

## **Policies and Procedures**

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| SECTION:<br>Human Research Protection Program | NUMBER:<br>133    |                              |
| CHAPTER:<br>Institutional Review Board        | ISSUED:<br>3/2011 | REVISED/REVIEWED:<br>11/2013 |
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### **1. PURPOSE**

The Creighton University Community-Based Research program has been developed by the Creighton University Institutional Review Board (IRB) and Human Research Protection Program (HRPP) to address the needs of Creighton University researchers engaged in research collaborations or affiliations with non-University organizations, and to ensure regulatory compliance for researchers at Creighton University and their research affiliates throughout the community.

Creighton University, under certain circumstances, will agree to serve as the IRB of record for community research partners that do not have their own IRB. IRB Letters of Agreement shall be obtained from non-Creighton University organizations on a per study basis for studies having a Principal Investigator from Creighton University and investigators from the community partner. General IRB oversight will not be provided for non-Creighton University organizations that are not collaborating with a Creighton University Principal Investigator. Non-Creighton University researchers may not apply independently for Creighton University IRB oversight.

### **2. WHAT IS THE IRB COMMUNITY-BASED RESEARCH PROGRAM?**

The Community-Based Research program has been developed to encourage and support Creighton University researchers engaged in translational, best practice, and community-based research. However, investigators in many academic areas may use the Community-Based Research program.

Within the IRB Office, the Community-Based Research Administrator and the Research and Compliance Education Coordinator have been assigned to manage the Community-Based Research program and will serve as the point of contact for Creighton University Principal Investigators, research teams, and community research partners. The Community-Based Research Administrator will work closely with the researchers, IRB Chairs, and IRB administrators during the application process to identify the regulatory elements required by each study. The Community-Based Research program provides a regulatory navigation system to ensure that all required elements are completed in the correct sequence.

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### 3. WHAT IS COMMUNITY-BASED RESEARCH?

Community-based research is a joint effort that involves researchers and community representatives in all phases of the research process. The joint effort engages community members, employs local knowledge in the understanding of various issues and the design of interventions, and invests community members in the processes and products of research. In addition, the collaborative is invested in the dissemination and use of research findings to improve the community.

Research meeting all the following criteria is eligible for the Creighton University Community-Based Research program:

- 3.1. **A Creighton University Principal Investigator must initiate the IRB review process.** Organizations outside Creighton University that will not be affiliated with a Creighton University Principal Investigator may not apply independently for oversight of research activities by the Creighton University IRB.
- 3.2. **The study should meet the criteria of “no greater than minimal risk” research.** Under certain limited circumstances, the Creighton University IRB may agree to take on oversight for community-based research studies that are greater than minimal risk (i.e., those that require review at a convened meeting).
- 3.3. **The Community-Based Research program is available for studies being reviewed by the Creighton University IRB-01 (Biomedical) and IRB-02 (Social-Behavioral).**

### 4. IRB REVIEW PROCESS FOR COMMUNITY- BASED STUDIES

It is recommended that the Creighton University Principal Investigator who plans to work with potential community partners contact the IRB Community-Based Research Administrator early in the planning phase of the study for guidance. Certain types of research and certain funding sources have different regulatory requirements.

- 4.1. The Principal Investigator shall contact the IRB Community-Based Research Administrator prior to submitting an IRB application.

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- 4.2. The Community-Based Research Administrator and the Research and Compliance Education Coordinator will meet with the Principal Investigator to discuss:
  - 4.2.1. Study aims and research plan, including dissemination of results
  - 4.2.2. How the research leadership and authority is shared with the community partner
  - 4.2.3. Creighton University IRB application process
  - 4.2.4. Assurances and agreements that may be needed for community partners
  - 4.2.5. IRB educational requirements for community partners
- 4.3. The Community-Based Research Administrator will provide information to the IRB Chair or designee with expertise in community-based research. The designated IRB Chair or designee shall review all community-based research for both IRB-01 and IRB-02.
- 4.4. The IRB Chair or designee with expertise in community-based research will decide whether the proposed study meets the criteria for the Creighton University Community-Based Research program.
  - 4.4.1. The IRB Chair or designee may decide that further community review would be useful and may send it to a community entity or individual within the appropriate community for review and comment.
- 4.5. The decisions of the IRB Chair or designee will be sent to the Creighton University Principal Investigator by email along with instructions for proceeding in the IRB review process for those studies allowed to proceed.
- 4.6. The process for IRB review will follow IRB Policy 105, "[IRB Review Process](#)." In addition, one IRB community representative will review the information provided by the Creighton University Principal Investigator and community partners.

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### 5. REQUIREMENTS TO BE COMPLETED PRIOR TO CREIGHTON UNIVERSITY IRB REVIEW

- 5.1. All Creighton University Principal Investigators, investigators, and research staff shall comply with the educational requirements set forth in IRB Policy 123, [“Human Subjects Research Education Program.”](#)
- 5.2. All community partner investigators who participate in the conduct of the research shall complete the CITI Human Subjects in Research Basic Course. For biomedical research, they shall complete the biomedical course; for social-behavioral, they shall complete the social-behavioral course.
- 5.3. For all funded studies (both federal and other), additional training may be required.
- 5.4. If the community partner does not have a current Federal-wide Assurance (FWA), the community partner may need to [apply for an FWA](#). This depends on the type of study and directions from the funding agency.
- 5.5. The Creighton University Principal Investigator shall obtain a [Creighton University Letter of Agreement](#) from the Institutional Official at the community partner.
- 5.6. Prior to final IRB approval, all requirements shall be completed.

### 6. THE IRB APPLICATION FOR THE NEW PROJECT

The Creighton University Principal Investigator may begin the IRB application for the study at any time. The IRB application may be submitted and reviewed while the requirements listed in Section 5 of this policy are being completed.