

## Guidance: Applying the 7 criteria for approval

### Overview

All research protocols that meet the federal definitions of research and human subject are required to meet criteria for approval before the research may begin. The criteria are based on federal regulations and the ethical principles discussed in the Belmont Report.

The IRB forms are designed to address these criteria and thereby assist the IRB in collecting enough information to make a determination of approval. For minimal risk protocols, where expedited review is appropriate, the assigned reviewer will complete a reviewer guide which include the seven criteria. For more than minimal risk protocols, that are reviewed by the convened IRB, discussion will take place regarding the seven criteria and the meeting minutes will reflect the Board's determination.

#### **Criterion #1: Risks to subjects are minimized.**

- By using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
- By addressing the likelihood of harm and magnitude of harm encompassing physical, psychological, social, economic, and/or legal risks to the subjects.

#### **Criterion #2: Risks to subjects are reasonable in relation to benefits.**

- anticipated benefits, if any, to subjects, and
- importance of the knowledge that may reasonably be expected to result.

When evaluating risks and benefits, the IRB considers only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

The IRB also considers the professional qualifications and resources of the research team as identified in the Research Team Form to ensure appropriate expertise is represented.

#### **Criterion #3: Selection of subjects is equitable.**

In making this assessment, the IRB takes into account the purposes of the research and the setting in which the research will be conducted and is particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, fetuses, neonates, adults with impaired decision-making capacity, or economically or educationally disadvantaged persons.

#### *Vulnerable populations:*

When appropriate, additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence. When some or all of the subjects, such as children, prisoners, adults with impaired decision-making capacity, or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence or for subjects found

at international sites, IRB consider whether additional safeguards have been included in the study, to protect the rights and welfare of these subjects.

**Criterion #4: Informed consent will be sought from each prospective subject or the subject's legally authorized representative unless this requirement is waived by the IRB.**

Informed consent is a process. To minimize coercion, the IRB considers the circumstances under which consent is obtained including but not limited to: timing; relationship between prospective subject and individual obtaining informed consent; language used to recruit prospective subjects; and qualifications of individuals obtaining informed consent. Also, informed consent, whether oral or written, may not include any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence. Compensation language to accommodate industry sponsored research protocols may be considered on a case-by-case basis.

**Criterion #5: Informed consent will be appropriately documented as required by local, state and federal regulations unless the requirement is waived by the IRB.**

Documentation of informed consent is also important. The IRB informed consent form template is designed to ensure that documentation of informed consent includes federally mandated basic and additional elements of informed consent. No informed consent, whether oral or written, may include any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

**Criterion #6: For greater than minimal risk research or NIH funded/FDA regulated clinical investigations, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. The proposed plan should be commensurate with the nature, size, and complexity of the research as well as the degree of risk involved.**

The IRB reviews if applicable:

- Procedures for promptly detecting harm and mitigating potential injuries.
- Implementation of data and safety monitoring procedures (considering what data and safety information will be collected, frequency of collection, and by whom).
- Procedures for review or analysis of cumulative safety data to determine whether harm is occurring?
- Procedures for ensuring appropriate reporting of findings to the IRB.
- Conditions or criteria that could trigger an immediate suspension/ termination of the research and procedures for reporting the suspension/ termination to the appropriate entities.
- Procedures for communications such as protocol modifications, data safety monitoring reports, and, unanticipated problems between sites when research is part of a multicenter study in which Northeastern is the coordinating institution or a Northeastern investigator is the lead investigator.
- Plans for establishment of an independent individual or data and safety monitoring board (DSMB) if warranted and plans for providing DSMB reports, (routine and urgent), to the IRB.

**Criterion #7: Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.**

The IRB reviews, when applicable:

- The methods used to identify and contact potential human subjects.
- The settings in which an individual will be interacting with an investigator.
- The appropriateness of all personnel present for research activities.
- The methods used to obtain information about subjects.
- The nature of the requested information.
- Information that is obtained about individuals other than the “target subjects,” and whether such individuals meet the regulatory definition of “human subject” (e.g., a subject provides information about a family member for a survey).
- Privacy guidelines developed by relevant professional associations and scholarly disciplines (e.g., oral history, anthropology, psychology).
- How to access the minimum amount of information necessary to complete the study.
- The long-range plan for protecting the confidentiality of research data, including a schedule for destruction of identifiers associated with the data.
- The consent form and other information presented to potential research subjects to ensure limits to confidentiality are clearly and adequately described.
- The informed consent process and the informed consent document, and if applicable the HIPAA authorization form, to ensure that subjects are informed regarding who will have access to the subject’s information and under what circumstances data may be shared (i.e., government agencies, sponsors).