

DEPARTMENT: Yale University Human Investigation Committee  
POLICY NUMBER:  
SECTION: IRB Policies for Research Affiliate Institutions  
REVIEW RESPONSIBILITY: IRB Leadership Committee and HIC Policy Review  
ORIGINAL CREATION DATE: May 31, 2006  
REVISION DATE: September 5, 2006, November 2, 2007

## **Yale University School of Medicine HIC Policy Regarding: International Research**

### **I. Purpose:**

This policy addresses the Human Investigation Committee (HIC) requirements relating to the conduct of human subjects research outside the United States.

### **II. Policy Statement:**

1. Human subjects research conducted outside the United States should be submitted to the HIC for review and approval, should conform to the same ethical and regulatory standards to which research conducted in the United States is held, and should be conducted in accordance with U.S. regulations for the protection of human research subjects (45 CFR 46, et seq.) regardless of the funding source to the extent possible given the laws of the country in which the research is conducted. All human subjects research conducted outside the United States must receive HIC and local IRB approval or justification for why local IRB approval can not be obtained before researchers initiate work under the protocol
2. Research conducted outside the United States will comply with the relevant laws of the host country. Researchers will collaborate whenever possible with a research or educational institution or investigator familiar with the local culture and research-related issues.
3. If an international institution or site is considered “engaged” in research ( <http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm> ), and if the research is supported by federal funding, the international institution must obtain and maintain compliance with a Federalwide Assurance (FWA) from the US Department of Health and Human Services, and must receive approval from a local IRB registered with the Office of Human Research Protections of DHHS,
4. Researchers should seek review by a local IRB or Ethics Board whenever possible, even for research not supported by federal funding. The local IRB or Ethics Board must be knowledgeable about and sensitive to local community composition, mores, and standards of conduct. In the event that no such local IRB or Ethics Board exists in the immediate area where the research is to take place, the investigator should take steps either to identify such a review board within the general region or to identify a local institution that can serve in a comparable capacity (e.g., a tribal council, school board, town committee, hospital board). Copies of the local approval should be maintained with other pertinent research documentation by the Human Protections Administrator at the local institution. A copy should also be submitted to the Yale HIC.

5. The investigator must obtain the voluntary informed consent of the prospective subject or, in the case of an individual who is not capable of giving informed consent, the permission of a legally authorized representative in accordance with applicable law or provide justification for a waiver of consent.
6. It is the responsibility of the Yale University PI and the foreign institution or site to assure that the resources and facilities are appropriate for the nature of the research.
7. The Yale University PI and the foreign institution or site must notify the HIC promptly if a change in research activities alters the performance of the site's engagement in the research (e.g., a site "not engaged" begins consenting subjects).
8. HIPAA regulations do not apply to research conducted internationally; however, researchers need to comply with all applicable local privacy laws. If identifiable health information collected internationally is stored within a Yale University HIPAA-covered component, it becomes subject to HIPAA regulation.

### **III. Procedure**

1. The protocol application packet submitted to the HIC for approval must be written in English and include the following:
  - a) the initial proposed informed consent document(s)
  - b) the informed consent document(s) which is translated into the local language and suits the level of understanding of the population being recruited into the study,
  - c) the informed consent document(s) which has (have) been translated from the local language (back) into English,
  - d) a letter indicating that the study has been reviewed and approved by the local IRB or Ethics Review Board or justification for why such review is not possible. Translated documents should indicate who performed the translation services.
  - e) a list of proposed foreign investigators collaborating in the research, if applicable.
2. The informed consent discussion and all consent documents should be in the subjects' native language (See HIC Policy Regarding Participation of Non English Speaking Individuals: <http://info.med.yale.edu/hic/policy/index.html>). The researcher should consider employing a translator/interpreter to help with the consent process. A family member of a potential subject should not be used as the translator for that individual because he or she may have a conflicting interest relating to the study and may not be able to fully explain the study's risks and benefits to the potential subject. If subjects are likely to be unable to provide written consent, the researchers should provide justification in the protocol submitted to the IRB for a waiver of written consent as well as an acceptable alternative method of obtaining oral consent that is appropriate to both the subjects and their culture.

3. The HIC may require documentation of regular correspondence between the PI and the foreign institution or site.

**Guidance:**

For information on IRBs and IECs in a large number of countries, see [https://webapps.sph.harvard.edu/live/gremap/index\\_main.cfm?CFID=26597&CFTOKEN=26302008](https://webapps.sph.harvard.edu/live/gremap/index_main.cfm?CFID=26597&CFTOKEN=26302008)

See [http://oscar.med.yale.edu/hsp/module\\_1/6\\_develop\\_ethical\\_codes.asp](http://oscar.med.yale.edu/hsp/module_1/6_develop_ethical_codes.asp)

**References:**

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI, Ethical Principles for Medical Research Involving Human Subjects, <http://www.wma.net/e/policy/b3.htm>

Office for Human Research Protections (OHRP), International Issues, <http://www.hhs.gov/ohrp/international/>

Council for International Organizations of Medical Sciences (CIOMS), International Ethical Guidelines for Biomedical Research Involving Human Subjects, [http://www.cioms.ch/frame\\_guidelines\\_nov\\_2002.htm](http://www.cioms.ch/frame_guidelines_nov_2002.htm)

Vanderbilt Medical Center IRB Policies and Procedures