
Yale University Institutional Review Boards

IRB Policy 450 International Research

Responsible Office	Office of Research Administration	Effective Date	
Responsible Official	IRB Director	Last Revision	5/23/2011

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Scope

This policy addresses the Yale University Institutional Review Board requirements relating to the review and approval of human research conducted outside the United States.

Policy Statement

Human research conducted outside the United States must conform to the same ethical and regulatory standards to which research conducted in the United States is held, and must conform to applicable local laws and norms of the host country. International human research must be conducted in accordance with applicable Yale policies for the conduct and review of human research, including those concerning informed consent and participation of vulnerable populations. All human research conducted outside the United States must receive approval from the Yale IRB and, where available, from the IRB or Independent Ethics Committee (IEC) used by the international site. If approval from the host country IRB cannot be obtained before researchers wish to initiate work under the protocol, a justification for moving ahead without the host country's IRB must be provided to and approved by the Yale IRB.

If an international institution or site is considered to be "engaged" in research supported by federal funding, the international institution must obtain and maintain compliance with a Federal-wide Assurance (FWA) from the US Department of Health and Human Services (DHHS), and must receive approval for the research from an IRB familiar with the local context and registered with the Office of Human Research Protections of DHHS, or obtain DHHS approval as an equivalent host country entity.

Reason for the Policy

It is important that all research with living human beings adequately protects the rights and welfare of the research participants, irrespective of whether the research is conducted in the United States or at foreign sites. In the international setting, special attention should be given to the involvement of local participants in the design and conduct of the research to ensure respect for differences in language, education, cultural and social history, and social mores, as well as compliance with local law. In addition, national policies such as the availability of national health insurance, philosophically different legal systems, and social policies distinguish international research from U.S. research and must be considered carefully by investigators and the Yale IRB when contemplating conducting and reviewing such research.

Definitions

Federalwide Assurance (FWA)

A formal written, binding agreement in which an institution assures DHHS that it will comply with applicable U.S. federal regulations governing research with human participants.

Engagement in Research

An individual is considered engaged in human research when he/she for the purposes of the non-exempt research project, obtains: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research. An institution is considered engaged when its employees or agents conduct the above activities, or when the institution receives a direct federal award to conduct human subject research, even when all activities involving human subjects are carried out by a subcontractor.

Independent Ethics Committee (IEC)

A specially constituted review body whose responsibility is to ensure the protection of the rights, welfare and safety of research participants. An IEC shares the same general composition and operations as an Institutional Review Board.

Local Research Context

Knowledge of the non-U.S. institution(s), local cultural norms, community environment, and applicable law in which human research will be conducted.

Policy Sections

450.1 Investigator Responsibilities

Local IRB Review

In addition to obtaining Yale IRB approval, a Yale principal investigator (PI) must seek review of his/her human research protocol by a local IRB, Ethics Board or Independent Ethics Committee (IEC) whenever possible. The local IRB, Ethics Board, or IEC must be knowledgeable about and sensitive to local community composition, mores, laws, and standards of conduct. In the event that no such local IRB, Ethics Board, or IEC exists or when such a local ethics board is unable or unwilling to review the research, the PI must take steps either to identify 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, or hospital board). Research that is particularly complex or presents significant risk to subjects may require consultation with Yale legal counsel to ensure that the rights of participating subjects are appropriately protected, and that the research is conducted in conformance with local law. A copy of the local IRB or IEC approval must be submitted to the Yale IRB.

Informed Consent

The PI and other IRB-approved study personnel must obtain the voluntary informed consent of the prospective participant or, in the case of an individual who is not capable of giving informed consent, the permission of a legally authorized representative or surrogate in accordance with IRB Policy 200, Informed Consent for Human Research, and applicable local law. Informed consent processes must be sensitive to local cultural norms. The informed consent discussion and all consent documents must be in the language understood by participants (See 200 GD.2 Inclusion of Non-English Speaking Participants in Human Research). If participants are likely to be unable to provide written consent, then the investigator, when submitting a protocol for IRB approval, must provide justification for a waiver of written consent and propose an acceptable alternative method of obtaining oral consent that is appropriate to both the participants and their culture.

Appropriate Resources and Facilities

The protocol must provide evidence of sufficient local resources and facilities to support the proposed human subjects protocol in compliance with this policy and local law. The Yale University Principal Investigator and the foreign institution or site are responsible for ensuring that the resources and facilities are appropriate for the nature of the research, and are responsible for

the ongoing monitoring of the research, including the ability to respond to emergent issues that occur during the course of the research.

Export Controls/Embargoed Countries

In some circumstances, the University may be required to obtain prior approval from a U.S. government agency before allowing foreign nationals to participate in research, collaborating with a foreign company, or sharing research results with foreign nationals. For example, the Treasury Department's Office of Foreign Assets Control (OFAC) regulates trade embargoes, sanctions, and travel restrictions and restricts exportation of information and research articles to embargoed entities and persons. Investigators conducting international research should review the University's Grants and Contracts website on Export Controls, (See <http://www.yale.edu/grants/policies/exportcontrols.html>)

HIPAA Applicability

HIPAA regulations do not apply to health information obtained and held at international sites; however, researchers must comply with all applicable local privacy laws. If identifiable health information collected at an international site is stored within a Yale University HIPAA-covered component, it becomes subject to HIPAA regulation. (See 450 GD.1: International Research.)

Change in Research Activity

The Yale University PI must notify the Yale IRB promptly if a change in research activities after the start of the project leads to or results in the foreign site's engagement in the research (e.g., a site previously "not engaged" begins consenting subjects).

450.2 IRB Responsibilities

IRB Review of Research

The IRB ensures the ethical and equitable treatment of research volunteers and protects the rights and welfare of those who participate in research. For international research involving human subjects, the IRB review must include confirmation of local IRB/IEC approval as applicable, current host institution FWA approval as applicable, and compliance with adverse event reporting and other Yale policies as they apply to human subjects research. For more information, see IRB Policy 100: IRB Review of Research Protocols, and associated Procedures and Guidance.

Knowledge of Local Research Context

In order to approve a protocol being carried out at a foreign site and to make an informed judgment about the level of risk to potential research participants, the Yale IRB must demonstrate that it has sufficient information about the local research context and local law by its review of written material, or through discussions with either IRB members knowledgeable about the local context or appropriate expert consultants. The level of knowledge about the local context and local law required for approval is based on the degree of risk to potential research participants. Higher risk studies require more thorough considerations of local context and inclusion of strategies to mitigate harm than do minimal risk studies.

Informed Consent Process

The Yale IRB will review the consent process, paying special consideration to maintaining sensitivity to local cultural norms and applicable law, including issues such as the following: disclosure of scientific and/or medical facts to individuals who may be unfamiliar with and distrustful of the concepts to be studied; differences in cultural and societal norms; differences in

the role of women in society; differences in the role of family and community in the consent process; multiple local languages; and literacy level.

Related Information

Yale University Policies and Procedures

IRB Policy 100: IRB Review of Research Protocols

IRB Policy 200: Informed Consent for Human Research

450 GD.1: International Research

Office for Human Research Protections (OHRP)

Office for Human Research Protections (OHRP), International Issues,

<http://www.hhs.gov/ohrp/international/index.html#NatIPol>

Office for Human Research Protections (OHRP): July 7, 2006 Notice on Interpretation of Assurance Requirements

Office for Human Research Protections (OHRP), Guidance on Engagement of Institutions in Human Subjects Research, <http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html>

Institutional Review Board Guidebook, CHAPTER VI, SPECIAL CLASSES OF SUBJECTS, International Research

International Compilation of Human Research Protections 2009 Edition, Compiled By: Office for Human Research Protections, U.S. Department of Health and Human Services
(<http://www.hhs.gov/ohrp/international/HSPCompilation.pdf>)

Other Resources

Vanderbilt University Medical Center Institutional Review Board Office of Research

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

See http://oscar.med.yale.edu/hsp/module_1/6_develop_ethical_codes.asp

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

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

Contacts

Subject	Contact	Phone
International Research: Biomedical.	Human Investigation Committees	203-785-4688 ysmhic@yale.edu
International Research: Social, Behavioral, Educational	Human Subjects Committee	203-436-3650

Roles and Responsibilities**Human Investigation Committees**

The HIC I, HIC II, HIC III and HIC IV serve as the Institutional Review Boards or IRBs for biomedical human subjects research conducted by Yale University.

Human Subjects Committee

The HSC is responsible for review and oversight of social and behavioral research involving human subjects conducted by Yale University.