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Summary of Edits

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7. Screening Visit 1 (SV1)

Overview

Screening visit 1 is the first of three formal screening visits to determine eligibility for PREMIER. It is intended to be a relatively brief visit that identifies major medical exclusions via the use of blood pressure measurements and questionnaire data. More invasive and time consuming procedures, including the collection of most baseline data, is deferred to the subsequent screening visits.

The SV1 may occur at any time within 4 months of the PSV, including the day of the PSV. If the SV1 is scheduled to occur more than 4 months after the PSV, the PSV data are invalid and must be recollected prior to obtaining SV1 data. If a participant is excluded on or after SV1, that individual cannot be rescreened for the same cohort. The participant may, however, be rescreened for later cohorts. Staff should be aware that randomization will occur no more than 6 months after SV1.

At the conclusion of SV1, staff may also choose to give participants materials and instructions for completion of a 24-hour urine collection. In addition, a number of questionnaires may be completed at any time during the screening period. These include the Patient History Questionnaire, and a number of psychosocial questionnaires. In order to minimize burden to both staff and participants, however, it is suggested that these questionnaires not be given to participants until after they complete the SV2 visit and are found eligible to continue to SV3.

Setting

The SV1 visit may take place at the clinical center or at a location in the community convenient to the population being recruited. If conducted offsite, the SV1 will usually be conducted in conjunction with the PSV visit. Persons who are eligible at PSV may immediately receive an SV1 visit or they may be scheduled for an SV1 visit at a later time. In order to conduct the SV1 visit in an off-site location, it is essential that appropriate space and facilities are available. This requires a quiet, private or semi-private setting where the required relaxed waiting time can occur before a random zero blood pressure is taken, and an interviewing setting that permits privacy of responses to the questions that are asked.

If the SV1 visit is conducted at the same time as the PSV visit, the PREMIER staff person should leave the room at the end of the PSV visit and ask the participant to sit quietly for five minutes with his legs uncrossed. The SV1 visit is then conducted.

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Preparations for SV1 Visit

The following materials are needed to conduct the SV1.

- Study charts for scheduled participants (if available)
- Random zero sphygmomanometer and stethoscope
- Standard mercury sphygmomanometer
- Stadiometer
- Scale
- Consent materials (if required by local IRB; see Chapter 5)
- SV1 Visit Form (Form #3)
- SV1 Blood Pressure Form (Form #2)
- Blood Pressure Escape Form – Screening (Form #32)
- Eligibility Questionnaire (Form #4)
- Rose Questionnaire — PVD (Form #5)
- Rose Questionnaire — Angina (Form #6)
- Diet and Physical Activity Change Checklist (Form #8)
- SV1/SV2 Activity Fact Sheet (Form #106)
- SV1 BMI Reference Chart (included with the instructions for Form #3)
- Participant Closeout Form (Form #28)
- Participant Contact Information Sheet (Form #100)

In addition, the following materials should also be on hand in case the PSV needs to be redone.

- Prescreen Eligibility Form (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 available as backup.

If the Prescreen Eligibility Form has already been entered, the participant will have been issued a study ID and preprinted ID labels should be available to use on the forms. If, however, this information is not available, then place the participant's name on each page of each completed form and keep these forms together with the Prescreen Eligibility Form. Once an ID is assigned and ID labels are available, they should be placed on all completed SV1 forms.

If a participant has been screened before, but no study ID exists and a hard copy of the Prescreen Eligibility Form cannot be found, then it must be readministered before the visit can proceed. In this case any old versions of the Prescreen Eligibility Form, if subsequently found, should be discarded.

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Conducting the SV1 Visit

SV1 activities are listed below. If required, obtain consent first. Whether consent is required or not, briefly re-describe PREMIER and obtain the participant's assurance that he is interested in participating. In general, blood pressure should be done before the other procedures because the forms need not be administered if the individual is not blood pressure eligible.

- Confirm participant ID and check visit window
- Obtain consent (if required by local procedures)
- Complete the Participant Contact Information form (Form #100)
- Measure blood pressure (Form #2)
- Complete the Eligibility Questionnaire (Form #4)
- Review study and confirm interest
- Complete the Diet and Physical Activity Change Checklist (Form #8)
- Weigh participant, measure height, and check BMI (Form #3)
- Complete the Rose PVD (Form #5) and Rose Angina Questionnaires (Form #6)
- Record events and final eligibility status on the SV1 Visit Form (Form #3)

Confirm participant ID and check visit window

Before each screening visit, clinical center staff should confirm the participant ID and check the visit window. The SV1 visit must occur within 4 months of the PSV visit. If this is not the case, then the PSV must be repeated. This holds even if the data from the first PSV has been entered into the computer. When the new PSV is entered, the computer will generate a new study ID for the participant. It will also be necessary to use a Participant Closeout Form (#28) to close out the old study ID in the data management system.

Obtain informed consent (if applicable)

If informed consent for the screening visits was not obtained as part of the PSV, then it must be obtained now.

Complete the Participant Contact Information form (Form #100)

Ask the participant to complete the Participant Contact Information Form (Form #100). Review to be sure participant has given permission for contacting their physician. If not, go over this with the participant.

Measure blood pressure (Form #2)

Take the participant's blood pressure using the random zero sphygmomanometer and the procedures described in MOP Chapter 17 (Blood Pressure Assessment). The cuff size must be

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appropriate. If it is impossible to get an accurate measurement (e.g., if large cuff covers the antecubital fossa or arm circumference is >52 cm.) the participant is excluded.

If the sum of two systolic blood pressures is between 235 and 340 mm Hg and the sum of the two diastolic blood pressures is between 155 and 200 mm Hg, the participant is eligible to continue to SV2. Participants who are excluded based on blood pressure readings above these limits need to be referred to a physician for further evaluation. The timing of the referral, within one week or within one month, depends on the threshold level that is reached (see Chapter 23, Safety Monitoring). These threshold levels are also shown on the SV1 Blood Pressure Form. If escape levels are reached, the Blood Pressure Escape Form – Screening (Form #32) also needs to be completed, with one copy placed in the participant’s chart at the site and one copy sent to the CC.

Eligibility Questionnaire (Form #4)

The Eligibility Questionnaire is primarily designed to identify persons who are ineligible for medical reasons. It also asks about a variety of other eligibility criteria. This form should be completed as part of the SV1 visit. It can be sent to the participant to complete at home prior to the visit, or simply given to the participant to complete during the visit. Inform participants that, when they have questions or are unsure about the answer to an item, they should check “unsure” and write a comment or question in the comment section for that item so that it can be reviewed with a staff person later.

Regardless of when the form is completed, a clinical center staff person should review it with the participant to verify its completeness and to attempt to resolve any “unsure” items. Be sure to place a label with the participant’s study ID on each page of the form. If an ID has not yet been assigned, write the participant’s name on each page of the form and keep the form together with the Prescreen Eligibility Form.

Although the Eligibility Questionnaire asks participants about their use of certain exclusionary medications, it is not intended as a complete assessment of medication use. This occurs during SV2. Instruct participants to bring to the SV2 visit all medications and over-the-counter products (including vitamins, supplements, and other non-prescription drugs) that they regularly take.

Review the study (Form #106) and confirm participant interest

Briefly describe PREMIER again, emphasizing the commitment required of participants. Give participant the SV1/SV2 Activity Fact Sheet (Form #106). Stress how important it is that those who enroll in the study follow through and complete the study, and confirm that the participant thinks s/he would like to participate if eligible.

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Diet and Physical Activity Change Checklist (Form #8)

The Diet and Physical Activity Change Checklist is an initial attempt to identify people who are unwilling to comply with any of the various components of the PREMIER interventions. This is a self-administered form that can be completed at home prior to the visit or by the participant during the visit. In either case, participants must review the SV1/SV2 Activity Fact Sheet prior to completing the checklist. Review the form with the participant for completeness and, if he has any questions about specific items, discuss them with him. To be eligible to continue, the participant must answer “Yes” or “Maybe” to every item (see coding instructions for Form #8).

Measure participant’s weight and height and check BMI (Form #3)

Measure the participant’s weight and height per the protocol outlined in MOP Chapter 20, Other Clinical Measurements. Enter the height and weight on the SV1 Visit Form and note the eligibility status. Although heights are measured in centimeters (rounded to the nearest 0.1 cm), weights are measured and recorded in pounds (to the nearest 0.25 pounds). Refer to the SV1 BMI Reference Chart (found in the instructions for Form #3) to determine if the participant is BMI eligible.

Rose PVD and Angina Questionnaires (Forms #5 and #6)

Participants who are still eligible after completing all of the above activities should next complete both the Rose PVD and the Rose Angina questionnaires. These should be the last questionnaires or measurements completed as part of the visit, and should only be given to eligible individuals. This is because a positive response to either questionnaire triggers a mandatory referral to the participant’s physician, including helping the participant find one if he does not already have one. Note that, if the participant were to have completed these forms at home prior to the visit, for instance, then the clinical centers would be ethically compelled to review the forms at the visit, even if the participant were already excluded for, say, high blood pressure.

The two Rose questionnaires are intended to be interviewer-administered. However, they can be self-administered if a clinic staff member carefully reviews them with the participant beforehand (to explain the skip patterns). The staff person will also need to go over the forms after they are completed to make sure they were filled out completely and accurately, and to answer any questions the participant may have.

Anyone who is positive on the angina questionnaire must be referred to her personal physician for evaluation and cannot participate unless approved to do so by both her physician and a study clinician. If the participant does not have a personal physician, she must be referred to one. The participant’s personal physician will be asked to confirm that the participant has had a negative exercise stress test within the last 6 months (defined as 6 months prior to the date the physician contacts PREMIER with the information), and that the physician approves of the patient

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participating in the PREMIER interventions. Next, a study clinician must review the study chart and also agree that the participant may continue in the study. If the decision is made that the participant should not continue, she can be excluded using the Participant Closeout Form (#28). If the participant will be continuing in the study (with personal physician and study clinician approval) this needs to be indicated on the Pre-Randomization Checklist (Form #19). The participant can continue in the screening process while this follow-up is taking place.

Anyone who is positive on the PVD questionnaire must be referred to her personal physician for evaluation and cannot participate unless approved to do so by both her physician and a study clinician. If the decision is made that the participant should not continue, she can be excluded using the Participant Closeout Form (#28). If the participant will be continuing in the study (with personal physician and study clinician approval) this needs to be indicated on the Pre-Randomization Checklist (Form #19). The participant can continue in the screening process while this follow-up is taking place.

SV1 Visit Form (Form #3)

After each portion of the visit is completed, a PREMIER staff person should check the appropriate “Done?” box on the SV1 Visit Form and (if applicable) indicate whether the participant is eligible or not eligible to continue based on that portion of the visit. At the end of the visit, a staff person should review this form to make sure that the participant has completed all of the necessary components. This staff person should also make sure that a single outcome status is coded at the bottom of the form and should enter her staff ID# in the “Reviewed by staff ID” field.

If a participant is excluded at the investigator’s discretion (i.e., not as part of the regular screening activities for that visit), complete the Participant Closeout Form (Form #28) to record the reason for the exclusion. The SV1 Visit Form does not need to be entered in this situation.

Ending SV1

To complete the SV1 visit, do the following:

If the participant is ineligible

You may inform participants of their eligibility status and terminate the visit whenever it is clear that they are not eligible for PREMIER. Explain the reasons for ineligibility to the participant. Enter the visit outcome status onto the SV1 Visit Form.

If the participant is eligible

If participant is eligible, schedule an appointment for SV2 at least seven days from SV1. The clinical center may wish to give participants some of the non-eligibility questionnaires (e.g., the

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psychosocial questionnaires or the patient history questionnaire) at this time to complete at home and return at the SV2 visit. This is discouraged, however, since many of these participants will go on to become ineligible at SV2. Instead, clinic staff are encouraged to distribute these forms after completion of the SV2 visit.

Finally, clinic staff need to enter the various forms into the data entry system. This should be done within two weeks of the visit, and preferably within one week. The SV1 Visit Form (Form #3) should not be entered until all of the other forms related to the visit have been entered.