

Reminders for International Human Subjects Research

When conducting human subjects research outside the United States, researchers must comply with both U.S. requirements and the laws of the host country.

- **Local Ethics Review:** Many countries require ethics review and approval by a nationally recognized or institutionally based research ethics committee (e.g., Comité de Ética en Investigación in Mexico, Research Ethics Committee in India, etc.). This requirement applies regardless of whether the study is biomedical, social-behavioral, or unfunded.
- **U.S. IRB Approval:** If your project involves human subjects and is overseen by this institution, you must still obtain U.S. IRB approval (unless determined otherwise under U.S. regulations).
- **Dual Review:** Approval from a U.S. IRB does not replace or override requirements for review in the host country. In some cases, both reviews will be required.
- **Investigator Responsibility:** It is the responsibility of the Principal Investigator to determine and document whether local ethics approval is required in the country where research activities will occur. Our IRB can assist in clarifying requirements, but ultimate responsibility lies with the research team.
- **Consequences of Noncompliance:** Conducting research without required host country ethics approval may violate foreign law, jeopardize collaborations, damage the institution's reputation, and limit opportunities for future international research.

Reminder: If you are planning research outside the United States, please consult/contact the IRB office early to discuss host-country requirements at IRB@uml.edu