Cornell University
Office of
Research Integrity and Assurance

DISCLAIMER: This document has not been updated to reflect regulatory changes effective January 21, 2019.

Human Research Participant Protection Program

Policy 2: Submission Requirements and Procedures for Requests for Exemption from IRB Review

1. Subject

Some types of research activities meet Cornell's definition of human participant research, but do not require review and oversight by the Institutional Review Board (IRB). These types of research projects are known as "exempt" because they are exempt from the requirements of IRB review and approval. This policy describes the criteria under which an exemption may be granted, and the procedures for applying for an exemption.

2. Policy statements

- A PI **may not** self-determine that his or her own research protocol qualifies for exemption from IRB review.
- A PI requesting an exemption must submit a Request for Exemption from IRB Review form to the Office of Research Integrity and Assurance (ORIA). The IRB staff in ORIA will determine if the research project meets the eligibility requirements for exemption from IRB review.
- If the research activities are not eligible for exemption, the research project must receive either expedited or full committee review by the IRB.
- Research activities may not commence until the PI receives a written notice of exemption from ORIA.
- Changes to any of the research activities or materials must be reviewed by the IRB staff to verify that the project continues to be eligible for exemption from IRB review.
- Researchers are responsible for ensuring full and continuing compliance with all University and IRB policies in the conduct of their research.

3. Procedures

3.1. After determining that his/her research constitutes research with human participants (*see* Policy 1: Determining Whether a Research Activity Needs IRB Review and Approval), a PI should submit a Request for Exemption form to the IRB office (e-mail to irbhp@cornell.edu), along with copies of study related materials (e.g., recruitment materials, consent forms, surveys, questionnaires, interview scripts/outlines, etc.). Instructions on how to complete and submit the form and additional guidance are available on the IRB website at http://www.irb.cornell.edu/.

3.2. Upon review of the application materials, if the IRB staff determines that the research project qualifies for exemption (see criteria in Section 4 of this document), they will issue a formal written notice to the PI via email. The review process for Requests for Exemption normally takes 5-10 business days.

3.3. A copy of the exemption notice and all submission documents will be archived by ORIA until five years after the termination of the research activity. The PI should maintain these documents for a period of five years after the research activity has concluded and all publications and/or reports have been accepted.

3.4. Protocols that are recognized as exempt from IRB review do not require continuing review (i.e., annual renewal of exemption is not necessary). However, for each change that is proposed or may need to be made while conducting the research, the PI should submit an amendment request so IRB staff can evaluate whether the change affects the research project's eligibility for exemption from IRB review. The PI must receive a written notice confirming that the project remains exempt before implementing the change in the research activities.

4. Criteria for granting exemption from IRB review

4.1. Research Activities that cannot be granted exemption from IRB review (other exclusions are specified in the criteria 1-6 below)

- Research involving prisoners.
- Research involving active collection of biological specimens or conducting biomedical/psychophysiological procedures.

4.2. Research Activities that may be granted Exemption from IRB review: If the proposed research activities are such that the **ONLY** involvement of human participants will be in one or more of the following categories, they may qualify for exemption:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: regular and special education instructional strategies, or effectiveness or comparison of instructional techniques, curricula, or classroom management methods.

2. Research involving one or more of the following:

i. Educational tests (cognitive, diagnostic, aptitude, achievement):

a. If the information is recorded in a manner that individuals **cannot** be identified (directly or through identifiers linked to the individual), OR

b. If the information may be recorded in a manner that individuals can be identified (directly or through identifiers linked to the individual), but disclosure of the information could **NOT** reasonably place the participants at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.*****

ii. Survey or interviewer procedures (*this exemption category does not apply to research activities with minors/children*):

a. If the information is recorded in a manner that individuals **cannot** be identified (directly or through identifiers linked to the individual), OR

b. If the information may be recorded in a manner that individuals can be identified (directly or through identifiers linked to the individual), but disclosure of the information could **NOT** reasonably place the participants at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.*****

iii. **Observation of public behavior:**

For minors/children: Observation of public behavior of minors is eligible for exemption only if the researcher **does not** participate in the activities being observed.

For non-minors: Generally considered exempt from IRB review as follows:

a. If the information is recorded in a manner that individuals **cannot** be identified (directly or through identifiers linked to the individual), OR

b. If the information may be recorded in a manner that individuals can be identified (directly or through identifiers linked to the individual), but disclosure of the information could **NOT** reasonably place the participants at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.*****

***Note:** Risks of criminal or civil liability, or of damage to financial standing, employability, or reputation can be dependent on the context of the research and are determined by the IRB staff based on experience, past precedent and benchmarked best practices. The IRB staff welcomes the input of investigators in determining the possibility of such risks, but if there is reasonable doubt about whether or not criteria b. applies, the research is not exempt.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interviewer procedures, or observation of public behavior, but is not eligible for the above exemption (2), can be exempted if the research participants are **elected or appointed public officials or candidates for public office**, or federal statute requires 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 *(i.e., existing before the request for exemption is submitted to ORIA to determine whether the research is exempt)* data, documents, records, pathological specimens, or diagnostic specimens:

   i. If these sources are publicly available; OR

   ii. If the sources are not publicly available, but the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.******

****Example:** A PI who receives restricted access data, but stores the data in a secure environment such as the Cornell Restricted Access Data Center (CRADC), may be eligible for

exemption under this category if s/he is not recording identifiable private information into her/his own research records, or is not merging datasets that may lead to identification of individuals. However, PIs should be advised that the owner of the dataset or funding agencies may have their own policies requiring IRB review.

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, evaluate, 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.

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.

5. Regulations and Guidance Applicable to Exemption from IRB Review for Research with Human Participants

5.1. Federal Regulations

Cornell has filed a Federal Wide Assurance (FWA) with the Office for Human Research Protections (OHRP) of the U.S. Department of Health & Human Services guaranteeing its application of the federal policy for the protection of human participants in 45 CFR 46 when engaging in human participant research funded by the Public Health Service (PHS). According to institutional policy, the same standards apply to all human participant research, regardless of funding support.

- Eligibility of certain research protocols to be exempt from IRB review: 45 CFR 46.101(b) http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101
- OHRP has developed Decision Charts for guidance on eligibility for exemption from regulatory requirements for IRB review: http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c2

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