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.

Submission requirements
Submission of an ‘F200: Application for Human Research’ is required to make a determination of exemption. If the project is considered non-exempt, the project will be approved as expedited or full committee review.

Exempt Categories
The regulations allow for six (6) categories of research that qualify for exempt status. In addition to the exemptions in the federal regulations, the UA HSPP has created two additional exempt categories for projects that are not federally funded, supported, or for an agency that has adopted the federal rules.

a) Exempt 7: Projects that do not conform to a specific exempt category under 45 CFR 46.

Examples include:
- Online surveys, in-person focus groups, and/or interviews involving minors as long as the information collected does not place the individual at greater than minimal risk
- Behavioral games
- Studies of traits of non-public, non-elected officials
- Studies requiring performance of tasks that incur no risk
- Studies involving focus groups, oral histories, ethnographies, or studies utilizing eye-tracking

b) Exempt 8: Research, involving no greater than minimal risk, where activity is limited to study of identifiable data.

Examples include:
- Medical or educational record reviews where data is extracted from records
- Data analysis of information collected from court records
- Collection or analysis of audio, video, or digital images
Exempt Research

Exempt category 8 may still require a HIPAA waiver. Studies that typically fall under expedited category 5 (involving analysis only of already collected data/documents/records) may now qualify for exempt category 8.

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 be written in a language that subjects can understand. Exempt projects, however, have much more flexibility in what is told to subjects and the manner in which subjects are informed about the project.

The information contained in the informed consent does not have to meet all 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. Please see the checklist [C100: Elements of Informed Consent](#) to help draft an appropriate, informative consent document for exempt research.

Amendments

Studies that are exempt do not need to submit amendments to the HSPP for review and approval unless the amendment changes the nature of the project from being exempt. Changes that affect the determination of exemption include, but are not limited to:

- Changes in PI/Co-PI’s;
- Research involving prisoners;
- New knowledge that increases the risk level;
- Removal or addition of funding;
- Addition of a B–UMG site;
- 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 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
Exempt Research

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.

If an exempt project requires an amendment that changes the nature of the project from being exempt, submit an 'F213: Amendment of Approved Human Research' with the requested change and the IRB will re-evaluate the risk level of the project.

Renewals

Human Research projects that are deemed exempt do not have a renewal requirement.

Concluding Exempt Research

Exempt projects are maintained in HSPP for five (5) years from approval. An updated application is required every five (5) years.

Investigators should submit a concluding form when the exempt project is complete, so that HSPP can update our records.

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.