Minimal Risk or Exempt Research

Human research that does not significantly affect the health and welfare of participants may be deemed minimal risk, or even less, exempt. 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 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 a Project Narrative is required to make a determination. The Human Research 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 or exempt projects, therefore, are still required to obtain informed consent from subjects. Provide consent in a language that subjects understand. It is not necessary to obtain written consent so long as participants are informed. A waiver of consent or a waiver of a signature may be required by the IRB.

- Minimal risk research that is federally funded or supported is required to obtain informed consent that meets the regulatory requirements found in 46 CFR 46.116.

- Minimal risk and exempt projects that are NOT federally funded or supported have much more flexibility in what and how participants to inform about the project. 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 and waiver appendices within the IRBNet library for more information on developing appropriate, informative consents.

Amendments

Studies that are federally funded or supported, or FDA regulated, are required to submit ALL changes to the HRPP for review by the IRB.

Studies that are not federally funded or supported, but deemed ‘minimal risk’ or ‘exempt’ need to submit amendments to the HRPP for review and approval as identified below. Submit an ‘Amendment to Approved Human Research’ with the
requested change. Amendments are required when:

- Changes in PI/Co-PI’s/Faculty Advisor’s;
- Changes in the consent process/forms;
- 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 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](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.

*Minor changes to non-federally funded or supported minimal research, or research deemed exempt, 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 clearer statement, 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 not deemed to be minimal risk, or are FDA regulated, are required to submit an annual renewal.
Human Research projects that are not FDA regulated and are deemed minimal risk or exempt do not have a renewal requirement except as noted below. However, depending on the type of research, the project will be given either a three-year or five-year expiration date so that the Human Research Protection Program can update its records. An updated application will be required.

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

- When the Principal Investigator (PI), co-PIs, or Faculty Advisor 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 HRPP can update the University’s records.

**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 five years past completion of the study.
- Ensure the subjects’ questions, concerns, and complaints are properly addressed and resolutions are documented and retained in the study record.

Report local information per HRPP requirement for Reporting of Local Informant.