and phone women for clarification of problems. *Form 20 – Personal Information* can be completed at this time or given to the woman to complete at home and bring to the SV1. An appointment for SV1 is made if the *FFQ* is reviewed at the end of the SV0, taking into account any preliminary eligibility determination.

Scenario 2:

Another scenario is to invite women to an SV0 after they have returned a completed *Form 2 – Eligibility Screen* in order to complete the *FFQ* and *Form 20 – Personal Information*.

Initial contact with a potential participant follows a mailing or media event. A *Form 3* has been completed over the phone or *Form 2* has been mailed and returned. Initial eligibility has been determined. An SV0 appointment confirmation letter, map, and the *FFQ* and *Form 20 – Personal Information* have previously been mailed to the woman and she brings these with her to the SV0.

The woman signs in at the reception desk, turns in her completed *FFQ* and *Form 20 – Personal Information*, receives a folder containing a welcome and agenda page, fact sheet, participant feedback form *Initial Informed Consent* to take home for informational purposes, and a name tag. The nutritionist does a cursory review of the *FFQ* and has the woman complete unanswered questions. The nutritionist or data coordinator then scans the *FFQ* into the computer.

A 30-minute presentation by CC staff uses an introductory video and slides of the staff, clinic, and the nutrition site. Following a question-and-answer session, the CC staff (2-3) speak individually to women to assess their interest and inform them of their eligibility status. An SV1 is scheduled for interested and eligible women. Hormone "washout" letters are given to interested women currently taking hormones to take to their physicians. Participant feedback forms are collected.

Cancellations and reschedules for SV0s should be recorded and tracked.

Table 3.1
Possible Pre-SV1 Recruitment Contacts

Options	Contact 1	Contact 2	Contact 3
1	Form 3	SV0: FFQ Completed, Scanned	SV1
2	Form 2 & FFQ Mailed	Form 2 & FFQ Scanned	SV1
3	Form 3	FFQ Mailed	SV1: FFQ Scanned
4	SV0: Form 2, FFQ Taken Home	SV1: FFQ Scanned	

Figure 3.1.
WHI Logo and Catch Phrase

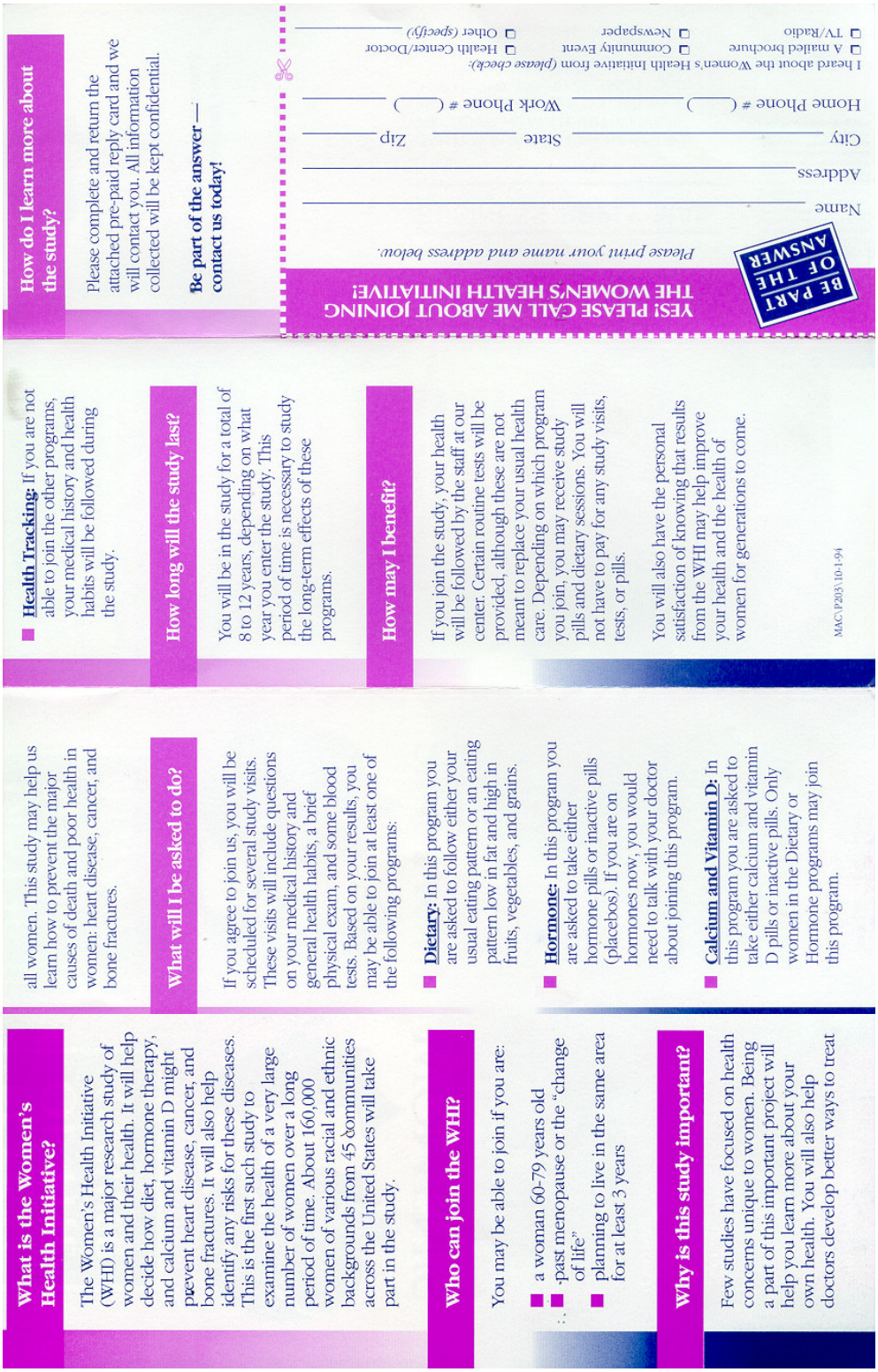
WHI Logo

WHI Catch Phrase

"Be Part of the Answer"

Figure 3.2.
WHI Recruitment Brochure

Figure 3.2.
WHI Recruitment Brochure
(Continued)



Section 3
Recruitment

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