Department: **UAMS Institutional Review Board**
Policy Number: **17.5**
Section: **Special Populations**
Effective Date: **July 31, 2002**
Revision Date: **August 24, 2004**

SUBJECT: International Research

Federal regulations recognize that "the procedures normally followed in foreign countries [in which the research will take place] may differ from those set forth in this policy" [45 CFR 46.101(h);]. Research may be approved, therefore, if "the procedures prescribed by the [foreign] institution afford protections that are at least equivalent to those provided in this policy." The foreign country's procedures may then be substituted for the procedures required by the federal regulations. Approval of the substitution is to be given by the relevant federal department or agency head after review of the foreign procedures; notice of actions taken on such reviews is to be published in the *Federal Register* (or elsewhere, as provided for in department or agency procedures). [Note that the FDA has not adopted this provision for research that it regulates. All FDA-*funded* research, however, must comply with both Department of Health and Human Services (DHHS) and U.S. Food and Drug Administration (FDA) regulations.]

The procedure for approving DHHS-supported research with a foreign component begins with the domestic institution (UAMS) with which the U.S. investigator(s) are affiliated. There must be an approved FWA from UAMS on file with DHHS and the proposed research must be reviewed and approved by the IRB before submission for funding, as with any research involving human subjects. If DHHS funds the research, each foreign institution should, upon request, submit an appropriate Assurance to the Office for Human Research Protections (OHRP). Since, at the present time, no international code prescribes exactly the same procedures for protecting human subjects as do the U.S. regulations, OHRP reviews the actual procedures detailed by the foreign institution as the primary basis for negotiating acceptable Assurances. International codes will, however, be taken into consideration in the negotiations. If the foreign institution's practices are not equivalent to the U.S. regulations, OHRP can require that particular procedures be followed before recommending approval of the substitution.

IRB REVIEW

In performing reviewing tasks, the IRB shall request documentation of the following:

1) That the foreign study is done under the oversight of an IRB or Ethics Board in country of origin.
2) Subjects must have signed an IRB Ethics Board approved consent form.
3) If samples are involved,
   - ascertain if they are deidentified and when they will be destroyed.
   - that the PI will use them only for the methods in the signed consent form.