

PREMIER Clinical Manual of Procedures

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Summary of Edits

Summary of changes between Version 1.0 and 1.1:

- Titles of this chapter, Forms #104, and #105 changed to “Food Interview” from “Diet Recall”

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19. 24-Hour Food Interviews

Overview

Collection of 24-hour food interviews (originally called “diet recalls”) will be used to assess the participants’ baseline dietary intake and adherence to the PREMIER dietary guidelines. These interviews will be collected via telephone by dietary staff at Pennsylvania State University (PSU).

Two unannounced 24-hour diet recalls will be conducted between SV3 and the randomization visit to provide baseline dietary intake data. Two followup diet recalls will be conducted at 6 months and 18 months. Each pair of recalls will occur within a 3-week period, on non-contiguous days, one of which will be a weekend day.

Procedure

The procedure to be followed is the same for each set of recalls (baseline, 6 months, and 18 months).

Hand out materials to participants during their clinic visit

Clinic staff need to hand out and review the following materials with the participants:

Food Interview Instruction Sheet (Form #104): This contains background information about Penn State (so the participants know who will be calling them) and the diet recall process. This instruction sheet should be reviewed at SV3, and again at 6 and 18 months.

Poster: This has information participants will need during the call. Each participant will need to have their poster handy when they receive their phone call from Penn State. The posters will be purchased by Penn State and shipped directly to each site for distribution. Posters will be handed out at SV3. Some participants may need replacement posters at 6 and 18 months.

Complete Convenient Times Schedule

This schedule (Form #105) is filled out by the participants to indicate how they can be reached and at what times they will be available. It also has space at the bottom for indicating special situations (participants who need to be paged, etc.). If a participant will be out of town during the entire calling period, be sure to get a number where they can be reached. If a participant can not be reached during the calling period, they will not be able to be randomized.

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It is important to be sure that each participant identifies at least one time that they can be called for each day of the week.

This form will be completed at the SV3 visit and again at the 6 and 18-month visits.

There are three versions of this form, one for each time zone. It is important that sites use the correct form to ensure that participants can be reached for their recalls. The time slots that are available are:

	<-----Morning----->			<-----Afternoon----->			<-----Evening----->			
Eastern (Baltimore and Durham):	9-10	10-11	11-12	1-2	2-3	3-4	4-5	6-7	7-8	8-9
Central (Baton Rouge):	8-9	9-10	10-11	12-1	1-2	2-3	3-4	5-6	6-7	7-8
Pacific (Portland):	6-7	7-8	8-9	10-11	11-12	12-1	1-2	3-4	4-5	5-6

Some issues that may come up when completing this form:

Work phones: Penn State can call participants at work, if that is the only way to reach them. However, clinic staff needs to be clear with participants that if they list a time when they can be called at work, they need to be able to interrupt their work for the 20 minutes or more that the recall will take.

Pagers: Penn State prefers not to contact participants via pagers because this reduces the randomness of the recall (the participant gets to decide when to call back). However, if there is a participant where this is the only way they can be reached, note this information on the bottom of the form and Penn State will make every effort to reach the participant via pager.

Fax schedules

The sites will fax the Convenient Times Schedules to Penn State as they are completed. Fax and phone numbers for Penn State are available from the staff directory on the PREMIER web site. Because participant names appear on this form, staff at clinical sites as well as at Penn State need to be careful to avoid breaches of confidentiality. Fax numbers should be dialed carefully, and these forms should not be left sitting on the fax machine unattended at either end of the transmission.

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Selection of calling days

Penn State will randomly select the two days they will be calling. They will select one weekday and one weekend. Weekend will be defined as Saturday and Sunday for all participants, even if this is not the participant's normal "weekend". Penn State will make every effort to complete the two recalls on the appropriate days. If they have trouble reaching a participant, they may have to call on a different day. This means that a small percentage of participants will end up with two weekday or two weekend recalls.

Calls completed and sites notified

Penn State plans to complete most calls within 14 days. They will fax each site a list of completed recalls on day 16 or 17. To protect confidentiality, this fax will contain study ID numbers only, **not participant names**. Penn State will continue to try to complete the remaining recalls over the next week. Sites will be notified of each additional completed recall on a case-by-case basis. Any fax or e-mail **follow-up** communications between Penn State and the clinical sites should reference participants by study ID number, not participant names.

Each completed recall should be logged on the appropriate visit form. If the recall cannot be completed within the three-week window, the incomplete outcome should be logged on the visit form. For SV3, the information should be logged on the Pre-Randomization Checklist (Form #19). For the 6 and 18 month visits, the information should be logged on the 6 and 18 Month Visit Forms (#57 and #59).

Data file delivered to Penn State

After participants have been randomized, the coordinating center will ship Penn State a data file with dates of birth and gender for each of the participants. This information is needed for Penn State's analyses. This file will be delivered electronically, and will not contain any participant names or identifiers other than the study ID.