Tip Sheet: IRB Member Review of International Research

- Protocols involving human subjects research (HSR) must be written in accordance with regulatory requirements and consideration of ethical guidelines. The value system of any culture must be considered when conducting international research.
- HSR conducted by NIH investigators must comply with U.S. federal law, regulation and NIH policy, regardless of whether the research is conducted domestically or internationally.
- Such research should reflect U.S. and international ethical standards and may require additional consideration of international participants' rights and welfare within different cultural contexts and local regulations.
- When NIH-supported non-exempt HSR is conducted in a foreign country, the foreign institution where the research will be conducted must hold an active Federal Wide Assurance (FWA) or have equivalent protections consistent with 45 CFR 46.101(h). In practice, OHRP almost never (if ever) considers regulations regarding such protections to be equivalent to those under US regulations. (See OHRP database for FWA numbers for IRB/ECs).

What Happens When NIH Investigators are Engaged in HSR Conducted in a Foreign Country, and the NIH IRB is Reviewing the Protocol?

- When NIH investigators are engaged in HSR and the NIH IRB is reviewing the protocol, the IRB will review the protocol in its entirety to ensure that it meets US regulatory requirements and applicable NIH policy. The IRB will not make determinations regarding whether the research is compliant with laws or regulations of any foreign nation, and these will be determined by the in-country IRB/Ethics Committee (EC). The IRB will not approve a study that has been disapproved by the in-country IRB/EC.
- When there is no in-country IRB/EC, the NIH IRB will require a written assessment of the research by an individual who is independent of the research team and who has appropriate expertise to evaluate the protocol for its consistency with the foreign country's laws and regulations, as well as local customs and culture.
- The IRB will not issue an approval for HSR conducted in a foreign county until the research is approved by an in-country IRB/EC or until the IRB considers the required independent review as described above.
- The NIH IRB has no oversight authority over the local investigators, nor their conduct of the research at the international site.

What Information Should IRB Members Review in the Protocol and Consent Forms When Research Will be Conducted in Another Country?

- Information about the site in the foreign nation where the research will be done (e.g., name, location, local PI, local site's FWA).
- Documentation of approval from the in-country IRB/EC. This is required before the NIH IRB can issue a final approval for the research unless there is no in-country IRB/EC. In such case, see information above.
- Ensure that the consent process, as described in the protocol, is appropriate to the local culture where the research is being conducted and that the overall literacy rate of the country has been considered.
- Consider local context information in making the final determination. (Why is the HSR being conducted in that country? Local legal age of consent? Local LAR standards (if appropriate?))
- For FDA regulated studies in which any drug or device will be shipped from the US to the foreign site, written documentation should be provided to the NIH IRB confirming that all necessary approvals for use of a test article under local laws have been obtained.

When is NIH IRB Review of Protocols Conducted Internationally Not Required?

- If NIH is supporting non-exempt human subjects research conducted in a foreign country, but the NIH is not otherwise engaged in the human subjects research, NIH IRB review of the protocol is not required, but in-country IRB/EC review is still required.

Where Can Additional Information About Local Regulations and IRB Review of International Research be found?

- See the *Guideline for International Research-Protocol Document* as well as *Guideline for International Research-IRB Review and Consent Document* that can be found posted with Policy 700 on the OHSRP website.
- See ClinRegs online database and the International Compilation of Human Research Standards.