TEXAS A&M UNIVERSITY SAN ANTONIO

Institutional Review Board

GUIDELINE # 7: INTERNATIONAL RESEARCH: INFORMATION ON CONDUCTING RESARCH OUTSIDE OF THE UNITED STATES

I. PURPOSE

This guideline is to ensure research conducted by Texas A&M- SA faculty, staff or students in foreign countries poses unique and complex ethical challenges. Each country has different cultures and values, and it is crucial to understand the local context. As a result, the IRB expects you to acknowledge and understand the following:

- **You must obtain IRB approval before your research can begin.** Whether you are a faculty member, staff or student, your protocol must be approved by the IRB before it can begin. *To reduce confusion, make sure you have the IRB's approval before you leave the country. It is suggested you apply to the IRB with adequate time for reviews before you leave.*
- **Demonstrate cultural understanding and sensitivity.** Your IRB protocol should describe any anticipated cultural sensitivities of conducting your research and how you intend to overcome those barriers. The researcher should be familiar with local customs, culture, and religious norms in the country where the research will be conducted. Is the typical process of signing an informed consent document culturally acceptable for your protocol? How should recruitment be done? Are there other cultural barriers you might encounter? The IRB will consider alternative consent form formats or methods if culturally appropriate.
- **Understand the research ethics guidelines of the host country.** Investigators will be required to obtain IRB approval for research done internationally from the IRB and also from the local IRB/Ethics Committee within the country in which they will be doing their research. This approval must be on file with the IRB prior to IRB approval being granted. *The IRB strongly recommends you clearly understand the host country's requirements for reviewing and approving human subject research.* Some countries have clear ethical guidelines that must be met for conducting domestic and/or international research. Other countries will not have a formal process but might rely on other neighboring countries to assist with the review. Where there is no equivalent board or group, researchers must rely on local experts or community leaders to provide approval. If the researcher has difficulty determining the existence of an IRB/Ethics Committee in the foreign country, they should contact the A&M-SA IRB.
    - The Office of Human Research Protections (OHRP) publishes the **International Compilation of Human Research Standards,** a listing of over 1,000 laws, regulations, and guidelines on human subjects protections in over 100 countries and several international organizations. Researchers should check this document to determine the countries applicable laws, regulations and guidelines on Human Subjects Researcher.
    - The Office of Human Research Protection (OHRP) has issued a **Listing of 27 Social-Behavioral Research Standards** . This includes laws, guidelines, and regulations applicable to social-behavioral research around the world.
    - **Know the data laws.** While not specifically under the IRB's domain, you should know that there are some restrictions on bringing identifiable data into/out of some countries. The EU, for example, has laws surrounding what kind of identifiable information can be taken out of Europe and brought to the US (this applies to electronic data that will be housed on a US server as well). Data export laws may also affect your research in countries with which the US has embargoes or trade restrictions, such as Iran.

- **Please contact the IRB while abroad if you encounter any problems or need to change your IRB-approved protocol.** If you find that upon arrival in the host country, some aspects of your research must be modified for whatever reason, *please notify the IRB office immediately*. The IRB will do its best to quickly respond to your notification with further instructions and guidance. Please wait to hear back from the IRB before making any changes to your protocol.

What information should be in your IRB application?

In your IRB submission, it is important that you inform the IRB what you know about the country and where the research is being conducted. The IRB relies on the information you provide to help assess whether the rights protections are in place for subjects. In addition to the usually required information submitted for review to the IRB, the following points should be addressed in your submission.

- Your IRB protocol should describe relevant local context information, any anticipated cultural sensitivities of conducting your research and how you intend to overcome those barriers. This should include, but not limited to the following:
    1. Cities, regions, countries where research will be conducted.
    2. Scientific/ethical justification for conducting research in an international setting.
    3. Economic status of the country/community.
    4. Current events or socio-political environment in the country may impact research conduct or alter the risks or benefits to subjects.
    5. Societal and cultural beliefs in the country may impact research conduct or alter the risks or benefits to subjects.
    6. The role of women and children in the society, including their autonomy and legal capacity to make decisions.
    7. Literacy rate of the potential subject population.
    8. Languages and dialects of the potential subject population.
    9. Involvement of organizations, community leaders, or experts in engaging the subject population or conducting research.
    10. Description of the research team's knowledge of or experience in the host country.
    11. Relevance of the research to the area's health, economic, educational, or other needs.
    12. Distribution of risks and current and future benefits.
    13. Detail any proposed remuneration (payment, gifts, incentives, etc.) for subjects including:
        - Specific description of the remuneration (payment, gifts, incentives, etc.)
        - Value both in US and local currency
        - Local household income information (e.g., how much an average household earns in a month or a year in US and local currency)
        - When remuneration will be given during the research (the payment schedule)
        - To whom remuneration will be given
        - Whether the remuneration could pose undue influence on the subject's decision to participate.

- Approval letter from the local IRB Committee within the country where research will be conducted, equivalent board or group, researchers should provide an explanation of such and should consult with local experts or community leaders to provide an approval letter that the research as proposed meets local standards.

- The consent form should be submitted in both the local language of the host country and in English. Please clearly label each form for the IRB. The application should also indicate who conducted the translation of the forms and provide a letter certifying the translations are correct.
- Local contact information for participants to contact about research related questions.
- Recruitment materials to be used in both the local language of the host country and in English.
- Describe how you will keep your data secure at all stages: while you are collecting it in the host country, while you are traveling back to the US and once you arrive in the US.

II. STATEMENT

All human subjects research irrespective of the funding source must be submitted and reviewed in accordance with the Texas A&M- SA Institutional Review Board policies and procedures. All research will comply with applicable federal research regulations and A&M-SA IRB SOPs.

III. SCOPE

This guideline applies to all research conducted where the A&M- SA IRB serves as the Reviewing IRB.

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