



SOP 301: RESEARCH SUBMISSION REQUIREMENTS

PURPOSE

The University of Utah Institutional Review Board (IRB) members rely on the documentation submitted by investigators for new study, continuing review, and amendment applications to provide enough information to assess if a study adequately meets or continues to meet the IRB's criteria for approval.

SCOPE

This policy applies to research submissions to the University of Utah IRB.

POLICY

The University of Utah Electronic Research Integrity and Compliance Administration system (ERICA) uses a smart form application which requires specific information based upon the responses of the applicant (e.g., if an investigator indicates that the study will be a placebo-controlled trial, an additional page in the application will be required). Applications which are incomplete cannot be submitted electronically. The application may require additional documents such as consent forms and recruitment materials. In some cases, ancillary approval may be required, and additional information will be requested in the ERICA application. A comprehensive list of required documents and ancillary approvals essential for new study, continuing review, and amendment applications is found on the IRB website.

A research proposal (with associated documents) is submitted via ERICA. The submission by the responsible investigator in ERICA is considered an electronic signature, legally valid as if the research proposal was submitted in paper format with a printed signature. A submitted proposal is scheduled for IRB review once the IRB staff determines that the application and required documents present an adequate description of the proposed research.

All study personnel who play a role and hold responsibilities in the design, conduct, and/or reporting of the research, as outlined in the research proposal, must be included in the ERICA application.

If the IRB or IRB staff determines that the submitted information is not adequate, investigators may be required to submit additional information, or their presence may be required to answer questions or explain the details of the study. Incomplete submissions will not be reviewed by the IRB.

Complete submissions as outlined in this policy are made available to IRB members for expedited and convened review via ERICA.

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.