



SOP 401B: RESEARCH ACTIVITIES EXEMPT FROM IRB REVIEW

POLICY

Federally funded research activities that meet all applicable criteria set forth by the federal regulations (45 CFR 46.104) and involve no greater than “minimal risk” may qualify for exemption from IRB review. Additionally, non-federally funded research activities that meet all applicable criteria set forth by the University of Utah (UUIRB) may qualify for exemption from IRB review. An exemption must be determined by the IRB, not an individual investigator. The exemption categories are posted on the UUIRB web site. The IRB may rule a proposal is exempt if it fits into one of the exemption categories and is no greater than minimal risk. However, the UUIRB may determine that there are studies that may pose ethical concerns and are reviewed as with any other new study application.

The IRB administrator is an IRB member designated by the IRB Chair to review all requests for exemption and make a final determination. Such claims of exemption are recorded and stored in the ERICA online system.

All exempt reviews conducted by UUIRB designated members meet the requirements of a limited IRB review by ensuring that when appropriate, the research plan includes adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

The University of Utah retains the authority to suspend or terminate IRB approval of research approved with a limited review.

University of Utah IRB does not utilize broad consent. Exemption categories intended for research using broad consent are not applied at the University of Utah. See the UUIRB Website for detailed descriptions of the exemption categories (IGS: Exempt Research).

Continuing review is not required for studies determined to be exempt.

PROCEDURES

1. Exempt Research Activities

- 1.1. The investigator submits a new study application in ERICA.
- 1.2. The IRB administrator conducts a review of the research proposal using the IRB internal checklist (Determining if Human Research is Exempt from IRB review) within the ERICA online system. When one or more of the exemption categories are applicable to the research, the IRB administrator documents the applicable category(ies) using the internal checklist and makes the final exemption determination.

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



- 1.3. VA research determined exempt from IRB review must be reviewed by the R&D Committee prior to initiation and must be included in annual R&D Committee Review of research projects.
- 1.4. All exemption determinations are communicated to the investigator via the ERICA online system, and includes the applicable category(ies) justifying the exemption determination.
- 1.5. If the IRB administrator determines the proposal is not eligible for an exempt determination, including limited review, the IRB administrator will move the application to an expedited or convened board review. The research may only be tabled or disapproved by the convened IRB.

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