

Title: IRB Review of Exempt Research
Standard Operating Procedure: #8
Department: Human Research Protection Program/Institutional Review Board
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Subject: IRB Review of Human Subjects Research—Exempt

Policy:

Research studies involving humans subjects may be determined to be exempt from the requirements that they receive expedited or full committee review, under 45 CFR 46.101(b)(1)-(6), 45 CFR 406.301(a), 45 CFR 46.401(b) and 21 CFR 6.104(d). Only the IRB Chair, IRB Manager, or their designee may determine if a study qualifies for an exemption. A research study involving human subjects may not begin until after a determination has been made that the study qualifies for an exemption, or the study has been approved after an expedited or full committee review. Investigators do not have the authority to make an independent determination that research involving human subjects qualifies for an exemption.

An investigator may request review under a particular category of exemption, but the final determination of which category of exemption, if any, applies to a study will be made by the IRB Chair, IRB Manager, or their designee.

Research subjects enrolled in a research study that has been determined to qualify for exemption are entitled to the same subject protections and ethical standards as outlined in *The Belmont Report*. Consequently, if the IRB determines that a study may involve greater than minimal risk to the subjects or there is a need for additional protections for research subjects, the IRB may require that the study be resubmitted for expedited or full committee review.

The categories of research that are exempt from expedited or full committee review are listed below. **Note:** These categories do not apply to research involving prisoners, and categories 1-5 do not apply to Food and Drug Administration-regulated research.

Exemption Categories

1. Research conducted in established or commonly accepted educational setting, involving normal educational practices, such as:
 - a. Research on regular and special education instructional strategies; or
 - b. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) survey procedures, interview procedures, or observation of public behavior, unless:

- a. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
- b. Any disclosure of the human subjects' responses outside of 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.

If the research involves children as participants, the research must be limited to educational tests (cognitive, diagnostic, aptitude, achievement), and observation of public behavior when the investigator(s) do not participate in the activities being observed. Research that uses survey procedures, interview procedures, or observation of public behavior when the investigator(s) participate in the activities being observed cannot be granted an exemption.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category 2 above, if:
 - a. The human subjects are elected or appointed public officials or candidates for public office; or
 - b. Federal statutes require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publically available or the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. To qualify for this exemption, data, documents, records, or specimens must have been collected before the research project begins.
5. Research and demonstration projects, which are conducted by or subject to the approval of federal department or agency heads, and which are designed to study, evaluate, or otherwise examine:
 - a. Public benefit or service programs.
 - b. Procedures for obtaining benefits or services under those programs.
 - c. Possible changes in or alternatives to those programs or procedures.
 - d. Possible changes in methods or levels of payment for benefits or services under those programs.

The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services under the Older Americans Act):

- The research or demonstration project must be conducted pursuant to specific federal statutory authority.
- There must be no statutory requirements that the project be reviewed by the IRB.
- The project must not involve significant physical invasions or intrusions upon the privacy of participants.
- This exemption is for projects conducted by or subject to approval of federal agencies and is most appropriately invoked with authorization or concurrence by the funding agency.

6. Taste and food quality evaluation and consumer acceptance studies:

- a. If wholesome foods without additives are consumed; or
- b. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Procedures:

1. Investigator

- a. Investigators wishing to have a protocol classified as exempt will submit the protocol to the IRB Office within the LLNL Human Research Protection Office using and exempt application form. The investigator will indicate on the form which categories of exemption he or she believes the protocol qualifies under.
- b. If the protocol reviewer requires revisions to the protocol prior to the protocol being classified as exempt and the investigator does not wish to make the required revisions, the investigator may resubmit the protocol for expedited or full committee review.

2. LLNL Human Research Protection Office

- a. Upon receipt of an exempt application the IRB Office will enter relevant information regarding the protocol into the protocol-tracking database.
- b. The IRB Chair will review the protocol to ensure it meets the requirements for an exemption. If the protocol is not eligible for an exemption, the investigator will be notified in writing.
- c. If it is determined that an expedited or full committee review of the protocol is required, the exempt application form will be returned to

the investigator with instruction to resubmit the protocol for expedited or full committee review.

- d. If, per comments by the Chair, the protocol qualifies for an exemption, the required revisions will be communicated to the investigator.
- e. Upon verification that the required revisions have been made, the Chair will approve the protocol as exempt.
- f. If the investigator requests a waiver under HIPPA, the protocol will be assigned to the Chair for review.

3. Final Approval

Final approval of exemption applications will be made by the IRB Chair. *Although there is no regulatory requirement for renewal of exemptions, the LLNL IRB Office will update the exemption status on an annual basis (from the date of approval). This will be accomplished by way of a status update letter to be sent to all individuals holding IRB exemptions.*

Reference:

21CFR 56.104(d)

45 CFR 46.101(b)(1)-(6)

45 CFR 46.301(a)

45 CFR 46.401(b)