

## PREMIER Clinical Manual of Procedures

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**Summary of Edits**

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### **6. Prescreening Visit (PSV)**

#### *Overview*

In order to be randomized, participants must complete a series of screening visits. Each screening visit includes questions and procedures designed to determine eligibility for the trial.

The PSV is intended as a fast, efficient way to identify ineligible participants prior to scheduling them for a formal screening visit. In addition, clinical centers have the option of obtaining a single, non-RZ blood pressure measurement as part of the prescreen. Individuals who complete the PSV are either excluded from further participation or are scheduled for screening visit #1 (SV1), which may occur concurrently with the PSV.

If more than 4 months elapse between the PSV and SV1, the PSV must be repeated.

#### *Setting*

The PSV may take place at the clinical center (e.g., coincident with the initial screening visit), via telephone, or at a location in the community convenient to the population being recruited. If the PSV is being conducted at an off-site location, the clinic staff need to make sure that adequate space and facilities (e.g., tables and chairs) are available to accommodate the participant flow and to assure privacy for the participants when answering questions.

#### *Preparations for Prescreening Visit*

The following materials are needed to conduct the prescreening visit:

- Informed consent form for PSV (if required by local IRB, see Chapter 04)
- Standard (non-RZ) sphygmomanometer and stethoscope (optional)
- Prescreen Eligibility Form (Form #1)
- PSV BMI Reference Chart (included with the instructions for Form #1)
- PSV Script (included with the instructions for Form #1)

The number of forms and pieces of equipment are determined by local staffing configurations and the anticipated participant flow. If available, a spare sphygmomanometer should be on-hand as backup.

If SV1 is to be held in conjunction with the PSV, additional forms and equipment are also needed (see Chapter 07 for details).

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### ***Conducting the Prescreening Visit***

The procedures for conducting the PSV vary depending on whether it is being done over the phone or in person. This section provides procedures to cover each of these situations.

In general, however, the following sequence of activities will occur:

- Greet the participant
- Describe the study and answer the participant's questions
- Administer informed consent form (if appropriate)
- Administer the Prescreen Eligibility Form
- If face-to-face, conduct a single, non-RZ blood pressure measurement (optional)
- Schedule or conduct SV1 if eligible

### ***Procedures for Conducting the Visit by Phone***

At most sites, the initial direct contact between participants and clinic staff will most often be by telephone. Potential participants will usually be responding either to a direct mailing, radio advertisement, or some other recruitment effort. The level of knowledge about the study will vary greatly among respondents depending on the manner in which the participant heard about the study. For example, if the participant has received a copy of the PREMIER brochure, she may already be aware of some of the study's requirements and is likely to satisfy many of the PSV eligibility requirements.

#### ***Greet the Participant***

Telephone staff should identify themselves by name and should indicate the name of the institution where they work. For example,

“Hello, name of institution, this is first name of staffer speaking. May I help you?”

The participant will then identify herself and ask to speak with someone about the study. Participants may either identify the study by name or they may refer to it as the “blood pressure study” or use other similar language. Be sure that whoever answers the phones, if the line is used for more than one study, is familiar enough with the study and the recruitment materials to be able to properly refer the participant to a PREMIER staff member.

#### ***Describe the Study and Administer Prescreen Eligibility Form***

The PREMIER staff member should quickly confirm that the participant is calling about participating in the study, provide a brief overview, and begin to administer the Prescreen Eligibility Form. For example,

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“That’s right, the name of the study is PREMIER. Let me tell you a little bit about the study, and then, if you are still interested, I have a few quick questions to ask you to see if you might be eligible to participate.”

[Use script to review the key points of the study with the participant. A sample script is included in the instructions for Form #1]

“Does the study sound like something you might be interested in?”

If No,

“Well, thanks for your interest anyway.”

[Enter “No” for the outcome of question #23 on Form #1, and code the visit outcome as “ineligible”. Or do not fill out a Form #1 at all]

If Yes,

“Great. What I’d like to do then is to ask you a few questions and, if you are still eligible, schedule you for a clinic visit. Are you ready?”

[Enter “Yes” for the outcome of question #23 on Form #1]

Begin administering the Prescreen Eligibility Form, the instructions for which may be found in the Forms Manual. At any point that it becomes evident that the participant is not eligible, you can terminate the contact.

### ***Procedures for Conducting the Visit in Person***

In some cases, such as health fairs, the initial contact with the participant will be in person. Depending on the nature of these contacts, the participants may or may not have heard about the study when they meet the study staff person. For example, they may simply think they are waiting for a free blood pressure screening, or they may have been given a copy of the PREMIER brochure to read while they were waiting in line. If blood pressure is measured as the first part of the visit and the participant is ineligible (see guidelines below), the Prescreen Eligibility Form need not be completed.

#### ***Describe the Study and Administer Prescreen Eligibility Form***

Whenever it makes sense to do so in the context of the screening, the PREMIER staff member should introduce herself as part of the study, provide a brief overview of the study, and begin to administer the Prescreen Eligibility Form. For example,

“Your blood pressure is xxx over xxx, which is above the optimal range, and as a result you might be eligible to participate in a study we are doing to help people reduce their

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blood pressure without medications. The name of the study is PREMIER. Let me tell you a little bit about the study, and then, if you are still interested, I have a few quick questions to ask you to see if you might still be eligible to participate.”

[Use script to review the key points of the study with the participant. A sample script is included in the instructions for Form #1]

“Does the study sound like something you might be interested in?”

If No,

“Well, thanks for your interest anyway.”

[Enter “No” for the outcome of question #23 on Form #1, and code the visit outcome as “ineligible”. Or do not fill out a Form #1 at all]

If Yes,

“Great. What I’d like to do then is to ask you a few questions and, if you are still eligible, schedule you for a clinic visit. Are you ready?”

[Enter “Yes” for the outcome of question #23 on Form #1]

Begin administering the Prescreen Eligibility Form, the instructions for which may be found in the Forms Manual. At any point that it becomes evident that the participant is not eligible, you can terminate the visit.

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### *Assess Blood Pressure (Optional)*

The optional PSV blood pressure assessment consists of a single, non-RZ blood pressure measurement conducted in a seated position. No eligibility limits are established for the PSV blood pressure measurement, although for safety reasons participants with a SBP  $\geq$  180 mm Hg or a DBP  $\geq$  110 mm Hg must be referred to their provider within one week and excluded from further participation. It is recommended that individuals with a SBP less than 118 mm Hg or a DBP less than 78 also be excluded. Individual clinical centers may choose to use more restrictive upper limits.

### *Ending the Prescreening Visit*

If, after completing the Prescreen Eligibility Form (Form #1) and blood pressure assessment, the participant is ineligible, thank her for her time and interest and indicate that she is not eligible to participate in the study. Clinical centers are encouraged to tell participants the reason for exclusion.

If the participant is eligible to continue in the study, schedule a date for the SV1 visit and thank the participant for his interest in the study.

### *After the Prescreening Visit*

The Prescreen Eligibility Form (Form #1) is entered into the data entry/management system only for participants who are eligible to continue onto SV1. Clinical centers who wish to track information for ineligible participants will need to create their own database for this purpose.

If the participant is eligible, make sure that the following items have been completed:

- The participant's contact information on the first page of the Prescreen Eligibility Form. At least the name and phone number should be completed at this time. Sites can choose to complete the rest of the contact information at a later date.
- The screening questions on page 2. These are not entered but they must be completed for eligible participants.
- All questions on page 3. These items will be entered.

When the Prescreen Eligibility Form (Form #1) is entered, the data entry application assigns a unique, anonymous study ID#. Record this ID# on the Prescreen Eligibility Form. After entry of the Prescreen Eligibility Form, the data entry person or the clinic coordinator can print out participant labels from the data management application to use on future forms.

Once labels have been printed, attach one to each of the three pages of the Prescreen Eligibility Form. At this point the first page of the form, which contains contact information, should be removed from the rest of the form and filed separately so that identifying information is not inadvertently faxed or mailed to the Coordinating Center. The final two pages of the form should

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then identify the participant only through his anonymous study ID and can therefore be safely faxed or mailed.

Participant IDs are assigned using the following algorithm: The first three letters of the participant's last name, followed by the first two letters of the first name, followed by a one-digit site ID number, followed by a four-digit number that is unique to that site. This latter number is assigned sequentially at each site, starting with 0001. If the last name or first name has fewer characters than needed to use this algorithm, an "X" will be used as a placeholder. For example, if the participant's name is Sue Wu, the first five characters of the ID will be WUXSU. When entering data or looking up data in the data entry/management application, the clinic coordinator will need to include the "X" in the participant's ID. (See Data Entry and Data Management User's Manuals for further information on ID numbers.)