NAVIGATING THE SBS IRB

Cheryl M. Danton MHS, CIP
IRB Managing Director, SBS
Agenda Items

• What projects need IRB approval?

• IRB Checklist, Common Reasons for Delays
What is an IRB?

• IRB stands for **Institutional Review Board**

• Purpose: is to protect the rights and welfare of human subjects involved in research activities being conducted under its authority.

• The SBS IRB serves all University of Chicago schools, divisions, and departments that do not fall under the jurisdiction of the BSD IRB or the SSA IRB.

• The SBS IRB office also provides ethical and regulatory educational sessions for classrooms, student groups, or research centers upon request. We also welcome individual appointments via Zoom
  • We are 100% remote!

[About | Social & Behavioral Sciences IRB Office (uchicago.edu)](https://socialbehavioral.uchicago.edu/irb/other/what-is-irb)
Do I have to go through the IRB?

- I’m just an undergrad!
- My advisor told me not to go through the IRB
- My research isn’t risky at all

If you are doing “research” with “human subjects” as defined in the regulations, then you must go through the IRB office
What is “Research”?  

“Research” means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Not considered ‘research’ under this definition: Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
Examples of “Not Research”

• Classroom project **not intended to be generalizable** (not presented on larger stage or put into library/repository)

• *Oral history targeting specific individuals to capture their stories for purposes of preservation (not generalizable)

• Quality improvement program conducted at the request of an organization or department and for internal purposes only (not generalizable).

*Oral history when added to a mixed methods approach may require IRB review.
What are “Human Subjects”?

“Human subject” means a living individual about whom an investigator (whether professional or student) conducting research

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
Examples of “Not Human Subjects”

• Data analysis of publicly available records with no personally identifying information.

• Data analysis of completely de-identified records (or coded with no link and no intention to re-identify)

• Data analysis of aggregated information

• Surveys or interviews asking only facts about an organization (no information about individuals and no opinion questions).
IRB Levels of Review

- **Exempt** - Federally designated categories for certain minimal risk activities
  - No direct interaction with minors unless education research
  - No prisoners
  - Limits on deception

- **Expedited** - Federally designated categories for certain minimal risk activities.
  - Allows for inclusion of vulnerable populations: minors, prisoners

- **Committee Review** - research that poses greater than minimal risk or that does not fit into 1 of the expedited categories.
Committee Review

Reasons why proposals are scheduled for Committee Review:

- Research does not fit into an exempt or expedited review category

- Collection of sensitive information that could cause risk of civil liability, insurability, reputation or financial standing **IF** the information were to be breached.

- Vulnerable populations: minors, prisoners, decisionally impaired, etc.

If you think your proposal may require Committee Review, please conduct the SBS IRB for consult.

The Committee meets once per month.
What do I need to submit?

✓ Find a Principal Investigator (faculty member)
✓ Human Subjects Protection Training
  • citiprogram.org “Social and Behavioral Sciences IRB Human Subjects Protection Training Course”
✓ ‘Protocol’ is built into individual smart forms.
✓ Informed consent forms
✓ Surveys, interview or focus group guides, assessments, etc.
✓ Letters of Support, if working with NGO, school system, etc.
✓ Local IRB approval for international research
✓ IRB document templates: Templates | Social & Behavioral Sciences IRB Office (uchicago.edu)
Submitting in AURA IRB

All proposals must be submitted through AURA IRB: https://aura.uchicago.edu/

Researchers or students new to the University may have to request access to the AURA-IRB system by sending a message to the AURA help desk. Please include your name, department, University position, and CNET ID to AURA-Help@uchicago.edu and a member of the AURA team will contact you.

Once you are a registered user in AURA, you may log in to the system to create a new study application or view protocol study application to which you have been given access.

Additional info at AURA IRB (Application) | Social & Behavioral Sciences IRB Office (uchicago.edu)
Common Reasons for Delays

• Proposal not submitted to IRB (pre-submission)
• CITI training not completed or not in system (attach certificate in AURA IRB)
• Vague, general, or incomplete description of study procedures
• Documents not attached: recruitment, consent, surveys or other
• Details in protocol (procedures, time commitment, compensation) do not match details in the recruitment or consent documents
• Inadequate data security procedures
The SBS IRB is 100% remote!
Contact the SBS IRB Office at
sbs-irb@uchicago.edu

OR
Cheryl Danton at (203)-499-7242
cdanton@uchicago.edu