Series 402 IRB Review Activities | Institutional Review Board

IRB Review Activities from Series 402 of Standard Operating Procedures

I. Review Activities of the Institutional Review Board

The Institutional Review Board at Utah State University reviews research involving human participants by utilizing Limited IRB Review of exemptions, Exemption determinations, Expedited review procedures, review via the Convened IRB, review of proposed modifications, and local context reviews. The Institutional Review Board is also the sole entity with the ability to determine whether a project constitutes research with human participants, as defined in USU Policy 584, which is accomplished through the submission of a NHSR Determination form as described below.

During and following the review processes articulated above, the IRB may:

1. return for insufficiency;
2. determine not to be human subjects research;
3. require revisions to gain approval, exemption, or limited IRB approval;
4. approve or determine exempt;
5. defer (or table);
6. approve with minor, specified changes;
7. disapprove;
8. suspend; or
9. terminate a protocol submission.

Approval and exemption actions may be taken after the criteria for approval or exemption, outlined in in this Series,have been satisfied by the investigators.

II. Delegation of Certain IRB Review Actions

To promote the expeditious and thorough review of all submissions to the Institutional Review Board, certain review activities or actions are delegated by the Convened IRB to appropriately qualified persons.

1. Non Human Subjects Research (NHSR) Determinations are delegated to individual members of the Institutional Review Board. A member of the Institutional Review Board will be assigned a NHSR submission via the IRB's electronic protocol management system – the only manner in which such determinations may be made - and will render a determination using the definitions provided in USU Policy 584 and consultation, as appropriate, with an individual possessing expertise in that field. NHSR Determinations cannot be made outside of the IRB's electronic protocol management system.
2. The IRB Chair shall, at least annually, determine which IRB members, appearing on the scientific roster, are qualified to conduct Expedited reviews and in what areas of expertise. After a qualified Expedited reviewer pool is established, the IRB Chair may assign reviewers to protocol submissions qualifying for Expedited review, or may delegate review assignments to the Director of Human Research Protections.
3. Limited IRB Reviews and Exemption determinations are delegated to appropriately qualified members of the Institutional Review Board. These determinations and Limited Review processes are typically conducted by HRP staff who are also qualified members of the Institutional Review Board.

Ensuring Sufficient Materials for Review

The Utah State University IRB utilizes Kuali Protocols for all submissions to the IRB except for certain Reliance Agreement requests, which are submitted via SMART IRB. These systems are designed to ensure that researchers provide complete and thorough materials to the IRB for consideration. No submissions outside of the Kuali Protocols or SMART IRB systems are eligible for review, though the IRB might utilize other systems to support reviews taking place in Kuali Protocols or SMART IRB.

III. The Pre-Review Process

Every submission to the IRB undergoes a pre-review process. The pre-review process is designed to ensure that the IRB member who will receive the submission has the information required to render the appropriate determination. Within two business days of submission, the HRP Office staff will complete a pre-review checklist for the newly-submitted item. For initial submissions, the pre-review process checks for the following elements:

1. That the PI is able to serve as a PI per the requirements in Policy 584 and SOP 302
2. That all members of the study team listed have appropriate CITI Training
3. If there is external funding, it is appropriately noted
4. That the PI on the external funding award matches the PI for the protocol
5. Whether there is a Corrective Action Plan or outstanding Status Report Request from this PI that must first be completed before new submissions are permitted
6. If the project is to be used for a thesis or dissertation project, that the appropriate committee approvals have been provided
7. If there are Non-USU researchers involved, that the appropriate agreement has been initiated
8. Whether all appropriate documents have been uploaded. This varies depending on the specifics of the project, but generally, the pre-review checks for:
    a. Recruitment material
    b. Informed Consent documentation. If the PI uses an IRB-provided template, they must use the most up-to-date template, and it must be provided in Word
    c. HIPAA Authorizations or Waiver Requests, which must be provided in Word
    d. A proposal
    e. A site-based letter of support
    f. Any ancillary review needs

Submissions that do not comport with the pre-review checklist requirements are returned to the research team for completion, along with documentation regarding the insufficiency so that it can be corrected and resubmitted at the research team's earliest convenience. A protocol is not considered complete and ready for substantive review until a pre-review checklist confirms the presence of all necessary materials for review.

IV. Notification of IRB Review Actions

Documentation regarding the IRB's review actions will be provided to the appropriate investigators and officials and maintained by the IRB in its records. Investigators will receive documentation regarding IRB review actions on their protocol submissions, usually via the electronic notifications generated by Kuali Protocols and SMART IRB. The Convened IRB will receive monthly documentation regarding review activities that have been delegated according to Section II of this SOP. The Institutional Official will receive documentation, via electronic records sharing, regarding the activities of the IRB.

V. Research Not Covered by USU HRP Review Activities

There are certain areas of research where USU's researchers do not generally complete work and thus, USU's Human Research Protection Program is unable to provide or easily locate the relevant expertise to complete a thorough review. As a result, the USU IRB generally does not accept research for review having to do with the following areas or involving the following populations:

- Fetuses or neonates
- Classified research
- Drugs or devices, or research otherwise falling under the FDA regulations
- Research overseen by the Veteran’s Administration (VA)

Researchers at Utah State University wishing to conduct research in the areas articulated above should get in touch with the Director of Human Research Protections as early as is practicable to discuss pathways for review. A Reliance Agreement process may be available to cover this type of work, and the HRP Office would be happy to assist in navigating those review processes.