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Institutional Review Board (IRB)

HUMAN RESEARCH PARTICIPANT PROTECTION PROGRAM

Procedure 1
Determining whether a research activity needs IRB review and approval

1. Subject

All research activities that involved the collection of information through intervention, interaction with, or observation of individuals, or the collection or use of private information about individuals, must be evaluated to determine whether they constitute human participant research, and the type of review required before the research activities can begin. This policy provides guidelines for making this determination and outlines the appropriate review requirements.

2. Scope

All International Institute for Restorative Practices (IIRP) IRB policies and procedures apply to all human participant research projects conducted by IIRP faculty, staff or students, or by anyone conducting research in which the participation of IIRP meets the definition of engagement as indicated by the Office of Human Research Protections (OHRP) (http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html).

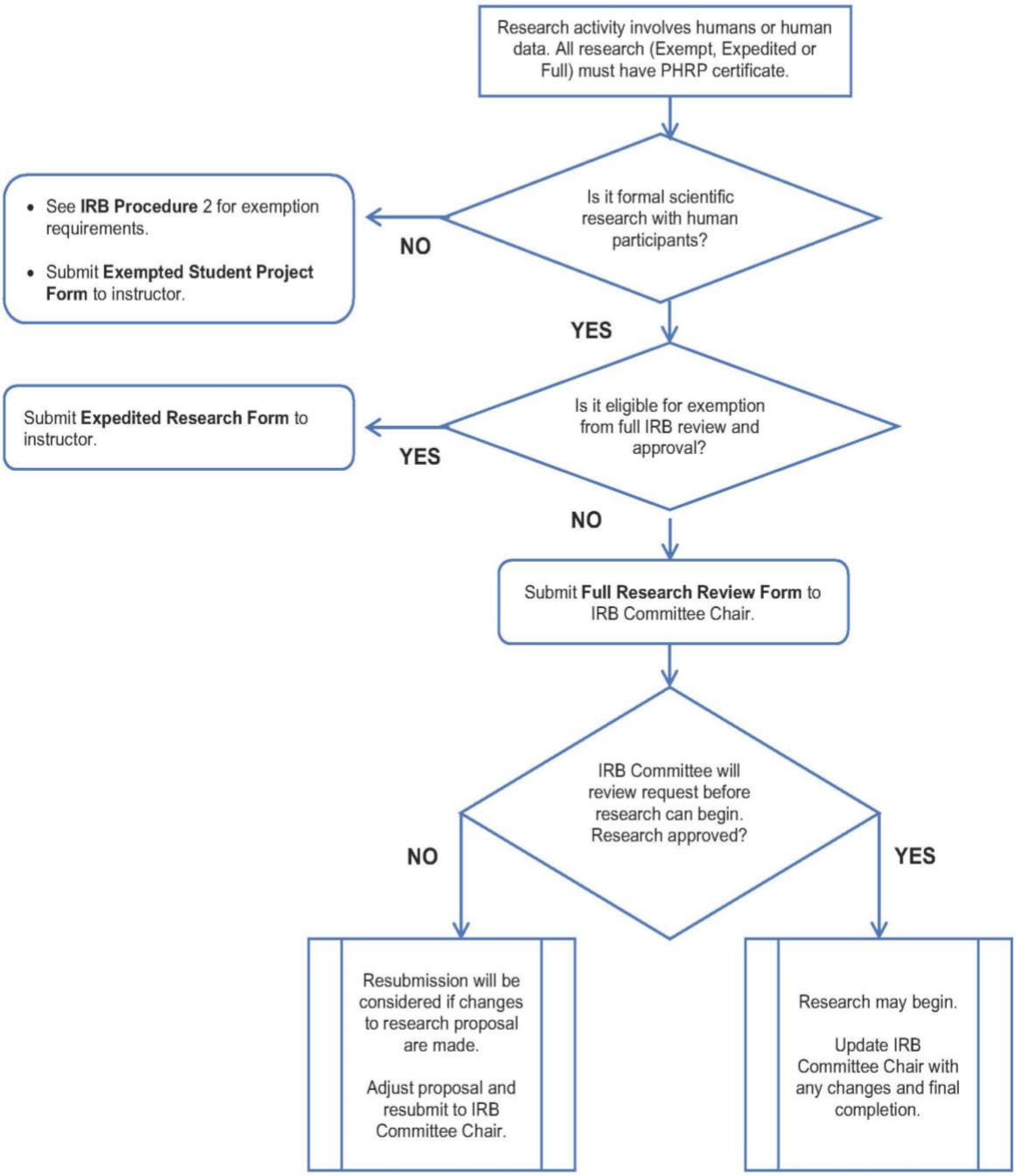
3. Policy Statements

- The researcher is responsible for ensuring full and continuing compliance with all IIRP and IRB policies in the conduct of his/her research.
- A researcher may, in consultation with the IRB Committee or using the flowchart, make a self-determination whether the proposed research activity does or does not constitute human participant research.
- If the research activity does not constitute human participant research, the researcher may initiate the research without review or approval by the IRB Committee.
- If the research activity does constitute human participant research, the researcher must submit a completed application to the IRB Committee for review. Research activities may not commence until the researcher receives a written letter of IRB approval or a notice of exemption from IRB review. Investigator self-experimentation is considered to be research with human participants (see Addendum).

4. Procedures

Consult this flowchart for an outline of next steps.

ALL STUDENTS MUST OBTAIN PHRP TRAINING CERTIFICATION
PRIOR TO UNDERTAKING RESEARCH INVOLVING HUMAN SUBJECTS



4.1 Research activities that do <u>not</u> constitute Human Participant Research

- The Principal Investigator (PI) should consult the flowchart to determine whether the research activity does or does not constitute human research.

- If the PI determines that the research activity does not involve human participant research, s/he may initiate the project without seeking approval from the IRB Committee for the research, and is not required to complete the NIH Human Participant training.
- For each change that is proposed or occurs during the execution of the research, the PI may need to re-consult the IRB flowchart to determine whether the change affects the classification of the project as "not human participant research."

4.2 Research activities that do constitute Human Participant Research

- If the research activity does not involve human participant research, the PI must complete and submit to the IRB Committee a Request for Exemption from IRB Review form or an Initial Approval Request form and instruments required for review.
- No research activities may begin until the PI receives a written letter of IRB approval or notice of exemption for the protocol from IRB.

4.3 Research activities that are eligible for Exemption from IRB review

- If the IRB Committee determines that the research project is human participant research but eligible for exemption from IRB review, the IRB Committee will issue a formal notice of exemption to the PI.
- A copy of this notice and all submission documents will be archived by the IRB Committee until five years after the termination of the research activity. In addition, the PI should maintain these documents for a period of five years after the research has concluded and all publication and/or reports have been accepted.
- For each change that is proposed or occurs during the execution of the research activity, the PI should consult with the IRB Committee to determine if the change affects the eligibility of the research activity to continue to be exempt from IRB review and approval.
- Consult *IRB Procedure 2: Submission requirements and prcedures for requests for exemption from IRB review* for requirements and procedures for review and continuing approval of requests for exemption.

4.4 Research activities that require IRB Review and Approval

- For research activities that are determined to require IRB review and approval, the IRB Committee will review applications and instruments for completeness and consistency, and will also confirm completion of Human Participant Research training requirements. The IRB Committee will then forward the materials to the IRB for review and approval via the Expedited Review Process); see flowchart.
- Research activities that do not qualify for expedited review will undergo Full Committee Review.
- All personnel named on the protocol must complete the NIH human participant training *before* the IRB can approve the protocol.

5. Regulations and Guidance Applicable to Human Participant Research Determination

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 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). By institutional policy, the same standards apply to all human participant research, regardless of funding support. IIRP's appointment of an appropriately constituted IRB is included in the FWA.

- Requirement for IRB review and approval of human participant research before its initiation: 45 CFR 46.108(b).
- Definitions of human participant research: 45 CFR 46.101-103.

5.2 Ethical codes

- The Nuremberg Code (1948) (https://history.nih.gov/research/downloads/nuremberg.pdf)
- The Belmont Report (1974) (http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/)
- Declaration of Helsinki (last revised in 2013) (http://www.wma.net/en/30publications/10policies/b3/index.html)

Addendum

Investigator Self-Experimentation

Federal regulations are silent on the matter of researchers who want to participate in their own studies. However, the regulations do not distinguish between self-experimentation and research on people who are recruited for a specific project. As part of its commitment to the protection of the rights and welfare of individuals participating in research, IIRP requires investigators who wish to act as participants in their own studies to submit for review and approval following standard procedures outlined in the IRB policies.

Though investigator self-experimentation may not raise the conventional ethical concerns outlined in the Belmont Report (http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/), all human research projects should undergo ethical review to assure the safety of people involved and the integrity of the research at the institution. While researchers may be aware of the risks of self-experimentation, they may also be more willing to accept risks that are ill advised. Application for review with the IRB Committee allows a neutral third party to raise concerns and/or propose measures to promote the welfare of researchers.