

2.5 Criteria for IRB Approval

1.0 Purpose

The purpose of this policy and procedure is to describe the Organization's criteria for IRB approval for human subject research, reviewed both by the full convened IRB or thorough an expedited review process.

2.0 Policy

It is the policy of the Organization human subject research must satisfy certain basic ethical and regulatory requirements, including those described in 45 CFR 46.111 and 21 CFR 56.111.

3.0 Criteria for IRB Approval

Each of the following criteria for IRB approval must be satisfied in full accordance with applicable federal regulations and HRPP policies which contain greater detail about how the IRB interprets and applies these criteria. The criteria must be met before the IRB can grant approval of any submission by expedited review or full IRB review.

- **3.1.** Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures, already being performed on the subjects for diagnostic or treatment purposes.
 - **3.1.1.** The IRB will:
 - **3.1.1.1.** Ensure that the PI and other study personnel have the necessary qualifications, experience and medical licensure
 - **3.1.1.1.1.** The credentialing processes at Nebraska Medicine, BMC or CHMC in advance of IRB review will facilitate IRB assessment that investigators and study staff are qualified
 - **3.1.1.2.** Evaluate the research design in order to ensure that it is both sound and does not unnecessarily expose subjects to risk.
 - **3.1.1.3.** Ensuring that the research uses procedures already being performed on the subjects for diagnostic or treatment purposes
 - **3.1.1.4.** Assess whether risks are minimized by using alternative procedures that have less risk, precautions to decrease the likelihood that harms will occur, and contingencies to deal with harms if they occur.

- **3.1.1.5.** Utilize reviewers (or other members or consultants) who have familiarity with the procedures being performed, and who therefore can more ably assess whether risks are minimized.
- **3.2.** Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
 - **3.2.1.** The IRB will only consider those risks and benefits that may result from the research as distinguished from risks and benefits of therapies (or other interventions) the subjects would receive if not participating in the research.
 - **3.2.2.** The IRB will not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) in determining whether the risk-benefit relationship is acceptable.
 - **3.2.3.** The IRB will carefully evaluate the protocol in order to identify all risks. A risk is a potential harm (injury) associated with the research that a reasonable person in the subject position would likely consider significant. Risks can be generally categorized as physical, psychological, sociological, economic, and legal.
 - **3.2.4.** In evaluating the risk(s) of the research, the IRB will use the criteria that the risk(s) must be “reasonably foreseeable”. This means data exists which indicate there is a reasonable possibility that the subject could experience the harm described. It does not mean that every known risk associated with each research intervention must be addressed. It is also important to consider when a harm may be irreversible.
 - **3.2.5.** The IRB will assess the anticipated benefits to subjects (if any) and the importance of the knowledge that may be reasonably expected to result from the research. In making this assessment, the IRB will consider the background section, the literature citations, and other sections of the IRB application and other related materials (for example, the detailed protocol or the published literature) which support the PI’s statement of anticipated benefits. The IRB does not classify financial compensation to the subject as a “benefit” in the context of the risk-benefit relationship.
 - **3.2.6.** The IRB will assess the risk/benefit relationship of the research and ensure that it is both acceptable and that subjects are not disadvantaged by participating in research as opposed to choosing available alternatives which may be more advantageous.
 - **3.2.7.** The IRB will assess that the research has the necessary resources to protect subjects:
 - **3.2.7.1.** Adequate time for the researchers to conduct and complete the research.
 - **3.2.7.2.** Adequate number of qualified staff.
 - **3.2.7.3.** Adequate facilities.
 - **3.2.7.4.** Access to a population that will allow recruitment of the necessary number of participants.
 - **3.2.7.5.** Availability of medical or psychosocial resources that participants may need as a consequence of the research.
- **3.3.** Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

- **3.3.1.** The IRB will assess the IRB application and other related materials (for example, recruitment materials) in order to ensure that the selection of subjects is equitable with respect to age, gender, reproductive status, ethnicity, inclusion of vulnerable populations and any other factors that affect the equitable selection of subjects. No group should receive a disproportionate share of the benefits of the research or bear a disproportionate burden.
- **3.3.2.** In making this assessment the IRB will evaluate at least the following:
 - **3.3.2.1.** Purpose of the research.
 - **3.3.2.2.** Setting in which the research occurs
 - **3.3.2.3.** Whether prospective subjects will be vulnerable to coercion or undue influence
 - **3.3.2.4.** The selection (inclusion/exclusion) criteria
 - **3.3.2.5.** Scientific and ethical justification for inclusion of vulnerable populations
 - **3.3.2.6.** Scientific and ethical justification for excluding classes of persons who might benefit from the research.
 - **3.3.2.7.** Subject recruitment and enrollment procedures
 - **3.3.2.8.** The influence of compensation to participants
- **3.3.3.** The IRB's assessment of equitable subject selection will be made at the time of initial review, continuing review, and changes in protocol.
- **3.4.** Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by the Federal Regulations.
 - **3.4.1.** The IRB will review the IRB application and ICFs in order to determine that legally effective informed consent will be sought from each prospective subject or the subject's Legally Authorized Representative (LAR) under circumstances that provide sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence, and which includes information that a reasonable person would want to have in order to make an informed decision about whether to participate. In addition to ensuring that the ICF contains all required elements of informed consent, the Board must also determine there is an appropriate process of informed consent in consideration of the nature of the research, risks associated with the research, and the characteristics of the subject population.
 - **3.4.2.** The IRB will determine which projects should have a third party observe the consent process.
- **3.5.** Informed consent will be appropriately documented, in accordance with, and to the extent required by the Federal Regulations.
 - **3.5.1.** The IRB will review the IRB application and ICFs in order to determine that all individuals involved in the obtainment and documentation of informed consent have the necessary expertise as well as sufficient knowledge about the protocol and IRB consent requirements.
 - **3.5.2.** Under certain circumstances, the IRB may determine that obtainment and documentation of informed consent by a physician or dentist will be required for some trials.
- **3.6.** When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
 - **3.6.1.** The IRB will review the IRB application and other related materials (e.g., detailed protocol) in order to determine that the safety monitoring plan makes adequate provision for monitoring the involvement of subjects and the collection of data to ensure the safety of subjects.

- **3.6.2.** The overall elements of the monitoring plan will vary depending on the potential risks, complexity, and nature of the research. These may vary from monitoring by the PI in a small, low risk study to the establishment of an independent data and safety monitoring board (DSMB).
 - **3.6.3.** The IRB will also determine whether the research requires review more often than annually, as described in HRPP policy 3.1 (Assessing the Need for Increased Monitoring, Interim Continuing Review, and Verification from Sources Other than the PI).
 - **3.6.4.** The approval period will be documented in the IRB records and conveyed to the PI.
 - **3.6.5.** The IRB will determine which projects need verification from sources other than the PI that no material changes have occurred in the research since the previous IRB review.
 - **3.6.6.** The IRB will determine which projects require an audit of research records.
 - **3.7.** When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
 - **3.7.1.** Privacy refers to persons and their interest in controlling access to themselves. In order to ensure protection of subject's privacy, the IRB will apply the following criteria:
 - **3.7.1.1.** The methods used to identify and contact prospective subjects is acceptable.
 - **3.7.1.2.** The settings in which the individual will participate in the consent process as well as the research adequately protect privacy.
 - **3.7.1.3.** The personnel involved in the research are appropriate in consideration of their responsibilities.
 - **3.7.1.4.** All necessary procedures are in place during the research to protect privacy.
 - **3.7.2.** Confidentiality refers to protecting data. In order to ensure there is an appropriate plan to maintain confidentiality and minimize the possibility that information will be inappropriately disclosed, the IRB will apply the following criteria:
 - **3.7.2.1.** The reason(s) for disclosing data to individuals, sponsors or other organizations is justified.
 - **3.7.2.2.** The procedures for securing and transmitting data are acceptable.
 - **3.7.2.3.** The potential harm that may result from inappropriate disclosure of research data is minimized.
 - **3.8.** When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.
 - **3.8.1.** The IRB will review the characteristics of the proposed subject population in consideration of:
 - **3.8.1.1.** The nature and risks of the research.
 - **3.8.1.2.** Whether the subjects are likely to be vulnerable to coercion, undue influence, or more susceptible to risk.
 - **3.8.2.** The IRB will ensure that additional safeguards are included in the protocol in order to fully protect the rights and welfare of vulnerable subjects in accordance with HRPP policy 4.1 (Additional Protections for Vulnerable Populations).
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4.0 Additional Considerations

In addition to the specific criteria described in section 3.0, the IRB will consider other applicable federal, state and local law and regulations, Organization policies, and basic ethical principles (as described in the Belmont Report, or the World Medical Association Declaration of Helsinki) when deciding whether a research proposal is approvable.

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