THE UNIVERSITY OF ARIZONA
Research
Innovation & Impact

Exempt and Minimal Risk Research

Overview

Federal regulations designate certain types of research involving human subjects as being exempt from further IRB oversight. A designation of 'exempt' means the project is human research, but it is very low risk and not subject to further requirements in the federal regulations.

Determination of whether a project is exempt from further IRB oversight requires a determination by a designated IRB member. Investigators cannot make determinations whether human research projects meet the regulatory criteria for exemption. The criteria allowing exemption are outlined on this webpage which details all exemption categories.

Projects approved as "minimal risk 2018" adhere to the University's *Flexible Review* Guidance as well as the guidance provided below. This review process applies to studies that are not federally funded or supported, are not regulated by the FDA, and do not significantly affect the health and welfare of participants. These studies can be deemed as "minimal risk 2018."

Limited IRB Review

Under the 2018 rules, certain exemptions require a limited IRB review. Limited IRB review requires either a data/security review OR review and verification that broad consent was obtained. See the guidance on *Limited IRB Review* for more information. The limited IRB review will occur at the same time the project is reviewed for a determination of exemption.

Submission Requirements

Submission of the appropriate *IRB Protocol for Human Subjects Research* is required to make a determination of exemption. The Human Subjects Protection Program (HSPP) and designated IRB members will review the request for exemption. The investigator will receive a formal letter of determination of exemption.

Informed Consent

Obtaining informed consent from participants fulfills the ethical requirements of Respect for Persons discussed in the Belmont Report. Exempt projects are still required to obtain informed consent from subjects and consent should be provided in a language that subjects understand. Exempt projects, however, have much more flexibility in what and how participants are informed about the project. It is not necessary to obtain written consent for exempt studies, so long as participants are informed.

The information contained in the informed consent does not have to meet the regulatory requirements found in 46 CFR 46.116; however, potential subjects should have all the information regarding the study (e.g., purpose, procedures, risks and benefits, and contact information), prior to agreeing to participate in the study.

Modifications

Studies that are exempt need to submit Modifications in eIRB for IRB review and approval as identified below. IRB records in eIRB are source documents for what the IRB has approved. If your project does not require a Modification, but you wish to make changes to your documents, you will

need to keep your documents updated in your own regulatory files. Submit a Modification in eIRB with the requested change. Modifications are required for:

- Changes in PI;
- Addition or removal of PI Proxies;
- Changes in the scope of previously approved research topic (such as an addition of a new survey addressing a slightly different topic)

- Change in the data storage and protection of identifiable private information or biospecimens that impact limited IRB review;
- Research involving prisoners that more than incidentally collects information on prisoners;
- New knowledge that increases the risk level;
- Removal or addition of funding;
- Addition of Banner as a research site;
- Addition of a single IRB or multi-site research project;
- Survey or interview procedures that involve children (i.e., individuals under the age of 18) that do not fall under exempt category 1 which describes research in commonly accepted educational settings;
- Observational research of children that involves participation by the researcher;
- Research subject to GDPR regulations;
- The use of any methods described in the Expedited review categories that do not meet the exempt criteria (e.g., blood draws). For information about Expedited review categories, please refer to this link: http://www.hhs.gov/ohrp/policy/expedited98.html.
- Change in the way identifiers are recorded (directly or indirectly) from existing data, documents, records, pathological specimens, or diagnostic specimens so that subjects can be identified;
- Records review that involves prospective collection of data;
- Addition of an instrument, survey, etc. from which information obtained is recorded in such a manner that (i) human subjects can be identified, directly or through identifiers linked to the subjects; *and* (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation;
- Addition of vulnerable populations and research activities that may pose more than minimal risk to the participant.
- Any additional modifications the investigator wishes the IRB to approve.

Minor changes to exempt research do not need to be reviewed by the IRB. Minor changes include simple revisions to already approved language (e.g., rewording survey language to make a statement clearer, adding new survey questions in line with the already approved purpose and questions, or updating recruitment materials to reflect new contact information). For modifications that do not require IRB review, download the relevant approved documents within eIRB, make the necessary changes, and save them separately in a regulatory folder within your protected departmental drive. All modifications not reviewed by the IRB should be documented in a systematic way to maintain an accurate record of all study activities to date.

Continuing Reviews

Human research projects that are deemed exempt or minimal risk do not have a Continuing Review requirement except as noted in the *Continuing Review of Human Research* guidance. This includes exempt research that received a limited IRB review. The University of Arizona has chosen to require Continuing Review on certain types of exempt research. Refer to *Continuing Review of Human Research* guidance.

Concluding Exempt Research

Investigators should submit a Continuing Review in eIRB when the exempt project is complete, so that the HSPP can update the University's records.

Conflict of Interest

The HSPP will validate COI only for research personnel who are listed both in eIRB and on the Institutional Proposal or Award that is linked to the protocol in eIRB for funded research. It is the responsibility of the Principal Investigator (PI) to ensure that the correct personnel are listed as an Investigator on the Sponsored Projects Institutional Proposal or Award. All other personnel, for both funded and unfunded research, are independently responsible for ensuring that they have submitted all appropriate disclosures and are in compliance with the Conflicts of Interest and Commitment Policy. For questions about your disclosure requirements, contact the Office for Responsible Outside Interests at coi@arizona.edu.

Under the University's COI policy, an Investigator is any person who shares the responsibility of Conducting Research. This includes, but is not limited to, the Principal Investigator (PI), Co-Investigator (Co-I), Project Director (PD), Co-PD, Senior/Key Personnel, and any other person, regardless of title or position, who is responsible for Conducting Research performed by or under the auspices of the University. Conducting Research includes the design, development, testing, evaluation, conduct, reporting, review, and oversight of a program of scientific inquiry. For questions, please contact the COI Office at (520) 626-6406.

Investigator Responsibilities

- Maintain a regulatory file to support IRB determination, at minimum, the finalized protocol, the IRB application, and the approval letter regarding the exempt determination.
- Ensure that research staff are appropriately trained and are qualified to conduct the tasks assigned.
- Ensure the correct personnel are listed as an Investigator on the Sponsored Projects Institutional Proposal or Award for Sponsored research. All other personnel not listed on the Institutional Proposal or Award are responsible for ensuring that they have submitted all appropriate disclosures and are in compliance with the University's Conflicts of Interest and Commitment Policy.
- Oversee the conduct of all research activities. Investigators may delegate responsibilities, but documentation of delegation is required, and the PI must maintain oversight of all research activities.
- Conduct research in compliance with the finalized protocol.
- Maintain research records (including signed consents if obtained) for six years past completion of the study. See HSPP guidance, *Data Security and Records Retention*, for more information.

- Ensure the subjects' questions, concerns, and complaints are properly addressed and resolutions are documented and retained in the study record.