



Institutional Review Board
University of Missouri-Columbia

Standard Operating Procedure
Transnational Research

Transnational Research

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1.0 Purpose

Transnational research activities will be consistent with the ethical principles set forth in our Human Research Protection Program and meet equivalent levels of participant protection as research conducted in our principal location while complying with local laws and taking into account cultural context.

2.0 Scope

The SOP applies to all human subject research falling under the purview of the University of Missouri Institutional Review Board.

3.0 Policy/Procedure

Protections afforded to research participants internationally must have the equivalent protections that participants would be afforded in the United States. Researchers should have sufficient knowledge of the local customs and traditions to carry out the research in a way that protects the rights and welfare of the participants while producing viable research results.

OHRP provides a compilation of regulations and guidelines that govern human subject's research in other countries, as well as standards from a number of international and regional organizations. [See OHRP *International Compilation of Human Subject Protections* at <http://www.hhs.gov/ohrp/international/intlcompilation/intlcompil2012.doc.doc>]

Researcher Responsibilities

When studies are conducted in other countries researchers should be knowledgeable about the local laws and customs which apply to the research, and the cultural context in which they will be working.

The researcher should consider influencing factors including but not limited to:

- Local Laws
- Regulations
- Customs
- Socio-economic factors
- Politics
- Culture
- Language
- Literacy

These factors may affect the study design, the risks, the consent and consent process.

Risks

Some items to consider:

1. Methods may have increased risk when being conducted in a different country
2. Innocuous questions may be offensive
3. Maintaining or assuring confidentiality may be difficult
4. Breach of confidentiality may be dangerous for subjects

Obtaining Informed consent:

Informed consent is a decision to participate in research, by a competent individual who has received the necessary information; who adequately understands the information; and who, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation. In some circumstances it may be inappropriate

to document consent by using the standard written and signed consent document. The consent should be obtained in the language that is most familiar to the prospective participant. Other factors to consider are the potential for different rules on determining who may serve as a legally authorized representative, age of majority, children as subjects and potential differences in the authority structure.

Regardless of the research, Waiver of informed consent is regarded as uncommon and exceptional

See SOP Non-English Speaking Subjects for applicability

IRB Review

The IRB will review in accordance to the regulations that apply to the local area. The most stringent requirements for protection of human subjects will prevail when there are differences. The IRB office will ensure appropriate expertise and knowledge of the country(ies) either through IRB membership or consultants. The IRB will also confirm the qualifications of the Researchers and Research Staff for conducting research in that country(ies). The IRB has the authority to rely on the approval of another country's IRB if applicable.

The investigator is responsible for completing the initial review, amendments, continuing reviews, events, and following all IRB policies and procedures. Researchers are required to complete the Completion Report once the study has ended.

Federally Funded/ FDA regulated Research

For federally funded research, the regulations of that sponsoring agency apply and the required federal protections must be provided; it is not sufficient to provide "equivalent" protections.

FDA and ICH-GCP <http://www.fda.gov/RegulatoryInformation/Guidances/ucm122049.htm> regulations apply to international research studies utilizing drugs, devices or biologics

For DHHS funded research, 45 CFR 46 applies. For other guidance by OHRP on international research please go to <http://www.hhs.gov/ohrp/international/>

International Ethical Guidelines for Biomedical Research Involving Human Subjects
http://www.cioms.ch/publications/layout_guide2002.pdf