

INSTRUCTIONS: CLAIM OF EXEMPTION

BEFORE BEGINNING THIS SUBMISSION, PLEASE REFER TO THE IRB GUIDANCE DOCUMENT: IS IRB REVIEW REQUIRED?

WHAT DOES “EXEMPT” MEAN?

The federal regulations [45 CFR 46.101](#) and [21 CFR 50.104](#), allow specific categories of research to be exempt from human subject review.

In order for research to qualify for exempt status, the attached Claim of Exemption form must be submitted and approved by the IRB before initiating any study procedures, including recruitment.

The exempt categories ***do not*** apply to research involving:

Exemptions do not apply to research involving prisoners.

Only Category 6 (below) applies to research when regulated by the FDA.

Category 2 does not apply to research with children involving survey or interview procedures or observations of public behavior except for research involving observations of public behavior where the investigator does not participate in the activities being observed.

EXEMPT CATEGORIES:

Category 1

- The research is conducted in established or commonly accepted educational settings.
- The research involves normal educational practices, such as:
 - Research on regular and special education instructional strategies.
 - Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- The research does not involve prisoners as participants.
- The research is not FDA-regulated.

2. Category 2

- The research involved the use of one or more of the following:
 - Educational tests (cognitive, diagnostic, aptitude, achievement).
 - Survey procedures.
 - Interview procedures.
 - Observation of public behavior.
- If any disclosure of the participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation, the information obtained is not recorded in such a manner that participants can be identified, directly or indirectly through identifiers linked to the participants.
- If the research involves children as participants, the procedures do not involve any of the following:
 - Survey procedures.
 - Interview procedures.
 - Observation of public behavior where the investigators participate in the activities being observed.
- The research does not involve prisoners as participants.
- The research is not FDA-regulated.

3. Category 3

- The research is not exempt under Category 2.
- Research involving the use of one or more of the following:
 - Educational tests (cognitive, diagnostic, aptitude, achievement).
 - Survey procedures.
 - Interview procedures.
 - Observation of public behavior.
- Either of the following is true:
 - The participants are elected or appointed public officials or candidates for public office.
 - Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- The research does not involve prisoners as participants.
- The research is not FDA-regulated.

4. Category 4

- The research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens.
- Either of the following is true:
 - The sources are publicly available.
 - The investigator records information in such a manner that participants cannot be identified, directly or indirectly through identifiers linked to the participants.
- The research does not involve prisoners as participants.
- The research is not FDA-regulated.

5. Category 5

- The project is a research or demonstration project.
- The research is conducted by or subject to the approval of federal Department or Agency heads.
- The research is designed to study, evaluate, or otherwise examine one or more of the following:
 - Public benefit or service programs.
 - Procedures for obtaining benefits or services under those programs.
 - Possible changes in or alternatives to those programs or procedures.
 - Possible changes in methods or levels of payment for benefits or services under those programs.
- The program under study delivers 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 as provided under the Older Americans Act).
- The research is conducted pursuant to specific federal statutory authority.
- There is no statutory requirement that an IRB review the research.
- The research does not involve significant physical invasions or intrusions upon the privacy of participants.
- The research does not involve prisoners as participants.
- The research is not FDA-regulated.

6. Category 6

- The research involves taste and food quality evaluation or is a consumer acceptance study.
- Either of the following is true:
 - Wholesome foods without additives are consumed.
 - If a food is consumed that contains a food ingredient or an agricultural chemical or environmental contaminant, the food ingredient or agricultural chemical or environmental contaminant is at or below the level and for a use found to be safe by one of the following:
 - The Food and Drug Administration.
 - The Environmental Protection Agency.
 - The Food Safety and Inspection Service of the U.S. Department of Agriculture.

The research does not involve prisoners as participants.

HOW TO APPLY FOR EXEMPTION:

If an investigator believes that a study meets the criteria for exemption, the investigator is required to submit the Claim of Exemption Form to the IRB.

The Claim of Exemption Form is reviewed by the IRB Administrator. The IRB Administrator will review the application to determine that the research qualifies for exemption and meets the following ethical standards:

- The research presents no more than minimal risk to participants.
- Selection of participants is equitable.
- If the research involves interactions with participants, the circumstances of consent minimize coercion and undue influence.
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- Participants will be informed that the study involves research, will be provided with information about the study procedures that the research is voluntary, and will be provided with information about whom to contact with questions.
- Provisions for protecting the privacy interests of participants are adequate
- If private identifying data are recorded, provisions for maintaining the confidentiality of data are adequate.

If the reviewer determines that the activity is exempt from review, the reviewer will notify the investigator IRB with any required changes.

Research determined to be exempt is approved for 3 years. Investigators must, however, report to the IRB any modifications that fall outside of the exemption categories.