

REQUIRED FORMS AND DOCUMENTS FOR BIOMEDICAL/COVERED ENTITY PROJECTS

- Protocol Summary
- 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
 - Questionnaire 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)
- Conflict of Interest Disclosure (form completed in the ERICA system, dependent on your response in ERICA)
- 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 in the ERICA new study application)
 - FDA Form 1572
 - 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 and assessment instruments
- IRB approvals from collaborating, external institutions or other approvals from

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

Institutional Review Board

University of Utah

participating facilities (e.g. school districts, private companies, etc.)

- VA Form 10-1223 for VA studies
- Documentation of ancillary approvals from subcommittees for which the University of Utah has oversight of research, such as (click on link to see specific requirements)
 - o [Clinical Cancer Investigations Committee \(CCIC\)](#)
 - o [Conflict of Interest \(COI\)](#)
 - o [Institutional Biosafety Committee \(IBC\)](#)
 - o [Primary Children's Medical Center \(PCMC\)](#)
 - o [Radiological Drug Research Committee \(RDRC\)](#)
 - o [Resource for Genetic and Epidemiological Research \(RGE\)](#)
 - o [Technology Commercialization Office \(TCO\)](#)
 - o [Veteran Affairs Salt Lake City Health Care System \(VASLCHCS\)](#)
- 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)
- Any other supporting materials relevant to the proposed research, if it exists

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