

PREMIER Clinical Manual of Procedures

1.	TRIAL POLICIES	3
	Protocol _____	3
	Manual of Procedures _____	3
	Protocol and Procedure Exceptions _____	3
	Institutional Review Board (IRB) _____	4
	Provision of Medical Care to Participants _____	4
	Disclosure of Study Results _____	4
	Publicity _____	5
	Access to Stored Laboratory Specimens _____	5
	Archiving of Source Documents and Biological Specimens _____	5

PREMIER Clinical Manual of Procedures

Summary of Edits

Changes between Version 1.0 and 1.1:

- Adds new language to allow reserving discussion of process data to colleagues within each clinical site PI's departments or institutions.

PREMIER Clinical Manual of Procedures

1. Trial Policies

This section records policies that have been approved by the Steering Committee.

Protocol

The Protocol is a document that presents the scientific background, design, and governing policies of the study. Changes to the Protocol may be proposed by any member of the Steering Committee. Proposed modifications must be approved by the Steering Committee, the Data and Safety Monitoring Board, and appropriate offices at the NHLBI in the order listed. Voting on changes is done at regularly scheduled meetings and conference calls of the Steering Committee or the Data and Safety Monitoring Board. A majority vote of approval is required for each committee before forwarding to the next level. Protocol changes that affect participant eligibility or management must be submitted by each clinical center to its Institutional Review Board (IRB) according to local IRB guidelines. Changes must be approved by the IRB before being instituted at any site.

Manual of Procedures

The Manual of Procedures (MOP) is a working document that translates the Protocol into working procedures. Its goal is to describe the procedures with sufficient clarity to ensure that all clinical centers use the same examination procedures, participant management, intervention schedules, definitions, and, as far as possible, the same equipment.

The Coordinating Center is responsible for minor revisions of the MOP. Substantive changes require approval of the Steering Committee. A majority vote of approval by the Steering Committee is required for adoption of a substantive modification. A mail ballot may be used as necessary. Changes to the MOP and relevant forms are made as soon as practical and, unless otherwise noted, become effective on receipt of the revised procedures at the clinical centers.

Once accepted, the policies in the Protocol and the procedures described in the MOP must be followed by each clinical center. The Coordinating Center monitors adherence to the MOP and prepares regular reports for the Steering Committee summarizing adherence to protocol and deviations from these documents.

Protocol and Procedure Exceptions

It is the policy of the PREMIER Steering Committee not to allow exceptions to the procedures laid out in the study Protocol and Manual of Procedures. Investigators wishing exceptions should instead petition the Steering Committee to amend the Protocol and/or MOP to formally allow the exception.

PREMIER Clinical Manual of Procedures

Nonetheless, unusual circumstances will arise where this procedure is not practical. In these instances the PI or designee can petition the principal investigator of the Coordinating Center, or his designee, to grant the exception. This decision can further be appealed to the full Steering Committee. The Coordinating Center will maintain and regularly circulate a list of allowed and disallowed exceptions, as well as a list of clarifications to the Protocol and MOP.

Institutional Review Board (IRB)

The Coordinating Center and each clinical center must obtain permission from its local IRB to conduct the study before beginning recruitment. As noted above, all changes to the Protocol must also be submitted for IRB review and approval according to local IRB guidelines. Documentation of local IRB approval from each PREMIER center should be sent to the Coordinating Center, along with approvals of subsequent changes. Periodically, the Coordinating Center will provide each PI with trial-wide information on adverse events for their IRB.

Provision of Medical Care to Participants

In the course of screening participants and conducting interventions, medical problems will occasionally be identified among participants. The responsibility of clinical centers in following up such problems will vary from site to site according to generally accepted medical guidelines, individual IRB requirements, and the resources available to provide referral and follow-up services. In no instances, however, should resources essential to the proper implementation of the Protocol be utilized to provide medical care services.

Disclosure of Study Results

Participants are told their baseline blood pressure measurements and also receive a summary of their six-month blood pressure measurements. Provision of such information is appropriate in view of the fact that many participants will have stage 1 hypertension. Participants also receive a complete set of blood pressure results, along with a summary of their laboratory measurements and information about the overall findings of the trial, at the conclusion of intervention. Participants are alerted if their blood pressure goes above a predetermined escape level at any point in the trial.

Confidential study data may be provided to a participant or health care provider on a need-to-know basis, if necessary for medical management or other safety concerns. This option is not disclosed to participants in advance. Clinics will notify the Coordinating Center of any participant who is unblinded to their blood pressure values during the intervention period.

PREMIER Investigators may share process data within their own departments at their own institutions. Otherwise, no PREMIER results may be presented until after the main outcomes paper is in press.

PREMIER Clinical Manual of Procedures

Publicity

Unpublished results derived from PREMIER data may not be discussed or released without authorization of the Steering Committee. The Publications Committee will recommend to the SC general guidelines for the content and timing of news releases and interviews for presentations and publications. PREMIER investigators may discuss design and recruitment issues with the media, but should inform the Steering Committee of any PREMIER-related information scheduled for release in the national media.

Access to Stored Laboratory Specimens

PREMIER will store a variety of frozen blood, urine, and buffy coat samples from PREMIER participants. Proposals to use these samples should be submitted to the PREMIER Steering Committee in writing. These proposals should include the type of study/test proposed, the amount of each sample required to conduct it, the rationale for the test, the study questions and hypotheses to be addressed, the plans for publication of the data, the approximate cost of the proposed test(s), and the source of funds to conduct them. Study investigators not involved in the initial proposal may request to be included in the working group conducting the additional studies.

The discussion of whether to permit use of the stored samples should include attention to possible alternative uses of limited materials. That is, the Steering Committee will attempt to plan for optimal uses of the stored samples rather than simply to grant requests for their use on the basis of which were submitted first. Use of stored specimens requires that an ancillary studies request be submitted.

Any analysis of biological specimens must be approved by each center's IRB.

Archiving of Source Documents and Biological Specimens

All source documents and biological specimens obtained during the conduct of PREMIER should be stored until the year 2007 or until the PC formally dissolves. Before any source documents or biological specimens are discarded, approval must be sought from the Steering Committee. Before disbanding, the Steering Committee will determine the future storage or disposal of source documents and stored biological specimens.