THE UNIVERSITY OF ARIZONA
Research
Innovation & Impact

Minimal Risk Research

Projects approved under this guidance are reviewed according to the University's Flexible Guidance for review of projects that are not federally funded or supported, or FDA regulated. Human research that is not federally funded or supported, or FDA regulated, and does not significantly affect the health and welfare of participants can be deemed minimal risk. Determination of a project's review level requires a determination by a designated IRB member. Investigators cannot make determinations whether Human Research projects meet the regulatory criteria.

Submission requirements

Submission of an 'Application for Human Research' is required to make a determination. The Human Subjects Protection Program and designated IRB members will review the request. The investigator will receive a formal letter of determination.

Informed Consent

Obtaining informed consent from participants fulfills the ethical requirements of 'respect for persons' discussed in the Belmont Report. Minimal risk projects, therefore, are still required to obtain informed consent from subjects, provided in a language that subjects understand. It is not necessary to obtain written consent so long as participants are informed.

- 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, but the consent does not need to meet the regulatory requirements found in the federal rule. Please see the informed consent templates on the HSPP website for more on developing consents.

Amendments

Studies deemed 'minimal risk' need to submit amendments to the HSPP for review and approval as identified below. Submit an 'Amendment to Approved Human Research' with the requested change. Amendments are required <u>when</u>:

- 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;
- 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 that 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 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 collection of HIPAA or FERPA protected 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 amendments the Investigator wishes to have IRB approval.

Renewals

Projects deemed minimal risk do not have a renewal requirement except as noted below. The project, however, will be given either a three-year or five-year expiration date so that the Human Subject Protection Program can update its records.

The University of Arizona has chosen to require renewals on certain types of minimal risk research, due to the sensitivity or oversight required. These activities include:

- Projects involving Native Americans;
- When the Principal Investigator (PI) or co-PIs have received a determination of continuing or serious non-compliance in the past two years;
- As determined by the IRB because of a change in risk, protection or inclusion of subjects, or other concerns that require increased oversight;
- Projects that involve deception that is not prospectively authorized; or
- A conflict of interest management plan exists.

Concluding Research

Investigators should submit the Renewal/Closure for Human Subjects form when the 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 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. This includes submitting all amendment requests, renewals, and/or study closures as applicable.
- 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.