## INTERNATIONAL RESEARCH

It is very important for investigators to be proactive when planning to conduct research in foreign countries.

## **Required Information**

The CMU IRB requires the following information in order to evaluate an application:

- 1. Documentation that the investigator is familiar with the local context in which the research will be conducted. (See for example, Canadian Guidelines for Research Involving Aboriginal People.)
- 2. Approval from a local official authorizing the proposed research (*eg*, director of a school, clinic or community center). Exactly who the authorized official is will vary with the type of research, the country, and the location of the research site. If none can be identified, investigators may be expected to document their efforts.
- 3. Documentation that the investigator is aware of the regulations governing the conduct of human subjects research in the foreign country. Research in many countries follows the ethical norms articulated in the Belmont Principles, but some countries follow different ethical codes. The <a href="International Compilation of Human Research Standards">International Compilation of Human Research Standards</a> is available from the Office of Human Research Protections.
- 4. Approval from a local IRB (also known as an Ethics Review Board or Helsinki Committee). In some cases, it may be difficult to identify whether an ethics board has jurisdiction to review the proposed research, but the investigator must show the CMU IRB that a good-faith effort was made to identify such a body. If the local IRB requires evidence of approval by the CMU IRB, the CMU IRB can make a determination of "approvable subject to approval by the local IRB."
- 5. All consent forms and other documents to be presented to potential research subjects must be translated into languages they understand, unless it is anticipated that subjects will not be able to read. Further, the investigator must be able to document that the translations are accurate.

The time to make arrangements with local and government authorities in foreign countries and to obtain the required documentation can be very long, and CMU investigators should take this into account when planning foreign studies.

## **Personal Safety**

Although the IRB is not mandated to assess whether the proposed research presents risks to an investigator's safety (*eg*, conducting research in a war zone), any concerns that arise in the review process will be forwarded to the Vice President for Research.

## **Export Controls**

<u>Export Administration Regulations (EAR)</u>. Investigators wishing to conduct research in foreign countries should be aware that taking electronic devices such as laptops, tablets and cell phones, and associated software out of the US may be subject to US export and re-import regulations. The requirements vary by country being visited.

<u>Monetary transactions in foreign countries</u>. The Office of Foreign Asset Control (OFAC) of the US Treasury Department requires that researchers have a license to conduct monetary transactions, such as hiring translators and research assistants, in <u>certain foreign countries</u>, including Cuba and Iran.

For additional information, contact Robert Bienkowski, Director of Research Compliance