

STANDARD OPERATING PROCEDURE

OBJECTIVE

To describe the procedures for communicating information regarding initial protocol release, unanticipated problems, protocol amendments, and study specific items to sites participating in multi-center studies when NMDP/CIBMTR is considered the lead researcher (i.e., responsible for the overall conduct of the study).

MATERIALS

Not applicable

SAFETY

Not applicable

DEFINITIONS

- 1. Center for International Blood and Marrow Transplant Research (CIBMTR):** A combined research program of the National Marrow Donor Program (NMDP) and the Medical College of Wisconsin (MCW). CIBMTR facilitates critical research in hematopoietic cell transplantation and cellular therapy.
- 2. Participating site:** The location where trial-related activities are actually conducted.
- 3. Consent form:** Document used during the consent process that is the basis for explaining to potential subjects the risks and potential benefits of a study and the rights and responsibilities of the parties involved.
- 4. Electronic Data Capture System:** A computerized system designed for the collection of clinical data in electronic format for use mainly in human clinical studies.
- 5. Institutional Review Board (IRB):** Any board, committee or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of research involving human subjects.

- 6. Numbered memo:** A written memorandum with key information for distribution to all participating sites. Each memorandum is assigned a number in sequential order as distributed.
- 7. Principal Investigator (PI):** The individual who is ultimately responsible for the clinical study. The study PI is generally the individual who writes and submits the grant application, if applicable, and oversees the scientific and technical conduct of the project.
- 8. Protocol:** The study plan on which the clinical study is based. The plan is carefully designed to safeguard the safety, privacy and confidentiality of the participants as well as answer specific research questions. A protocol describes what types of people may participate in the study, study procedures, and the length of the study.

GENERAL PROCEDURE

- 1. Initial communication and distribution of protocol and study materials**
 - 1.1. The protocol, consent forms(s), and study materials are distributed to participating sites upon NMDP IRB approval of the study.
 - 1.1.1. If the study is utilizing an electronic data capture system provided by CIBMTR, the approved materials are posted on the study specific page of that electronic data capture system.
 - 1.1.2. An email containing the approved study materials is sent to the Principal Investigator (PI), study coordinator, and regulatory coordinator (if known) at each participating site. The email directs the site to complete the following steps:
 - 1.1.2.1. Submit their site-specific consent form(s) to the CIBMTR study coordinator for CIBMTR review and approval prior to submitting the study to their local IRB.
 - 1.1.2.2. After the CIBMTR study coordinator approves the site's consent form(s), the site must submit the study to their local IRB.
 - 1.1.2.3. Upon local IRB approval, the site must send a copy of the IRB approval notice and approved consent form(s) to CIBMTR.

- 1.1.2.4. EXCEPTION: Apheresis centers are not required to obtain consent from unrelated donors for the NMDP PBSC study. Although they are required to obtain local IRB approval of the protocol, apheresis centers need not maintain IRB-approved consent forms.
- 1.2. For all multi-center studies where NMDP/CIBMTR is considered the lead researcher, regardless of the funding entity, the NMDP Contracts department will negotiate a formal agreement with each participating site that specifies the roles and responsibilities of each party. This agreement will be in one of the following two formats:
 - 1.2.1. Master Clinical Trial Agreement with a study specific rider
 - 1.2.2. Study addendum to the center's NMDP Network Center Participation Agreement.

2. Communication during study life-cycle

- 2.1. Protocol, consent form(s) and study material amendments
 - 2.1.1. Following NMDP IRB approval of any amendments to the protocol, consent form(s) or study materials, steps under section 1.1 of this standard operating procedure must be completed.
 - 2.1.1.1. EXCEPTION: For the CIBMTR Research Database and Research Sample Repository studies, revisions to site-specific consent forms do not need CIBMTR staff approval prior to submitting the revised consents to the site's local IRB.
- 2.2. Numbered memos
 - 2.2.1. Written memoranda are created if there are significant process changes, safety recommendations, research drug problems, unanticipated problems involving risks to participants or others, or any other significant communications.
 - 2.2.2. These memoranda are emailed to all PIs and study coordinators and also posted on the study specific page when an electronic data capture system is being used.
- 2.3. Annual reports and interim results
 - 2.3.1. If applicable, U.S. Food and Drug Administration (FDA) annual reports and interim results will be distributed to all sites both by email and by posting on the study specific page.

National Marrow Donor Program®**Title:** Multi-Site Study Communication**Number:** S00412**Revision:** 2**Page 4 of 4****REFERENCE DOCUMENTS**

1. 21 CFR 56

Revision History

Revision	Brief Description of Revision	Training Needed? Y/N*
S00412 rev. 1	New SOP. Procedure for communicating study information to centers participating in multi-center NMDP/CIBMTR studies	Y
S00412 rev. 2	Clarifications to sections 1.2 and 2.2.1.	N

*Use "NA" for SOP revisions approved prior to "Training Needed" column being added to this template.

ADDENDA

Not applicable