

International Research Section

Depending on your responses, additional questions may appear.

If you said yes to International Sites under Basic Information section, the International Research Section will appear.

Basic Information	<p>* International Sites</p> <p>Will any research activities occur at non-US sites?</p> <p><input checked="" type="radio"/> Yes</p> <p><input type="radio"/> No</p>
Study Design	
Study Protocol	

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International Research

✱ **Justification of International Setting**

Explain the scientific and ethical justification for conducting research in an international setting.

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✖ International Locations

List all cities and countries where research will be conducted.

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International Research	<p>* International Collaborators</p> <p>List and describe all collaborating international sites, agencies, or institutions involved in research. Be sure to address the following:</p> <ul style="list-style-type: none">Name of siteRole of site (e.g., performance site, data coordinating center, etc.)Names and qualifications of individuals at the site participating in researchRole/activities of any individuals at the site related to the research
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* Data/Specimen Access

Identify the institution(s)/government(s) who will have access to the data/specimens, and specify the level of data/specimens which they will access (e.g., anonymous, coded, individually identifiable, etc.).

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Basic Information	Local Context Information
Study Design	For each site, as applicable, address the questions below.
Study Selection	<p>* International Oversight Requirements</p> <p>Identify all required local permissions required to conduct research (e.g., institutional permissions, local government requirements/procedures, etc.). Explain if you will obtain approval from a local IRB or ethics committee, evaluation by a consultant, or input from another individual or entity with knowledge of the study site.</p>
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Study Selection	<p>★ Local Expert</p> <p>Local Expert: Under our policies (see HRPP 038: International Research), a local expert must be included with your research. A local expert is an individual who is familiar and has knowledge of the culture's customs, public policies, history, law, etc of the country where research is to be conducted. An expert may be a current resident of the culture, a PI, or research staff).</p> <ol style="list-style-type: none">1. Provide the name of who your local expert will be2. Describe their expertise in the proposed research area3. How will they be involved in the research? How will they provide expertise?4. Are they knowledgeable on local laws, culture's customs, and history of the proposed research area?
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• **Applicability of Research to Location**

Describe how the research may address an important scientific question regarding the host community/country. If applicable, describe how the proposal is responsive to local health needs of the host community/country. Describe both the standard of care in the USA and the available standard of care/alternatives in the host community/country.







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• **Community Consultation**

Outline the PI's knowledge of the local community.

- Include discussion of planned or completed community consultation activities regarding the consent process, consent documentation, study instruments.
- Identify the participants in the planned or completed community consultation.
- Describe the methods, discussions, and meetings.

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Additional Local Context

Describe any other relevant aspects of the local context where the research will take place. Include information about local customs, laws, standard of care, privacy concerns, logistics, etc.

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Project Personnel	<h3>Participant Protections</h3> <p>For each site, as applicable, address the questions below.</p> <p>* Literacy and Study Documents</p> <ul style="list-style-type: none"> Describe the literacy level of the population. Discuss how subjects' comprehension of the consent process will be maximized. Explain how the cultural appropriateness of the consent process and consent document (if applicable), study instruments, etc. has been determined. Describe your plan to ensure that consent form and other documents as applicable will be translated into the appropriate language(s) after the English versions are approved by the IRB.
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*** Status of Women**
Discuss the status of women in the local community/country.
If the status of women in the international location(s) is different than in the United States, address the following issues:

- How will you ensure women's voluntary participation in the research?
- If women's consent will be supplemented by a male (spouse, brother, father, etc.), explain why it is impossible to conduct the research without obtaining supplemental male permission for female subjects.
- Explain why failure to conduct the research could deny its potential benefits to women in the host country.
- Outline the measures to be incorporated in the research protocol to respect women's autonomy to consent.
- Provide written assurance that no competent adult woman be enrolled in research solely upon the permission of another person.

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*** Status of Children**

Discuss the status of children in the local community/country. If the status or definition of children in the international location(s) is different than in the United States, explain how.

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Clarification of Research vs. Treatment

Research may provide subjects with beneficial care. In some developing countries, the type and level of clinical care provided to subjects may not be available to those subjects outside of the research context. It is a misconception to believe that the purpose of clinical trials is to administer treatment rather than to conduct research. With that in mind, address the following:

- Explain how the investigator will minimize the likelihood subjects will believe mistakenly that the purpose of the research is solely to provide treatment rather than to contribute to scientific knowledge.
- Clarify whether there has been an effort to secure continued access for all subjects to needed experimental interventions that have been proven effective at the conclusion of the project.
- Explain how the investigator will secure continued access (for subjects) to needed experimental interventions that have been proven effective at the conclusion of the project. Alternately, explain why the investigator has not secured continued access (for subjects) to needed experimental interventions that have been proven effective at the conclusion of the project.
- Explain whether, if proven effective, the procedures will be available to some or all of the host country population. Also explain either (1) why the research procedures (if effective) will NOT be made available to the host country's population, OR, (2) how the research procedures (if effective) will be made available to the host country's population. Please include a description of any pre-negotiations among sponsors, host country officials, and other appropriate parties aimed at making interventions available after the research.

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Additional Documentation

Upload any additional documentation related to International Research, as applicable.

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End of International Research Section

Participant Protections Section, Consent Section: additional requirements

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Non-English Speaking Subjects

If consent is being obtained from non-English speaking subjects, explain the translation process for all documents seen by subjects, including consent documents. Describe the consent process in these circumstances.

Note: Provide copies of translated and back-translated consent documents and provide the translator's credentials.

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