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Institutional Review Board (IRB)

HUMAN RESEARCH PARTICIPANT PROTECTION PROGRAM

Procedure 2
Submission requirements and procedures for requests for exemption from IRB review

1. Subject

Some types of research activities meet the International Institute for Restorative Practice's (IIRP) 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

2.1 A principal investigator (PI) may not self-determine that his or her own research protocol qualifies for exemption from IRB review.

2.2 A PI requesting an exemption must submit a Request for Exemption from IRB Review form to the IRB Committee. The IRB Committee will determine if the project meets the eligibility requirements for exemption from IRB review.

2.3 If the research activities are not eligible for exemption, the research project must receive either expedited or full committee review by the IRB.

2.4 Research activities may not commence until the PI receives a written notice of exemption from the IRB Committee.

2.5 Changes to any of the research activities or materials must be reviewed by the IRB Committee to verify that the project continues to be eligible for exemption from IRB Review.

2.6 Researchers are responsible for ensuring full and continuing compliance with all IIRP 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 Procedure 1: Determining Whether a Research Activity Needs IRB Review and Approval), a PI should submit a Request for Exemption form to the IRB Committee via email to fridarundell@iirp.edu, along with copies of study-related materials (e.g., recruitment materials, consent forms, surveys, questionnaires, interview scripts/outlines, etc.).

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

3.3 A copy of the exemption notice and all submission documents will be archived by the IRB 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 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 criteria 1-6 below)

- Research involving prisoners.
- Research involving active collection of biological specimens or conducting biomedical/psychophysiological procedures.
- Research involving children.
- Research involving economically disadvantaged individuals.
- Research involving physically or mentally disabled individuals.

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:

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

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

ii. 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.*

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

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

ii. 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.*

c. 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:

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

ii. 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 Committee based on experience, past precedent and benchmarked best practices. The IRB Committee welcomes the input of investigators in determining the possibility of such risks, but if there is reasonable doubt about whether or not criteria ii 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 the IRB Committee to determine whether the research is exempt*) data, documents, records, pathological specimens or diagnostic specimens:

a. If these sources are publicly available; OR

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

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 to obtaining benefits or services under those programs, possible changes in alternatives to those programs or procedures, or possible changes to methods or levels of payment for benefits under those programs.

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

5.1 Federal regulations

- IIRP 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 to the federal policy for the protection of human participants in 45 CFT 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