

Policies and Procedures

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| SECTION: Human Research Protection Program | NUMBER: 114 | |
| CHAPTER: Institutional Review Board | ISSUED: 6/2006 | LATEST REVISION: 11/2018 |
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1. PURPOSE

This policy defines the procedure for investigators who conduct their research at institutions that are not covered under the Creighton University Federal-wide Assurance (FWA) and the site where the research is to be conducted requires local IRB review.

2. EXTERNAL REVIEW REQUIREMENTS

Standards of human subject protection can vary among institutions, so the Creighton University IRB shall review all human subject research funded through Creighton University, contracted agents or conducted by an investigator on behalf of Creighton University, regardless of where the study is performed. The IRB shall ensure that the rights and welfare of all Creighton University subjects are protected in accordance with Creighton University IRB standards. However, the IRB recognizes the importance of cooperative, multi-site research, and the potential for duplication of effort in IRB review of research proposals. Therefore, in accordance with HHS 45 CFR 46.114 and FDA 21 CFR 56.114 regulations regarding cooperative research, the IRB shall accept another institutional IRB review and approval of research under the following conditions:

- 2.1. Creighton University agents (includes faculty, administrators, staff, or students) shall conduct the research at an external institution only under the authority of that institution's IRB.
- 2.2. The external institution has accepted full responsibility to protect the rights and welfare of all subjects enrolled within its institution, in accordance with HHS regulations at 45 CFR 46 and FDA regulations at 21 CFR 50, 56 (if applicable). IRB oversight for all research includes the following:
 - 2.2.1. Initial review, continuing review, review of modifications to previously approved research
 - 2.2.2. Post-approval monitoring
 - 2.2.3. Handling of complaints, noncompliance, and unanticipated problems involving risk to subjects or others
- 2.3. The external institution has an FWA registered with the OHRP.
- 2.4. The Creighton University IRB has received a copy of the protocol, consent/permission/assent documents(s), and the external IRB approval.

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2.5. An inter-institutional reliance agreement is obtained for non-exempt research (or exempt research that requires limited review). This agreement shall be between Creighton University and the Institution (Contact the Creighton University Human Research Protection Program Office (IRB) to initiate an inter-institutional reliance agreement). This agreement shall be signed by both Institutional Officials prior to initiating the research. The Creighton University IRB will maintain a copy of this signed agreement in its records.

The Creighton University IRB Chair, Administrator, or designee shall review the submission and may accept external IRB approval. If approval is accepted, the full IRB shall be notified during regularly scheduled meetings via the IRB minutes. If the Chair, Administrator, or designee does not accept the external IRB approval, the investigator shall be notified in a letter and the project shall then require review by the Creighton University IRB.