Series 301 Researcher Responsibilities | Institutional Review Board

The Responsibilities of Those Carrying Out Human Subjects Research from Series 301 of the Standard Operating Procedures

I. Research Within the Context of the Human Research Protection Program

The mission of Utah State University's Human Research Protection Program (HRPP) is to protect the rights and welfare of participants in research that occurs under Utah State University (USU) oversight. All students, staff, faculty, units, and affiliates of Utah State University share in the responsibility for promoting the welfare of human research participants. The success of the HRPP depends on all stakeholders – institutional leadership, the Institutional Review Board, and researchers themselves – working together toward the shared goal of performing sound research in ways that emphasize care and respect for research participants.

Research is reviewed and approved (or exempted) by the IRB to ensure that it is structured in a manner that promotes the Belmont Report Principles: Respect for Persons, Justice, and Beneficence. It is primarily up to the research staff to ensure that those principles are realized in the actual performance of the research activities. One of the purposes of IRB review is to set researchers up for success in adhering to these principles. Fidelity to the approved protocol, then (including proposing changes to the IRB before those changes are effectuated in the research project) is critical to the success of a well-functioning Human Research Protection Program at Utah State University.

II. Investigator Responsibilities

Investigators on human subjects research projects will fulfill their ethical obligations to protect research participants. This includes ensuring the following:

- Obtaining IRB approval, exemption, or reliance prior to initiating human subjects research (including recruitment or data mining activities) in accordance with the 400 Series of these Standard Operating Procedures, USU Policy 584, and 45 CFR 46.
- Obtaining, at a minimum, the IRB-required trainings regarding the safe, ethical, and appropriate conduct of human subjects research, and other trainings as appropriate to ensure the safety and well-being of research participants;
- Understanding, disclosing to the IRB, and complying with all applicable provisions of USU HRP Standard Operating Procedures, USU Policy, federal and state laws, federal and state regulations, and local requirements;
- Communicating with and obtaining approvals from all necessary ancillary committees or offices (Conflict of Interest, Institutional Biosafety, Risk Management, etc.);
- Overseeing (in the case of the Principal Investigator) or diligently adhering to approved and established processes in (in the case of all investigators) the conduct of the research. This includes elements such as recruitment, informed consent processes, using correct informed consent documentation, managing data collection, ensuring appropriate data transfer and storage, maintaining security of the data, and ensuring accurate analysis of data;
- Ensuring that the research is conducted in accordance with an IRB-approved (or exempted) protocol, on file with the USU IRB, and that the conditions set forth in order to receive IRB approval or exemption are being carried out;
- Reporting all deviations (defined in SOP Series 600), adverse events, unanticipated problems, and noncompliance to the IRB in a prompt manner;
- Obtaining and documenting informed consent in accordance with the requirements outlined in 400 Series of these Standard Operating Procedures (unless waived by the IRB);
- Promptly communicating with participants who express questions or concerns about the research, and reporting those communications to the IRB when appropriate under the 600 Series of these SOPs

- Complying with all determinations of USU's Privacy Board for all research projects involving Protected Health Information;
- Delegating only those responsibilities that are appropriate for delegation, based on the training and qualifications of the researchers involved with the research study;
- Ensuring that there are adequate resources available to safely conduct the research and ensure the well-being of the research participants; and
- Providing up-to-date information to the IRB regarding the project. This includes proposing amendments before they are implemented in the research study, promptly reporting any Reportable Events (as defined in the 600 Series of these SOPs), providing information to the IRB in a timely manner as the protocol approaches expiration, and closing the protocol when work has been completed.

III. Documentation Requirements for Investigators

Investigators conducting human subjects research are required to maintain the following documentation in a readily accessible manner regarding each active protocol for which they have responsibilities:

- The most recent version of the IRB-approved protocol;
- The most recent approval letter for the IRB-approved protocol;
- The most recent version of any IRB-approved informed consent documents;
- The most recent version of IRB-approved recruitment materials;
- The most recent version of IRB-approved study instruments (surveys, questionnaires, coding sheets, intervention materials, etc.);
- All communications with participants in the study;
- Pertinent correspondence with the IRB, the sponsor (if applicable), and other regulatory committees and authorities (if applicable).

In addition, investigators must maintain historical records relating to each active protocol for which they have responsibilities, including:

- All amendments submitted to the IRB, including a record of whether they were approved or denied;
- All status report submissions to the IRB, which provide the necessary information for renewal;
- All progress reports, audit reports, and other historical information provided to or from a research sponsor;
- Previous versions of informed consent documents, particularly if there have been changes during the process of enrolling participants;
- Documentation of informed consent from participants or their legally authorized representatives. These documents must be maintained for **one year** after the closure of an exempt project, and for **three years** after the closure of an Expedited or Convened IRB project. Authorizations for the use of Protected Health Information must be maintained for **seven years** from the last date of access of the PHI from the Covered Entity.

IV. Withdrawal of Investigator Privileges

When circumstances demonstrate that an individual serving as an investigator is unfit to do so, the Institutional Review Board or Vice President for Research may withdraw an individual's status as an Investigator of human subjects research projects. Examples of circumstances that may warrant withdrawal of investigator status include:

- Research fraud or misconduct
- Serious or continuing noncompliance
- Failure to protect the rights, welfare, or well-being of research participants
- Inability to fulfill the responsibilities articulated in these SOPs

Withdrawals effectuated by the Institutional Review Board are not subject to appeal, and are usually for a definite duration of time. Particularly egregious violations, however, may result in the indefinite withdrawal of investigator privileges.