

OHRP: Institutional Review Board Guidance, Chapter 6, Section K

K. INTERNATIONAL RESEARCH

INTRODUCTION

It is important that all research with human subjects adequately protect the rights and welfare of the subjects. All human subjects research in which American investigators are involved, and which would be subject to the federal regulations if it were conducted wholly within the United States, must comply with the federal regulations for the protection of human subjects in all material respects.

IRB CONSIDERATIONS

The regulations recognize that "the procedures normally followed in the foreign countries [in which the research will take place] may differ from those set forth in this policy" [Federal Policy § ___.101(h); 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 are 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 DHHS and FDA regulations.]

The procedure for approving DHHS-supported research with a foreign component begins with the domestic institution with which the U.S. investigator(s) are affiliated. If the U.S. institution has an approved MPA on file with DHHS, the proposed research must be reviewed and approved by the institution's 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 OPRR. Since, at the present time, no international code prescribes exactly the same procedures for protecting human subjects as do the U.S. regulations, OPRR 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 institution's practices are not equivalent to the U.S. regulations, OPRR can require that particular procedures be followed before recommending approval of the substitution.

If the U.S. institution holds an MPA, but the research is funded by a non-DHHS source, DHHS is less involved in review of the protocols for human subjects protections. Rather, as required by 45 CFR 46.103, the MPA-holding institution retains responsibility for protecting the rights and welfare of all human subjects involved in research under the institution's auspices.

One difficult issue is determining what constitutes "protections that are at least equivalent" to the federal regulations. In the case of DHHS, this determination is made by OPRR. The broad policy outlines of international standards, such as the Declaration of Helsinki or the Nuremberg Code, are a starting place, but are not alone sufficient. Written descriptions of the specific procedural implementation of such policies that have been adopted by the foreign institution are required.

Departments and agencies other than DHHS follow different procedures for reviewing and approving research with foreign components. IRBs should consult the particular department or agency involved. [See list of persons to contact in Appendix 3.]

APPLICABLE LAWS AND REGULATIONS

Federal Policy § ___.101(h) [To what does this policy apply (foreign research)]

45 CFR 46.101(h) [DHHS: To what does this policy apply? (foreign research)]