Title: NMDP IRB Orientation and Training
Number: S00036
Revision: 11

STANDARD OPERATING PROCEDURE

OBJECTIVE/SCOPE

To ensure that NMDP Institutional Review Board (IRB) members, applicable NMDP employees, applicable NMDP Network staff, and external investigators and research staff are appropriately trained in human subjects protection.

MATERIALS

Not applicable

SAFETY

Not applicable

DEFINITIONS

Not applicable

RESPONSIBILITIES

1. **Center for Blood and Marrow Transplant Research (CIBMTR) Clinical Research Organization (CRO) Services**
   - Monitor human research protection training requirements of NMDP Network staff, as applicable
   - Inform NMDP Network staff of their human research protection training requirements, as applicable

2. **NMDP Education & Training Department**
   - Monitor human research protection training requirements of NMDP employees, as applicable
   - Inform NMDP employees of their human research protection training requirements, as applicable

3. **NMDP IRB Staff**
   - Monitor human research protection training requirements of NMDP IRB members
   - Inform NMDP IRB members of their human research protection training requirements

PROCEDURE

1. Orientation of new IRB members

1.1. All newly appointed IRB members must meet minimal training requirements prior to functioning as a voting member of the IRB. Refer to A00319, NMDP Education Program for the Protection of Human Research Participants for these requirements.

2. Training and continuing education of IRB members

2.1. Frequency

2.1.1. NMDP IRB members must participate in continuing education requirements. Refer to the NMDP Education Program for the Protection of Human Research Participants (A00319) for these requirements. Additional training may be performed periodically as new regulations or guidances are issued.

2.1.2. Additional training may be performed at the discretion of the NMDP IRB Administrator, the NMDP Institutional Official, the NMDP Organizational Official, or the NMDP IRB Chair.

2.1.3. Other continuing education opportunities will be communicated to the IRB as they arise.

2.2. Training methods may include, but are not limited to, the following:

2.2.1. Reading: Review of procedures, policies or other written materials that are applicable to carrying out responsibilities of the NMDP IRB.

2.2.2. Lecture: Verbal instruction presented in a lecture format that may or may not include audio-visual materials.

2.2.3. Discussion: Formal or informal group that allows the trainer and trainees to exchange information, discuss concepts, ask questions, and clarify information.

2.2.4. Visual: Training method in which videos, computer-generated tutorials, diagrams, or other visual materials are used with or without the accompanying audio materials.

2.2.5. Audio: Training method in which audio materials (e.g., tapes, CDs) are used with or without accompanying visual materials.

3. Orientation and training of IRB staff

3.1. NMDP IRB staff must meet orientation and on-going training requirements. Refer to the NMDP Education Program for the Protection of Human Research Participants (A00319) for these requirements.

4. Training of NMDP World Headquarters (WHQ) staff

4.1. WHQ staff who are required to complete training in human subjects protection will be selected by the NMDP department directors in consultation with the NMDP IRB Administrator or NMDP Organizational Official.

4.1.1. This includes all staff who serve as an Investigator or as part of a research team.

4.2. Refer to the NMDP Education Program for the Protection of Human Research Participants (A00319) for WHQ staff training requirements.

5. Training of Network medical directors

5.1. All medical directors of domestic donor centers that rely on the NMDP IRB are required to complete training in human subjects protection.

5.2. Refer to the NMDP Education Program for the Protection of Human Research Participants (A00319) for medical director training requirements.

6. Training of Network staff

6.1. Certain staff of domestic donor centers that rely on the NMDP IRB are required to complete training in human subjects protection. Refer to the NMDP Education Program for the Protection of Human Research Participants (A00319) for the job functions of staff required to take the training.

6.2. Refer to the NMDP Education Program for the Protection of Human Research Participants (A00319) for center staff training requirements.

7. Training of external investigators and research staff

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

8. Department of Navy (DON) education requirements

8.1. NMDP receives DON funding for certain research protocols. Therefore, as a DON-supported extramural performer, DON must receive documentation of key investigators' human research protection training. This is submitted to DON by the NMDP Contracts department.

8.2. DoD Components may evaluate the NMDP's education policies to ensure personnel are qualified to perform the research, based on the complexity and risk of the research. (Refer to DoD Instruction 3216.02 5d)

9. Monitoring of education requirements

9.1. Human research protection training requirements of IRB members are monitored by IRB staff.

9.1.1. If an IRB member does not satisfactorily complete the orientation or continuing education requirements, the Organizational Official, with input from the IRB Administrator or Institutional Official, may dismiss the member from the IRB, withhold compensation, or take other appropriate action.

9.2. Human research protection training requirements of NMDP employees (including IRB staff) are monitored by the Education & Training department.

9.2.1. If an NMDP employee does not satisfactorily complete the training requirements, the Institutional Official, with input from the IRB Administrator and/or Organizational Official, may ask the employee to cease his/her involvement in NMDP research until the requirements are completed.

9.3. Human research protection training requirements of Network staff (other than NMDP employees) are monitored by CIBMTR CRO Services.

9.3.1. If Network staff do not satisfactorily complete the training requirements, the Institutional Official, with input from the IRB Administrator and/or Organizational Official, may ask the Network staff person to cease his/her involvement in NMDP research until the requirements are completed.

9.4. Principal Investigators must submit proof of human research protection training along with their IRB application materials for initial review. At the time of continuing review, Principal Investigators are asked if they are in compliance with their institution's ongoing human research protection training requirements.

9.4.1. NMDP IRB approval of initial applications will not be granted until the Principal Investigator submits proof of human research protection training.

9.4.2. Principal Investigators that are not compliant with their institution's human research protection training requirements at the time of continuing review must complete such requirements before NMDP IRB approval of the continuing review application is granted.

9.5. Principal Investigators from institutions outside of the U.S. are required to follow their own institution's human research protection training requirements. Proof of such training may not be available; however, these Principal Investigators will be asked if they are in compliance with their institution's training requirements.

9.6. Individuals required to take human research protection training will be informed of such requirements by NMDP IRB staff, the Education & Training Department, or CIBMTR CRO Services as applicable.

10. **Reference materials**

10.1. Links to the Federal regulations and guidance are maintained on the NMDP Network website.

10.2. All NMDP IRB policies and procedures can be found in NMDP's document management system. NMDP IRB policies and procedures relevant to external investigators are located on the NMDP Network website.

REFERENCES

1. 21 CFR 50
2. 21 CFR 56
3. 45 CFR 46
4. NMDP IRB Policies and Procedures
5. Attachment #: A00319, NMDP Education Program for the Protection of Human Research Participants
6. Department of Defense Instruction (DoDI) 3216.02

Revision History

Revision	Brief Description of Revision
S00036 08/17/2001	New SOP
S00036 version 2.0	Annual Review: Update Continuing Education
S00036 version 3.0	Added an Applicable Reference Document. Updated Objective and sections 1 and 2. Added sections 3, 4, 5, and 6. Deleted former section 3 (Continuing Education). Added section 7.1.6.
S00036 version 4.0	Put into new SOP format. Title change for Roberta King (verifier). No content changes.
S00036 revision 5	Added 4.1.1 and 9.1.3. Added new section 7 (Training of investigators and research staff). Added new section 8 (Monitoring of education requirements). Clarifications to several other sections.
S00036 revision 6	Added section 8 on DON educ requirements. Added 9.5. Added DoDI and DON HRPP Training guidance as reference docs.
S00036 revision 7	Added Responsibilities section. Updated sect 5.1. and 6.1. removing reference to cord blood bank medical director and staff training requirements. Deleted reference to DoD FWA Addendum in sect 8.1. Added sect 9.4.3. Changed sect 10.1 from IRB Administrator to IRB staff. Added references to Be The

	Match.
S00036 revision 8	Deleted section 1.2
S00036 revision 9	Revised Objective/Scope. Added Responsibilities of CIBMTR Prospective Research Group. Revised Responsibilities of NMDP IRB Staff. Revised sect 9.3. Added sect 9.4. Revised sect 9.6 and sect 10. Revised References.
S00036 revision 10	Deleted apheresis centers from 5.1 and 6.1.
S00036 revision 11	Removed references to National Marrow Donor Program and Be The Match. Changed CIBMTR Prospective Research Group to CIBMTR CRO Services. Revised sect 8.1 re: DoN training requirements and added that training documentation is submitted to DoN by Contracts dept. Removed Master Control from 10.2. Changed Coordinating Center to WHQ.

ADDENDA

Not applicable