For international studies subject to the 45 CFR 46, U.S. regulations require that a study must be reviewed and approved by an IRB in the area where the study will be conducted. It is not enough that a U.S.-based IRB approve a study; it must also be approved by a board made up of members of the community in which the study will be performed. This requirement is in addition to complying with host country national guidelines or regulations.

Host-country national approval.
National systems for the approval of human subjects’ research vary widely from country to country. Some countries (e.g., India and The Gambia) have clear and robust guidelines for externally sponsored research as well as for domestic projects while other countries do not have review committees responsible for human subjects’ protection. In such cases the country may have other means of approving human subjects’ research such as review by the Ministry of Health (MOH).

Countries without specific guidelines.
Countries that do not have review boards may request assistance from neighboring countries. For example, in Guinea Bissau, once the government has considered a research proposal and decided that it is appropriate, it is sent to the National Ethics Committee in The Gambia for review and approval. Some Latin American countries have regulatory procedures that require both local scientific approval and approval by an independent ethics committee. Countries in Central and Eastern Europe also vary widely with the respect to IRB or Ethics Board review, from having established national committees to review foreign supported research to being in the process of developing and implementing national policies, procedures, and national IRBs.

Each investigator has the responsibility to clearly understand the mechanism and process of review of human subjects’ research in the host country.

Local IRBs
U.S. policy is that the local IRB reviewing a research study can be from the collaborating institution, another institution in the same geographical area or an independent IRB.

The Local IRB must:
Register with the U.S. Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP). See link below for step-by-step instruction for registering an IRB.

http://www.hhs.gov/ohrp/humansubjects/assurance/regirbi.htm

Assure OHRP that it will follow the current guidelines including the review of projects.

**Forming/Recognizing existing IRBs**

When an ethical review board exists at the host institution and meets the U.S. criteria for an IRB it can be registered and used as the IRB of record for the study.

A local independent IRB can also be registered and used as the IRB of record for the study.

If an ethical review board does not exist, the U.S. collaborator will need to supply information to the foreign collaborator on the makeup and duties of an IRB and assist in the formation of a suitable IRB.

**Other UA IRB Interests**

In addition to federal and international regulations, international research involves many cultural and community issues. The UA IRB wishes to see evidence in the IRB application that the investigator is aware of these issues, either through personal knowledge and experience working in that country/culture/community or through the presence of a qualified consultant. For example, does the research site require permission of a village headman or chief before one can approach participants? May male interviewers interview or treat female participants without the consent or presence of a related male? What local beliefs or customs will influence response to questions? What does the target group consider to be respectful behavior? How was the nature and appropriateness of any incentives determined? And last, will participants or their community receive anything that would empower them in some way, other than any direct personal benefits from the research? See UA IRB FORM: Checklist for Reviewers and Investigators for examples of what IRB wishes to see in applications. Also, identify any cultural/local consultants on the personnel page and describe their efforts and availability in the application.

**Useful References**

The website Science and Development Network and The Bulletin of the World Health Organization contain many useful articles on international research.

The Office for Human Research Protections (OHRP) publishes an annual list of international regulations from 90+ countries and provides information about a number of regional and international organizations. Go to http://www.hhs.gov/ohrp/index.html and click on “international” in the left-hand column.
Information about FDA acceptance of Foreign Clinical Studies is at http://www.fda.gov/oc/ohrt/irbs/toc4.html