



EXEMPT RESEARCH

1. Overview

Research involving human subjects may be exempt from federal regulations requiring IRB review. 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

Benign behavioral interventions: Interventions that are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

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.

De-identified: All direct personal identifiers are *permanently* removed (e.g., from data or biospecimens), 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).

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.*

Limited IRB review: IRB review to ensure that there are adequate privacy and confidentiality safeguards for identifiable private information and identifiable biospecimens.

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.

Privacy Board: A committee established to review requests for a waiver or alteration of the HIPAA research authorization requirement for uses and disclosures of protected health information (PHI) in a particular research study.



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 may not be determined to be exempt except when the research examines a broader population that only incidentally involves prisoners.
- 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 educational tests (cognitive, diagnostic, aptitude, achievement) or observations of public behavior when the investigator does not participate in the activities being observed.
- E. The exemption in DHHS regulations for benign behavioral interventions (Category 3) does not apply to research with children.
- F. Research that has been determined to pose a minimal risk to subjects using survey, interview, or subject interventions and is identifiable must undergo a limited IRB review to ensure participant privacy and confidentiality are adequately protected.
- G. The proposed research may not be greater than minimal risk to be determined exempt.
- H. Research that includes both exempt and non-exempt activities cannot be determined to be exempt.
- I. The regulatory exemption categories are not applied to proposed research (regardless of whether the research would otherwise be exempt) involving coercion, undue influence, 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 and/or IRB members 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. For a list of exempt submission requirements, refer to HRPP Policy [\[IRB Submissions and Pre-Review\]](#).

B. Review

1. 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.
2. In addition to applying the applicable exemption criteria, ORRP staff and/or IRB members 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 and/or interventions 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.
3. Research involving requests for waivers and/or alterations of HIPAA research authorization for use or disclosure of protected health information (PHI) must undergo review by Ohio State's Privacy Board.
4. 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 proposed research activity **IS** exempt and may be conducted with limited IRB review
 - The research is **NOT** exempt, and before performed, must be submitted for IRB review.
5. With one exception*, when two or more institutions collaborate on exempt research, each institution must make its own exempt determination; Ohio State's HRPP will not issue exempt determinations for activities at external institutions. For more information, refer to HRRP policy [\[Research Performance Sites and Collaborative Off-site Research\]](#).

**Note: Under Ohio State's reciprocity agreement with Nationwide Children's Hospital (NCH), Ohio State may issue an exempt determination for collaborative research activities occurring at both institutions.*



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. Amendments

1. Except for minor study team changes, no amendments to exempt research are permitted because of the possibility that the revised research may no longer meet 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.
2. Research personnel changes 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.

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, documentation as to why the research was judged not to be exempt, documentation of Privacy Board review, and/or documentation of limited IRB review, as applicable.

6. Applicable Regulations/Guidance

21 CFR 56.104, 21 CFR 56.115, pre-2018 and Final Rule (45 CFR 46.101, 45 CFR 46.104, 45 CFR 46.109, 45 CFR 46.110, 45 CFR 46.115, 45 CFR 46.201, 45 CFR 46.301, 45 CFR 46.401), 45 CFR 164, OHRP "Human Subject Regulations Decision Charts" (02/16/2016), "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", OHRP "Exempt Research Determination FAQs"

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, involving normal educational practices, so long as the research is not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction, 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

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following three criteria is met:
 - The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
 - Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
 - The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to ensure adequate protections are in place for protecting privacy and maintaining confidentiality.

Note: The exemption under category 2 does not apply to research involving survey or interview procedures or observation of public behavior when individuals under the age of 18 are subjects of the activity except for research involving educational tests or observations of public behavior when the investigator(s) do not participate in the activities being observed.

3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
 - The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
 - Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to



the subjects' financial standing, employability, educational advancement, or reputation; or

- The information obtained is recorded in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to ensure adequate protections are in place for protecting privacy and maintaining confidentiality.

Note: If the research involves deceiving subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

4. Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

- The identifiable private information or identifiable biospecimens are publicly available;
- The information, which may include information about biospecimens, is recorded by the investigator in such a way that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, and the investigator does not contact the subjects, and the investigator will not re-identify subjects;
- The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated by the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, for the purposes of health care operations or research, or for public health activities and purposes as defined in HIPAA; or
- The research is conducted by, or on behalf of, a federal department or agency using government-generated or government-collected information obtained for non-research activities, provided that the original collection was subject to specific federal privacy protections and continues to be protected.

Note: The exemption under category 4 does not apply to research involving identifiable health information regulated by HIPAA when that information is sent to or received from external collaborators who are not part of covered entities under the Privacy Rule.

5. Research and demonstration projects that are conducted or supported by a federal department or agency, or otherwise subject to the approval of department or agency heads, and that are designed to study, evaluate, improve, or otherwise examine:

- 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 or services under those programs.

Note: Projects eligible for exemption under this category will be posted on the applicable federal agency's publicly accessible website.



6. Taste and food quality evaluation and consumer acceptance studies, if:
 - Wholesome foods without additives are consumed; or
 - 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.

7. Storage or maintenance of identifiable data and/or biospecimens obtained with “broad consent”

Note: Not available at Ohio State.

8. Use of identifiable data and/or biospecimens obtained with “broad consent”

Note: Not available at Ohio State.

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:
 - Wholesome foods without additives are consumed; or
 - 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.