

# Healthcare Compliance Forms and Tools

## Sample Exempt Research Guidance Summary

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Research, Discovery, and Innovation

Exempt Research

Federal regulations designate certain types of research involving human subjects as being exempt from further institutional review board (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 (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 45 C.F.R. § 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.

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Submit the “Amendment to Approved Human Research” with the requested change. Amendments are required:

- When principal investigators (PIs)/co-PIs change;
- When there are changes in the data storage and protection of identifiable private information or biospecimens that affect limited IRB review;
- When research involving prisoners more than incidentally collects information on prisoners;
- When new knowledge increases the risk level;
- If there is removal or addition of funding;
- If Banner is added as a research site;
- If a single IRB or multisite research project is added;
- If survey or interview procedures that involve children (i.e., individuals under the age of 18) do not fall under exempt category 1, which describes research in commonly accepted educational settings;
- When there is observational research of children that involves participation by the researcher;
- If the research is subject to Food and Drug Administration regulations;
- If there are any methods described in the Expedited review categories that do not meet the exempt criteria (for information about Expedited review categories, please refer to this link: <http://www.hhs.gov/ohrp/policy/expedited98.html>);
- When there is a 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;
- If there is a records review that involves prospective collection of data;
- If there is an 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; or
- If vulnerable populations and research activities are added 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 clearer, 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 HSPP 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.

## 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.

HSPP Use Only: Guidance Exempt Research v Jan 2019

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