



EXEMPT RESEARCH

1. Overview

Research involving human subjects may be exempt from federal regulations requiring IRB review. The Ohio State University Human Research Protection Program (HRPP) is responsible for determining whether research involving human subjects meets the criteria for exemption in accordance with applicable regulations. Investigators may not make this determination. Research that includes both exempt and non-exempt activities cannot be determined to be exempt.

The purpose of this policy is to describe exempt research as defined by DHHS and/or FDA regulations and the process by which the HRPP determines that research involving human subjects is exempt from the regulations and the requirements for IRB review.

2. Definitions

Exempt research: Research that involves human subjects that is not subject to regulations requiring IRB review and approval. Categories of research activities that may be determined to be exempt from review by the IRB are defined by federal regulations and university policy. *Note: Investigators performing exempt research must comply with the requirements of the HRPP even when the research is exempt.*

Child/Children: Person(s) who have not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted. For purposes of HRPP policy, individuals under 18 years of age are considered children in Ohio unless they meet the definition of emancipated minors.

Prisoner: An individual involuntarily confined or detained in a penal institution (e.g., prison, jail, or juvenile offender facility), with restricted ability to leave the institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

De-identified: All direct personal identifiers are *permanently* removed (e.g., from data or specimens), no code or key exists to link the materials to their original source(s), and the remaining information cannot reasonably be used by anyone to identify the source(s). *Note: For purposes of HRPP policy, protected health information is de-identified when it does not contain any of the 18 identifiers specified by the HIPAA Privacy Rule at 45 CFR Part 164 (or has been determined to be de-identified by a statistician in accordance with the standards established by the Privacy Rule). For more information, including the list of identifiers that must be removed to de-identify health information, see [HIPAA and Human Subjects Research](#).*

Existing: Available or “on the shelf” (e.g., data, specimens) at the time the research is submitted for a determination of whether the research is exempt.



3. Research Eligible/Ineligible for Exemption

- A. Research that involves only activities listed in one or more of the categories specified in DHHS and/or FDA regulations (see Attachment 1) may be determined to be exempt.
- B. Research involving prisoners (with the exception of emergency use) may not be determined to be exempt.
- C. Research that is subject to FDA regulations may not be determined to be exempt under DHHS exemption categories.
- D. The exemption in DHHS regulations for research involving survey or interview procedures or observation of public behavior (Category 2) does not apply to research with children, except for research involving observations of public behavior when the investigator does not participate in the activities being observed.
- E. At The Ohio State University, proposed research may not be greater than minimal risk to be determined exempt.
- F. At Ohio State, the regulatory exemption categories are not applied to proposed research (regardless of whether the research would otherwise be exempt) involving coercion, undue influence, deception, or any practice that does not uphold the ethical principles of respect for persons, beneficence, and justice as described in the Belmont Report.

4. Exempt Determinations

Exempt determinations are made by designated ORRP staff who have no direct involvement in the proposed activity. Investigators are not permitted to make their own determinations of exemption. Additionally, ORRP staff must determine that the research meets the ethical standards described in the Belmont Report and that adequate participant protections are in place as described below.

A. Submission

Investigators must provide sufficient information about proposed research to determine whether it is exempt and, when appropriate, that protections are provided to participants by submitting an Exempt Research application in Buck-IRB, along with any required attachments. HRPP requirements for submission of non-exempt research (i.e., regarding PI eligibility, completion of human subjects education, etc.) also apply to exempt research.

B. Review

The criteria for exemption specified in DHHS regulations are applied unless the research is FDA-regulated. For research subject to FDA regulations, only FDA exemption categories apply.

In addition to applying the applicable exemption criteria, ORRP staff will make the following additional determinations (as applicable) to ensure protection of potential participants:

- The research involves no more than minimal risk



- Selection of subjects is equitable
- When identifiable information is to be recorded, there are adequate provisions to maintain the confidentiality of data
- There are adequate provisions to maintain the privacy interests of participants
- When there are to be interactions with participants, informed consent will be obtained by a process that will disclose adequate information, including that the activity involves research, participation is voluntary, a description of the procedures, and investigator contact information.

Upon review, ORRP staff will make one of the following determinations:

- The submission does not meet the federal definitions for research involving human subjects
- The proposed research activity **IS** exempt and may be conducted without IRB review
- The research is **NOT** exempt, and before performed, must be submitted for IRB review.

Up to two weeks may be required for processing applications. Additional time should be allowed for any modifications and/or clarifications that may be required as a result of review, for Privacy Board review of exempt research involving protected health information, and for resubmission to the IRB for review in the event the research is determined not to be exempt.

C. Notification

Exempt research activities may not begin until the investigator receives notification of the exempt determination by email through the Buck-IRB system. Notifications will include the exempt category or categories under which the determination was made.

D. Modifications

Only changes to research personnel that do not otherwise affect the research protocol or participant materials can be requested by submitting an amendment application in Buck-IRB. No personnel changes can be implemented until ORRP staff accept the changes and notify the investigators.

Additional modifications may not be made to exempt research because of the possibility that proposed changes may change the research in a way that it no longer meets the criteria for exemption. A new application for exempt determination must be submitted and reviewed prior to modifying the research activity or materials, unless the investigator believes that the change must be made to prevent harm to participants. All such changes must be reported to ORRP staff or the IRB.

5. Record Retention

Records of exempt determinations, including materials submitted and related correspondence, are retained by the Office of Responsible Research Practices in accordance with HRPP policy [[IRB Recordkeeping](#)]. Records will include the exempt



category or categories under which the determination was made or documentation as to why the research was judged not to be exempt.

6. Applicable Regulations/Guidance

21 CFR 56.104, 21 CFR 56.115, 45 CFR 46.101, 45 CFR 46.115, 45 CFR 46.201, 45 CFR 46.301, 45 CFR 46.401, OHRP “Human Subject Regulations Decision Charts” (09/24/04), “OHRP Guidance on the Involvement of Prisoners in Research” (05/23/03), OHRP Guidance “Exempt Research and Research That May Undergo Expedited Review” (05/05/95), OHRP Guidance “Exemption for Research and Demonstration Projects on Public Benefit and Service Programs”

7. History

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**Attachment 1.****Categories of Research That May Qualify for Exemption under Federal Regulations****DHHS Categories of Exemption**

1. Research conducted in established or commonly accepted educational settings (e.g., schools, colleges, and other sites where educational activities regularly occur), 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 participant; and
 - b. Any disclosure of the human subjects' 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.

Note: The exemption above for research involving survey or interview procedures or observation of public behavior does not apply to research with children, except for research involving observations of public behavior when the investigator does not participate in the activities being observed.

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 #2 above, if:
 - a. The human subjects are elected or appointed public officials or candidates for public office (Note: this applies to senior officials such as a mayor or school superintendent, rather than a police officer or teacher); or
 - b. Federal statute(s) requires(s) 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 publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.
5. Research and demonstration projects that are conducted by or subject to the approval of department or agency heads, and that 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; or



- d. Possible changes in methods or levels of payment for benefits or services under those programs.
 - e. Additional requirements (all must apply):
 - The programs 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 IRB; and
 - The project must not involve significant physical invasions or intrusions upon the privacy of participants.
6. Taste and food quality evaluation and consumer acceptance studies, if:
- a. Wholesome foods without additives are consumed; or
 - b. 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.

FDA Categories of Exemption

1. Any investigation that began before July 27, 1981, that was subject to requirements for IRB review under FDA regulations before that date, provided that the investigation remains subject to review of an IRB that meets the FDA requirements in effect before July 27, 1981.
2. Any investigation begun before July 27, 1981, that was not otherwise subject to requirements for IRB review under FDA regulations before that date.
3. Emergency use of a test article, provided that the emergency use is reported to the IRB within five working days. (Note: Any subsequent use of the test article at the institution is subject to IRB review.)
4. Taste and food quality evaluations and consumer acceptance studies, if:
 - a. Wholesome foods without additives are consumed; or
 - b. 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.