

**PREMIER Manual of Procedures**

<b>16. PARTICIPANT CLOSE-OUT</b>	<b>3</b>
<b>Purpose</b> _____	<b>3</b>
<b>Close out Prior to Randomization</b> _____	<b>3</b>
<b>Early Termination after Randomization</b> _____	<b>3</b>
<b>Unblinding</b> _____	<b>4</b>
<b>End of Cohort Close Out</b> _____	<b>5</b>
<b>Participant Closeout</b> _____	<b>5</b>
End of Cohort _____	<b>5</b>
End of Trial _____	<b>5</b>

## **PREMIER Manual of Procedures**

### **Summary of Edits**

#### **Summary of changes between Version 1.0 and 1.1**

- Deleted reference to pregnancy in statement regarding 4 sets of intervention blood pressures and other closeout procedures for randomized participants unable to complete the study. Participants who become pregnant do not receive any end of study measurements.

#### **Summary of changes between Version 1.1 and 1.2**

- Added table in unblinding reflecting SC decisions about when to give results and trialwide information to be given to participants

## **16. Participant Close-out**

### *Purpose*

This chapter contains instructions for closing out participants prior to randomization, early termination after randomization, and for closing out randomized participants at the end of the cohort.

### *Close out Prior to Randomization*

If a participant refuses to participate in the study or becomes ineligible prior to randomization, they are closed out of the PREMIER data entry system in one of two ways.

At a screening visit: If refusal/ineligibility is determined at a screening visit, the participant can simply be closed out by marking "ineligible" or "refusal" on the bottom of the relevant screening visit form and then entering that form into the system. All completed data collection forms for that participant for that visit should be entered into the PREMIER data entry system before officially closing them out by entering the "visit outcome" into the data management system.

Between screening visits: If refusal/ineligibility is determined between screening visits, the participant can be closed out using the Participant Closeout Form (#28). For example, a participant's local lab results may be received in-between SV2 and SV3, or a participant may call in to cancel the next screening visit and refuse to participate any further. All prior screening data collection forms that have been collected should be entered before closing out the participant. Once refusal or ineligibility is determined, no additional data collection is required. The Participants in Limbo report located in the data management system can be run at any time to identify any non-randomized participants that still have an "eligible" code in the system and need to be closed out. A final status needs to be resolved for all participants on the Randomized Participants in Limbo report by the end of the each cohort.

### *Early Termination after Randomization*

If a participant becomes pregnant during the study, she is excluded immediately from further participation in all study activities.

Participants reaching the blood pressure escape thresholds are referred to their personal physician for evaluation and possible drug treatment. If possible, before blood pressure medications are started, the clinical center should endeavor to obtain four sets of end-of-intervention blood pressure measurements on all participants who meet one of the BP escape criteria.

Participants who suffer a morbid event with lasting effect on blood pressure (e.g., myocardial infarction, stroke) may continue with the interventions and follow-up clinical visits with the

## PREMIER Manual of Procedures

approval of their primary physician and study clinician in order to study secondary outcomes and adherence.

If a participant develops any other exclusionary condition (e.g. cancer) following randomization, further participation is determined by a study clinician in conjunction with the participant's personal physician.

Where possible, randomized individuals who are unable to complete the study for any reason (escape blood pressure, morbid event, etc.) should have 4 sets of end of intervention blood pressures, all other end of intervention measurements and receive a closeout briefing. This briefing should occur as soon after the terminating event as the participant's condition permits. However, it need not be done as a face-to-face meeting; the information may be sent by mail.

For any randomized participant who doesn't complete the intervention, the Premature Study Termination Form (#37) should be completed and entered into the PREMIER data entry system. Be sure to review the coding instructions on the Premature Termination Form for additional termination codes. If the termination reason is coded as "other", the clinic coordinator should fax a copy of the termination form to the CC data manager for review. The CC will add additional codes if necessary or recode the "other" response if possible. Also, before entering the termination form, be sure that all other remaining data has been entered.

### *Unblinding*

Participants are told their baseline blood pressure measurements and also receive a summary of their six-month blood pressure measurements. At the conclusion of intervention (at 18 months), participants receive a complete set of blood pressure results, along with a summary of their laboratory measurements.

Information is given to participants as follows:

	<b>Group A</b>	<b>Groups B and C</b>
<b>Baseline</b>	BP, lab	BP, lab, fitness <sup>1</sup>
<b>6 months</b>	BP, lab	BP, lab, fitness <sup>1</sup>
<b>18 months*</b>	BP, lab, fitness <sup>1</sup> , PAR, diet recall	BP, lab, fitness <sup>1</sup> , PAR, diet recall
<b>EOS</b>	Trialwide data	Trialwide data

\* Give comprehensive data as soon as possible after intervention (24 months for C1). Give whatever data you can immediately. Rationale for the time lag for cohort 1 is to have the feedback occur after the 6 month collection for C4.

1 This information is conveyed by an interventionist or other unblinded staff. Give baseline results at the randomization visit.

## **PREMIER Manual of Procedures**

### ***End of Cohort Close Out***

This section contains instructions on the final closing out of participants from the PREMIER data management system.

All participants should have all data collection forms entered into the PREMIER data entry system. Next, the 18-month visit data completeness report should be run and checked to verify that all data has been entered. Finally, the 18-month Visit Form (#59) can be entered. This closes out the participant and no further data can be entered.

The Randomized Participants in Limbo report located in the data management system can be run at any time to identify any randomized participants for past cohorts that still have an "eligible" code in the system and need to be closed out. The data needs to be resolved for all participants on the Randomized Participants in Limbo report after the end of the each cohort.

### ***Participant Closeout***

#### ***End of Cohort***

Refer to the INTERVENTION MOP for detailed instructions on participant closeout activities.

#### ***End of Trial***

At the conclusion of the full trial, after all cohorts have been completed, study participants are informed about the overall findings of the trial.