

WHI Dietary Assessment Substudy Clinic Procedures

Table of Contents

Contents	Page
1. Inviting Women to Join the Dietary Assessment Study (DAS)	2
1.1 DAS Eligibility Criteria	2
2. Informed Consent for DAS (Required at SV1).....	3
2.1 Description of the DAS.....	3
2.2 Review of the DAS Consent Form (Required).....	3
2.3 Signing the DAS Consent Form (Required).....	3
3. Procedures for DAS Participants (Required).....	5
3.1 Overview.....	5
3.2 Clinic Activities Unique to DAS Participants	8
3.3 Questionnaires and Procedures Administered at VCC Visits for the DAS	8
4. DAS Quality Assurance Procedures.....	10
5. Exit Interviews.....	11
 Figures	
1. DAS Consent Script	4
2. WHI Dietary Assessment Validity Study Activities.....	5
3. Overview of WHI Dietary Assessment Study	7
4. DAS Checklist of Clinic Procedures	10

WHI DIETARY ASSESSMENT SUBSTUDY**CLINIC PROCEDURES****INTRODUCTION**

There is general agreement in the scientific community that Food Frequency Questionnaires (FFQs) should be validated within specific study populations. The primary goal of this Dietary Assessment Study (DAS) is to provide a detailed description of the WHI FFQ and its measurement characteristics.

The data collection activities for the DAS are a collaborative effort with the participant, the Vanguard Clinical Centers (VCCs), and the Clinical Coordinating Center (CCC) volunteering to collect these data. If all VCCs participate, each VCC will enroll 10 women in this study. One-half of the DAS participants will have a baseline FFQ nutrient analysis greater than or equal to 32% energy from fat, and one-half less than 32% energy from fat. Vanguard Clinical Center staff will ask all DAS participants sign a special Consent Form at Screening Visit 1 (SV1).

Clinic activities for DAS participants are as follows:

Screening Visit 0 (SV0)/SV1

- Review *Form 60 - Food Questionnaire* for completeness and scan
- Review *Form 2/3 - Eligibility Screen* for completeness
- Review *Form 20 - Personal Information* for completeness

Screening Visit 1 (SV1)

- Consent participant (DAS Consent Form)
- Take physical measurements (*Form 80 - Physical Measurements*)
- Collect data on Current Supplements (direct entry or *Form 45*)
- Immediately notify CCC that DAS participant has been enrolled in study

Screening Visit 2 (SV2)

- Conduct Four-Day Food Record (*4DFR*) Instruction and assign days to record
- Review *Form 34 - Personal Habits Questionnaire* for completeness

Screening Visit 3 (SV3)

- Review *Form 62 - Four-Day Food Record* for completeness
- Give copy of *Form 62* to participant and mail original food record to CCC

Between SV1 and SV2, the CCC will mail participants a repeat FFQ and a postage paid return envelope and conduct four 24-Hour Dietary Recalls. The CCC will review and scan the repeat FFQ, and document and code the *4DFRs*.

Form 60 - Food Questionnaire is the primary dietary assessment instrument in WHI, and therefore it is important to understand how well it measures diet in WHI participants. Comparison of the nutrient measures from the baseline FFQ with the reference measures from the four 24-Hour Dietary Recalls and the *4DFRs* will allow us to describe and quantify measurement error in the WHI FFQ.

1. Inviting Women to Join the Dietary Assessment Study (DAS)

Vanguard Clinical Center staff invite prospective participants to be part of the study. Starting on a date assigned by the CCC, each VCC will recruit all DM potential participants in the order screened until it has enrolled 10 women. One-half of these women will have a baseline FFQ nutrients analysis greater than or equal to 32% energy from fat, and one-half less than 32% energy from fat. All DAS participants must meet DAS eligibility criteria (see *Section 1.1 - DAS Eligibility Criteria*) and will sign a DAS Consent form at SV1.

Identify Five DAS Participants with a Baseline FFQ Nutrient Analysis Greater Than or Equal to 32% Energy from Fat

These DAS participants will meet all DAS eligibility criteria as specified below (*Section 1.1 - DAS Eligibility Criteria*) and have a baseline FFQ nutrient analysis greater than or equal to 32% energy from fat.

The most efficient recruitment scheme is to simply enroll women who are interested and eligible for the DM, and therefore are undergoing all SV1, SV2, and SV3 screening activities. A participant completing all usual screening activities will have completed almost all activities for the DAS. This participant would also complete the study activities unique to DAS participants (See *Section 3.2 - Clinic Activities Unique to DAS Participants*).

Identify Five DAS Participants with a Baseline FFQ Nutrient Analysis of Less than 32% Energy from Fat

These DAS participants will meet all DAS eligibility criteria as specified below (*Section 1.1 - DAS Eligibility Criteria*) and their baseline FFQ nutrient analyses will be less than 32% energy from fat. These DAS participants may be Observation Study (OS) participants. Hormone Replacement Therapy (HRT) participants may also be enrolled in the DAS study, unless they are currently in an HRT "Wash-Out" period.

1.1 DAS Eligibility Criteria

The DAS eligibility criteria are as follows:

- **Food Frequency Questionnaire (Form 60).** Participants must be able to complete an FFQ. Women are ineligible for the DAS if their baseline FFQ nutrient analyses are less than 600 kilocalories or more than 5,000 kilocalories. One-half of DAS participants will have a dietary fat intake greater than or equal to 32% energy from fat; one-half of DAS participants will have diets with less than 32% energy from fat.
- **Low Fiber (Form 2/3).** Participants with a physician-prescribed dietary restriction incompatible with the increased fruits, vegetables, and grains of the DM Intervention program are not eligible for the DAS.
- **BMI (Form 80).** Participants who have a BMI > 40 or BMI < 18 are not eligible for the DAS.
- **Number of Meals Prepared Away from Home (Form 2/3).** Participants who eat 10 or more meals away from home are not eligible for the DAS.
- **Diabetes (Form 2/3).** Women with Type I, or insulin requiring diabetes, are not eligible for the DAS.

2. Informed Consent for DAS (Required at SV1)

Once you have identified a potential participant for the DAS, review the DAS Consent Form with her.

A model of the Informed Consent is provided in *Appendix A* of this manual. Each VCC will need to obtain IRB approval for this study.

2.1 Description of the DAS

Describe the purpose and the procedures of the DAS to the potential participant. Inform her that she is eligible for the DAS. A suggested script you might follow is shown on page 4 (*Figure 1 - DAS Consent Script*).

Even if the script is not followed, you **must** cover the following points in the session:

- A full description of the DAS study.
- The study is completely voluntary and the participant may withdraw at any time.
- Any information she gives will be kept completely confidential and will be released to no one except WHI personnel.
- The participant's responses will be added to those of other women and only composite or grouped information will be released. Neither her name nor any other identifying information will be released in WHI reports or publications.

2.2 Review of the DAS Consent Form (Required)

Give the participant a copy of the DAS Consent Form to read. Some women may benefit from having the Consent Form read to them. Review the Consent Form with her, answer any questions she may have, and ask her to sign.

2.3 Signing the DAS Consent Form (Required)

Ask the participant to sign and date two copies of the consent form in the appropriate places. Sign and date one or two copies of the form yourself as required by your CC's IRB as a WHI representative. Some VCC IRB approvals may require a third signature from a witness not associated with the WHI. Give one copy of the signed consent form to the participant to take home with her. File the original in the participant's chart. If the participant declines to sign the DAS Consent form, do no further DAS activities and thank her for her time.

Figure 1
DAS Consent Script

Suggested Script for Dietary Assessment Consent:

"There are several points I want to go over with you about the Women's Health Initiative Dietary Assessment Study. I'm sure you have several questions about this study, and this may answer some of those questions."

First, I'd like to tell you about the Women's Health Initiative. The Women's Health Initiative (WHI) is a study of ways to prevent breast cancer, colon cancer, heart disease, and bone fractures (breaks). About 160,000 women from 40 centers in the United States will take part in this study.

An important part of WHI is to study the effect that diet may have on the health of women age 50 to 79. The Dietary Assessment Study will collect information on different ways of measuring women's diets. There are many ways to measure a woman's diet and no one is sure which is the best way. If we have more information about the different ways of assessing food intake, it will help us better understand the results of the entire WHI study.

Women in the Dietary Assessment Study will come to Clinical Center for three visits. You will be asked to fill out several questionnaires and forms. You may choose to answer or not to answer any questions on the study forms. These forms will ask questions about your health, your diet, and personal habits. Your height, weight, waist and hips will be measured; and your pulse and blood pressure will be taken. WHI staff from the Seattle Coordinating Center will also call you four different times to ask about the foods you ate on the previous day. There are no known risks associated with any of the things you will be asked to do.

The Dietary Assessment Study is an extra part of the Women's Health Initiative, and you may also be in other parts of the study, such as the Diet Modification study or the Observational Study. As with all parts of the WHI, taking part in the Dietary Assessment Study is completely voluntary and you may withdraw at any time. Any information you give us will be kept completely confidential and will be released to no one except WHI personnel. Your responses will be added to those of other women and only composite or grouped information will be released. Neither your name or any other identifying information will be released in WHI reports or publications.

We are hoping you will join the Dietary Assessment Study. By taking part in this study, you will help increase scientific knowledge about ways to measure food intake in women. Unless volunteers like you agree to join, this study will not be possible.

Remember, you can call the Clinical Center at any time throughout the study if you're having any problems or if you have any questions. Do you have any questions right now?

3. Procedures for DAS Participants (Required)

3.1 Overview

Figure 2 - WHI Dietary Assessment Validity Study Activities, gives an overview of the DAS activities which occur at the screening visit, including the time to complete the task (for the VCC staff, the participant, and the CCC). *Figure 3 - Overview of WHI Dietary Assessment Study* provides an overview in a flowchart format. Procedures, forms, questionnaires, and data-entry procedures used for the Dietary Assessment Study are identical to those currently being used in VCCs for screening visits 1, 2 and 3.

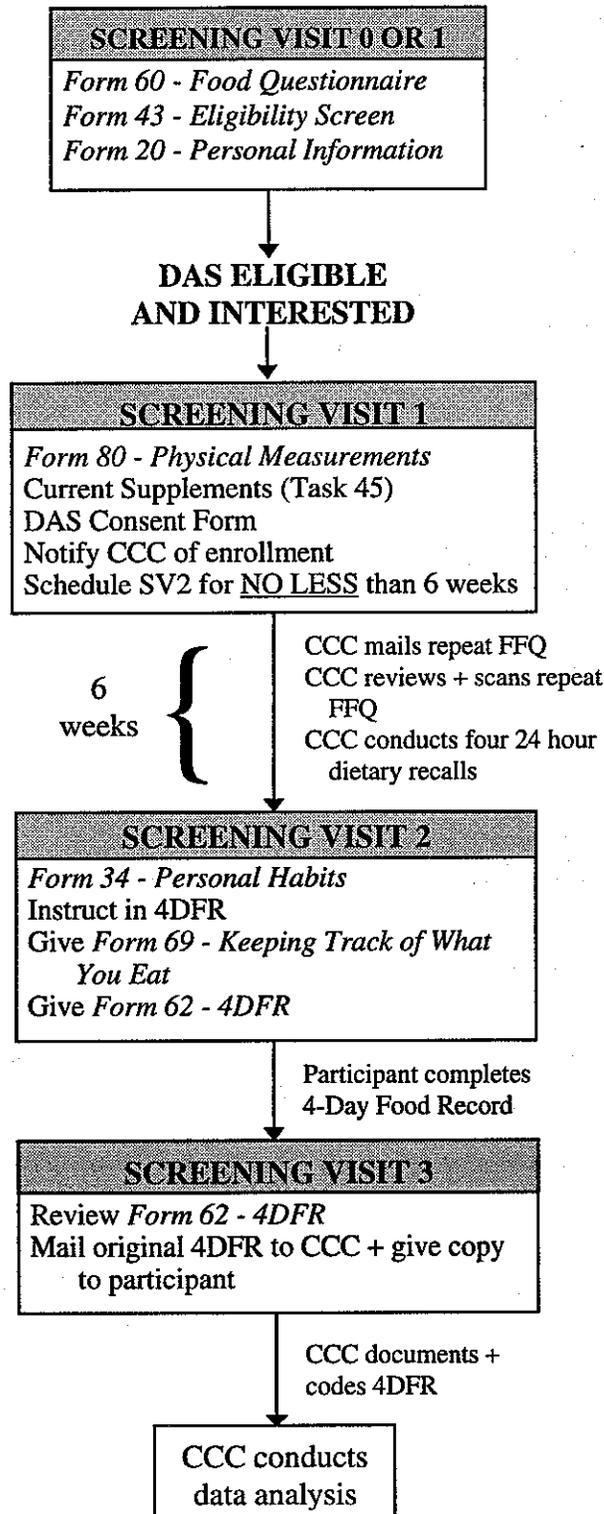
Figure 2
WHI Dietary Assessment Validity Study Activities

(Note: Screening visit scenarios may vary across VCCs.)

	Minutes to Complete Activity		
	VCC Staff	Participant	CCC
Screening Visit 0 or 1			
Provide <i>Form 60 - Food Questionnaire, Form 61 - How to Fill Out the Food Questionnaire, Form 2/3 - Eligibility Screen, and Form 20 - Personal Information.</i>	5		
Complete <i>Form 60 - Food Questionnaire, Form 2/3 - Eligibility Screen, and Form 20 - Personal Information</i> (at home or in CC).		95	
Screening Visit 1			
Reception	5	5	
Review self-administered questionnaires.	5	5	
Review and scan <i>Form 60 - Food Questionnaire.</i>	5		
Explain Dietary Assessment Study and recruit participant (see <i>Figure 1 - DAS Consent Script</i>).	10	10	
Sign DAS Informed Consent.	15	15	
Distribute <i>Form 34 - Personal Habits.</i>	2	2	
Perform <i>Form 80 - Physical Measurements.</i>	20	20	
Complete current supplements inventory (Task 45).	10	10	
Schedule second screening visit for no less than 6 weeks later.	5	5	
Notify CCC by phone or e-mail that participant is enrolled in study.	5		5
	1 hour, 27 minutes	2 hours, 47 minutes	5 minutes

	Minutes to Complete Activity		
	VCC Staff	Participant	CCC
Between Screening Visit 1 and 2			
CCC mails <i>Form 60 - Food Questionnaire</i> and <i>Form 61 - How to Fill Out the Food Questionnaire</i> .			5
Complete <i>Form 60 - Food Questionnaire</i> before recalls. Mail form back to CCC in postage paid envelope.		45	
CCC conducts four 24-hour dietary recalls.		90	115
Complete <i>Form 34 - Personal Habits</i> at home or in the clinic.		10	
Review and scan Repeat <i>Form 60 - Food Questionnaire</i> .			5
	0	2 hours, 25 minutes	2 hours, 5 minutes
Screening Visit 2			
Review <i>Form 34 - Personal Habits</i> for completeness.	2	2	
Perform <i>4DFR</i> instruction and assign days to record	30	30	
Schedule third visit.	5	5	
	37 minutes	37 minutes	0
Screening Visit 3			
Review <i>Form 62 - 4DFR</i> for completeness.	10	10	
Make 2 copies of <i>4DFR</i> . Send one copy home with participant and mail original to CCC.	10		
Exit interview.	5	5	
CCC codes the <i>4DFR</i> (documents if necessary).		10	70
	27 minutes	25 minutes	1 hour, 10 minutes

Figure 3
Overview of WHI Dietary Assessment Study
 (Note: Screening visit scenarios may vary across VCCs)



3.2 Clinic Activities Unique to DAS Participants

The following list of activities are Clinic Procedures that are unique to the DAS. Please review the list carefully to see how these activities vary from your normal screening activities.

Clinic activities unique to DAS participants:

- Describe the nature of the study to the participant (see suggested script in *Figure 1 - DAS Consent Script*).
- Ask her to sign the DAS Consent Form and give her a copy of the Form for her records (see *Figure 1 - DAS Consent Script*) for a more detailed description of the informed consent procedure). A model of the Informed Consent is provided in *Appendix A* of this document. Each VCC will need to obtain IRB approval for this study.
- Contact the CCC (Julie Van Slyke, 206-667-6051) via phone or e-mail (jvanslyk%ccc@hub.fhrc.org) to notify the CCC that the participant has been enrolled, and provide the participant's address and preferred times and numbers for calling (*Form 2/3 - Eligibility Screen*). This notification should occur within 24 hours of enrolling the participant so that the CCC can complete the dietary recalls before SV2.
- Schedule the participant for SV2 in six or more weeks. This 6-week time interval is necessary for the CCC to mail the participant a packet of materials, including a repeat FFQ, and to conduct four 24-hour dietary recalls.
- After reviewing the Food Record for completeness at SV3, make two copies of the participant's food record; give one copy to the participant and immediately mail the original to the CCC. File the other copy at the CC as per usual procedures. The CCC will contact the participant if additional details are needed for coding the food record.

3.3 Questionnaires and Procedures Administered at VCC Visits for the DAS

The tasks outlined in this section must be completed during VCC screening visits. All tasks, questionnaires, and procedures are identical to those currently in use at the VCCs.

The following self-administered questionnaires are required on all DAS participants:

- *Form 2/3 - Eligibility Screen*
- *Form 60 - Food Questionnaire*
- *Form 20 - Personal Information*
- *Form 34 - Personal Habits*

The following questionnaires and procedures administered by VCCs are required on all DAS participants:

- *DAS Informed Consent*
- *Current Supplements (direct data entry or Form 45)*
- *Form 80 - Physical Measurements*

A *4DFR* must be completed by all DAS participants. VCC staff must review the record for completeness at SV3. The CCC will document and code the food record, and will call the participant for additional details if necessary.

4DFR Instruction at SV2. Have DAS participants watch the *4DFR* videotape and provide them with *Form 69 - Keeping track of What you Eat* and *Form 62 - 4DFR*. Record in the booklet the specific days to record. Provide the participant with the name of a Dietary Assessment staff person to call with questions. A Dietary Assessment staff person should be available to answer questions at the end of the video.

Review 4DFR for Completeness at SV3. The *4DFR* should meet the following criteria for completeness:

- All four days should be completed.
- The food record should be legible.
- Descriptions need to be complete. Select one or two different food items (e.g., main dishes, side dishes, desserts) on each page. Briefly review how the food is described. Use the examples provided on pages 6, 8, and 10 of the *4DFR* as a guide.
- **Serving sizes must be recorded.** Review the record to ensure that the participant has completed the "Amount" column of the Food Record.

4. DAS Quality Assurance Procedures

Quality assurance procedures associated with the DAS forms and procedures are the same as those for the CT. Before the participant leaves the VCC at the end of SV1, do a final check to see that she has signed the DAS Consent Form and that all DAS procedures have been completed. Consult *Figure 4 - DAS Checklist of Clinic Procedures* at the end of each screening visit to make sure you have completed all the tasks required for the study. Review all self-administered questionnaires for completeness; if one or more pages are missing, return to the woman to complete.

Figure 4
DAS Checklist of Clinic Procedures

Screening Visit 0 (SV0) or SV1

- Review *Form 60 - Food Questionnaire* for completeness and scan
- Review *Form 2/3 - Eligibility Screen* for completeness
- Review *Form 20 - Personal Information* for completeness

Screening Visit 1 (SV1)

- Consent participant (DAS Consent Form)
- Take physical measurements (*Form 80 - Physical Measurements*)
- Collect data on Current Supplements (direct entry or *Form 45*)
- Schedule participant for SV2 in six or more weeks
- Immediately notify CCC that DAS participant has been enrolled in study

Screening Visit 2 (SV2)

- Conduct *4DFR* Instruction and assign days to record
- Review *Form 34 - Personal Habits* for completeness

Screening Visit 3 (SV3)

- Review *Form 62 - Four Day Food Record* for completeness
- Give a copy of *Form 62* to participant, and original food record to CCC
- Exit Interview

5. Exit Interviews

Exit interviews should be conducted at end of SV1 and SV2 per usual clinic procedures (See *WHI Manuals, Vol. 2, Section 4 - Screening*).

At the end of SV3, thank the participant for her contribution to WHI. Remind her that staff from the WHI CCC in Seattle may call her to ask questions about her *4DFR*.