

PREMIER Clinical Manual of Procedures

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Summary of Edits

Summary of changes between Version 1.0 and 1.1:

- Use Form #201, Weight Loss Medications that Affect Blood Pressure, when completing Form #11, Baseline Medication Use Questionnaire

8. Screening Visit 2 (SV2)

Overview

The purpose of SV2 is to continue to screen participants for eligibility as accurately and efficiently as possible. This visit occurs at least 7 days after SV1. The activities listed below include completion of the Medication Use Questionnaire; measurement of blood pressure; collection of a non-fasting blood sample for creatinine and glucose; distribution of the instructions and supplies for the 24-hour urine collection; and distribution of instructions and form for the one-day Food Record.

The Food Record is to be completed by the participant and returned at SV3. The SV2 Blood Pressure eligibility is determined by summing up four total BPs, the two BPs from SV1 and the two BPs from SV2. Participants who are found eligible at the end of this visit are scheduled for an SV3 visit.

The visit may also be used to perform the fasting blood draw and to receive and process the 24-hour urine specimen, both of which must occur at some time between SV1 and randomization. The blood draw, which requires a minimum of a 12-hour fast, is processed centrally for analysis of lipids, insulin, glucose, and homocysteine. The 24-hour urine collection is analyzed centrally for sodium, potassium, phosphorus, creatinine, and urea nitrogen (See Chapter 21, Central Laboratory Procedures, for details). The instructions for processing the fasting blood and urine collections should be followed no matter when the specimen is returned. The Central Lab Collection Form—Fasting Blood (Form #21) and the Central Lab Collection Form—24-hour Urine (Form #20) are used for processing the blood and urine samples.

A number of questionnaires may also be completed at any time prior to randomization. These include the Patient History Questionnaire and a number of psychosocial questionnaires. It is suggested that they not be given to participants until after they complete the SV2 visit and are found eligible to continue to SV3. Although these forms do not have to be entered prior to randomization, they should be completed prior to the randomization/intervention visit so that ample time is available to resolve data edits. Record the completion of these questionnaires on Form #19.

Setting

The SV2 visit takes place at the clinical center. It requires a quiet, private or semi-private setting where the participant can wait relaxed prior to the random zero blood pressure measurement. Questionnaires also need to be administered and reviewed in a setting that permits privacy for the participant.

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Preparations for SV2

The following materials are needed to conduct the SV2.

- Study charts for scheduled participants
- Consent materials (if required by local IRB, see Chapter 4)
- Random zero sphygmomanometer, standard sphygmomanometer and stethoscope
- SV2 Blood Pressure Form (Form #9)
- Baseline Medication Use Questionnaire (Form #11)
- Weight Loss Medications that Affect Blood Pressure (Form #201)
- Local Lab Worksheet (Form #12)
- Local laboratory chemistry panel blood supplies
- Participant instructions and materials for 24-hour urine
- SV2 Visit Form (Form #10)
- One-Day Food Record Screening Form (Form #200) and instructions
- SV1/SV2 Activity Fact Sheet (Form #106)
- Blood Pressure Escape Form – Screening (Form #32)
- Participant Closeout Form (Form #28)

Preprinted ID labels should be available to use on the forms. The number of forms and pieces of equipment are determined by local staffing configurations and the anticipated participant flow. If available, a spare (back up) sphygmomanometer should be available.

Conducting SV2

SV2 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 measured before doing other procedures because the forms need not be administered if the individual is not blood pressure eligible. Performing the SV2 activities in the order listed below should provide the most efficient identification of ineligible subjects. SV2 may be politely concluded at any point after an exclusionary condition or situation has been identified.

- Attach a pre-printed participant label on all forms
- Confirm participant ID and check visit window
- Obtain informed consent (if required)
- Review study and confirm interest (Form #106)
- Measure blood pressure (Form #9)
- Complete Medication Use Questionnaire (Form #11)
- Collect non-fasting blood specimen (for local lab)

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- Optional: distribute instructions and supplies for the 24-hour urine sample (Note: women must complete collection when NOT menstruating)
- Distribute Food Record Form (Form #200) and instructions
- Record events and eligibility status on the SV2 Visit Form (Form #10)

Confirm ID, check visit window, and obtain informed consent

Confirm the participant ID and check the visit window. SV2 must occur at least seven days after SV1. If necessary, obtain informed consent for the visit.

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

Briefly describe PREMIER again, emphasizing the commitment required of participants. Give participants 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 participant thinks she would like to participate if eligible.

Measure blood pressure (Form #9)

Take the participant's blood pressure using the random zero sphygmomanometer and the procedures described in MOP Chapter 17 (Blood Pressure Assessment). **Be sure to use the same cuff size as was used in SV1, except as noted in chapter 17.** If the participant cuff size is found to differ from that used during SV1 and the cuff size is not appropriate for the participant, a replacement blood pressure should be taken using the proper cuff if participant has not left the clinic. Otherwise the original measurement stands.

If the cumulative sum of the four systolic blood pressure measurements from SV1 and SV2 is between 474 and 661 mm Hg and the cumulative sum of the four SV1 and SV2 diastolic blood pressure measurements is between 314 and 393 mm Hg (inclusive), the participant is eligible to continue to SV3.

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 SV2 Blood Pressure Form. If the threshold levels are exceeded, the Blood Pressure Escape Form – Screening (Form #32) needs to be completed, with one copy placed in the participant's study chart and one copy sent to the CC. The participant may also be referred to a physician if deemed appropriate based on symptoms and clinical judgment even if the BP is lower than the above limits.

If the cuff size is found to be different from that used during SV1 (except as noted in chapter 17), and the participant has not left the building, a replacement blood pressure should be taken using the appropriate size cuff. Otherwise, the original measurement will stand.

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Complete the Baseline Medication Use Questionnaire (Form #11)

Confirm that the participant has brought in all medications, over-the-counter products, or nutritional supplements that they are currently using. Check the participant's medication containers and complete the Baseline Medication Use Questionnaire. If the participant fails to bring her current medications, it will be necessary to call the participant at home to review her medications. Use Form #201, Weight Loss Medications that Affect Blood Pressure, to check weight loss medications.

If the participant is eligible to continue and reports taking *any* medications, a PREMIER clinician must review and sign the form assuring that the participant is not using any exclusionary products. If the participant is taking a medication that is clearly exclusionary, the form does not need to be reviewed by a clinician.

Collect laboratory samples

Draw the necessary non-fasting blood samples for the local exclusionary labs. Follow the procedures outlined in MOP Chapter 21 for collection and processing. Remind the participant that you may recall him for additional blood draws if any questions arise. The Local Lab Worksheet (Form #12) is used to track: whether the blood specimens are collected; the creatinine and glucose results; if a repeat test is ordered; and the eligibility status of the participant based on the results of the test.

Lab tests can be repeated at investigator discretion. Each test can only be repeated once. Clinical centers can choose to do fasting or non-fasting blood collections for the initial or repeat tests. Eligibility is based on the results of the repeat specimen, if one is done.

The Local Lab Worksheet cannot be completed until after results from the local lab are received. So, the SV2 Visit Form cannot be completed until the results are in.

Distribute urine container and instructions for the 24-hour urine sample

Distribute the 24-hour urine container and instructions to the participant. Review the instructions. Remind the participant that the sample needs to be returned to the clinic within 24 hours of collection. In unusual circumstances, such as when collection starts on a Friday, samples may be kept refrigerated and returned to the clinic within 48 hours. The 24-hour urine sample must be returned before the randomization visit, preferably at SV3. Some clinical centers may prefer to wait to initiate this process until after participants are SV3 eligible. If this is the case, make a note of this on the SV2 Visit Form, and also add a reminder note to the SV3 Visit Form (#15) that participant will need to get their 24-hour urine materials at that visit.

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Make sure that a label is affixed to the collection jug. Refer to the Interim Visit Chapter (Chapter 10) of the MOP for detailed instructions. Note: Instruct pre-menopausal women to collect the 24-hour urine specimen when they are not menstruating.

Distribute instructions and form for the One-Day Food Record Screening Form (Form #200)

Distribute the One-Day Food Record Screening Form to the participant, and review the instructions for filling it out. Inform the participant that the form needs to be completed and returned at the SV3 visit. Make sure that the participant's label is on each page of the form. Explain to participant that completing this form is a requirement of the study.

SV2 Visit Form (Form #10)

After each portion of the visit is completed, a PREMIER staff person should check the appropriate "Done?" box on the SV2 Visit Form and (if applicable) indicate whether the participant is eligible or not eligible to continue based on information gathered at 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 person should also make sure that a single eligibility outcome status is coded at the bottom of the form and should enter his ID in the appropriate field. Eligibility status on the SV2 Visit Form cannot be indicated until after the medication review and after a clinician signs the form.

If a participant is excluded at the investigator's discretion (i.e., not as part of the regular screening activities for this visit), complete the Participant Closeout Form (Form #28) to record the reason for the exclusion. In this case, do not enter an outcome on the SV2 Visit Form, and do not enter the SV2 Visit Form.

Ending SV2

To complete the SV2 visit, do the following:

If the participant is ineligible:

You may inform the participant of her eligibility status and terminate the visit wherever it is clear that the individual is not eligible for PREMIER. Explain the reasons for ineligibility to the participant. Enter the visit outcome status on the SV2 Visit Form.

If the participant is eligible:

Schedule an appointment for SV3 at least 7 days after SV2. The Clinical Center may wish to give participants some of the non-eligibility questionnaires at this time to complete at home and return at the SV3 visit. Warn the participant that it is possible that their lab test results may make

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them ineligible. Clinical centers may decide to put off scheduling the SV3 Visit until after the local lab test results have been received and the participant is determined to be eligible.

When all data on the SV2 Visit Form have been collected, enter the SV2 BP Form, the Medication Use Questionnaire, and the Local Lab Worksheet into the data entry/management system. After those forms have been entered, enter the SV2 Visit Form. All of this data entry should be completed within two weeks of the visit; preferably within one week.