REQUIRED DOCUMENTS AND FORMS FOR IRB APPLICATIONS

New Study Applications
Attach required and supporting documents to the Documents and Attachments page

<table>
<thead>
<tr>
<th>Social and Behavioral Science Projects</th>
<th>Biomedical and Health Sciences Projects</th>
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| Method of Consent (and Authorization, as applicable) Documentation; may include one or all of the following:  
  - Consent and Authorization Document  
  - Parental Permission and Authorization Document  
  - Assent Document  
  - Consent Cover Letter  
  - Short Form and Written Summary  
  - Request for Waiver of Documentation of Consent and/or Authorization (form completed in the ERICA new study application, dependent on your response in ERICA) | Method of Consent (and Authorization, as applicable) Documentation; may include one or all of the following:  
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  - Request for Waiver of Documentation of Consent and/or Authorization (form completed in the ERICA new study application, dependent on your response in ERICA) |
| Conflict of Interest Disclosure (completed electronically in the BRR system) | Conflict of Interest Disclosure (completed electronically in the BRR system) |
| Recruitment materials, including advertisements or information intended to be seen or heard by potential participants | 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. | 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) | DHHS-approved sample consent document (when one exists) |
| Grant application with budget but no appendices, for federal granting agencies | |
| Questionnaires and assessment instruments | 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 |
| Documentation of ancillary approvals from subcommittees for which the University of Utah has research oversight, such as:  
  - Protocol Review and Monitoring Committee (PRMC) – received electronically in ERICA  
  - Conflict of Interest management plans (COI) – received electronically in ERICA  
  - Institutional Biosafety Committee (IBC)  
  - Primary Children’s Hospital – received electronically in ERICA  
  - Radiological Drug Research Committee (RDRC) – received electronically in ERICA  
  - Resource for Genetic and Epidemiological Research (RGE) – received electronically in ERICA  
  - Technology Commercialization Office (TCO)  
  - Veteran Affairs Salt Lake City Health Care System | 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- |

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.
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
  - 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. This request must be approved by the IRB.
- Any other supporting material relevant to the proposed research, if it 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:

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.
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 as well as 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) – received electronically in ERICA
  - Conflict of Interest management plans (COI) – received electronically in ERICA
  - Institutional Biosafety Committee (IBC)
  - Primary Children's Hospital
  - Radiological Drug Research Committee (RDRC)
  - Resource for Genetic and Epidemiological Research (RGE) – received electronically in ERICA
  - Technology Commercialization Office (TCO)
  - Veteran Affairs Salt Lake City Health Care System (VASLCHCS)
- IRB approvals from collaborating, external institutions or other approvals from participating facilities (e.g., school districts, privacy companies, etc.)