ILLINOIS
Office for the Protection of Research Subjects

Research Guidance Document

EXEMPT RESEARCH

What Does "Exempt" Mean?

Exempt studies are minimal risk and fit within a set of established exemption categories. Studies that qualify for exemption are only required to adhere to certain federal regulations and must also follow state laws and University policies applicable to research. Studies that qualify for exemption must adhere to principles of sound research design and ethics. Participant rights and welfare must also be protected in a manner appropriate for research that poses minimal risk.

Exemption determinations are made by the IRB and may not be made by the individual investigator. IRB review of exempt studies ensures that these standards and requirements are met prior to initiation of the research (see the IRB Responsibilities Related to Exempt Research section).

Studies that receive an exemption do not expire and are not required to obtain continuing review from the IRB; thus, continuing review applications are not required. However, the IRB must review any substantive changes to the study, via an amendment application, to ensure the study still qualifies for exempt status in light of the changes. Substantive changes include, but are not limited to the following:

- Changes that increase the risk to participants or change the risk:benefit ratio of the study
- Changes that affect a participant's willingness to participate in the study
- Changes to study procedures or study components that are not covered by the Exemption Category determined for this study (listed below)
- Changes to the study sponsor
- Changes to the targeted participant population
- Changes to the stamped consent document(s)

Research Team changes (addition or removal of investigators or study personnel) require an amendment even though it is not a substantial change to the research itself. These amendments are required as the institution is required to confirm education, training and potential conflicts of interest for all research team members.

Investigators should contact the OPRS Office if there are questions about whether an amendment consists of substantive changes.

Exempt studies must adhere to the University of Illinois Urbana-Champaign IRB reporting requirements for unanticipated problems and deviations. Exempt studies must be closed with the IRB once the research activities are complete.

Research Regulated by the Department of Health and Human Services (DHHS)

The Department of Health and Human Services has identified certain categories of research involving human subjects that qualify for exemption from certain federal regulations applicable to research. At

the University of Illinois Urbana-Champaign, the IRB makes federal exemption determinations (categories 1-8) according to 45 CFR 46.104.

- Subpart B (Pregnant women, fetuses and neonates): Each of the exemptions may be applied to research subject to subpart B if the conditions of the exemption are met.
- Subpart C (Prisoners): The exemptions at this section do not apply to research subject to subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners.
- Subpart D (Children): The exemptions may be applied to research subject to subpart D except for category 3. For category 2, children may only be involved as outlined below.

Research Regulated by the Food and Drug Administration (FDA)

The Food and Drug Administration does not have categories of research that qualify for exempt status like those listed by DHHS. The FDA does not exempt any research under its jurisdiction from IRB review except in extremely limited circumstances (e.g. emergency use, taste and food quality studies, etc.).

Research that is Not Federally Funded or Regulated

The University of Illinois Urbana-Champaign has elected to apply its Federal-wide Assurance to all funded and unfunded research which requires adherence to the Common Rule.

Obtaining Informed Consent in Exempt Research

Informed consent is a practice that helps to ensure that the rights and welfare of participants are protected. The IRB requires that informed consent from participants be obtained when it is reasonable and practicable to do so. Justification for waiving the informed consent process must be provided in the submission to the IRB.

The informed consent process may or may not include a consent document. The IRB requires that the consent process disclose at least the following information to potential participants:

- That the activity involves research
- A description of the procedures
- That participating is voluntary
- Name and contact information for the investigator
- UIUC Confidentiality Statement

Other information may be provided to the potential participants as appropriate in order for participants to make an informed decision.

Consent documents processed for exempted research are marked with an IRB stamp in the footer; however, because the project does not expire or require continuing review, no expiration date will appear with the stamp. The document may be used for the exempt study until another approved document supersedes it, or until the project is closed. Investigators should only use the most recent version of the document with the IRB approval stamp in the footer.

IRB Responsibilities Related to Exempt Research

The IRB ensures valid claims of exemption by reviewing the proposed research via an IRB application. A designated IRB member determines that the study is exempt from further IRB review and from applicable federal regulations governing human research, under 45 CFR 46.104. All research involving human subjects must be approved or exempted by the IRB before the research is conducted.

The IRB determines that the study is in compliance with applicable laws and regulations, including the HIPAA Privacy Rule, state law, and institutional policy.

Investigator Responsibilities Related to Exempt Research

1. The investigator submits proposed research to the IRB for review when exemption eligibility is anticipated. The investigator only begins research activities after documentation of IRB approval or exemption is received.
2. The investigator ensures that the study is conducted in compliance with applicable laws and regulations, including the HIPAA Privacy Rule, state law, and institutional policy.
3. The investigator ensures that the study conforms to the principles of sound research ethics, in accordance with principles of the Belmont Report, including but not limited to:
    a. Ensuring the research presents no more than minimal risk to participants;
    b. Selecting subjects equitably;
    c. If there is recording of identifiable information, maintaining the confidentiality of the data;
    d. If there are interactions with participants, conducting a consent process that will disclose such information as:
        - That the activity involves research
        - A description of the procedures
        - That participating is voluntary
        - Name and contact information for the investigator
        - UIUC Confidentiality Statement
    e. Maintaining the privacy interest of participants;
    f. Conducting the research in an ethical manner which does not adversely affect the rights and welfare of the participants.
4. The investigator conducts the research in compliance with the protocol as submitted to and exempted by the IRB.
5. The investigator obtains approval for any substantive changes to the protocol prior to implementing the changes.
6. The investigator adheres to IRB policy for reporting unanticipated problems and deviations.
7. The investigator adheres to all other the terms outlined in the Investigator's Statement of Assurance.

References & Links

- **45 CFR 46.104 Exempt Research**
  http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101(b).

- Bankert, E.A. and Amdur, R.J. **Institutional Review Board Management and Function, Second Edition** (2006). Jones and Bartlett Publishers, Inc.
- **OPRS SOP 402: Research Activities Exempt from IRB Review:** To be updated

EXEMPT CATEGORIES OF RESEARCH

Federal Exemption Categories (1-8)

1. **Research conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies and 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 criteria is met:**
   - **i.** The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects. Children may be included in the research involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities observed; **or**
   - **ii.** 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. Children may be included in the research involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities observed; **or**
   - **iii.** The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained, directly or through identifiers linked to the subjects, and a limited IRB review is conducted to make the determination that when appropriate, the research plan makes adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. This section may not be applied to research including children.

3. **Research involving benign behavioral interventions in conjunction with the collection of information from an adult (children may not be included in this exemption category) 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:**

i. 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; **or**

ii. 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**

iii. 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 a limited IRB review is conducted to make the determination that when appropriate, the research plan makes adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

For the purpose of this provision, benign behavioral interventions 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. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving the 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 or misled regarding the nature or purposes of the research.

4. ***Secondary research for which consent is not required.*** **Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:**

   i. The identifiable private information or identifiable biospecimens are publicly available; **or**

   ii. Information, which may include information about biospecimens, 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, the investigator does not contact the subjects, and the investigator will not re-identify subjects; **or**

   iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR 160 and 164 for the purposes of "health care operations" or "research" or for public health activities and purposes"; **or**

   iv. 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, if the research generates identifiable private information that is or will be maintained on information technology that is in compliance with applicable laws/privacy protections**.**

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 (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve or otherwise examine public benefit or service programs, including 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.**

6. **Taste and food quality evaluation and consumer acceptance studies:**
   - **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.

7. ***Storage or maintenance for secondary research for which broad consent is required.*** *The University of Illinois Urbana-Champaign IRB does not utilize broad consent. Because this exemption category is intended for research using broad consent, this exemption category is not applied at the University of Illinois Urbana-Champaign.* **Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if a limited IRB review is conducted and broad consent will be obtained.**

8. ***Secondary research for which broad consent is required.*** *The University of Illinois Urbana-Champaign IRB does not utilize broad consent. Because this exemption category is intended for research using broad consent, this exemption category is not applied at the University of Illinois Urbana-Champaign.* **Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria is met:**
   - **i.** Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained; **and**
   - **ii.** Documentation of informed consent or waiver of documentation of consent was obtained; **and**
   - **iii.** A limited IRB review is conducted to make the determination that when appropriate, the research plan makes adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data and the research to be conducted is within the scope of the broad consent; **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.