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Subject: Reviews Requiring Special Consideration
Division: IRB
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IRB Policy 110.2: INTERNATIONAL RESEARCH

Policy

All FRI research performed outside of the United States (50 states and the U.S. territories) will be subject to the following FRI policy, to ensure the protection of human subjects in international research studies and to comply with OHRP directives [August 27, 1998, updated July 21, 2000] requiring local context review of such studies.

Protocol review and approval is required by the outside country's IRB, Ethical Review Committee, or equivalent organization, and FRI's IRB.

If foreign collaborators do not have their own IRB or comparable review committee, they may designate another IRB willing to review the research as the IRB of record. That IRB could be FRI's IRB or another IRB in the host country.

If foreign collaborators do have their own IRB or comparable review committee, the FRI investigator must ensure that the host country's IRB has had current education and training in Fundamental Human Research Protections and that it has procedures in place to ensure that subjects will be protected in a manner commensurate with the Common Rule. These procedures must be described in an agreement called an "assurance of compliance" with OHRP.

The federal regulations acknowledge that local customs, norms, and laws where the research will take place may differ from the Common Rule and provide options for listing different standards in foreign assurances of compliance. Optional standards include, among others, the Canadian Tri-Council Policy, the Indian Council of Medical Research, and the CIOMS International Ethical Guidelines (biomedical).

FRI IRB Review

All of the FRI IRB policies for research studies conducted within the United States apply to international research. In addition international research protocols should include:

1. Explanations of cultural differences that influenced the study design and the consent process;

2. Rationale for conducting the study with an international population;

3. Information regarding the host country's IRB, Ethical Review Committee or equivalent organization and documentation of its approval of the research, if applicable (The FRI IRB may require meeting minutes from the committee in the host country);

4. A copy of the letter(s) of agreement on letterhead stationary with signatures from the local host institution(s), and from government officials (as necessary) to cooperate in the proposed research;

5. A copy of the consent form (if used) in English, a copy in the appropriate native language(s), and a copy of the "back translation";

6. Information regarding the literacy level of the expected subjects and how this may affect the informed consent process;

7. Information regarding why women were or were not included in the study;

8. A description of the informed consent process including methods for minimizing the possibility of coercion or undue influence in seeking consent and safeguards to protect the rights and welfare of vulnerable subjects;

9. A description of the processes for assuring anonymity and/or confidentiality of all data, and a description of the methods of transport and security of data to the United States, if applicable;

10. If data will be collected by someone other than the researcher, the curriculum vitae of the individual and letters of agreement, should be included on letterhead stationary and with signatures from the research institutions;

11. If compensation is given to subjects, justification for the amount of money or goods should be provided and an explanation as to how this compensation is proportionate to the average annual income of people in the host country.

It is the practice of the FRI IRB to give full board review to all research studies conducted outside the United States that include human subject contact. For studies that involve no contact with subjects and that are minimal risk (e.g., chart reviews or additional laboratory analysis of previously collected samples), expedited review of the study may be granted by the FRI IRB. If a minimal risk study receives expedited review, a consultant familiar with the local context will be asked to provide to the reviewer a written evaluation for local context review.

Special IRB Considerations:

For studies involving populations that have no written language:

- Use an English consent form as a template for translation into the oral language.
- The consent form should be signed by the interpreter, the study Principal Investigator, and the subject, who will be requested to make a mark or thumb print, as appropriate.
- Include a statement about the process of informed consent.

For studies involving populations that utilize group consent:

- Describe and justify the use of group consent.
- Provide a method to obtain private or individual subject assent, if possible.
- Provide a method of protecting those who choose not to participate in the study.

For "non-therapeutic" research:

- Provisions must be made for the study population to benefit from the research study.

For "therapeutic" research:

- Provisions must be made and documented to address the issue of why the study should or should not provide continued access to the experimental intervention (should it prove efficacious) or other research benefits, by the host after the completion of the study.

For Federally funded studies:

- A Federalwide Assurance is necessary to document that the international institution or performance site will conduct the research in accordance with United States Federal policies and regulations.

For studies involving minors (participants under the age of 18 years):

- The FRI requirements for assent for minors in research studies are applicable.

- Written, parental permission is also required. If local customs and regulations are such that active parental permission would be culturally inappropriate, the researcher must supply the IRB with proof that such permission is not culturally appropriate. Examples of such proof would be specific regulations (in English and certified to be accurate) that indicate that such permission is not required, an official letter from a ranking official in the country of interest indicating that such permission is not culturally appropriate, or the appearance at an FRI IRB meeting by someone of official standing in the research or academic community who can attest to the cultural inappropriateness of the requirement for active parental permission.

- In those cases where seeking active parental permission for minors to participate in research is culturally inappropriate, a waiver of such permission may be granted at the discretion of the FRI IRB, as long as the research does not place the participant(s) at untoward risk. Regardless of the type of risk, the participant(s) in the research retain(s) the right to discontinue participation, without penalty, at any time.

- If a waiver of active parental permission is granted, and if a letter informing the parents of the research is deemed appropriate, it must be written at a literacy level that would be understood by the parents, and should be sent to them by the most expeditious method possible. FRI's IRB will review the "back translation" of this letter.

Local Context Consultant

The key requirement for local context review is that a person who is familiar with the customs and culture of the study population participates in the review at the FRI IRB meeting. Consultants must be native to the country, have had knowledge of such customs and culture that was obtained through extended, direct experience in the community, or be a professional familiar with the local environment. The consultant will attend, in person or via telephone, convened FRI IRB meetings as an *ad hoc* non-voting member of the FRI IRB. Information on the protocol will be sent to the local context consultant at least one week in advance of the convened meeting. The review and recommendations of the consultant will be documented in the FRI IRB minutes.

The Chairperson of the FRI IRB or, if designated by the Chairperson, the IRB Administrator, will interview potential consultants and inform them of the responsibilities of local context consultants.

Continuing Review

A protocol will have only one local context review unless there are significant changes in the protocol or the risks to the subjects. FRI's standard continuing review requirements will apply to international research studies.

Applicable Regulations and Guidelines

The Belmont Report
45 CFR 46

21 CFR 56 and 21 CFR 50
Declaration of Helsinki