

## Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 101	
CHAPTER: Institutional Review Board	ISSUED: 7/2009	REVISED/REVIEWED: 7/2010; 11/2010; 11/2013
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### 1. POLICY

There are two Institutional Review Boards (IRBs) at Creighton University. Both IRBs review and approve research in accordance with the Department of Health and Human Services (DHHS) regulation (45 CFR 46). In addition, for studies involving products regulated by the Food and Drug Administration (FDA), IRB-01 complies with the requirements set forth in 21 CFR 11, 21 CFR 50, 21 CFR 56, 21 CFR 312, 21 CFR 812, and 21 CFR 814.

### 2. PURPOSE

The purpose of this policy is to provide guidelines on the types of research reviewed by each board.

### 3. IRB-01 BIOMEDICAL

3.1. The Biomedical Institutional Review Board (IRB-01) is one of the administrative bodies established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of Creighton University.

3.2. The IRB-01 shall review all biomedical research involving human subjects for compliance with federally mandated research guidelines.

3.2.1. *Biomedical research* (or *experimental medicine*), in general simply known as medical research, is basic research, applied research, or translational research conducted to add to the body of knowledge in the field of medicine. A new paradigm to biomedical research is being termed translational research, which focuses on iterative feedback loops between the basic and clinical research domains to accelerate knowledge translation from the bedside to the bench, and back again.

3.3. The IRB-01 shall review the following research categories:

3.3.1. Clinical trials (both drug and device)

3.3.2. Medical registries

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- 3.3.3. Patient medical treatment and outcome studies
- 3.3.4. Biological samples (including genetics and pathology)
- 3.3.5. Research involving medical procedures (including labs and radiology)
- 3.3.6. Medical chart reviews
- 3.3.7. Epidemiological research using any of the above
- 3.4. The IRB-01 meets regularly and is composed of faculty/staff from Creighton University and representatives from the community. A full roster and meeting schedule are available on the [IRB web site](#).

## 4. IRB-02 SOCIAL-BEHAVIORAL

- 4.1. The Social-Behavioral Institutional Review Board (IRB-02) is one of the administrative bodies established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of Creighton University.
- 4.2. The IRB-02 shall review all social and behavioral research involving human subjects for compliance with federally mandated research guidelines.
  - 4.2.1. Research on social and behavioral processes involves the study of humans at the level of the individual, small group, institution, organization, community, or population. At the individual level, this research may involve the study of behavioral factors such as cognition, memory, language, perception, personality, emotion, motivation, and others. At higher levels of aggregation, it includes the study of social variables such as the structure and dynamics of small groups (e.g., couples, families, work groups, etc.); institutions and organizations (e.g., schools, religious organizations, etc.); communities (defined by geography or common interest); and larger demographic, political, economic, and cultural systems. Research on social and behavioral processes also includes the study of the interactions within and between these two levels of aggregation, such as the influence of socio-cultural factors on cognitive processes or emotional responses. Finally, this research also includes the

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study of environmental factors (both natural and human created) such as climate, noise, environmental hazards, and residential and other built environments and their effects on social and behavioral functioning.  
(National Institutes of Health definition)

4.3. The IRB-02 shall review the following research categories:

- 4.3.1. Experimental non-medical research (cognitive, behavioral, group, etc.)
  - 4.3.2. Archival research (except medical chart reviews)
  - 4.3.3. Survey/questionnaire research
  - 4.3.4. Observational research
  - 4.3.5. Research interviews
  - 4.3.6. Oral histories
  - 4.3.7. Educational research
  - 4.3.8. Epidemiological research using only social-behavioral methodologies
- 4.4. The IRB-02 meets regularly and is composed of faculty/staff from Creighton University and representatives from the community. A full roster and meeting schedule is available on the [IRB web site](#).

## 5. PROJECT ASSIGNMENT

- 5.1. The Investigator shall submit a new study to the appropriate board based on the above definitions. However, the IRB Chair or designee of either committee may transfer oversight for a study if there is more appropriate expertise on the other IRB. The Chair or designee may seek collaboration with the other board for complex studies.

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### **6. POLICY REVIEW**

- 6.1. The Creighton University IRBs shall review policies and procedures regularly, or as dictated by changes in federal and state regulations and guidelines. Review shall be done by IRB administrative staff. Significant changes to policies shall be taken to the full IRBs for review and approval.
- 6.2. Changes and updates to policies and procedures are based on federal, state, and local laws. If there is a conflict between these laws, the IRB will adopt the most restrictive guideline or law.
- 6.3. When changes to policies are approved by the IRB(s), the revised policies shall be posted on the web site and an alert shall be sent via email to all investigators listed on active protocols.
- 6.4. Investigators shall share all updated and new policies and procedures with research personnel, including students and sponsors (upon request).