**WHAT DOES “EXEMPT” MEAN?**

The federal regulations [45 CFR 46.101](https://www.federalregister.gov/a/84537) and [21 CFR 50.104](https://www.federalregister.gov/a/84537), allow specific categories of research to be exempt from human subject review.

Before beginning this submission, please refer to the IRB guidance document: Is IRB Review Required?

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**
Research conducted in established educational settings that involve normal educational practices, such as:
- research on regular and special educational instructional strategies, or
- research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.

**Category 2**
Research that involves the use of:
- educational tests ONLY (cognitive, diagnostic, aptitude, achievement), or
- research that involves ONLY observation of public behavior of adults UNLESS
  - Information is recorded with identifiers linked to the subjects AND
  - Subject's' responses outside the research could place the subjects at risk (e.g. criminal or civil liability, financial standing, employability, or reputation).

**Category 3**
Research that involves the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or the observation of public behavior is exempt if:
- The human subjects are elected or appointed public officials, or candidates for public office, or
- Federal statute(s) require(s) confidentiality of identifiable information to be maintained during the research and permanently thereafter.

**Category 4**
Research that involves the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens if these sources are publicly available.
NOTE: The data or specimens must be “on the shelf” at the time the research is proposed to qualify for Category 4 exemption.

**Category 5**
Research and demonstration projects that are conducted by or subject to the approval of federal
department or agency heads, and are designed to study or evaluate:
- Public benefit or service programs;
- Procedures for obtaining benefits or services under those programs;
- Possible changes in or alternatives to those programs or procedures; or
- Possible changes in methods or levels of payment for benefits under those programs.

OHRP has determined that the following criteria must be satisfied to invoke the exemption for research and demonstration projects examining "public benefit or service programs" as specified under Department of Health and Human Services (HHS) regulations at 45 CFR 46.101(b)(5):

- 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 as provided under the Older Americans Act). The research or demonstration project must be conducted pursuant to specific federal statutory authority.
- There must be no statutory requirement that the project be reviewed by an Institutional Review Board (IRB).
- The project must not involve significant physical invasions or intrusions upon the privacy of participants.
- The funding agency must be contacted and provide approval to utilize this exemption category.

Category 6
- Taste and food quality evaluation that involves wholesome/safe foods (i) if wholesome foods without additives are consumed or (ii) 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.

**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.