STANDARD OPERATING PROCEDURE

OBJECTIVE/SCOPE

To ensure that Principal Investigators meet all requirements related to research for which National Marrow Donor Program (NMDP) Institutional Review Board (IRB) approval is required.

NOTE: If an NMDP investigator wishes to rely on an external IRB (i.e., **not** the NMDP IRB), reference S00592 *NMDP IRB Reliance Agreements and Cooperative IRB Reviews* for requirements and responsibilities.

MATERIALS

Not applicable

SAFETY

Not applicable

DEFINITIONS

1. **IRB of record:** The IRB of record is the IRB responsible for conducting the IRB reviews of a study on behalf of a participating study site.
2. **Research protocol:** General term used to refer to a study proposal, research project, concept paper, etc.

RESPONSIBILITIES

Not applicable

PROCEDURE

1. **Principal Investigator application submission**

    1.1. Submission of IRB application must be performed according to NMDP IRB requirements. (Refer to SOP #: S00038, *NMDP IRB Materials Required for Review.*)

2. Principal Investigator reporting to the NMDP IRB

2.1. Principal Investigators are required to promptly report unanticipated problems involving risks to participants or others to the NMDP IRB. (Refer to SOP #: S00407, *Unanticipated Problems Involving Risks to Participants or Others*.)

2.2. Donor adverse events (that meet the criteria for unanticipated problems involving risks to participants or others) for donors obtained through the Be the Match Registry® will be reported to the NMDP IRB by the NMDP staff.

2.3. Stopping a study must be reported to the NMDP IRB.

2.3.1. Stoppage of a study may be required for a number of reasons, such as, but not limited to, the following:

2.3.1.1. Completion of the study
2.3.1.2. Unexpected adverse events
2.3.1.3. Protocol noncompliance

2.3.2. Restart of the study after stoppage regardless of the reason must be performed according to NMDP IRB requirements. (Refer to SOP #: S00040, *NMDP IRB Protocol Review*.)

2.4. Changes in research activities, including changes in the protocol and/or informed consent document shall be submitted to the NMDP IRB prior to implementation of the change except where necessary to eliminate apparent immediate hazards to the human subjects.

2.5. Study progress reports for non-exempt human subjects research shall be submitted on at least an annual basis.

2.6. Any instance of serious or continuing noncompliance with 21 CFR 56, 45 CFR 46, or any other NMDP IRB requirements shall be reported to the NMDP IRB. (Refer to SOP# S00213, *NMDP IRB: Managing and Reporting Non-Compliance with Human Research Protection Program Requirements*)

3. Informed consent

3.1. In the case of studies involving the unrelated volunteer donor obtained through the Be the Match Registry, the informed consent document is developed and maintained by the NMDP staff. Administration of informed consent is performed according to specific NMDP requirements by staff, such as a donor center coordinator, at an organization identified by the NMDP.

3.2. The development, maintenance, and administration of informed consent documents for all other subjects on a study (other than Be The Match unrelated donors) are the Principal Investigator's responsibility.

3.3. It is the Principal Investigator's responsibility to post the clinical trial consent form on a publicly available Federal website in accordance with 45 CFR 46.116(h) regulations.

3.3.1. The consent form must be posted on the website after the clinical trial is closed to recruitment, but no later than 60 days after the last study visit by any subject, as required by the protocol.

3.3.2. If the Principal Investigator (PI) wishes to request an exception to the consent form posting requirement, the PI should contact the Administrative Grant Specialist of the Federal department or Agency to request the exception.

3.3.3. The Federal department or agency supporting the research may permit or require redactions of proprietary, sensitive or non-public information in the consent form (e.g., confidential commercial information). The PI should contact the Administrative Grant Specialist of the Federal department or Agency to inquire about the process for redacting such information from the informed consent form prior to posting.

4. Principal Investigator reporting to the study subject

4.1. Stoppage of a study due to subject safety must be reported to the enrolled research subject(s).

4.1.1. If the research subjects' safety or well being may be in question as a result of their enrollment within the study, this must be reported to the study subject.

4.1.2. Subject follow-up that will continue after the study has been stopped shall be reported to the study subject.

5. Principal Investigator training requirements

5.1. Investigators and research staff who are employed by the NMDP are expected to follow the human research protection initial and continuing training requirements set forth by the NMDP. (Refer to A00319, *NMDP Education Program for the Protection of Human Research Participants*)

5.2. Investigators and research staff who are employed by an institution other than the NMDP are expected to follow the human research protection initial and continuing training requirements set forth by their own institution.

6. Principal Investigator compliance

6.1. When conducting human subjects research, investigators and research staff are expected to comply with the following (Refer to SOP# S00034, *NMDP IRB General Operations and Functions*):

6.1.1. all applicable federal and state laws, regulations, codes and guidance,

6.1.2. the ethical principles set forth in *The Belmont Report*,

6.1.3. the NMDP IRB's determinations, and

6.1.4. the NMDP's policies and procedures for protecting research participants.

6.1.4.1. Policies and procedures shall be available to all NMDP employees through NMDP's document control system.

6.1.4.2. Relevant policies and procedures are available on the Network tab of the Be The Match Clinical website (www.bethematchclinical.org) to researchers and research staff external to NMDP.

7. Principal Investigator assurance of resource adequacy

7.1. Principal Investigators are responsible for performing research with sufficient resources necessary to protect participants. Such resources include, but are not limited to, the following:

7.1.1. adequate time to conduct and complete the research,

7.1.2. adequate number of qualified staff,

7.1.3. adequate facilities,

7.1.4. access to a population that will allow recruitment of the necessary number of participants,

7.1.5. availability of medical or psychosocial resources that participants may need as a consequence of the research, and

7.1.6. a process to ensure that all persons assisting with the research are adequately informed about the protocol and their research-related duties and functions.

REFERENCES

1. 21 CFR 312.32
2. 21 CFR 56 Subpart C
3. 45 CFR 46
4. A00319, NMDP Education Program for the Protection of Human Research Participants
5. SOP#: S00034, NMDP IRB General Operations and Functions
6. SOP#: S00038, NMDP IRB Materials Required for Review
7. SOP#: S00040, NMDP IRB Protocol Review
8. SOP#: S00213, NMDP IRB: Managing and Reporting Non-Compliance with Human Research Protection Program Requirements
9. SOP#: S00407, Unanticipated Problems Involving Risks to Participants or Others
10. SOP#: S00592, NMDP IRB Reliance Agreements and Cooperative IRB Reviews

Revision History

Revision	Brief Description of Revision
S00048 08/17/2001	New SOP
S00048 version 2.0	Annual Review: removed PI Protocol Development and Training
S00048 version 2.1	Formatting changes.
S00048 rev. 3	Added S00213 as an applicable reference document. Changed references from NMDP Registry to Be the Match Registry.
S00048 rev. 4	Added definition of Research protocol. Deleted 3.2 and 4.2. Clarifications in new 3.2. Reworded 4.1. Added sections 6, 7 and 8 and their respective subsections.
S00048 rev. 5	Clarification to objective. Revised 2.1. Added reference documents
S00048 rev. 6	Deleted definition of CRO. Added definition of IRB of record. Added Responsibilities section. Revised 2.6 and 3.2. Deleted section 4 regarding PI's reporting to the FDA. Changed NMDP website reference to www.bethematchclinical.org.
S00048 rev. 7	Clarifications to each sub-section of sect 2
S00048 rev. 8	Added clarifying Note to Objective/Scope. Added 3.3 regarding posting of clinical trial consent form.

ADDENDA

Not applicable