IRB REVIEW OF INTERNATIONAL RESEARCH

POLICY

The University of Cincinnati Institutional Review Board (UC IRB) shall ensure that research conducted at a location outside the United States (international research) meets the same criteria for approval as that conducted at UC (UC HRP Policy III.01). All UC IRB Policies and Procedures shall apply to international research unless specifically waived by the IRB based on research-specific considerations. Researchers will also comply with local laws and guidelines in the country where the research is taking place.

REVIEW OF RESEARCH

The IRB must ensure that equivalent protections are provided to research participants enrolled in research in another country. The IRB will also make determinations and decisions based on laws and knowledge of the country in which the research will be conducted. These may include:

a. Applicable laws or guidance related to human research subject protections.
b. When there are other laws that will need to be factored into the research.
c. When the local or government has their own required approvals.

The UC IRB might need to take additional actions to ensure adequate review of international research. These may include (but not limited to) the following:

- Seeking consultation from someone who is familiar with the international location and population to ensure the appropriate expertise and knowledge for IRB review (UC HRP Procedure 305).
- Obtaining additional information from the researcher regarding local context, cultural considerations, and plans for meeting any special needs at the international location.
- Reviewing the experience and background of the researcher and research team regarding the international site and population to confirm his/her qualifications to conduct research in the given country.
- Assessing the potential for coercion of participants in the international location and actions that may be needed to reduce it (UC HRP Policy V.03 Protecting Vulnerable Populations).
- Requiring translated materials and/or the presence of a translator on the research team when there will be interaction with international participants (UC HRP Policy II.01 Obtaining Informed Consent).
Human Research Protection
Program Policy

- Requiring additional training of the researcher and research team about research ethics in an international context (UC HRP Policy IV.03).
- Assessing the type and frequency of study monitoring that should be conducted after IRB approval has been obtained (UC HRP Policy VII.01 Quality Improvement).
- Requiring additional information in the study protocol, such as:
  o a description of how communication will occur with the IRB and the local ethics committee
  o a description of how continuing review, amendments, complaints, non-compliance, and unanticipated problems involving risks to others will be addressed and by whom
  o a local contact in the event the principal Investigator or faculty advisor cannot be reached

Applicable Regulations and Documents: (do not list AAHRPP Domain)
HRPP Policy # II.01, III.01, V.03, IV.03, VII.01
HRPP Procedures # 305,
OHRP International Compilation of Human Subject Protections
VHA Handbook 1200.05

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Date Adopted  _September 2014_  Signature  _signed copy on file_