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Title: Applicable Federal and State Laws Regarding Human Subjects Research

Number: P00069

Revision: 6

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POLICY

POLICY STATEMENT

NMDP requires that its Institutional Review Board (IRB) ensure that Human Subjects Research is conducted in accordance with all applicable local, federal and state laws.

BUSINESS SECTION/DEPARTMENT

CIBMTR-Minneapolis

PURPOSE

This Policy describes how NMDP assures compliance with applicable local, federal and state laws when reviewing research involving human subjects. In addition, this Policy imposes an obligation on the IRB to ensure that prospective research participants who are members of vulnerable populations are appropriately protected.

SCOPE

This policy applies to all Human Subjects Research conducted by NMDP and affects, specifically, prospective research participants who are members of vulnerable populations.

RELATED DOCUMENTS

Consent forms

DEFINITIONS

Human Subject Research: Any activity that represents research involving human subjects as defined by the Department of Health and Human Services (DHHS) regulations, or any activity that represents a clinical investigation involving human subjects as defined by U.S. Food and Drug Administration regulations, or any activity that represents research involving human beings as experimental subjects as defined by the Department of Defense regulations.

RESPONSIBILITIES

1. Senior Director, Strategic Programs

- Manage this policy.
- Receive and answer questions related to this policy.

2. IRB

- Review IRB submissions and determine whether any additional protections are required for human research subjects in accordance with this policy.
- Consult with the Office of Administration when necessary.

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REQUIREMENTS

A. General Statement of Compliance

All requirements of 45 C.F.R. § 46, as applicable, will be met for all research regardless of sponsorship, except for the following for non-federally funded studies: 1) NMDP IRB will not report determinations of unanticipated problems involving risks to subjects or others, serious non-compliance, continuing non-compliance, or suspensions or terminations to the Office of Human Research Protections (OHRP); 2) NMDP IRB will not implement the Cooperative Research requirement.

Additional detail regarding compliance with 45 C.F.R. § 46 Subpart D (Additional Protections for Children Involved as Subjects in Research) is set out below. Because NMDP does not as a matter of practice engage in research involving pregnant women, human fetuses and neonates as subjects, nor does NMDP as a matter of practice engage in research involving prisoners as subjects, 45 C.F.R. § 46 Subparts B and C are not expressly addressed in this Policy, however compliance with the provisions of those Subparts is expected in the atypical case that those regulations apply.

Any studies that fall under the jurisdiction of the Food and Drug Administration (FDA) will be conducted in accordance with applicable FDA-administered statutes and regulations, including 21 C.F.R. § 50 (Protection of Human Subjects), 21 C.F.R. § 56 (Guidance for IRBs and Clinical Investigators), 21 C.F.R. § 312 (Investigational New Drug/IND), and 21 C.F.R. § 812 (Investigational Device Exemptions/IDE), as applicable.

Any studies falling within the scope of the Department of Defense (DoD)-issued regulations at 32 C.F.R. § 219 will be conducted in accordance with those regulations as well as any DoD-issued Instructions, and the like, as applicable.

In addition to federal regulations, the NMDP follows certain state-specific requirements relating to the ethical conduct of research. Where state regulations differ from federal regulations, the more stringent regulations shall be followed. The NMDP Office of Administration is available to provide legal counsel to the IRB in applying federal, state, and local laws to the review of research involving human subjects.

B. New Laws and Regulations

As needed, and in consultation with the NMDP Office of Administration if necessary, IRB staff will develop educational materials for investigators and IRB members and staff relating to new state and federal laws and regulations.

C. State Laws

Because of the unique scope of research in which the NMDP IRB becomes involved, laws of multiple jurisdictions may apply in any given set of circumstances. As each state has different

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laws, NMDP investigators are expected to adhere to the laws of the state in which research is being conducted.

The NMDP Office of Administration, outside attorneys retained by the NMDP, or legal counsel for the institution with which the investigator is affiliated may provide direction on and interpretation of state laws. Specifically, the IRB may consult with legal counsel to determine which individuals meet the Department of Health and Human Services (DHHS) and FDA definitions of “child,” “legally authorized representative,” and “guardian,” under the laws of the other jurisdictions.

D. Research Participation by Children

Since children are considered a vulnerable population, the IRB imposes additional protections on research involving children, in accordance with the requirements of the DHHS regulations at 45 C.F.R. § 46, Subpart D and FDA regulations at 21 C.F.R. § 50, Subpart D. This includes the investigator obtaining the permission of parents or a guardian through the consent process and of the assent of the child, and the IRB being able to make certain findings based on the level of risk and benefit of the research.

1) Determining who is a “child” and who is an “adult” for purposes of consent

According to the federal regulations governing Human Subjects Research, “children” are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. Since children cannot legally give consent, informed consent must be obtained from parents or the legally appointed guardian. The IRB requires the investigator to obtain the permission of a child’s parent(s) or guardian before enrolling the child in a study. Both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. See 45 C.F.R. § 46.408(b); 21 C.F.R. § 50.55(e)(2).

However, according to DHHS guidance, if research on a specific treatment involves solely treatments or procedures for which minors can give consent outside the research context under applicable state and local laws, minors may provide their own informed consent to participate in the research and parental permission, or waiver of permission, is not necessary. (See *OHRP Research with Children FAQs at <http://answers.hhs.gov/ohrp/categories/1570>*).

2) Defining “parent” and “guardian” for children

Under federal regulations governing human subjects protection, a parent or guardian may consent to a child’s participation in research.

a) Parent

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Under DHHS and FDA regulations, a “parent” means a biological or adoptive parent of a child. 45 C.F.R. § 46.402(d); 21 C.F.R. § 50.3(p).

b) Guardian

Under DHHS regulations governing Human Subjects Research, a “guardian” who can give consent on behalf of a child to participate in Human Subjects Research, is an individual or official appointed pursuant to state and local law to consent on behalf of a child to general medical care. 45 C.F.R. § 46.402(e). Under FDA regulations, a “guardian” is an individual authorized under applicable state or local law to consent on behalf of a child to general medical care when general medical care includes participation in research or to participate in research. 21 C.F.R. § 50.3(s).

Either a parent or a guardian may consent to his or her minor’s participation in Human Subjects Research conducted under the jurisdiction of the IRB. Before someone other than the parent or guardian can provide permission for a child to take part in research, the principal investigator must consult with NMDP IRB staff, who must consult with NMDP’s Legal Department, to confirm that the person is authorized under applicable law to consent on behalf of a child to general medical care.

3) Obtaining Assent

When, in the judgment of the IRB, a child is capable of providing assent, the IRB shall determine that adequate provisions are made for soliciting the assent of the child. This includes a determination of whether and how assent must be documented. See 45 C.F.R. § 46.408; 21 C.F.R. § 50.55. The term “assent” refers to a child’s affirmative agreement to participate in research. Absent affirmative agreement, mere failure to object is not assent. Generally, children aged 7 and above may be asked to give their assent to participation.

4) Wards

In those rare circumstances where research is approved pursuant to 45 C.F.R § 46.406 or 46.407, the NMDP Organizational Official shall ensure that the IRB assesses, determines, and documents that the requirements of § 46.409 have been sufficiently met.

REFERENCES

45 C.F.R. § 46; 21 C.F.R. § 50; 21 C.F.R. § 56; 21 C.F.R. § 312; 21 C.F.R. § 812; and 32 C.F.R. § 219

REVISION HISTORY

| Revision | Brief Description of Revision |
|--------------|-------------------------------|
| P00069 rev 1 | New Policy |

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| P00069 rev 2 | (revisions not documented) |
| P00069 rev 3 | Formatted to new Policy template. Changed NMDP Legal Department to NMDP Office of General Counsel. Added the paragraph under Scope. Added Dept of Defense regulations to the definition of Human Subjects Research. Added Responsibilities of IRB. Added Requirements heading and References section. |
| P00069 rev 4 | Added exceptions to following Common Rule requirements for studies that are not federally funded in section A. |
| P00069 rev 5 | Changed Vice President, CIBMTR-Mpls to Director, Strategic Programs |
| P00069 rev 6 | Removed references to National Marrow Donor Program and Be The Match. Changed Director, Strategic Programs to Senior Director, Strategic Programs. Changed Office of General Counsel to Office of Administration. |

ADDENDA

Not applicable