

Social and Behavioral Sciences IRB Newsletter

University of Chicago

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Preparing for International Research

If you are planning to travel abroad to do research, you want to be sure you have thought through everything you will need ahead of time to ensure that you can begin your research without delay once you arrive at your destination. International research has particular IRB implications that differ from domestic research. Following the advice in this newsletter will save you from any unnecessary IRB delays as you prepare for your travel.

• **Submit your IRB protocol early**

Be aware of IRB turnaround times and plan accordingly. Minimal risk studies should be submitted *one month* before travel dates to ensure ample time for IRB staff to ask for clarifications and for board members to review the research. Studies that are more than minimal risk should be submitted at least *two months* in advance of travel to allow for the full board to review the protocol at a monthly meeting. Meeting dates are published on the [IRB website](#). Please note the SBS IRB typically does not meet over the summer.



• **Local laws and site permissions**

Researchers bear the responsibility of investigating what local or national laws govern research in the locales to which they will travel. The HHS Office for Human Research Protections' website provides a document listing laws on human subjects research by country. You can find this document, the "International Compilation of Human Research Standards" on the [OHRP website](#). Many of the laws listed in the Compilation of Human Research Standards pertain to biomedical research, but it is still a good idea to check the Compilation to see what laws might apply to doing research in the country where you will be doing your study.

The UChicago IRB will expect that you have done the legwork to know the laws and customs of the country where you want to do research. Keep in mind that many types of laws can impact research being done in other countries, including laws on who is considered a minor, laws on data privacy and data encryption, and laws on mandatory reporting of abuse.

The IRB will want to know what expertise you have or have obtained on the local ethics and customs of the country where you will do research -- that expertise could come from a variety of sources, including review by an IRB or equivalent in the country where you will be doing your research, review by a semi-formal ethics board/committee at a local institution or organization in

that country, input from a group of qualified individuals (such as local community leaders), or other sources of information on the local ethical standards and customs of that country. We ask that you secure any specific site permissions necessary (NGOs, universities, schools, hospitals, etc). These approvals should be in hand prior to submission to the University of Chicago IRB.

• **Consent and assent procedures**

We do not relax our standards for ethical conduct of research or for a meaningful consent process for research that will be done outside the United States. However, local customs might affect what type of consent is appropriate (e.g. a waiver of signature in countries with lower rates of literacy or where asking for a written signature could be intimidating to potential participants). If the research includes enrollment of children in other countries, the principal investigator is responsible for providing the IRB with sufficient information to verify the age at which participants in such jurisdictions have the ability to assent to participation in research.

• **Local language considerations**

If you will be conducting your research in another language, we will need you to submit the study materials in the language you will be using in addition to English translations. We recommend obtaining IRB approval of the English versions of your consent and assent forms first and then having them translated – you can submit the translated documents to the IRB through an amendment, and this will minimize back-and-forth with the translator.

If you will be using an interpreter, please make this clear in your IRB application and detail any confidentiality agreements you will put in place with the interpreter.

• **Data security considerations**

Special attention should be paid to creating a thorough data security plan, especially if your research includes topics considered taboo or sensitive in the local context or will be conducted in areas of political or civil instability. Here are guidelines on data security practices when collecting research data outside the United States:

A. General

- Take steps to protect from loss from theft or otherwise, any electronic devices or documents that might have participant data.
- Understand export and customs laws that govern computing devices and data in the country, and those of any country through which you will be passing; and take steps to manage and protect your data in compliance with those requirements. For tips from UChicago's IT Services on using electronic devices safely and productively while traveling, see <https://answers.uchicago.edu/page.php?id=16284>

B. To prevent the possibility of data loss of paper files, field notes, recordings, or other records:

- Transcribe and electronically store notes as quickly as possible.
- Keep a back-up copy of the electronic files in UChicago Box (with restricted permissions).

We recommend that you create any UChicago Box folders needed for your research and share them as needed with research colleagues (e.g., your faculty advisor) before you leave the

United States. Review folder security settings to be sure that data stored there is only shared as you intend.

UChicago Box is free to UChicago personnel. For more information on UChicago Box, see <https://answers.uchicago.edu/page.php?id=45044>

C. To prevent exposure of data that was obtained under a promise of confidentiality:

- Collect the minimum amount of identifiable data needed
- Use systems to mask the identities of participants
- Minimize the number of local research staff members who have access to identifiable data
- Transcribe, encrypt, and electronically store notes as quickly as possible and destroy physical files if possible. Otherwise keep them secure under your control.
- Protect computers and all electronic devices, and individual files, with 'complex' passwords. Guidance on creating good passwords is available at <https://answers.uchicago.edu/page.php?id=16276>
- Encrypt all data -- see information about encryption methods on the IT Services website at <https://answers.uchicago.edu/page.php?id=15736>. If you do not have full disk or device-level encryption enabled, and you will be storing sensitive research data in Microsoft Word or Excel files, use Word or Excel to encrypt those individual files
- Do not store identifiable data in personal Cloud file share services
- Do not transmit identifiable data via e-mail
- Store identifiable data on mobile devices only when the device is encrypted and only as long as it takes to access a secure internet connection and upload encrypted data to UChicago Box
- Always upload to UChicago Box and erase files from mobile devices before crossing international borders

NOTE: UChicago Box can be used to store student education records (FERPA) data. UChicago Box cannot be used to store Patient Health Information (PHI), or Credit Card or Payment Card Industry (PCI) data.

Good luck as you plan your research, and please contact the IRB if you have any questions about the IRB process!

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