

ADDITIONAL REQUIRED DOCUMENTS FOR CONTINUING REVIEW OF BIOMEDICAL/COVERED ENTITY PROJECTS AND BEHAVIORAL AND SOCIAL SCIENCE PROJECTS

- 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. This request must be approved by the IRB.
- Any other supporting materials relevant to the proposed research, if it exists. This includes relevant multi-center trial reports, current risk-benefit assessments based on study results, and participant benefits.

In addition, applicants will be required to submit, if applicable to the research:

- 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 \(VASLCHCS\)](#)
- IRB approvals from collaborating, external institutions or other approvals from participating facilities (e.g. school districts, private companies, etc.)

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