

GUIDELINE FOR EXEMPT STATUS DETERMINATION

The Office for Human Subject Protection (OHSP) Policy 501 describes the levels of RSRB review for proposed research activities, including certain types of research which are exempt from the HHS regulations at 45CFR46.104. This guideline describes the regulatory categories and institutional standards for Investigators proposing research activities to the Research Subject Review Board (RSRB) to determine whether an exemption is applicable. The RSRB reserves the right to deny exemption requests whenever there is a concern for the welfare of human subjects.

1. Pre-Submission Regulatory Considerations

The RSRB will consider human subjects research Categories 1-8 of exemption as identified in the regulations 45CFR46.104(d) and 21CFR56.104. At this time, the RSRB is not implementing exemption 7 or 8 due to the lack of guidance from the federal government. An exempt status determination means the research is “exempt” from federal regulations such as annual review requirements and IRB notification of study closure. *There is an institutional requirement to use an information sheet(s), as needed, to support the ethical principle of “Respect for Persons”.* See *Appendix 1 Exemption Categories*, for descriptions and examples.

NOTE: Exemption categories do not apply to the following research activities:

- Research involving prisoners as a targeted or known population
- Category 2 – Research involving educational tests, survey or interview procedures involving children where information recorded is identifiable to the individual
- Category 2 – Observation of public behavior involving children (unless the Investigator/research team does not participate in the activities being observed)
- FDA regulated research (except Categories 5 and 6)

2. Investigator Submission Requirements

- a. The submitting Investigator must meet the qualifications and requirements of Principal Investigator (PI) as defined in OHSP [Policy 901 Investigator Responsibilities](#).
 - Note that a Department or School may require that a full time faculty member be listed as PI.
- b. When submitting an application for initial review, Investigators must include all applicable materials for submission listed in [Policy 502 Types of RSRB Submissions](#).
 - The [Social/Behavioral/Educational](#) or Secondary Analysis of [Specimens/Records](#) Protocol Template and [Information Sheets](#) may be utilized as applicable to ensure sufficient information is provided for the RSRB to make a review determination and that institutional standards are met.
- c. Upon receipt of an application by the RSRB Specialist, a pre-review of the submission will be completed (e.g., to verify whether the submission materials are completed, required education is completed, etc.). The Specialist makes an initial determination as to whether the activities involve human subject research (see OHSP [Guideline for Determining](#)

[Human Subject Research](#)) and is eligible for exempt review (i.e., meets regulatory qualifications). The Specialist may request more information from the Investigator or study team during this pre-review process for clarification or completeness of the application. Once the application is considered complete, the Specialist will proceed with review under the exempt review process, or may re-assign the application for consideration of expedited or convened board review if appropriate.

3. Exempt Review Procedures

a. Initial Review

- i. The RSRB Specialist will review the submission to ensure the research meets the institution's ethical standards, regulatory, and additional RSRB requirements, including but not limited to the following:
 - The research holds out no more than minimal risk to subjects.
 - There are adequate provisions to maintain subject privacy;
 - If there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of data (i.e., appropriate encryption measures are in place according to the [UR Information Technology Policies](#));
 - Selection of subjects is equitable;
 - If there is subject interaction, there is an adequate process to disclose the following information, at a minimum: activity involves research, description of the procedures, participation is voluntary, and the name and contact information for the Investigator or study team and the RSRB.
 - This process is typically achieved through an information letter or verbal script.
 - There may be certain research activities meeting an exempt status where written informed consent should be obtained and documented (e.g., obtaining written permission from parents for research involving educational strategies for their children, obtaining written informed consent to meet limited IRB review requirements, or used as appropriate to the culture in which the research is being conducted).
- ii. The application may be sent back to the Investigator or study team at any point during the review process prior to a final review determination, should more information or clarification be requested.
- iii. Once a review determination is made, the application does not need further review by the RSRB, as long as no changes are made.

b. Modifications to Research Previously Determined as Exempt

- i. The RSRB Specialist receives all information submitted to change the research, including the modification and revised study materials. These materials will be reviewed to ensure the research activities continue to meet the criteria for exemption.
- ii. If the research no longer meets the criteria for exemption based on the submitted changes, the Specialist will review the modification consistent with the appropriate review level (i.e., expedited or convened board review).

4. Exempt Review Determination and Notifications

- a. Once an initial exempt determination is made by the RSRB Staff, the study is sent to the designated RSRB reviewer to record the final review determination within the electronic submission system. Review determinations may be made by the RSRB Specialist (as determined in *Policy 401 Functions of the RSRB Office*) or an RSRB Experienced Member, as applicable to the exemption category.
 - *Note:* Research granted exempt status by the RSRB may be “exempt” from federal regulations; however, it does not mean that the research is exempt from RSRB oversight and the reporting of new information ([*Policy 801 Reporting Research Events*](#)). Compliance with institutional policies pertaining to security and privacy, and the Health Insurance Portability and Accountability Act (HIPAA) may also be required based on the activities being conducted.
- b. Investigators are notified of an exempt review determination according to OHSP [*Policy 403 Notification of RSRB Determinations*](#).
- c. Upon confirmation of an exempt determination, Investigators are required to follow the responsibilities outlined in the OHSP [*Summary of Responsibilities for Investigators Conducting Exempt Research*](#).

Appendix 1: Exemption Categories and Examples

1. Educational Research Conducted in Educational Settings

Research conducted in established or commonly accepted educational settings, specifically involving normal educational practices that are not likely to adversely affect students' opportunity to learn required educational content or the assessment of educators who provide instruction, such as

- (i) research on regular and special education instructional strategies; or
- (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

"Commonly accepted educational settings" include (but are not limited to) K-12 schools and college/university classrooms. They may also include after-school programs, preschools, vocational schools, alternative education programs, residency programs, and other sites where educational activities regularly occur.

"Normal educational practices" are activities that could occur regardless of whether the research is conducted. Examples include established teaching methods (not considered to be experimental) or curriculum, and commonly accepted classroom management techniques that are planned and implemented by the classroom teacher.

Examples of research that is exempt under Category 1:

- A study evaluating the effectiveness of a commonly accepted science curriculum. For the study, researchers will observe classroom instruction and collect quizzes and class evaluations that are part of the curriculum and classroom practice.
- A study comparing two curricula that are currently being implemented (or one that is current but recently replaced an older version). Researchers will observe classrooms as well as interview instructors about their experiences implementing the instructional materials and collect class evaluations.
- A study involving interviews of 3rd Grade teachers regarding their experiences and techniques with implementing new math standards. Researchers will obtain lesson plans and ask the teachers to provide reflective journals for one week.
- A study comparing driver's education curricula offered by area driving schools. The researcher will observe and compare group driving test scores at the end of the courses.
- A study comparing two current methods for teaching surgical residents a surgical technique. The study will involve classroom observation, interviews of the students, and surveys. .

2. Surveys/Interviews/Educational Tests/Observation of Public Behavior

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, if at least one of the following is met:

- (i) Information obtained is recorded in a manner such that identity of the human subjects cannot be readily ascertained, directly or through identifiers link to the subject (DE-IDENTIFIED);;
- (ii) Any disclosure of the human subjects' response 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, or reputation (NOT HARMFUL OR RISKY);
- (iii) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, and the RSRB conducts limited IRB review (IDENTIFIABLE AND POSSIBLY HARMFUL, BUT LIMITED IRB REVIEW CONFIRMS APPROPRIATE PRIVACY AND CONFIDENTIALITY PROTECTIONS)

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EXCEPTION: This exemption does not apply to research with children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

Public behavior:

Refers to behavior taking place in a publicly accessible location in which the subject does not have an expectation of privacy (e.g., a public plaza or park, a street, a building lobby, a government building, some websites and social media sites (where the user's account is set to public)). If subjects have a reasonable expectation of privacy (e.g., medical exam room, private office) at the location where the researcher is conducting the observation, the project may not be considered exempt.

(i) Anonymous:

- No identifiers can be connected to the data, either directly or through a coding system.
- Video/audio recordings, images and photographs are considered to be identifiable; therefore, any data collection that involves these activities would not be considered anonymous.
- Multiple pieces of information, none of which are identifiable on their own, may uniquely identify a person when brought together; in this case, the data would be identifiable and would not be considered anonymous.

(ii) Identifiable, but not harmful or risky:

- Allows for identifiable data to be collected, but the information is so innocuous that, in the event of disclosure outside of the research, there would be no detrimental consequences to the subject.

Examples of research that is exempt under Category 2:

- An anonymous survey about workplace satisfaction is given to employees at local businesses.
- An observational study of children playing in a public park; the researcher takes notes of what occurs, recording sex, race, and length of activity of children, but does not interact with subjects.
- A study in which college seniors (age 18 and older) are interviewed about their plans after graduation. The researcher will record their date of birth and give the participant an algorithm to create a unique code (e.g., the last 4 digits of your cell phone number + the first four letters of your mother's maiden name). This could be identifiable, but the answers to questions asked would present no risks to subjects if divulged outside the research.
- A study in which surveys are collected from patients about their about recent visit for treatment on depression, the Investigator has a very robust plan to protect the privacy of the subjects who participate and the confidentiality of the potentially risky data collected.
- A study involving an anonymous survey of college seniors regarding recreational drug use.

Examples of research that is NOT exempt under Category 2:

- Research involving interviews with the underage children about their TV habits. Research involving the survey of minors does not qualify for Category 2 exemption.
- An observational study where a researcher pretends to fall and records helping behavior in children in a public park. Observational research involving children does not qualify for Category 2 exemption in cases where the researcher will interact with participants.

3. Benign Behavioral Interventions

Research involving benign behavioral interventions in conjunction with collection of information from adult subjects through verbal or written responses or audiovisual recording, if the subject prospectively agrees to participate, and at least one of the following is met:

- (A) information obtained is recorded in a manner such that identity of the human subjects cannot be readily ascertained, directly or through identifiers link to the subject (DE-IDENTIFIED);
- (B) 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 or reputation (NOT HARMFUL OR RISKY);
- (C) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects and the RSRB conducts limited IRB review (IDENTIFIABLE, BUT LIMITED IRB REVIEW CONFIRMS APPROPRIATE PRIVACY AND CONFIDENTIALITY PROTECTIONS).

Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on subjects, and the Investigator has no reason to think subjects will find the intervention(s) offensive or embarrassing.

The research may only involving deceiving subjects as long as the subject authorizes the deception through prospective agreement to participate in which the subject is informed that he or she will be unaware of or misled regarding the nature or purpose of the research.

EXCEPTION: *This exemption does not apply to research with children.*

Examples of possible benign behavioral interventions:

- Asking subjects to physically manipulate an object
- Asking subjects to play a game
- Asking subjects to complete a specific physical action
- Activities such as reading, writing, looking at visual stimuli, listening to auditory stimuli, music lyrics, or imagining something may be tasks, or may instead simply be part of questions being asked.
- Playing an on-line game
- Solving puzzles under various noise conditions
- Additional examples provided by [OHRP Guidance and Educational Tool for Benign Behavioral Interventions](#).

Research procedures in this exempt category should generally be limited to:

- *communication or interpersonal contact with the subject,*
- *the performance of a cognitive, intellectual, educational or behavioral task, or*
- *manipulation of the subject's physical, sensory, social, or emotional environment*

Data collection in this exempt category is limited to:

- *verbal (oral) or written responses by the subject*
- *data entry by the subject*
- *observation of the subject*
- *audiovisual recording*

This category does not include the use of activity monitors (e.g., FitBit, actiwatch, pedometer, activity tracking apps, etc.).

4. Secondary Research Use of Identifiable Private Information or Identifiable Biospecimens

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

- i) if these sources are publicly available;
- ii) if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly, or indirectly through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
- iii) research involves only information collection and analysis involving use of identifiable private information that is regulated under HIPAA;
- iv) 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.

Examples of research that is exempt under Category 4:

- Obtaining an identifiable data set from a commercial entity for a fee.
- Analyzing identifiable data from medical records for which Investigator has routine access and is part of the covered entity (i.e., HIPAA regulations).

A copy of the data or specimen collection sheet(s) must be submitted.

5. Evaluation of Public Benefit or Service Program

Research and demonstration projects which are conducted or supported by a Federal department or agency, or otherwise subject to the approval of Department or Agency heads, and which are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under such programs, possible changes or alternatives to the programs, or possible changes in methods or levels of payment for benefits or services under the programs. The Federal department or agency conducting or supporting the research must establish a publicly accessible Federal website with a list of the projects, inclusive of the proposed research prior to commencing the research.

Example of research that is exempt under Category 5:

- Food stamps, AFDC, welfare reform

6. Taste and Food Quality Evaluation

Taste and food quality evaluation or consumer acceptance studies:

- i) if wholesome foods without additives are consumed, or
- ii) if 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 FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Example of research that is exempt under Category 6:

- Taste comparison of two marketed nutritional drinks.

- 7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §__.111(a)(8).**

The RSRB is not implementing this exemption at this time due to the lack of guidance from the federal government.

- 8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:**

- (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §__.116(a)(1) through (4), (a)(6), and (d);
- (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §__.117;
- (iii) An IRB conducts a limited IRB review and makes the determination required by §__.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

The RSRB is not implementing this exemption at this time due to the lack of guidance from the federal government.