

# Social and Behavioral Sciences IRB Newsletter

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## The Student Issue

If you are a Masters or PhD student, you may be going through the IRB process for the first time. For many of you, this is the first IRB protocol of many that you will submit in your research career. We hope to lay the foundation for you to have a positive experience with the IRB and view us as a partner and resource. Please use the tips in this newsletter to help you plan your research protocol and move through the IRB process smoothly.

- **Determine whether your research requires IRB review**

If your project involves “human subjects” and “research” as those terms are defined in the regulations, then it will require IRB review. If you aren’t sure whether your project needs IRB review, visit <http://sbsirb.uchicago.edu/page/does-my-research-need-irb-review-0>

When in doubt, contact the IRB.



- **Determine who will serve as the Principal Investigator (PI)**

Only certain individuals may serve as PI on a research project according to the University Research Administration’s policy on PI eligibility. If there is any question regarding PI eligibility contact the SBS IRB. You may view this policy at the following link to assist you in selecting someone who is eligible:

[http://researchadmin.uchicago.edu/policies\\_compliance/policies/eligibility\\_principal\\_investigator.shtml](http://researchadmin.uchicago.edu/policies_compliance/policies/eligibility_principal_investigator.shtml)

- **AURA Training Is Recommended**

All submissions to the IRB are conducted online through the AURA IRB software system. Many researchers and students find it helpful to attend an AURA training session to become familiar navigating the software. This training is not required by the IRB, but we do recommend it. See upcoming training sessions and sign up here:

<http://aura.uchicago.edu/page/aura-irb-training>

For FAQs on using the AURA software for IRB submissions, see

[http://aura.uchicago.edu/sites/aura.uchicago.edu/files/uploads/AURA%20IRB%20FAQ\\_8.2014.pdf](http://aura.uchicago.edu/sites/aura.uchicago.edu/files/uploads/AURA%20IRB%20FAQ_8.2014.pdf)

- **Plan ahead and be aware of the IRB’s review time requirements**

IRB review timelines depend on the level of review required of your project (Exempt, Expedited, or Full Board). The full board meets once per month during the school year and does not meet on a regular basis in July, August, and September. Studies that qualify for exemption or expedited review are reviewed year-round on a rolling basis as they are submitted to the IRB.

Typical review times are as follows:

Exempt: 2 to 3 days

Expedited: 2 to 3 weeks

Full board: 1-2 months

The SBS IRB determines the level of review using federal regulations. In general, the level of risk subjects face and the vulnerability of the population of subjects determines the review level. For an explanation of these different types of review procedures, see

<https://sbsirb.uchicago.edu/page/types-irb-review>

- **Obtain letters of permission from research sites**

Research conducted at schools, hospitals, etc. requires a letter of permission from someone in authority. For international research, you will need to show the IRB that you have checked on national and local requirements of human subject research and have appropriate permissions.

- **Take Human Subjects Protection Training**

We require all researchers who will be obtaining informed consent, interacting with subjects to collect research data, or analyzing identifiable data about human subjects to take human subjects protection training. UC students and employees may take the online course at [www.citiprogram.org](http://www.citiprogram.org). The CITI course that satisfies the human subjects training requirement for SBS IRB submissions is: Social /Behavioral Sciences Investigators and Key Personnel, Stage 1 - Basic Course

- **Plan appropriate data security measures**

Think through your data plan carefully to determine how you will keep subjects' data secure. See recommendations on the IT Services website at <https://itservices.uchicago.edu/page/data-security>.

- **Prepare consent and assent forms**

Save time by using the templates on the SBS IRB website as your starting point for developing consent and assent forms. The template forms are at <http://sbsirb.uchicago.edu/page/consent-form-templates-and-examples>.

- **Determine the appropriate consent process**

Determine whether you will obtain signed written consent from your study participants, a waiver of the participant's signature on the consent form (either oral consent or "click" consent for online studies), or a waiver/alteration of consent. Make sure you request the correct type of consent in section 16.1 of your application. Studies that will use deception or incomplete disclosure *must* request a waiver/alteration of particular elements of informed consent.

- **Be thorough in your IRB submission**

Your IRB submission documents must explain in detail the "who, what, when, where, how and why" of your study (or with amendments, specific changes you are proposing to your study).

You will save a lot of time during the IRB review process if you provide sufficient detail on research procedures, subject population, recruitment methods, compensation, consent and assent procedures, etc.

• **Become familiar with ongoing requirements of research:**

After the initial IRB protocol is approved, researchers are responsible for maintaining IRB approval through Continuing Reviews, Amendments, and on occasion, Unanticipated Problem Reports. An explanation of each is below.

Continuing Reviews -- Studies that are exempt do not undergo continuing review. Studies that are approved via expedited review or by the full IRB must undergo continuing review each year until all activities (including data analysis and write-up) are complete. Submit your continuing review application at least 2 to 3 weeks before the expiration date of IRB approval. The number of subjects enrolled and consented to date and enrolled in the past year will be requested. *Please keep track of these figures.*

Amendments – When you have received IRB approval for your study, any subsequent changes you make to research procedures, subject population, compensation, recruitment, consent/assent, etc. must be reviewed and approved by the IRB before you can implement changes to your study. This requirement applies to Exempt studies as well as Expedited and Full Board studies. Note that there are two parts to an Amendment: (1) Completion of the Amendment application and (2) Changing the protocol itself. The last page of the Amendment application directs you to the protocol where you can make changes to the study itself. Please consider what parts of your protocol are affected by the changes you are making and revise your protocol accordingly in AURA.

Unanticipated Problems – If something unexpected happens in your research that indicates increased risks to subjects (subjects' data is stolen, a subject becomes upset, etc.), you must report the incident to the IRB. Contact us as soon as possible if this happens. We will instruct you on completing an Unanticipated Problem report if it is necessary.

• **Other topics**

Use our website or call us for specific guidance on other topics, including:

Multi-institutional research  
International Research  
Research with Children  
Research in Schools and with Educational Records  
Secondary Data Analysis  
Considerations in Handling Payment to Subjects  
Mandatory Reporting Requirements

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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