THE UNIVERSITY OF ARIZONA
Research
Innovation & Impact

Exempt Research

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.

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 an 'Application for Human Research' is required to make a determination of exemption. The Human Subjects Protection Program 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.

Amendments

Studies that are exempt need to submit amendments to the HSPP for review and approval as identified below. Submit 'Amendment to Approved Human Research' with the requested change. Amendments are required when:

- Changes in PI/Co-PIs;
- Addition or removal of key personnel (i.e., alternate contact, primary coordinator, etc.) who need to be added to or removed from automatic system notifications;
- Change in the data storage and protection of identifiable private information or biospecimens that impact limited IRB review;
- Research involving prisoners that more that incidentally collect 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 FDA 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 involve 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.

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 more clear, adding new survey questions in line with the already approved purpose and questions, or updating recruitment materials to reflect new contact information).

Renewals

Human Research projects that are deemed exempt do not have a renewal requirement. This includes exempt research that received a limited IRB review. However, exempt research will be given a five-year expiration date so that the Human Subject Protection Program can update its records.

Concluding Exempt Research

Investigators should submit the Renewal/Closure for Human Subjects form when the exempt project is complete, so that HSPP can update the University's records.

Conflict of Interest

If a person is added to a project who meets the definition of a COI Investigator, that investigator must manually add the project to their COI disclosure. Instructions for this are found on the COI webpage.

Under the University's COI policy, an Investigator is "any person who is responsible for the design, conduct or reporting of Research." This includes all persons who are responsible for the design, conduct, or reporting of Research regardless of their title. While this may include students, trainees, collaborators, volunteers and consultants if those individuals have some degree of independence in

performing some aspect of the design, conduct or reporting of the Research, it does not include individuals whose performance is purely ancillary or occurs solely under immediate supervision. For example, “Investigator” includes individuals who are directly involved in the research intervention or consenting or evaluation of human research subjects but does not include hospital or office staff who provide only ancillary or intermittent care and do not make direct and significant contributions to the research data. 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 application, and the approval letter regarding the exempt determination.
- 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 record (including signed consents if obtained) for six years past completion of the study. See HSPP guidance, 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.
- Report local information per HSPP requirements for Reporting of Local Information.