

FORM:	62 - FOUR-DAY FOOD RECORD
Version:	2 - July 8, 1994
Description:	Completed by participant; 40-page booklet with several lined pages for recording and documenting food and beverage consumption during the assigned 4-day period; last page key-entered at Clinical Center (CC).
When used:	Completed by all potential Dietary Modification (DM) participants between the Screening Visit 2 (SV2) and Screening Visit 3 (SV3), and at designated annual CC visits by a subsample of DM participants.
Purpose:	To screen potential DM participants for (1) ability to record food intake in sufficient detail to complete the self-monitoring activities of the DM and (2) eating patterns that are incompatible with the goals of the DM.
	Documents all food and beverages consumed by participants during the assigned four days.

GENERAL INSTRUCTIONS

The form is printed in English (*Form 62*) and Spanish (*Form 62S*) versions. Use the form appropriate for the participant.

Baseline Four-Day Food Record (4DFR)

1. Dietary Assessment staff give the *4DFR* and *Form 69 - Keeping Track of What you Eat* to each woman interested in the DM at SV2 and assign four alternate days (four days every other day, for example Monday, Wednesday, Friday and Sunday) and dates for completion.
2. Dietary Assessment staff: (1) record the days and dates for completion, the name and phone number of the study contact person, and the date, time, and place for the participant's next appointment on page 1 of the *4DFR*, and (2) affix participant barcode label on the back page of the *4DFR*.
3. The participant completes pages 4 and 5 (general questions regarding vitamin and mineral supplements and brands and types of foods used during the record keeping period).
4. The participant records foods and beverages eaten for each of the days assigned, beginning on page 12.
5. At SV3, before randomization, Dietary Assessment staff review the completed *4DFR* with the participant as part of the DM Eligibility Checklist in *Vol. 2 - Procedures, Section 4 - Screening*. Complete Items 1 - 6 of the data entry box (shaded section on page 40) and give the form to the Data Entry staff.
6. Data Entry staff key-enter the data for these items according to procedures specified in *Vol. 5 - Data Systems Manual, Appendix B.3. - Step-By-Step Task Instructions* and initial the form after key-entry. Data Entry staff return the *4DFR* to Dietary Assessment staff.
7. At SV3, after randomization, Dietary Assessment staff document the completed *4DFR* with each participant identified in the *4DFR* subsample using the WHI Documentation Checklist and the Guidelines for Documenting the Fat Added Columns (both in *Vol. 2 - Procedures, Section 10 - Dietary Assessment*). Following documentation of the *4DFR*, complete Items 7 and 8 of the data entry box, and give the *4DFR* to a second Dietary Assessment staff person for peer review.
8. A second Dietary Assessment staff person conducts the peer review within three working days, using the WHI Documentation Checklist and the *4DFR* Screening Checklist (both in *Vol. 2 - Procedures, Section 10 - Dietary Assessment*), completes Items 9 and 10 of the data entry box, and gives the *4DFR* to Data Entry staff.
9. Data Entry staff key-enter Items 7 - 10 of the data entry box, review the items key-entered earlier for any changes, and initial the form after key-entry. Data Entry staff return the *4DFR* to Dietary Assessment staff.

10. Clinical Center staff copy the documented *4DFRs* of all participants in the *4DFR* subsample and file the copies at the CC. Completed original (non-documented) *4DFRs* are also stored at the CC.
11. Clinical Center staff mail the original documented *4DFRs* and a completed *4DFR* packing slip to the Clinical Coordinating Center (CCC) weekly on the assigned day.

Follow-Up 4DFR

1. Clinical Center staff mail a *4DFR* and *Form 69* to each participant in the *4DFR* subsample two weeks prior to the annual CC visit. Before the forms are mailed, CC Dietary Assessment staff (1) assign the days on which the *4DFR* is to be kept, record the days and dates for completion, the name and phone number of the study contact person, and the date, time, and place for the participant's next appointment on page 1 of the *4DFR*, and (2) affix a participant barcode label on the back page of the *4DFR*.
2. Dietary Assessment staff document the completed *4DFR* with the participant at the annual CC visit using the WHI Documentation Checklist and the Guidelines for Documenting the Fat Added Columns. Following documentation of the *4DFR*, complete Items 1 - 5, 7 and 8 of the data entry box (shaded section on page 40), and give the form to a second Dietary Assessment staff person for peer review.
3. A second Dietary Assessment staff person conducts the peer review within three working days, using the WHI Documentation Checklist and the *4DFR* Screening Checklist, completes Items 9 and 10 of the data entry box, and gives the *4DFR* to Data Entry staff.
4. Data Entry staff key-enter the data in the data entry box and initial the form after key-entry. Data Entry staff return the *4DFR* to Dietary Assessment staff.
5. Clinical Center staff copy the documented *4DFRs* and file the copies at the CC.
6. Clinical Center staff mail the original documented *4DFRs* and a completed *4DFR* packing slip to the CCC weekly on the assigned day.

Item Instructions

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| 1. | Date received | Date <i>4DFR</i> is received at the CC. At baseline, this is the date the DM Eligibility Checklist is reviewed with the participant. |
| 2. | Received by | Standard 3-digit WHI employee ID of the staff person who received the <i>4DFR</i> . (See common data items.) At baseline, this is the employee who reviewed the DM Eligibility Checklist with the participant. |
| 3. | Contact type | Mark appropriate oval or box. (See common data items.) |
| 4. | Visit type | Contact at which the form is received at the CC. Mark appropriate oval or box. Write in visit number as appropriate. (See common data items.) |
| 5. | First date of food record | Date of first day (page 12 of <i>4DFR</i>) the participant recorded in the <i>4DFR</i> . |
| 6. | 4DFR satisfactorily completed | No/Yes. Mark one answer.
Mark "0-No" in the following cases: <ul style="list-style-type: none"> • The writing on the form is not legible, • The participant completed less than three days, • The participant did not describe the food items consumed in sufficient detail, or • The participant did not record food amounts accurately. Otherwise, mark "1 - Yes."
Refer to <i>Vol. 2 - Procedures, Section 10 - Dietary Assessment</i> for more details. |
| 7. | Date documented | Date <i>4DFR</i> documented at CC. |
| 8. | Documented by | Standard 3-digit WHI employee ID of the staff person, who documented the <i>4DFR</i> . (See common data items.) |
| 9. | Date peer reviewed | Date <i>4DFR</i> peer reviewed at CC. |
| 10. | Peer reviewed by | Standard 3-digit WHI employee ID of the staff person who completed the peer review. (See common data items.) |
| | Language | Data Entry: English or Spanish version of the form. (See common data items.) |