International Research and the IRB: What you need to know before you go

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Ohio State's research community is perhaps the most comprehensive in the nation, and its breadth and excellence make it a leading force for change locally, nationally, and globally.
Session Objectives

- Identify common misconceptions concerning the international research approval process.
- Describe how to submit an application for international research.
- Discuss helpful tips to expedite the human subjects review process.
Common Misconceptions
Common Misconceptions

• International research cannot qualify for exemption.
• It is impossible to conduct international research because the approval process takes too long.
• You have to use the standard Ohio State consent template/form despite the fact it is not always the most appropriate.
Where to Begin
To Access Buck-IRB: go.osu.edu/Buck-IRB
Location of Research

Research to be conducted at locations other than approved performance sites may require a letter of support or another institution’s approval if personnel are engaged. See OHSP Engagement Guidance or contact ORSP at irinfo@osu.edu or 614-292-6457 for more information.

All fields marked with an * are required.

**OHIO STATE APPROVED RESEARCH SITES**

You have listed no Ohio State approved research sites.

**DOMESTIC RESEARCH SITES – NON-OHIO STATE LOCATIONS**

You have listed no alternate domestic research sites.

**INTERNATIONAL RESEARCH SITES**

You have listed no international research sites.
These questions take careful consideration for Ohio State researchers to determine if there are any potential risks in the study and steps researchers can take to mitigate these risks. The responses to these questions can help guide researchers whether to seek exemption or IRB review.
Describe any cultural, political, religious, or other local influences that may affect conduct of the proposed research and how these will be addressed (e.g., issues posing potential threats, requiring changes in recruitment methods, etc.).

You have entered 0 of 3000 characters.

- Not Applicable

Describe any local exceptions to the required consent process (e.g., the age at which legally effective informed consent can be provided, a request from an outsider to sign documents would be treated with suspicion based on customs, etc.). Provide a plan for addressing these differences.

You have entered 0 of 3000 characters.

- Not Applicable

Will children be enrolled in the study?

- Yes
- No

Will compensation be offered?

- Yes
- No
Explain any benefits to the local community that will remain with the community once the research is complete.*

You have entered 0 of 3000 characters.

Describe the researchers’ training/experience with conducting research (or studying or residing) in the research setting, including any relationship(s) with the community from which participants will be recruited.*

You have entered 0 of 3000 characters.

Provide contact details for two individuals who are not affiliated with the research (or researchers), are knowledgeable about the location and population, and could serve as a consultant(s) regarding proposed research.

Note: It is not required that these individuals reside or work in the research location

**First consultant contact**

Full name*  
Title*  
Phone  
Email  

* You must fill out either the contact phone or contact email.

**Second consultant contact**

Full name*
Researchers need to determine if the country where research will be conducted has a separate ethics review board process. Some countries require all researchers to submit a separate application to approve the research. *Note: ORRP cannot guarantee the duration of this process as it varies from country to country.

Commonly overlooked question: Be sure to describe both how data/records will be stored in-country and then also how they will be transported (or transferred) back to Ohio State.
Describe communication and oversight plans between the IRB and the researchers(s) who will be on-site.*

Will the research involve medical procedures and/or treatment?*  
Yes  No

Indicate if any planned research procedures are considered to be standard of care in the country or location.*

You have entered 0 of 3000 characters.

Describe provisions for emergency treatment that are available in the location.*

You have entered 0 of 3000 characters.

Provide local research and/or ethics review approval and/or local letters of support, as applicable.
What to do about consent?
What is informed consent?

• Essential ethical principle
• “Respect for persons”
• Interactive ongoing process
• Nature and circumstances
What is informed consent?

• Essential ethical principle
• “Respect for persons”
• Interactive ongoing process
• Nature and circumstances

Signatures are not required.
Waiver of Documentation

Minimal Risk Research

• Minimal risk of harm
• No procedures require written consent outside of research context
Waiver of Documentation

Risk of breach of confidentiality

• Consent form would be the only record linking participant & research
• Principal risk is harm from breach
• Each participant will be asked if they want documentation linking them to research
Waiver of Documentation (cont.)

• IRB must review a written script containing required elements and any applicable additional elements.

• IRB will request to also review contact information cards, or any information sheets outlining study procedures that will be provided to participants.
Tips:

• Sample script
  (http://orrp.osu.edu/irb/investigator-guidance/sample-research-documents/)

• Modify scripts based upon the culture and language.
Tips:

Examples:
• Consider appropriateness of words (e.g. injury)
• Avoid using American phrases.
• Use culturally relevant examples.
• Consider literacy level for word choices.

culture and language.
Additional Tips/Examples:

• Determine local norms for research/non-research activities.
• In some cases thumbprints may be used as signatures.
• Confirm the age of majority.
• Consider any customs unique to location.
Common Questions
Common questions from researchers

• If conducting research in a foreign language do I need to submit translations?
  • Only if the document will be provided to participants, not those done verbally.
  • Exempt research does not require translated documents.
Common questions from researchers

• If conducting research in a foreign language do I need to submit translations?
• Who can translate materials?
• Translations can be completed by anyone with who is fluent in English and the language in which the research will be conducted [including the researcher(s)]. You do not need to hire a professional service.
Common questions from researchers

• If conducting research in a foreign language do I need to submit translations?

• Who can translate materials?

• Do cultural contacts need to be academics?

• No. It can be whomever would be willing to provide their expertise and knowledge for review. This can be anyone who would provide a knowledgeable review of the research setting and risk/benefit considerations.
Common questions from researchers

• If conducting research in a foreign language do I need to submit translations?
• Who can translate materials?
• Do cultural contacts need to be academics?
• How do I determine if research approval is needed from the country I am traveling to?
  • Check with colleagues or academic professionals in the country or consult OHRP International Compilation.
Common questions from researchers

• If conducting research in a foreign language do I need to submit translations?
• Who can translate materials?
• Do cultural contacts need to be academics?
• How do I determine if research approval is needed from the country I am traveling to?
• Do translators need IRB approval?
• No, not if they are only providing a typical “for hire” service.
Common questions from researchers

- If conducting research in a foreign language do I need to submit translations?
- Who can translate materials?
- Do cultural contacts need to be academics?
- How do I determine if research approval is needed from the country I am traveling to?
- Do translators need IRB approval?
- What if I plan to partner with collaborators in country?
- Contact ORRP for guidance to determine if a collaborative agreement would be appropriate.
Summary Overview

• Study your country
• Consider verbal consent
• Take advantage of opportunities for assistance
Additional resources

- **International Compilation of Human Research Standard:**

- **Travel to Risk Designated Countries:**
Questions?

Office of Responsible Research Practices

Protecting Human Subjects in Research at Ohio State

Human Subjects

The Human Research Protection Program is responsible for all Ohio State research involving human subjects. The HRPP’s primary responsibility is to protect the rights and welfare of human research subjects, in accordance with Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) regulations.

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