2023

IRB GUIDANCE ON INTERNATIONAL RESEARCH

All research involving living human beings needs to adequately protect the rights and welfare of the research participants, whether the research is conducted in the United States or at non-U.S. sites. Research conducted under the auspices of an institution with a federal research assurance must follow U.S. federal human subjects research regulation (the Common Rule), institutional policy, and other ethical standards and guidance. No research project may begin before Institutional Review Board (IRB) approval is obtained.

In addition to the U.S. research regulations, other laws and regulations may also apply or be considerations in international research settings, as the Common Rule

- "does not affect any foreign laws or regulations that may otherwise be applicable and that provide additional protections to human subjects of research" ***(46.101, g),*** and
- "When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy" ***(46.101, h).***

All aspects of the University's IRB policy will apply. In addition, investigators conducting studies in international settings should take appropriate steps to ensure respect for differences in language, education, cultural and social history, and social norms and mores, as well as compliance with local law. Applications to the IRB for research should describe the investigator's awareness of any relevant considerations; investigators' awareness and addressing of any issues that may require unique cultural understanding and sensitivity; any language/translation needs to be addressed; research ethics guidelines of the host country; and international laws or regulations, including those relevant to human subjects' research training or qualifications, and how these issues will be addressed by all investigators and project personnel as relevant. Letters of support from key persons/entities within the host country may be helpful, and, in some cases, may also be required by the IRB.

University of Scranton researchers who are part of a research project undergoing review or otherwise conducting human subjects research under the auspices of another institutional IRB must review and comply with that institution's research policies. University of Scranton researchers are also responsible for verifying and obtaining any required University IRB approval, in addition to that of the other institution.

Investigators contemplating conducting international research should review additional information and policies provided by the Department of Health and Human Services: http://www.hhs.gov/ohrp/international/, and the OHRP's compilation on international human research standards.