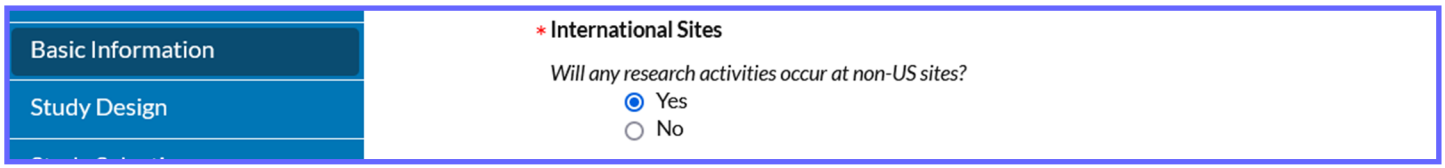
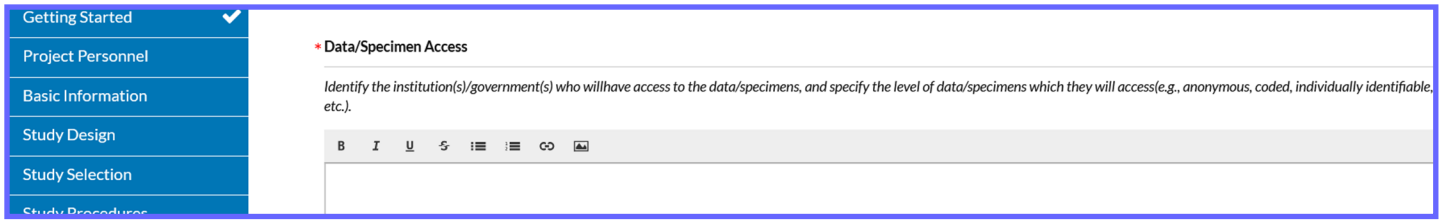
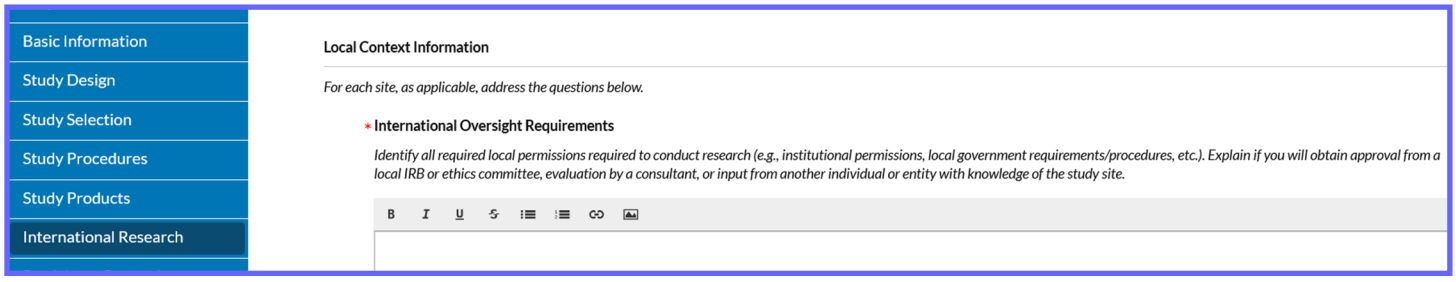
International Research Section

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.







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* **Local Expert**

***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).*

1. *Provide the name of who your local expert will be*
2. *Describe their expertise in the proposed research area*
3. *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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For each site, as applicable, address the questions below.

* **Literacy and Study Documents**

- *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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End of International Research Section

Participant Protections Section, Consent Section: additional requirements