



## **SOP 401B: RESEARCH ACTIVITIES EXEMPT FROM IRB REVIEW**

### **PURPOSE**

The University of Utah Institutional Review Board (IRB) oversees research involving human subjects. This policy defines what research may be exempt from IRB review and the procedures for determining when research may be exempt from IRB review.

### **SCOPE**

This policy applies to research conducted at the University of Utah.

### **DEFINITIONS**

- A. *Limited IRB review*** is a process that is required only for certain exemptions and does not require an IRB to consider all the IRB approval criteria in 45 CFR 46.111. In limited IRB review, the IRB must determine that certain conditions, which are specified in the regulations are met.
- B. *Minimal risk*** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

### **POLICY**

Human subject research that is categorized as exempt research is exempt from most of the requirements in the federal regulations for protection of human subjects. Exempt research must be no greater than minimal risk and must fit within an exemption category. Investigators are expected to adhere to principles of sound research design and ethics and follow any applicable state laws and University policies.

The University of Utah IRB utilizes the exemption categories 1-6 as outlined in 45 CFR 46.104 for federally funded research. University of Utah IRB does not utilize broad consent and the exemption categories intended for research using broad consent (categories 7-8) are not applied at the University of Utah. The University of Utah IRB designated additional exemption categories (A-E) for research with no federal oversight. The exemption categories (federal and non-federal) are posted on the University of Utah IRB web site.

For the purposes of this policy, IRB staff who are designated IRB members are termed IRB reviewers. Exemptions are determined by an IRB reviewer. In limited circumstances, investigators may obtain an exemption determination using a guided application process in the University of Utah Electronic Research Integrity and Compliance Administration system (ERICA). Guided exemptions are only offered for eligible projects based on answers in the new study application and cannot be requested by

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investigators. Investigators have the option to request that an IRB reviewer make the exemption determination rather than relying on the guided application process.

Exemption determinations are recorded and stored in ERICA. If an IRB reviewer believes that a study proposal may be eligible for exemption but poses ethical concerns, it will be reviewed as with any other new study application.

All exempt reviews conducted by an IRB reviewer 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. Investigators are not given an option to use the guided exemption if a limited IRB review is required. The University of Utah retains the authority to suspend or terminate IRB approval of research approved with a limited review.

Continuing review is not required for studies determined to be exempt. To keep the study open and active with the University of Utah IRB and Human Research Protection Program (HRPP), an Annual HRPP Progress Update must be submitted.

Substantive changes to the exempt study must be submitted via amendment application to ensure the study still qualifies for exempt status considering the changes. Exempt studies must adhere to the University of Utah IRB reporting requirements for unanticipated problems and deviations. Exempt studies must be closed with the IRB once the research activities are complete.

## PROCEDURES

### 1. Exempt Research

- 1.1. The investigator submits a new study application in ERICA.
- 1.2. Based on the responses provided in the new study application, some study proposals may be eligible for a guided exemption. If eligible, the investigator is given the option to receive a guided exemption or to request that the application be referred to an IRB reviewer for an exemption determination. If the investigator opts for the guided exemption, the investigator will follow all prompts and agree to all stipulations in ERICA in order to receive confirmation from ERICA of the exemption determination.
- 1.3. The IRB reviewer conducts a review of the research proposal using the IRB internal checklist (Determining if Human Research is Exempt from IRB review) within ERICA. When one or more of the exemption categories are applicable to the research, the IRB reviewer documents the applicable category(ies) using the internal checklist and makes the final exemption determination.
- 1.4. 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.
- 1.5. All exemption determinations are communicated to the investigator via ERICA, and includes the applicable category(ies) justifying the exemption determination.

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- 1.6. If the IRB reviewer determines the proposal is not eligible for an exempt determination, including limited review, the IRB reviewer 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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