REQUIRED DOCUMENTS AND FORMS FOR IRB APPLICATIONS

The IRB reviews and approves supporting documents to the IRB application for the following purposes:

1. Information included in the document is necessary for the IRB to determine if the study meets the Criteria for IRB Approval of Research, as well as other applicable federal regulations.
2. The document will be provided to research participants and will assist them in making an informed choice about participation in the study.

Supporting documents that do not meet these purposes should not be submitted to the IRB for review and approval. Investigators are responsible for maintaining up-to-date versions of all supporting documents, including those reviewed and approved by the IRB and those that do not require IRB review.

Documentation of Approval/Permission for Research Conducted in Collaboration with External Sites
The IRB does not generally require that documentation of approval or permission from external sites be attached to the IRB application. When the University of Utah Investigator is the Lead PI of a multi-site study, the Lead PI is responsible for maintaining documentation of IRB approval for all sites that are engaged in research. Similarly, if an external site is not engaged in research, University of Utah Investigators are responsible for documenting that permission from the site has been granted before research procedures are conducted at the site. All documentation of approval/permission must be included in the research record and made available upon request.

In exceptional circumstances, the IRB may require that approval/permission documentation be attached to the IRB application in order to receive IRB approval. Such circumstances include, but are not limited to, the following:

- The topic of the research is considered especially sensitive.
- The participant population has a high level of vulnerability.
- The legal or reputational risk to the participants or the institution is high.

This guidance document includes a list of supporting documents that are required to be included with the IRB application and meet the purposes described above.

New Study Applications

Attach required and supporting documents to the Documents and Attachments page of the New Study Application.

Social and Behavioral Science Projects	Biomedical and Health Sciences Projects
❑ Method of Consent Documentation; may include one or all of the following: o Consent Document o Parental Permission Document	❑ Method of Consent (and Authorization, as applicable) Documentation; may include one or all of the following: o Consent and Authorization Document o Parental Permission and Authorization Document

- Assent Document
- Consent Cover Letter
- Short Form and Written Summary (Short Form does not need to be attached if using the University of Utah IRB approved version)
- Request for Waiver of Documentation of Consent (form completed in the ERICA new study application, as applicable)

❑ Recruitment materials, including advertisements or information intended to be seen or heard by potential participants
❑ Full protocol (e.g., sponsor protocol), if the study is sponsor-initiated by industry, DHHS, etc.
❑ DHHS-approved sample consent document (when one exists)
❑ Grant application with budget but no appendices, for federal granting agencies
❑ Questionnaires, surveys, interview questions and assessment instruments that are being investigated as part of the research
❑ If applicable, translated versions of consent documents, recruitment materials, surveys, instruments, including verification of translation
❑ Literature Cited/References
❑ Principal Investigator's Scholarly Record (i.e., a curriculum vitae or resume)
❑ Faculty Sponsor's Scholarly Record (i.e., a curriculum vitae or resume, if the principal investigator is not faculty)
❑ Conflict of Interest Disclosure (completed electronically in the BRR system)
❑ Documentation of ancillary approvals from subcommittees for which the University of Utah has research oversight, such as:
- Protocol Review and Monitoring Committee (PRMC) *
- Conflict of Interest management plans (COI) *
- Institutional Biosafety Committee (IBC) *
- Primary Children's Hospital *
- Radiological Drug Research Committee (RDRC) *
- Resource for Genetic and Epidemiological Research (RGE) *
- PIVOT Center
- Veteran Affairs Salt Lake City Health Care System (VASLCHCS) *

❑ Any other supporting materials relevant to the proposed research, if it exists

- Assent Document
- Consent Cover Letter
- Short Form and Written Summary (Short Form does not need to be attached if using the University of Utah IRB approved version)
- Request for Waiver of Documentation of Consent and/or Authorization (form completed in the ERICA new study application, as applicable)

❑ Recruitment materials, including advertisements or information intended to be seen or heard by potential participants
❑ Full protocol (e.g., sponsor protocol), if the study is sponsor-initiated by industry, cooperative groups, DHHS, etc.
❑ DHHS-approved sample consent document (when one exists)
❑ For Investigational Drug and Biologic studies:
- Investigator Brochure or Product Insert/Information Sheets
- Investigational Drug Data Form (completed electronically in the ERICA new study application)
- Documentation of IND receipt; may be documented by one of the following:
  - FDA letter of IND receipt
  - A sponsor-generated document, such as the sponsor protocol, investigational brochure, or letter from the sponsor

❑ For Investigational Medical Device studies:
- Verification of the IDE number; may be documented by one of the following:
  - FDA letter providing the IDE
  - A sponsor-generated document, such as the sponsor protocol or letter from the sponsor
  - FDA letter granting an IDE for the proposed use or letter from sponsor stating that the study is a non-significant risk device study or letter explaining why the investigation is exempt from the IDE requirements under 21 CFR 812.2(c) or otherwise exempt

❑ Grant application with budget but no appendices, for federal granting agencies
❑ Questionnaires, surveys, and assessment instruments that are being investigated as part of the research
❑ If applicable, translated versions of consent documents, recruitment materials, surveys, instruments, including verification of translation
❑ Conflict of Interest Disclosure (completed electronically in the BRR system)
❑ Literature Cited/References
❑ Principal Investigator's Scholarly Record (i.e., a curriculum vitae or resume)

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

	❑ Faculty Sponsor's Scholarly Record (i.e., a curriculum vitae or resume, if the principal investigator is not faculty) ❑ Documentation of ancillary approvals from subcommittees for which the University of Utah has research oversight, such as: o Protocol Review and Monitoring Committee (PRMC) * o Conflict of Interest management plans (COI) * o Institutional Biosafety Committee (IBC) * o Primary Children's Hospital * o Radiological Drug Research Committee (RDRC) * o Resource for Genetic and Epidemiological Research (RGE) * o PIVOT Center o Veteran Affairs Salt Lake City Health Care System (VASLCHCS) * ❑ Other supporting materials that meet the IRB's criteria for review: o The information included in the document is necessary for the IRB to determine if the study meets the Criteria for IRB Approval of Research, as well as other applicable federal regulations. o The document will be provided to the research participants and will assist them in making an informed choice about participation in the study.

Continuing Review Applications

Attach any updated/revised documents to the Update Study application, Documents and Attachments page, including new consent documents that need to be approved for another year.

❑ Currently approved Method of Consent (and Authorization, as applicable) Documentation; must include a clean copy for a new electronic stamp
- o If a study is permanently closed to new enrollment, it is not necessary to provide a currently approved consent form. The consent document will not receive a re-approval stamp (i.e., watermark) unless there is a specific request and explanation from the principal investigator or sponsor.

❑ Any other supporting material relevant to the proposed research, it if exists. This includes relevant multi-center trial reports, current risk-benefit assessments based on the study results, and participant benefits.

In addition, applications are required to submit the following, if applicable to the research:

❑ Documentation of ancillary approvals from subcommittees for which the University of Utah has research oversight, such as:
- o Protocol Review and Monitoring Committee (PRMC) *
- o Conflict of Interest management plans (COI) *
- o Institutional Biosafety Committee (IBC) *

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

- Primary Children's Hospital *
- Radiological Drug Research Committee (RDRC) *
- Resource for Genetic and Epidemiological Research (RGE) *
- PIVOT Center
- Veteran Affairs Salt Lake City Health Care System (VASLCHCS) *

Amendment Applications

Attach any updated/revised documents to the Update Study application, Documents and Attachments page.

- ❑ All previously approved documents that are affected by the proposed changes must be submitted. A draft/tracked copy that highlights these changes and a clean copy are required for adequate review.
- ❑ Any new documents created/required as a result of the proposed changes.
- ❑ Any other supporting materials relevant to the proposed changes, if it exists.

In addition, applications are required to submit the following, if applicable to the research:

- ❑ Documentation of ancillary approvals from subcommittees for which the University of Utah has research oversight, such as:
  - Protocol Review and Monitoring Committee (PRMC) *
  - Conflict of Interest management plans (COI) *
  - Institutional Biosafety Committee (IBC) *
  - Primary Children's Hospital *
  - Radiological Drug Research Committee (RDRC) *
  - Resource for Genetic and Epidemiological Research (RGE) *
  - PIVOT Center
  - Veteran Affairs Salt Lake City Health Care System (VASLCHCS) *

* Received electronically in ERICA