

## Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 106	
CHAPTER: Institutional Review Board	ISSUED: 2/2000	REVISED/REVIWED: 9/2004; 6/2006; 8/2009; 11/2013
POLICY: Duties of IRB Members	PAGE 1 OF 5	

### 1. PURPOSE

This policy describes the duties of IRB members and gives members guidance to evaluate human research so that it will be conducted to safeguard human participants' rights and welfare, according to the codes of Federal regulations and within the mission of Creighton University.

### 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; and have an understanding of 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.
- 2.3. Ensuring that the investigators:
  - 2.3.1. use procedures that are consistent with sound research design and that minimize risk;
  - 2.3.2. whenever appropriate, use procedures already being performed on the subjects for diagnostic or treatment purposes; and
  - 2.3.3. follow a procedure for properly documenting informed consent.
- 2.4. Determining that 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 that selection of subjects is equitable. In making this assessment, the following should be taken into account:

## Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 106	
CHAPTER: Institutional Review Board	ISSUED: 2/2000	REVISED/REVIWED: 9/2004; 6/2006; 8/2009; 11/2013
POLICY: Duties of IRB Members	PAGE 2 OF 5	

- 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 participants.
- 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 that the research plan makes adequate provision for ensuring the safety of the subjects.
- 2.8. Determining that 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

## Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 106	
CHAPTER: Institutional Review Board	ISSUED: 2/2000	REVISED/REVIWED: 9/2004; 6/2006; 8/2009; 11/2013
POLICY: Duties of IRB Members	PAGE 3 OF 5	

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 119, “[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 participant’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.

## Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 106	
CHAPTER: Institutional Review Board	ISSUED: 2/2000	REVISED/REVIWED: 9/2004; 6/2006; 8/2009; 11/2013
POLICY: Duties of IRB Members	PAGE 4 OF 5	

- 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 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 it 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, pregnant women, cognitively or mentally impaired persons, or economically or educationally disadvantaged persons.

### 3. IRB MEETINGS

- 3.1. Before the IRB meeting, the IRB member shall:
- 3.1.1. Review all required documentation in the application submission package before the assigned project(s) is/are presented.
  - 3.1.2. Determine whether specific changes are needed in the application, protocol, or consent form, and come to the meeting with recommended wording to be transmitted to the investigator.
- 3.2. Attendance at committee meetings

See IRB Policy 102, “[About the IRB](#),” section 7.6, “Attendance.”

## Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 106	
CHAPTER: Institutional Review Board	ISSUED: 2/2000	REVISED/REVIWED: 9/2004; 6/2006; 8/2009; 11/2013
POLICY: Duties of IRB Members	PAGE 5 OF 5	

### 4. REMOVAL OF A MEMBER

4.1. When a committee member consistently fails to attend IRB meetings or fails to meet expectations, the IRB Chair and/or IRB Director 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 IRB Chair or the IRB Director 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 Associate Vice Provost for Research and Scholarship.

4.1.1. 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.

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

### 5. IRB CHECKLISTS AVAILABLE TO ASSIST MEMBER REVIEW

- 5.1. [Checklist for Board Members: Board Review](#) (full and expedited reviews)
- 5.2. [IRB Administrative Checklist for Research Involving Devices](#)
- 5.3. [IRB Administrative Checklist for Research Involving Drugs](#)
- 5.4. [IRB Review Checklist Application: Determination of Exempt Status](#)
- 5.5. [IRB Member Checklist: Projects Involving Children](#)
- 5.6. [IRB Member Checklist: Projects Involving Neonates](#)
- 5.7. [IRB Member Checklist: Projects Involving Pregnant Women and Fetuses](#)
- 5.8. [IRB Member Checklist: Projects Involving Prisoners](#)
- 5.9. [IRB Member Checklist: Informed Consent - Basic and Additional](#)
- 5.10. [IRB Member Checklist: Waiver/Alteration of Consent or Authorization \(Process and/or Documentation\)](#)