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International Research

Introduction

IRB review of international research raises additional considerations related to obtaining local knowledge of applicable laws, institutional commitments and regulations, standards of professional conduct and practice, cultural norms, and local community attitudes. Physical, social and psychological risks may vary from those the OHSU IRB is accustomed to reviewing. Assessing the risks and benefits of research conducted internationally may raise challenges if there is not adequate knowledge of the local setting. Care must be taken to ensure that the cultural norms of the host country are respected and that the participants will not suffer adverse consequences from participation, such as being subjected to retaliation from local authorities or the local community.

This Help Sheet is a supplement to **WORKSHEET HRP-410: Additional Criteria International**, which the IRB uses in reviewing research that is conducted by an OHSU investigator or student outside of the United States.

You can help your review go smoothly by ensuring that all of the applicable items on the worksheet are addressed in your protocol or International Supplement form.

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1. General Guidelines

- A. When an OHSU investigator conducts human subject research at a non-US site, the OHSU IRB has oversight authority for that research.
- B. The OHSU IRB and the PI will ensure that research under its jurisdiction conducted at international sites complies with the Common Rule or an equivalent system of human subjects protections. Special focus will be on the following:
 - Whether necessary information has been provided about the local research context,
 - If the consent process is appropriate to the population and procedures, and
 - If adequate provisions are outlined for data and safety monitoring.

- C. The IRB and investigators have an obligation to be knowledgeable about the setting where the research is to be performed. IRB review of research studies that involve human subjects in other countries must include appropriate expertise for evaluation of the study in the context of the specific international setting(s) and study population(s).
- D. OHRP requires knowledge of local research context and the IRB may secure knowledge of the local context in a variety of ways.
 - It should be determined whether a local IRB or other analogous review body exists to provide local context and guidance. Evaluation of the protocol by a review board local to the study site, consultation with an expert in the respective country, and/or other means to obtain knowledge of the local context is required.
 - The level of risk, amount of community involvement, logistical complexity, and potential for interaction with local laws will dictate the type of local level review that is required.
- E. The informed consent process and documents must be in a method and language that is understandable and culturally appropriate to the proposed participants.

2. Investigator's Responsibilities

- A. The investigator is responsible for identifying and ensuring compliance with all applicable laws, regulations, and guidelines for human subjects research in the country(ies) where the research will be conducted. This may include visa requirements for OHSU/American researchers in foreign countries, governmental approval for non-citizens to conduct research, etc.
- B. The investigator is responsible for completing the International Supplement and including it with the IRB application. This document helps provide the IRB with the necessary information to evaluate the research in light of the local research context.
- C. Allow at least 6 extra weeks for an international review.

3. Inducements in Low Resource Settings

- A. Inducements are permissible provided the IRB is satisfied that the amount or nature of the inducement is not unduly influential or coercive.
 - For monetary incentives, find out the local relative value.
 - For non-monetary, consider whether it would impair one's ability to make a rational decision (note that some study related benefits, such as more frequent check check-ups, may not be avoidable)
- B. Seek advice from local IRB/ethics committee or persons knowledgeable about local context.
- C. Recognize the tensions that are unavoidable in some circumstances.

4. Informed Consent Issues

- A. The consent process must incorporate a delicate balance of the typical IRB requirements (procedural and ethical) and local cultural norms.
 - Respect for persons includes respect for local culture.
 - Autonomy may include desire to confer with family, community, clergy and others.
 - Respect for community hierarchies may require a series of permissions to be obtained before individual consent is obtained.
 - Refer to the 2001 report by National Bioethics Advisory Commission for an excellent discussion of this issue.
 - Consultation with local IRB may also be helpful in ascertaining local norms for informed consent, documentation, and parental permission requirements.

- B. IRBs must be satisfied that translations are accurate. This can be accomplished through various methods.

5. IRB Review

- A. The IRB will review the study in accordance with 45 CFR 46 and secure adequate information regarding local context.
- B. The IRB will take into consideration input from local experts.
- C. If necessary, the IRB Chair will communicate with local IRB's and experts to facilitate review.

D. Risk of Harm

- The IRB should determine whether the study design anticipates and minimizes the political, social, economic and legal risks that are particular to prospective human subjects or their communities in the particular country and subculture.
- The IRB should determine whether the risks of adverse events are likely to be different in this population than in the same research performed elsewhere.
- The IRB should determine whether adequate care is readily available for injuries sustained in the course of research.

E. Justice/Benefit

- The IRB should determine whether the study is responsive to the needs of the subject population and whether the benefits of the study will be available to this human subject population. In other words, researchers may not utilize a human subject population merely for their own convenience and without the prospect of benefit to that population. Consideration should be given to producing benefits for the population that will continue after the termination of the study.
- If the study includes an experimental health treatment intervention, the IRB should determine whether an established effective treatment exists and whether it is available to this subject population. Incorporation of a placebo arm for a study when an effective treatment exists is always a serious ethical issue, but scrutiny must be particularly intense when there are additional issues of potential vulnerability in the subject population. If it is determined that the research intervention is an effective treatment, the IRB must determine whether it will be available to the human subjects and the subject population following completion of the research study.
- Regulations discourage consideration of long term impact of applying the results, but social justice considerations compel the IRB to ask about how the results will be used, assuming that the research addresses a local need.

Additional Resources

[World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects.](#)

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, [The Belmont Report - Ethical Principles and Guidelines for the Protection of Human Subjects of Research](#), April 18, 1979.

U.S. Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP), [Report of the HHS Equivalent Protections Working Group](#), 2003.

National Bioethics Advisory Commission, Rockville MD, [*Ethical and Policy Issues in International Research*](#), 2001.

The Council for International Organizations of Medical Sciences (CIOMS). [*International ethical guidelines for biomedical research involving human subjects*](#). Geneva, Switzerland: The Council for International Organizations of Medical Sciences (CIOMS), 2002.

U.S. Office for Human Research Protections' (OHRP, formerly OPRR) [*Protecting Human Research Subjects Guidebook*](#) (1993), Chapter VI, "Special Classes of Subjects."

OHRP Website:

[International Issues Page](#)

[International Compilation of Human Subject Research Protections](#)

[Terms of the Federalwide Assurance \(FWA\)](#)

Harvard School of Public Health: [*Global Research Ethics Map*](#)