THE OHIO STATE UNIVERSITY

International Research and the IRB:

What you need to know before you go

Jake Stoddard, BA, CIP

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*.

-Caroline Whitacre
Ohio State Vice President for Research

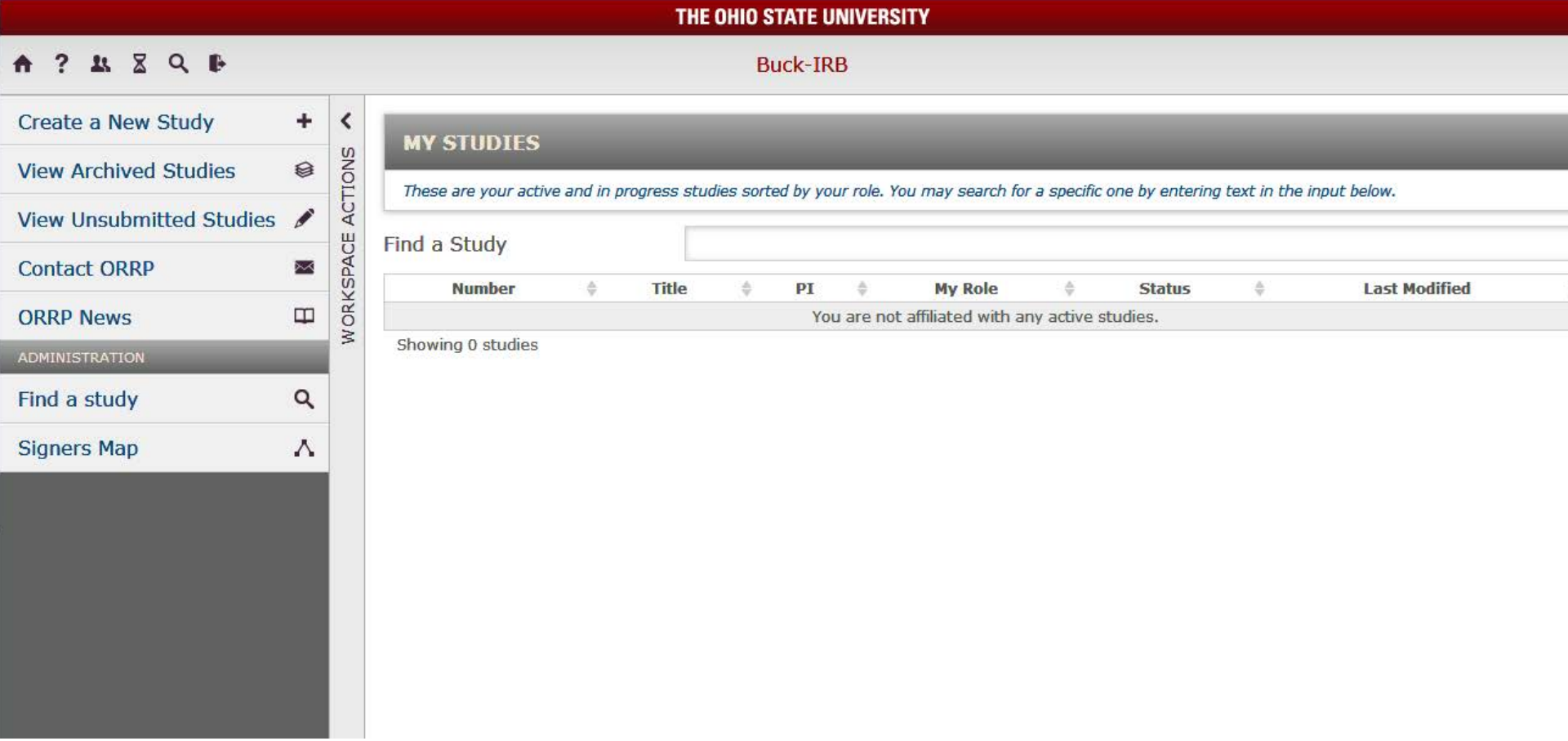
Common Misconceptions

- **International Research Cannot qualify for exemption.**

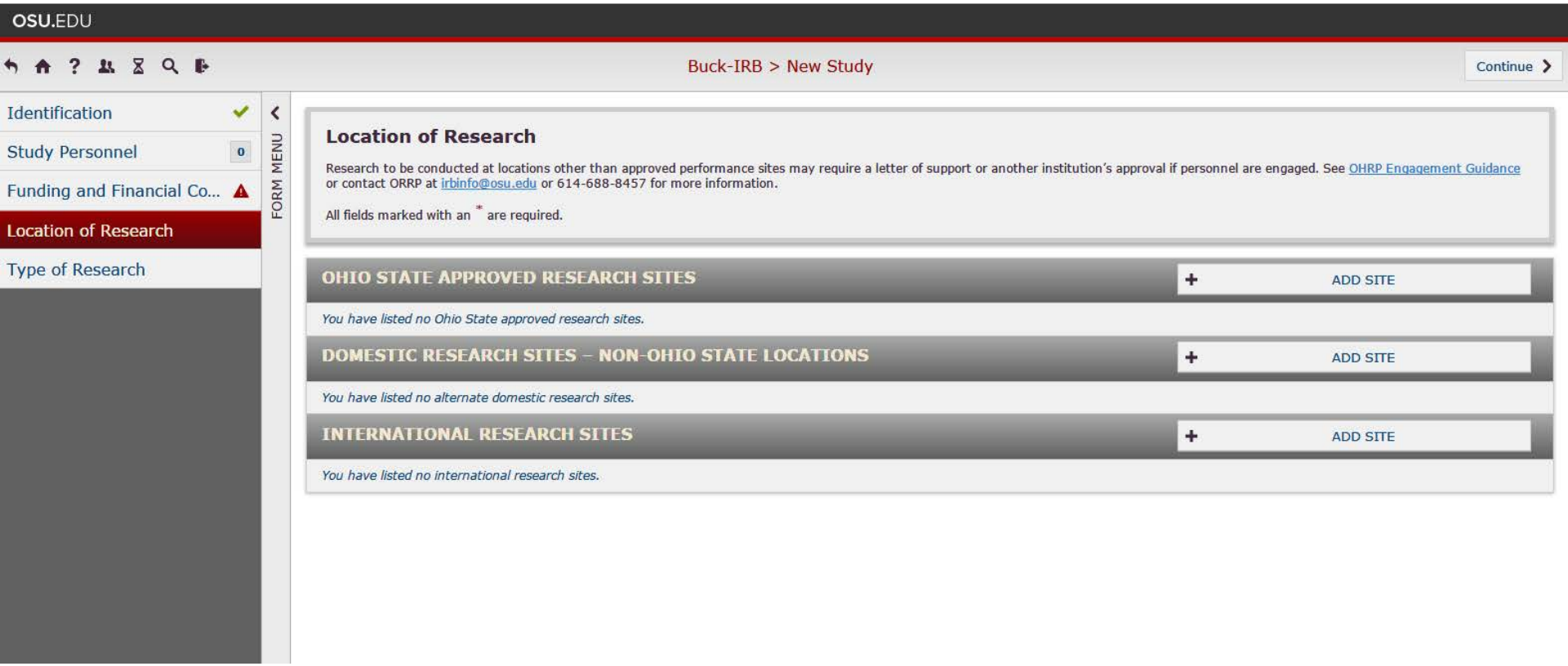
- **International Research Cannot qualify for exemption.**
- **It is impossible to conduct international research because the approval process takes too long.**

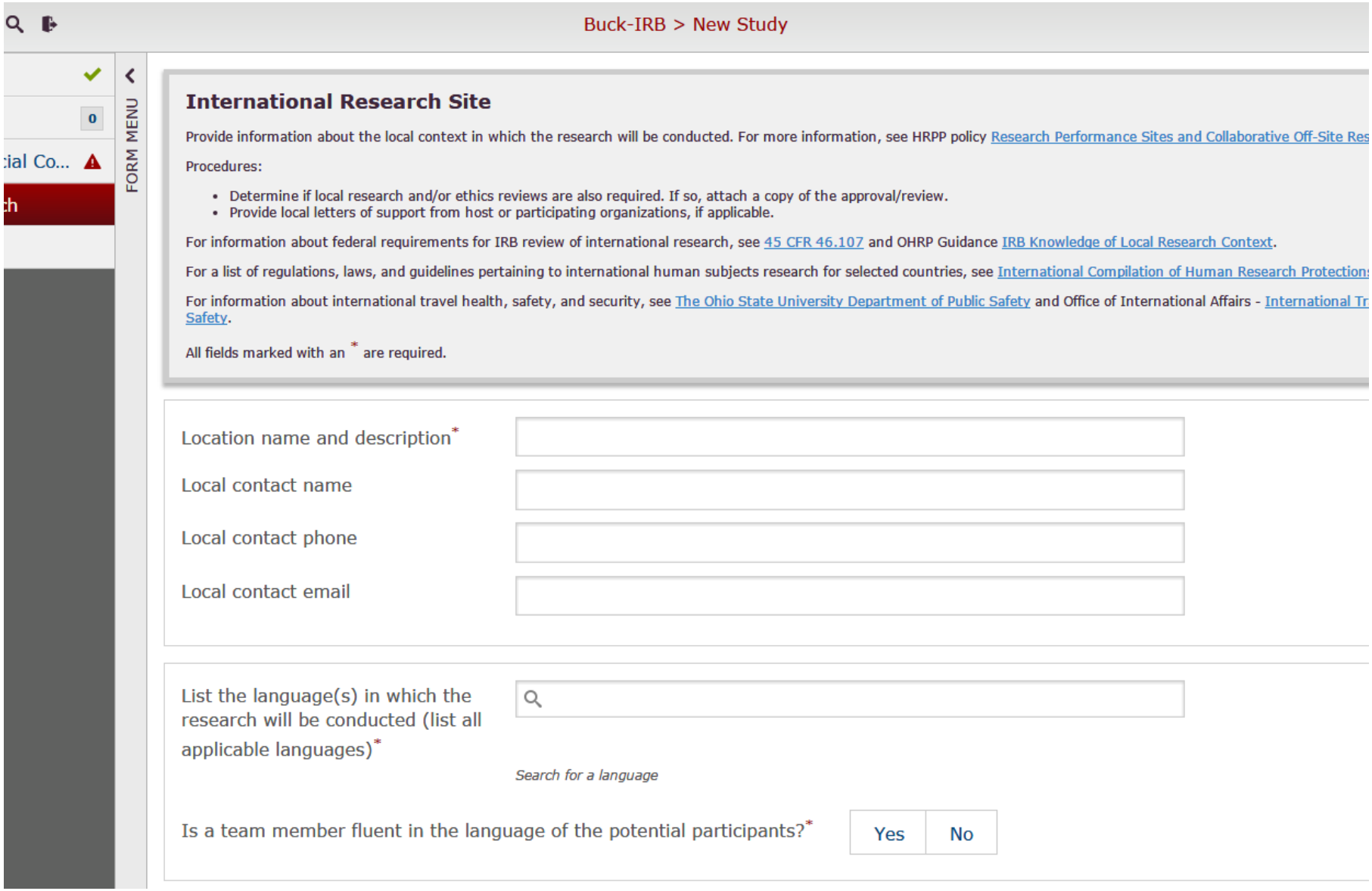
- **International Research Cannot qualify for exemption.**
- **It is impossible to conduct international research because the approval process takes too long.**
- **You have to use the standard American consent process despite the fact that it is inappropriate for some research in an international setting.**

Where to Begin



To Access Buck-IRB: go.osu.edu/Buck-IRB


OSU.EDU
Buck-IRB > New Study
Continue
Identification
Study Personnel
0
Funding and Financial Co...
Location of Research
Type of Research
FORM MENU
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 OHRP Engagement Guidance or contact ORRP at irbinfo@osu.edu or 614-688-8457 for more information.
All fields marked with an * are required.
OHIO STATE APPROVED RESEARCH SITES
ADD SITE
You have listed no Ohio State approved research sites.
DOMESTIC RESEARCH SITES – NON-OHIO STATE LOCATIONS
ADD SITE
You have listed no alternate domestic research sites.
INTERNATIONAL RESEARCH SITES
ADD SITE
You have listed no international research sites.


Buck-IRB > New Study
FORM MENU
International Research Site
Provide information about the local context in which the research will be conducted. For more information, see HRPP policy Research Performance Sites and Collaborative Off-Site Res
Procedures:
Determine if local research and/or ethics reviews are also required. If so, attach a copy of the approval/review.
Provide local letters of support from host or participating organizations, if applicable.
For information about federal requirements for IRB review of international research, see 45 CFR 46.107 and OHRP Guidance IRB Knowledge of Local Research Context.
For a list of regulations, laws, and guidelines pertaining to international human subjects research for selected countries, see International Compilation of Human Research Protection
For information about international travel health, safety, and security, see The Ohio State University Department of Public Safety and Office of International Affairs - International Tr
Safety.
All fields marked with an * are required.
Location name and description*
Local contact name
Local contact phone
Local contact email
List the language(s) in which the research will be conducted (list all applicable languages)*
Search for a language
Is a team member fluent in the language of the potential participants?*
Yes
No

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 300

Not Applicable

These questions take careful consideration and investigator 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 researchers guide whether to seek exemption or IRB review.

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) regar 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*

Describe communication and oversight plans between the IRB and the researchers(s) who will be on-site.*

You have entered 0 of 3000 characters.

Note: Consider how issues will be handled that might be relevant to the protection of participants (e.g., unanticipated problems, complaints, noncompliance, etc.)

Describe procedures for data storage in the local setting and for transfer of data to Ohio State.*

You have entered 0 of 3000 characters.

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

Researchers need to determine if the country where research to 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.

For files greater than 20MB, please see instructions for large files.

SELECT FILES

Save & Continu

What to do about consent?

What is informed consent?

- An essential part of ethical human subjects research
- Founded on the principle of “respect for persons”
- More than a form; an interactive ongoing process
- Nature and circumstances of the process are important aspects: who will provide consent, timing, place, etc.

What is informed consent?

- An essential part of ethical human subjects
- for
- ing
- cess are important aspects: who will provide consent, timing, place, etc.

There is no requirement that for all research a signature must be collected.

Waiver of Documentation

Risk of breach of confidentiality

- Only record linking participant & research
- Principal risk is harm from breach
- Each participant will be asked if they want documentation linking them to research
- Research is not FDA regulated

Minimal Risk Research

- Minimal risk of harm
- No procedures require written consent outside of research context

Waiver of Documentation (cont.)

- IRB must review a written script containing required elements and any applicable additional elements
- IRB may require an investigator to provide: consent forms without signature lines, contact information cards, or information sheets outlining study procedures

Tips:

- **Sample script (http://orrp.osu.edu/irb/investigator-guidance/sample-research-documents/)**
- **Consider literacy levels**
- **Modify scripts based upon the culture and language.**

Examples:

- Consider words like “injury” or “harm” and if they are appropriate– they may have implicit legal meanings.
- Avoid using American phrases (e.g. “flip a coin”).
- Use culturally relevant examples.
- Base word choice off of the average level of education/literacy of the participant group.
- Consider if words have equivalents in that culture (for instance the word “anonymous” may not but you could state “We will not write down your name.”

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.
- This only applies to IRB applications. Not exemption.

Common Questions from researchers

- If conducting research in a foreign language do I need to submit translations?
- Who can translate materials?
- Anyone with who is fluent in English and the language in which the research will be conducted. 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 should be whomever would be willing to provide their expertise and knowledge for review. This can be anyone who would be most appropriate and knowledgeable based upon the research.

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 travelling to?
- Check with colleagues or academic professionals in the country or consult with 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 travelling to?
- Do translators need added as researchers?
- 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 travelling to?
- Do translators need added as researchers?
- What if I plan to partner with collaborators in country?
- You may need to enter into an agreement with the individual or institution. Contact ORRP for guidance.

Additional Resources

- International Compilation of Human Research Standard: http://www.hhs.gov/ohrp/international/compilation-human-research-standards/
- Travel to Risk Designated Countries: https://oia.osu.edu/application-and-policies/travel-to-risk-designated-countries.html

Questions?