

STANDARD OPERATING PROCEDURE

OBJECTIVE/SCOPE

To define the role, purpose and membership criteria for the NMDP Institutional Review Board (IRB).

MATERIALS

Not applicable

SAFETY

Not applicable

DEFINITIONS

1. **Consultant:** An individual who has been invited to assist in the review of research which requires expertise beyond or in addition to that of the NMDP IRB members.
2. **IRB Authorization Agreement:** An agreement between two institutions that defines the scope of research that one institution's qualified IRB will be allowed to review on behalf of the other institution.
3. **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. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects. The term is synonymous with "institutional review committee."
4. **Federalwide Assurance (FWA):** A document filed with the Department of Health and Human Services (DHHS) stating that the institution will comply with DHHS protection of human subjects regulations.
5. **Immediate family:** Spouse or domestic partner, and dependent children.
6. **Research protocol:** General term used to refer to a study proposal, research project, concept paper, etc.

RESPONSIBILITIES

1. **NMDP Institutional Official**
 - Appoint IRB Chair

- Determine decisions for removal of IRB members
2. **NMDP IRB Staff**
 - Initiate and implement IRB member nomination process
 - Coordinate onboarding of new IRB members
 - Conduct annual evaluation of IRB Chair's turnaround time for expedited reviews
 - Annually compile meeting attendance and compliance with training requirements for each IRB member
 - Provide annual written evaluations to IRB members and IRB Chair
 3. **NMDP Organizational Official**
 - Appoint IRB members and grant IRB member renewal terms
 - Determine financial compensation for IRB Chair and IRB members

PROCEDURE

1. **NMDP Institutional Review Board (IRB)**
 - 1.1. Primary role: The NMDP IRB is a formally designated group whose primary role is to review research involving human subjects. The primary focus of the NMDP IRB human subject review is research involving cell therapies.
 - 1.2. Purpose: To assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in research.
2. **Selection and appointment of the NMDP IRB members and Chair**
 - 2.1. Requirements for selection:
 - 2.1.1. All NMDP IRB members must meet the qualifications as defined in SOP#: S00037, NMDP IRB Membership and Voting Requirements.
 - 2.1.2. The NMDP IRB Chair must meet additional qualifications as defined in SOP#: S00037, NMDP IRB Membership and Voting Requirements.
 - 2.1.3. A study investigator may not select IRB members.
 - 2.2. Nominations
 - 2.2.1. The NMDP IRB will accept nominations of new IRB members via the Nomination Form available on the IRB website.
 - 2.2.2. Recruitment of a new member shall begin four months prior to the existing member's end of term, or sooner if needed.
 - 2.2.2.1. A recruitment announcement shall be sent, as appropriate, to the Network audience representing the member's background (e.g., Transplant Center Coordinators, Donor Center Coordinators, Medical Directors)

- 2.2.3. Nomination Forms received shall be reviewed and discussed at the IRB staff meeting.
 - 2.2.4. IRB staff shall select one to three candidates to recommend to the IRB Chair.
 - 2.3. Appointment:
 - 2.3.1. Appointment of IRB members is performed by the NMDP IRB Organizational Official in consultation with the IRB Chair and Institutional Official, as needed.
 - 2.3.2. The Chair is appointed by the Institutional Official.
 - 2.3.3. Once it has been determined that the member meets the necessary qualifications, the member may be appointed to participate as either a primary or alternate member.
 - 2.3.3.1. Members who serve as an alternate member may later be appointed as a primary member, assuming they still meet all necessary qualifications.
 - 2.3.3.2. Primary members may later be appointed as alternate members.
 - 2.3.3.3. A change in type of appointment requires a change in the member's service agreement with NMDP that outlines his/her responsibilities in the scope of work.
 - 2.3.4. Alternate members will be appointed on the basis of comparable qualifications to the primary member for whom they will serve as an alternate.
3. **Onboarding of new NMDP IRB members**
 - 3.1. Once a new IRB member has been appointed, he/she will sign a Service Agreement.
 - 3.1.1. IRB staff will coordinate with NMDP Contracts and Procurement to send the Agreement to the member.
 - 3.2. Once the new member has signed the Service Agreement, IRB staff will communicate the following to the new member:
 - 3.2.1. orientation and training requirements
 - 3.2.2. access to IRB meeting materials
4. **Term**
 - 4.1. IRB members are appointed for a three-year term with one three-year renewable term.
 - 4.2. Membership renewals will be decided by the NMDP IRB Organizational Official in consultation with the Institutional Official and IRB Chair, as needed. The Organizational Official is responsible for granting the membership renewal.

5. Member duties

5.1. Primary member

5.1.1. The responsibility of a primary member is to perform initial and periodic review of research protocols, the corresponding study progress reports, and reports of unanticipated problems and serious and/or continuing non-compliance to ensure that appropriate steps are being taken to protect the rights and welfare of humans participating as subjects in research. Following the review, the member participates in discussion, deliberation and voting.

5.2. Alternate member

5.2.1. An alternate member is requested by the NMDP IRB to serve as a replacement for a primary member. The responsibility of an alternate member is to perform initial and periodic review of research protocols, the corresponding study progress reports, and reports of unanticipated problems and serious and/or continuing non-compliance to ensure that appropriate steps are being taken to protect the rights and welfare of humans participating as subjects in research. Following the review, the member participates in discussion, deliberation and voting.

6. Participation by primary members

6.1. Participation by attending meetings and actively providing input is an expectation of all primary members.

6.2. Primary members must attend orientation and training sessions when appointed to the NMDP IRB. Primary members must also comply with continuing education requirements. (Refer to SOP#: S00036, NMDP IRB Orientation and Training.)

7. Participation of alternate members

7.1. Participation by attending meetings and actively providing input is an expectation of all alternate members when they have been asked to serve as an alternate at a specific meeting.

7.2. An alternate is allowed to attend meetings and participate in discussion and deliberations in meetings for which they have not been asked to serve as a replacement for a primary member. They are not permitted to vote under these circumstances.

7.3. Alternate members must attend orientation and training sessions when appointed to the NMDP IRB. Alternate members must also comply with continuing education requirements. (Refer to SOP#: S00036, NMDP IRB Orientation and Training.)

8. Attendance

- 8.1. Primary members should attend at least 75% of the regularly scheduled meetings in any one calendar year to ensure continuity in discussion and also to ensure quorum is achieved.
- 8.2. Prompt arrival at meetings is essential to ensure a quorum has been achieved.
 - 8.2.1. At the discretion of the IRB Administrator and Chair; joining a meeting late or leaving a meeting early may qualify as having missed the entire meeting.
- 8.3. If the attendance requirement is not met, the member may be removed. The NMDP IRB Administrator and the Institutional Official determine this decision.

9. Member evaluation

- 9.1. IRB Chair
 - 9.1.1. On an annual basis, IRB members will be asked to complete an anonymous survey that includes questions regarding evaluation of the IRB Chair. The questions will be based on, but not limited to, the Chair's leadership, time management at meetings, allowing members to express opinions and concerns, and representation of the IRB's interests.
 - 9.1.2. On an annual basis, IRB staff will conduct an evaluation of the IRB Chair's protocol review turnaround time for expedited review of IRB applications.
 - 9.1.3. After consultation with the Organizational Official, IRB staff will provide a written evaluation to the IRB Chair based on evaluations by IRB members and the evaluation of the IRB Chair's protocol review turnaround time. The evaluation will be shared with the Institutional Official. If there are specific concerns about the Chair, the Organizational Official or Institutional Official will confidentially speak with the Chair about a course of action to improve performance.
- 9.2. IRB Members
 - 9.2.1. IRB members (including the IRB Chair) will be evaluated annually by the other members of the NMDP IRB. The evaluation will be based on, but not limited to, contributions at IRB meetings and knowledge of the IRB process.
 - 9.2.2. On an annual basis, IRB staff will compile information regarding meeting attendance and compliance with training requirements for each IRB member.
 - 9.2.3. The IRB staff will provide a written evaluation to each IRB member based on the evaluations by other IRB members and compliance with meeting attendance and training requirements. If there are specific concerns about any member, the Chair, along with the IRB Administrator

or Institutional Official, will confidentially speak with the individual member about a course of action to improve performance.

10. Member dismissal

10.1. Voluntary

A member who no longer wishes to participate as an NMDP IRB member must notify the NMDP IRB Administrator or Institutional Official in writing of their withdrawal as a member.

10.2. Involuntary

10.2.1. A member who does not voluntarily withdraw from membership may be dismissed as a member for reasons that include, but are not limited to, the following:

10.2.1.1. The member does not actively contribute to the NMDP IRB process.

10.2.1.2. The member does not satisfactorily complete IRB orientation or continuing education requirements.

10.2.1.3. The member no longer meets the membership qualifications.

10.2.1.4. The member no longer meets attendance requirements.

10.2.2. The Institutional Official, with input from the IRB Administrator, will determine the decision for dismissal. Notification of dismissal will be performed in writing and will include the reason for dismissal.

11. Member compensation

11.1. Primary or alternate members may be financially compensated for participating as a member. The alternate member shall not qualify for compensation unless they have been asked to participate in a specific meeting by the NMDP IRB. The NMDP Organizational Official shall determine the financial compensation.

11.2. Should the need for financial compensation arise, the necessity and amount shall be evaluated on a case-by-case basis by NMDP. NMDP employees who serve as voting or non-voting members are eligible for additional financial compensation as long as all responsibilities related to their IRB membership are fulfilled outside of their NMDP work hours.

12. Conflict of interest

12.1. Financial conflict of interest occurs when an IRB member (or a member of their immediate family) has a Significant Financial Interest in the research protocol. A Significant Financial Interest is:

- 12.1.1. Anything of monetary value, whether or not the value is readily ascertainable, consisting of one or more of the following interests that reasonably appear to be related to the IRB member's "Institutional Responsibilities," as that term is defined in the Financial Conflict of Interest Policy Applicable to Sponsored Research Awards (see P00002):
 - 12.1.1.1. With regard to any publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
 - 12.1.1.2. With regard to any non-publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure, when aggregated, exceeds \$5,000, or when the IRB member (or the IRB member's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 - 12.1.1.3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- 12.1.2. IRB members also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the IRB member and not reimbursed to the IRB member so that the exact monetary value may not be readily available), related to their Institutional Responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. This disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, any known monetary value associated with the travel, the destination, and the duration.
- 12.1.3. The term **does not** include the following types of Financial Interests:
 - 12.1.3.1. salary, royalties, or other remuneration paid by the Institution to the IRB member if the IRB member is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
 - 12.1.3.2. any ownership interest in the Institution held by the IRB member, if the Institution is a commercial or for-profit organization;
 - 12.1.3.3. income from investment vehicles, such as mutual funds and retirement accounts, as long as the IRB member does not directly control the investment decisions made in these vehicles;

- 12.1.3.4. income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institution that is affiliated with an institution of higher education; or
- 12.1.3.5. income from service on advisory committees or review panels for a Federal, state, or local government agency, an institution of higher education as defined at 20. USC. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
- 12.2. For IRB members, conflict of interest with a protocol under review may also occur in, but is not limited to, the following circumstances:
 - 12.2.1. when the IRB member (or a member of his/her immediate family) serves as a Principal Investigator, co-investigator, or other member of the research team,
 - 12.2.2. when the IRB member (or a member of his/her immediate family) is an executive or director of the agency or company sponsoring the research,
 - 12.2.3. any time the IRB member has an interest that he/she believes conflicts with his/her ability to objectively review a protocol.
- 12.3. Members should not serve on the IRB if they know in advance that they will have financial or other conflicts of interest with all, or many of, the prospective or current Principal Investigators or institutions that the Principal Investigators represent.
- 12.4. Policies and procedures regarding conflicts of interest cover each type of review, including:
 - 12.4.1. Review by a convened IRB,
 - 12.4.2. Review by the expedited procedure,
 - 12.4.3. Review of unanticipated problems involving risks to participants or others,
 - 12.4.4. Review of allegations of non-compliance or incidents of non-compliance that have been determined to have basis in fact.
- 12.5. IRB members and consultants who have a financial or other conflict of interest pertinent to a research protocol or Principal Investigator shall disclose the conflict of interest at the convened IRB meeting prior to discussion of the study.
- 12.6. Members who have a financial or other conflict of interest pertinent to a research protocol or Principal Investigator shall not participate in the deliberation and voting process related to that specific research protocol, except when requested by the IRB to provide specific information.
- 12.7. Policies and procedures regarding conflicts of interest also pertain to consultants and their immediate family members.

12.7.1. Consultants who have a financial or other conflict of interest pertinent to a research protocol or Principal Investigator shall not be present during the deliberation and voting process related to that specific research protocol.

13. Member liability coverage

13.1. Liability coverage may be provided to the NMDP IRB members by NMDP.

REFERENCES

1. FDA Information sheets, Frequently Asked Questions, IRB Membership
2. Policy #: P00002, Financial Conflict of Interest Policy Applicable to Sponsored Research Awards
3. SOP#: S00036, NMDP IRB Orientation and Training
4. SOP#: S00037, NMDP IRB Membership and Voting Requirements

Revision History

| Revision | Brief Description of Revision |
|--------------------|--|
| S00035 08/17/2001 | New SOP |
| S00035 version 2.0 | Annual Review: Updated definitions, deleted Coop Research, added Authorization Agreements |
| S00035 version 3.0 | Renumbered section 3. Reworded sections 6.2, 7.3, 8.1, 9.2, 14.1, and 14.1.1. Formatting changes. |
| S00035 rev. 4 | Put into new SOP format. Added definitions for consultant and immediate family. Changed references from NMDP Registry to Be the Match Registry. Deleted Performance section and incorporated content into Member Dismissal section. Revised section 13. |
| S00035 rev. 5 | Added definition of Research protocol. Deleted former section 2 (IRB Authorization Agreements). Added 2.1.2. Added section 8 (Member evaluation). Added significant content to section 11 (Conflict of interest). Added clarifications to several subsections. |
| S00035 rev. 6 | Revised definition of Significant Financial Interest in section 11. Added P00002 as reference doc. |
| S00035 rev. 7 | Revised 8.1.2 and 8.1.3 removing evaluation of IRB Chair |

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| | by IRB staff. |
| S00035 rev. 8 | Added Responsibilities section. Revised primary focus of IRB in sect 1.1. Broke sect 2.2.3 into three subparts. Sect 4.1.1 and 4.2.1 changed adverse experiences to reports of unanticipated problems and serious and/or continuing non-compliance. Deleted "This rule does not apply to ad hoc meetings" from sect 7.2.1. Sect 8.2.3 changed from IRB Chair to IRB staff will provide a written evaluation... |
| S00035 rev. 9 | Revised section 3 to implement term limits. |
| S00035 rev. 10 | Revised section 2.2.1 to state that appointment of IRB members is performed by the Organizational Official. Added section 3 regarding onboarding of new IRB members. |
| S00035 rev. 11 | Added 2.2 Nominations process. Revised 4.2 to state that Organizational Official decides and grants IRB member renewal terms. Revised 9.1.3 to state IRB staff provides IRB Chair with written evaluation. Revised 11.2 to state that NMDP employees may be eligible for additional compensation as IRB members. |
| S00035 rev. 12 | Re-branding - removed references to National Marrow Donor Program and Be The Match. |

ADDENDA

Not applicable