Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 105	
CHAPTER: Institutional Review Board	ISSUED: 2/2000	LATEST REVIEW/REVISION: 11/2018
POLICY: Duties of IRB Members	PAGE 1 OF 8	

1. PURPOSE

This policy describes the IRB member's responsibilities when reviewing protocols for scientific merit and presents topics IRB members should consider in these reviews. The IRB shall evaluate whether a research study is designed to minimize risks to subjects and to determine that the potential benefits to the subjects from the research justify those potential risks. This obligation is set forth in Department of Health and Human Services and corresponding FDA regulations, and supported by accepted ethical codes such as the Declaration of Helsinki of 2000 (sections 11, 18 and 29) and the Nuremberg Code of 1949 (point 3).

2. IRB MEMBER RESPONSIBILITIES

Members of the IRB shall review human subject application materials in advance of meetings and be prepared to discuss issues related to human subjects' protections; serve as an expedited reviewer when requested by the IRB Chair or designee; as well as exempt research activities under section 46.104 for which a limited review is condition of exemption and understand the specific requirements of human subjects' regulations. Member responsibilities include:

2.1. Protecting the rights and welfare of research subjects.

2.2. Determining that risks to subjects are minimized.

2.2.1. use procedures consistent with sound research design and minimize risk

2.2.2. whenever appropriate, use procedures already being performed on the subjects for diagnostic or treatment purposes

2.2.3. follow a procedure for properly documenting informed consent

2.3. The IRB shall not approve or review a research protocol if:

2.3.1. The study objectives can be achieved through procedures that pose fewer risks to subjects

2.3.2. The study involves risks to subjects and is not designed to ask a question that is important

2.3.3. The study design likely will yield results of no discernible value (see below for exceptions related to protocols involving little or no risk to subjects)

2.4. Determining risks to subjects are reasonable in relation to the anticipated benefits to subjects, if any, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB member should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB member should not consider possible long-range effects (beneficial or detrimental) of applying knowledge gained in the research.

2.5. Determining selection of subjects is equitable. In making this assessment, the following should be considered:

2.5.1. The purpose(s) of the research and the setting in which it is conducted

2.5.2. Special issues in research involving vulnerable populations, such as children, prisoners, pregnant women, cognitively or mentally impaired persons, or economically or educationally disadvantaged persons

2.5.2.1. Women and members of minority groups and their subpopulations shall be included in all clinical research, unless a clear and compelling rationale and justification establishes to the satisfaction of the IRB that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research

2.5.2.2. The inclusion (recruitment process) of women and members of minority groups and their subpopulations shall be addressed in developing a research design or contract proposal appropriate to the scientific objectives of the study/contract. The research plan/proposal should describe the composition of the proposed study population in terms of sex/gender and racial/ethnic group and provide a rationale for selection of such subjects. Such a

plan/proposal should contain a description of the proposed outreach programs for recruiting women and minorities as subjects

2.6. Determining whether the informed consent is adequate and contains all other federally or locally mandated elements, and if it does not, requesting clarifications to and changes in the consent form to adequately explain the purpose of the research, as well as the risks and benefits entailed therein.

2.7. Determining the research plan makes adequate provision for ensuring the safety of the subjects.

2.8. Determining there are adequate provisions to protect the privacy of subjects and to maintain the privacy of the subjects and confidentiality of the data, in accordance with the DHHS and FDA regulations. Investigators shall develop a plan for each protocol submitted to protect the privacy and confidentiality of subjects. The conditions for maintaining confidentiality of the subjects and the research records are required for the life of the data:

2.8.1. Protected Health Information – Refer to IRB Policy, "HIPAA for Researchers"

2.8.2. Confidentiality – Researchers shall respect the confidentiality of personal information collected during research. Research projects vary substantially in the sensitivity of the information involved, the possibility of identifying particular individuals, and the magnitude and probability of harms that may result from identification of research subjects. Breaches in confidentiality may also have a negative impact on family and friends or groups to which the research subject belongs. The researcher shall protect research subjects from harm resulting from unauthorized release of identifiable personal information

2.8.3. Privacy – Privacy refers to persons and their interest in controlling the extent, timing, and circumstances of sharing themselves (physically, behaviorally, or intellectually) with others. Investigators must put in place procedures to respect and protect the subject's privacy while in the study

2.8.4. Anonymity – When information collected through research is disseminated, research subjects normally are anonymous, unless identification has been agreed to or requested by the research subject. Often, data are presented in aggregate form, which also reduces the

potential to link specific responses to individuals

2.8.5. Limits – In some instances, research results may be disclosed to the government, government agencies, the research sponsor, the IRB or its designees, a regulatory agency, or those individuals who may be responsible for financial oversight at the institution at which the research is conducted. Nebraska and Iowa statutes may require reporting of child abuse, sexually transmitted diseases, and other communicable diseases (Nebraska and Iowa). Additionally, in the cases of well-known individuals, those who have very rare conditions, or research that requires presentation of photographs or videotapes, it may be impossible to present the data without identifying the research subject. Investigators shall make research subjects aware of any limitations to anonymity in these situations

2.8.6. Legal Issues – In other cases, research records may be liable to subpoena in judicial and administrative proceedings, and data may be vulnerable to search warrants. Researchers have a duty to protect the confidentiality undertaken in the free and informed process to the extent possible within the law, so it is legitimate for the researcher and the institution to argue the issue in court. In fact, this may be the only legal option open to a researcher to protect the confidentiality of research data

2.8.7. Plan Assessment – The IRB reviewer shall summarize the investigator's plan and indicate, in the reviewer's opinion, whether the plan provides adequate physical protection of the data and subject's privacy. There are no absolute protections. For example, the plan should indicate that the data are coded or de-identified; the subject's Personal Health Information (PHI) is protected and only PHI and data necessary for the research are collected and retained; and data are stored in a secured area or password-protected computer and locked in a space where access is limited to only the investigator or key study personnel who have a need. Other means of security may be identified or required depending on the nature of the research and the sensitivity of the data collected

2.9. Ensuring additional safeguards are in place to protect the rights and welfare of subjects who are likely to be vulnerable to coercion or undue influence, such as children, students, prisoners, cognitively or mentally impaired persons, or economically or educationally disadvantaged persons.

3. SCIENTIFIC REVIEW

Evaluation of the scientific aspects of a research study (e.g., statistical validity, prospect of study value) may require specific expertise. The scientific members of the IRB shall review protocols to evaluate study design; however, depending on IRB membership background and availability, this expertise may not be available or sufficient to address the complexities of a protocol. The IRB may rely, in part, on prior scientific review (e.g., NIH peer review, internal and external scientific committee reviews). The IRB may also utilize an outside consultant with specific expertise for study design review.

4. PROTOCOLS INVOLVING LITTLE OR NO RISK TO SUBJECTS

Judgment and common sense also have a place in determining whether to approve a research protocol. The IRB reviews a large volume of social science research. Many of these protocols pose little or no risk to the subjects (e.g., surveys that ask the subject non-sensitive questions). If an investigator's study design is flawed (e.g., not likely to render the information necessary to answer the research question), the IRB may make recommendations to improve study design, but it is not bound by ethical guidelines to disapprove such research.

5. MINIMIZATION OF RISKS IN CLINICAL STUDIES

When the research procedure carries a high level of risk with no potential benefit to subjects, the Principal Investigator (PI) shall justify why the procedure is necessary to achieve the research objectives, or why enrollment should not be limited to those already scheduled for the procedure for non-research purposes. Whenever feasible, studies should utilize procedures that are already being performed on the subjects for diagnostic or treatment purposes. Certain types of clinical protocols may require special attention from the PI to minimize risks. Several examples are described below:

5.1. **Placebo-controlled studies**

5.1.1. A protocol that involves removing subjects from the standard medication for their disease or condition and randomizing them to receive either an investigational agent or a placebo may raise issues of subject safety. If some subjects will receive no potentially beneficial drug for all or a significant portion of the trial, the PI shall specify in the protocol and consent form the nature and severity of the associated risk to those subjects. Depending upon the degree of risk, the PI should consider modification of study design to minimize the risk. The study design might be modified to define a benchmark for unacceptable worsening of the

subject's disease or condition, together with a monitoring plan for timely detection of subjects who reach the benchmark and a "rescue mechanism" for ameliorating the subject's condition once the benchmark is reached. Alternatively, the PI might consider modifying the research design to include a cross-over design (from placebo to investigational drug and vice versa)

5.1.2. Other design options include restricting eligibility to individuals who refuse, or have been shown not to respond to, the standard medication, or who have only a mild form of the disease or condition. In situations in which the standard treatment is tolerated by and known to prevent serious harm, such as death or irreversible morbidity, in the subject population, the IRB may determine a placebo design is not acceptable

5.2. **Active control studies**

Study designs in which some subjects receive the investigational agent but are removed from standard therapy for serious conditions may raise similar issues, as the investigational treatment may turn out to be ineffective. Unless there is strong reason to expect the investigational drug will be at least as good as the standard therapy, consideration should be given to one of the design modifications discussed above.

5.3. **Deliberate induction of undesirable states**

Investigators shall put in place special measures to minimize risk in research that deliberately induces an undesirable state or condition in subjects (e.g., pain, panic attack, allergic attack) to learn more about the undesirable state or condition. The IRB, with expert advice as needed, shall scrutinize thoroughly the design aspects of such research to ensure adequate measures have been instituted to minimize subject risks.

6. IRB MEETINGS

6.1. Before the IRB meeting, the IRB member shall:

6.1.1. Review all required documentation in the application submission before the assigned project(s) is/are presented. The member will document their pre-review in the electronic IRB record prior to the convened meeting

6.1.2. Determine whether specific changes are needed in the application, protocol, or consent form, and come to the meeting with recommended wording to be communicated to the investigator. Suggested changes can be made to any submitted document and uploaded to the electronic system

6.1.3. Applicable regulations shall be available for reference at every convened meeting of the IRB

6.2. Attendance at committee meetings

See IRB Policy, "About the IRB," section, "Attendance."

7. REMOVAL OF A MEMBER

7.1. When a committee member consistently fails to attend IRB meetings or fails to meet expectations, the Research Compliance/HRPP Director, the IRB Chair and/or IRB Administrator shall meet with the committee member to determine the cause. If the IRB member indicates an inability to continue to function effectively as an IRB member, the Research Compliance/HRPP Director, the IRB Chair or the IRB Administrator shall work with the department chair to obtain a replacement member to serve on the IRB. Members who do not adequately fulfill their responsibilities as judged by the IRB Chair may be asked to step down from IRB membership by the Institutional Official (IO) or designee.

7.1.1. Members of the IRB may be removed if their participation in IRB activities is deemed to be inadequate, inappropriate, or damaging to the reputation of the University and its research activities

7.1.2. The length of IRB membership shall not have a term limit

8. IRB CHECKLISTS AVAILABLE TO ASSIST MEMBER REVIEW (FOUND IN THE ELECTRONIC IRB SYSTEM)

8.1. Checklist for Board Members: Board Review (full and expedited reviews)

8.2. IRB Member Checklist: Projects Involving Children

8.3. IRB Member Checklist: Projects Involving Neonates

8.4. IRB Member Checklist: Projects Involving Fetuses

8.5. IRB Member Checklist: Projects Involving Prisoners

8.6. IRB Member Checklist: Informed Consent - Basic and Additional

8.7. IRB Member Checklist: Waiver/Alteration of Consent or Authorization (Process and/or Documentation)

9. SOURCES AND RESOURCES

9.1. Following is a list of potential resources:

9.1.1. OHRP Institutional Review Board Guidebook found at hhs.gov under, Chapter IV *Conditions of Research Design*

9.1.2. *Institutional Review Board Management and Function*, by Robert J. Amdur and Elizabeth A. Bankert, Jones and Bartlett Publishers, 2006

9.1.3. *Institutional Review Board Member Handbook*, by Robert J. Amdur and Elizabeth A. Bankert, Jones and Bartlett Publishers, 2007