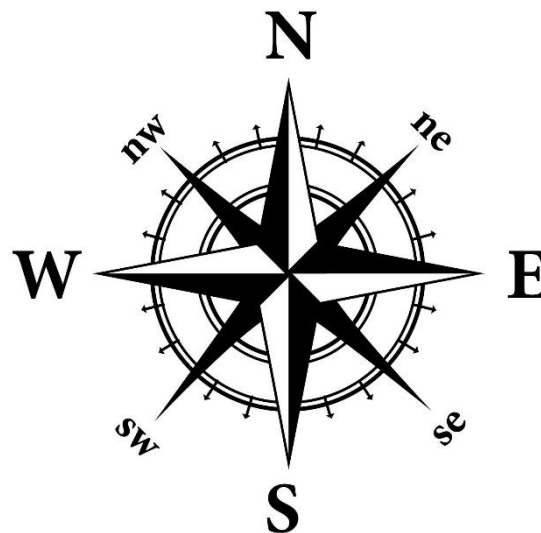




THE UNIVERSITY OF
CHICAGO

**Social and
Behavioral Sciences
Institutional Review Board**



Navigating the IRB Process

Things to Cover:

- History
- Definitions
- Process
- Review Categories
- Training & Practical Advice
- Questions



Select History:

- **Nazi Medical War Crimes**
- **The Syphilis Study at Tuskegee**
 - Long-term study of the natural history of untreated syphilis in black males. Initiated in the 1930s and continued until 1972. Participants were led to believe that research procedures (such as spinal taps) were treatment. In the 1940s, penicillin was found to be effective in the treatment of syphilis. The study continued and men were neither informed about nor treated with the antibiotic

Select History:

- 1939 Monster Study on Stuttering
- 1944-1980s Radiation Studies
- 1946-1948 Guatemala Studies
- 1944 Statesville Prison
- 1962 Milgram Obedience Study
- 1963-1966 Willowbrook Hepatitis Study
- 1960s Tearoom Study
- 1970s San Antonio Contraception Study
- 1971 Stanford Prison Experiment

Public Outcry

- Lack of consent
- Use of vulnerable populations as populations of convenience
- Violations of privacy & confidentiality
- Coercion
- Questions of risk vs. benefit
- Conflict of interest
- Lack of oversight & accountability



Timeline of Rules, Regulations, and Policies

- 1947 Nuremberg Code
- 1947 American Psychological Association
- 1948 United Nations adopted Universal Declaration of Human Rights
- 1953 First U.S. Federal Policy for Protection of Human Subjects
- 1964 Declaration of Helsinki
- 1974 US National Research Act & National Commission
- 1979 The Belmont Report



Timeline of Rules, Regulations, and Policies

- 1980 Publication of the FDA Regulations
- 1981 HHS & FDA Revise Regulations
- 1982 Council for the International Organization of Medical Sciences Guidelines
- 1991 Publication of the Common Rule
- 1995 Establishment of The National Bioethics Advisory Commission
- 1996 Health Insurance Portability and Accountability Act (HIPAA)—clarification and compliance/research rules
- 2003
- 2018 Revised Common Rule

Belmont Report (1978)

Respect for Persons

- Investigators should allow individuals to make their own decisions as autonomous agents
- Individuals who are less able to make decisions for themselves require additional protections

Beneficence

- Do no harm
- Investigators should design research studies so as to maximize benefits and to minimize risks to individuals

Justice

- The burdens and benefits of research should be fairly distributed among individuals, groups, societies, etc.

45 CFR 46: The Common Rule (1991, revised 2018)

Subpart A: Basic HHS Protections of Human Research Subjects

Subpart B: Pregnant Women, Fetuses, and Neonates

Subpart C: Prisoners

Subpart D: Children

Other vulnerable populations

- Include, but are not limited to, mentally disabled persons and economically and/or educationally disadvantaged persons. While the regulations do not specify what additional protections are necessary for these groups, the regulations do require that investigators include additional safeguards in the study to protect the rights and welfare of these individuals when some or all of the subjects are likely to be vulnerable to *coercion* or *undue influence*

Issues Continue Today:

- Things in the news:
 - 2001 Columbia Restaurant Study
 - 2010 Havasupai Tribe
 - 2014 OKCupid Mismatched Matchmaking Experiment
 - 2014 Facebook Emotional Contagion Study
 - 2014 Voter Studies
- Emerging and evolving ethical issues:
 - Use of Big Data
 - Use of genetic information
 - Expectations of privacy
 - When is informed consent necessary?
 - Blurring of business activities/partnerships and academic research

**What is an
IRB?**

What is an IRB?

- IRB stands for **Institutional Review Board**
- Made up of faculty, community members, and full-time staff tasked with reviewing, approving and monitoring human subjects research to **protect the rights and welfare of participants**
- Multiple IRB offices at UChicago
 - BSD
 - SSA
 - SBS



Do I have to go through the IRB?

- “I’m just an student”
- “My research is exploratory”
- “I’m probably not going to publish at this stage”
- “My research isn’t risky at all”
- “I’m just accessing data”

If you are doing *research* with *human subjects* as defined in the regulations, then you must go through the IRB office to secure IRB approval or obtain an exempt determination

How are review requirements determined?

There are three main questions to determine if review is required:

Definitions	Yes	No
Is the project research according to the applicable regulations (DHHS, FDA, etc.)?	continue	stop
Does the project involve human subjects according to the applicable regulations (DHHS, FDA, etc.)?	continue	stop
Is our institution engaged in the research involving human subjects?	continue	stop

Is the project *research* according to DHHS regulations?

- A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge

*NOTE: FDA definition differs



Examples of activities that do not meet the definition of *research*:

- Data collection solely for internal departmental, business, or other university administrative purposes
- Internal class projects not designed or intended to be generalizable or used beyond the class
- Data collection/analysis purely for internal quality improvement/assessment purposes
- Data collection for a biography
- Data access for a single case report

Note: Other processes and requirements may still apply (HIPAA, FERPA, Data Use Agreements, internal quality improvement and/or assessment review process, etc.)

Does the project involve *human subjects* according to DHHS regulations?

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

*NOTE: FDA definition differs



Examples of activities that do not meet the definition of *human subjects*:

- Most data or specimens purchased from a commercial provider
- Data available to the general public
- Interviews with individuals or experts only providing purely factual information about a business or organization—no information about individuals or their thoughts/opinions
- Analysis of data/specimens from deceased individuals
- Observations in a public park

Note: again, other processes and requirements may still apply (HIPAA, FERPA, Data Use Agreements, internal quality improvement and/or assessment review process, etc.)

What if I'm not sure whether my project is regulated human subjects research?

- Contact the IRB office and we will help you figure out whether your project needs IRB review
- Use of secondary data can be especially difficult when it comes to determining if a project needs IRB review – we recommend contacting the IRB office
- Not obtaining IRB approval for regulated human subjects research activities can have serious consequences (e.g., ability to publish findings, keep or receive funding, use data towards future research, as well as institutional consequences)



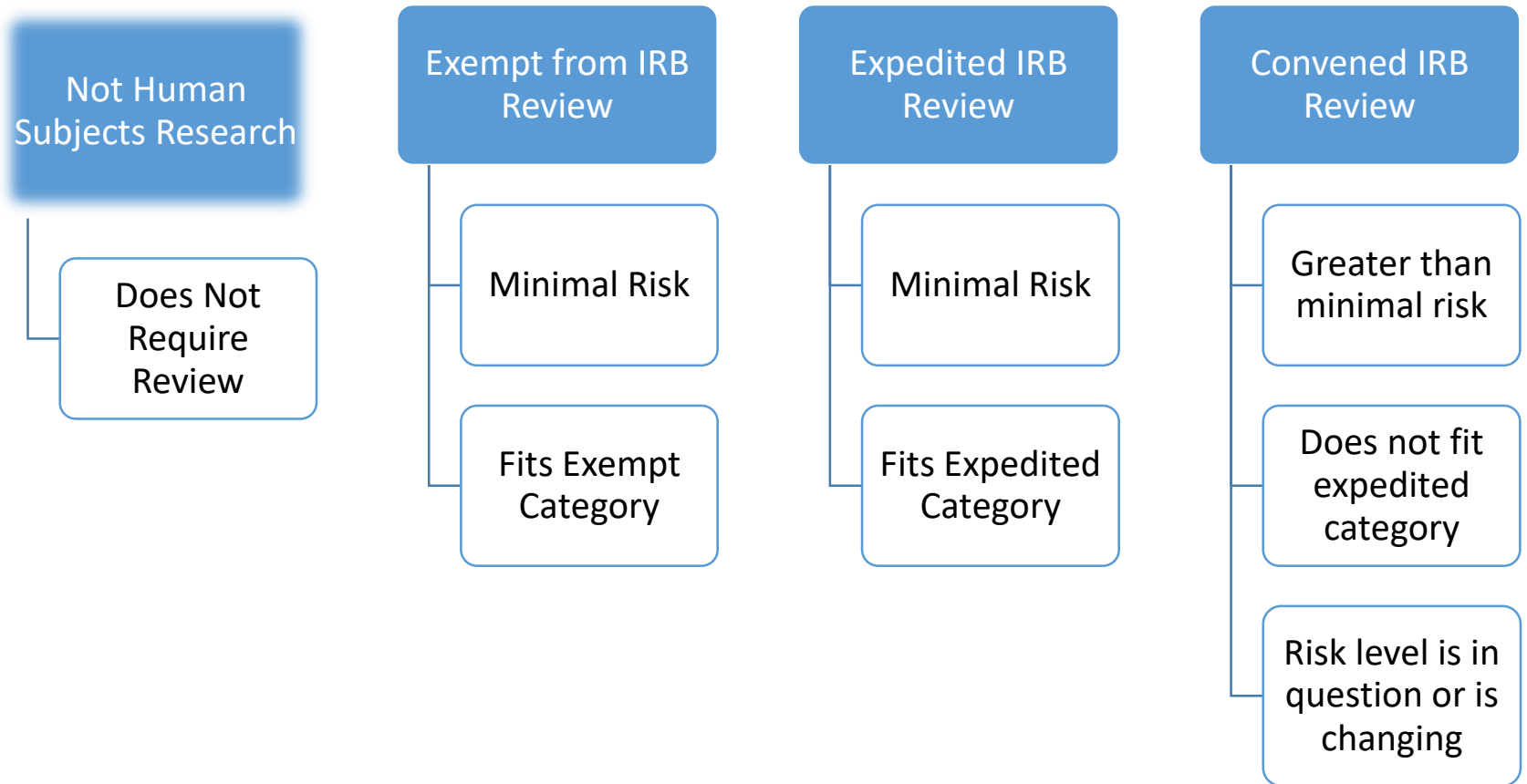
The Review Process

AURA IRB

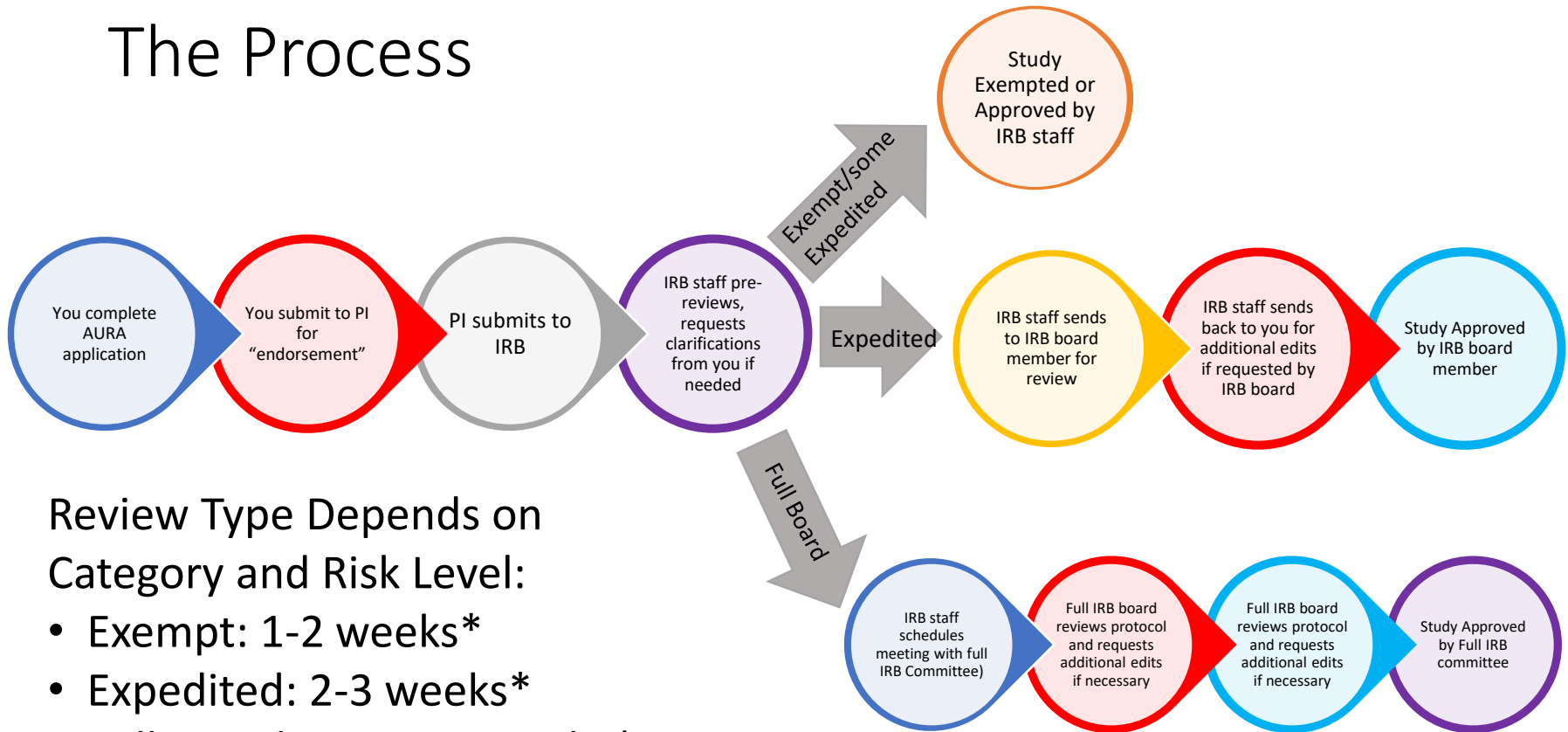
- Online application: <https://aura.uchicago.edu/>
- Application begins the same for all IRBs on campus
- Smart form
- Communication through the online system & email



The Continuum of Review



The Process



Review Type Depends on Category and Risk Level:

- Exempt: 1-2 weeks*
- Expedited: 2-3 weeks*
- Full Board: up to 2 months*

*SBS IRB Timelines

Exemptions

Exempt Review

- Eight categories under revised Common Rule
- All activities in the project must fall under one or more of the exemption categories
- Still meets the definition of research involving human subjects
- Categories do not apply to research that is also FDA-regulated
- Prisoners can not be included except for research aimed at involving a broader subject population that only incidentally includes prisoners
- Limitations on children
- Determinations made by office staff with limited IRB review as required

Category 1

Education Research

Research, conducted in **established or commonly accepted educational settings**, that specifically involves **normal educational practices** that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods

Category 2

Research that only includes **interactions** involving **educational tests** (cognitive, diagnostic, aptitude, achievement), **survey** procedures, **interview** procedures, or **observation of public behavior** (including visual or auditory recording) if at least one of the following criteria is met:

- i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; **or**
- iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § .111(a)(7): *“When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.”*

Category 3

Research involving **benign behavioral interventions** in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

- i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; **or**
- iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § .111(a)(7): *“When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.”*

Category 3, continued

- For the purpose of this provision, benign behavioral interventions are **brief** in duration, **harmless, painless, not physically invasive, not likely** to have a **significant adverse lasting impact** on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else
- If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research

Category 4

Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

- i. The identifiable private information or identifiable biospecimens are publicly available;
- ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
- iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated [*under HIPAA*] **or**
- iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities [*under certain conditions*]

Category 5

Research and demonstration projects that are **conducted** or **supported** by a **Federal department or agency**, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs [...]

*The Federal Agency will provide documentation that this exemption can be used as it is required to register the project on a federal website.

Category 6

Taste and food quality evaluation and consumer acceptance studies:

- i. If wholesome foods without additives are consumed, **or**
- ii. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Categories 7 & 8

Category 7

Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by § .111(a)(8)

Category 8

Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met [*proper broad consent, proper documentation or waiver of documentation of consent, limited IRB review*]

IRB Review

Types of IRB Review

Limited

- For exemptions that require it
- Assessing that privacy & confidentiality protections adequate

Expedited

- Minimal risk
- Reviewed by one or more members outside of a meeting
- Must fit one of 9 categories

Full Board

- Reviewed at a meeting with quorum
- Does not fit an expedited category, or
- Greater or potentially greater than minimal risk

Expedited Categories

1. Certain clinical studies with approved or equivalent drugs and devices
2. Blood draws (with stipulations)
3. Prospective collection of biological specimens for research purposes by noninvasive means.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

Expedited Categories, continued

5. Secondary use of data and specimens
6. Collection of data from voice, video, digital, or image recordings made for research purposes
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

*Categories 8 and 9 apply to continuing reviews only, not new studies

General IRB Considerations

- Rights and welfare of participants
- Risks of study procedures must be reasonable in relation to benefits
- Informed consent will be sought from each prospective subject or the subject's legally authorized representative in accordance with, and to the extent required by, the regulations
- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data

Complying with Other Laws & Policies

- **University Policies & Procedures:** data use agreements, data retention, data storage, legal requirements, conflict of interest
- **HIPAA:** analyzing Protected Health Information (PHI)
- **FERPA:** obtaining identifiable information from student records
- **PPRA:** The Protection of Pupil Rights Amendment (PPRA) is a federal law that affords certain rights to parents of minor students with regard to surveys that ask questions of a personal nature
- **Mandatory Reporting:** interacting with minors
- **State laws**
- **International** laws, requirements, and considerations
<https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html>

Training & Practical Advice

CITI Training

UChicago requires human subjects protection training for any research study personnel considered engaged in human subjects research activities (e.g., responsible for overseeing or designing the study, obtaining consent, collecting data, interacting with human subjects, analysis of identifiable data, etc.)

- SSA, SBS, and BSD IRBs have slightly different requirements and basic courses
- Good for at least three years (depending on the IRB requirements) and then refreshers offered
- Make sure you are taking the correct course!

SBS Basic CITI Training

- “Social and Behavioral Sciences IRB Human Subjects Protection Training Course”
- Instructions for the SBS IRB and link at <https://voices.uchicago.edu/sbsirb/training/>
- Covers basics: regulations, risk, privacy & confidentiality
- Allows choice of electives for specific training related to specific populations and research types (e.g., children, prisoners, schools, international, internet-based, older adults, decisionally impaired, socially or economically disadvantaged , research on illegal activities or undocumented status)
- Optional offerings on a variety of topics (e.g., community-based participatory research, FERPA, consent tools, incentives, incidental findings, disaster and conflict research, etc.)

Other CITI Training Courses

CITI offers many other types of training that you can complete that may be necessary or helpful throughout your research career

- Responsible Conduct of Research: The National Science Foundation (NSF), National Institutes for Health (NIH), and several other federal agencies require grant recipients and study staff to take the "Responsible Conduct of Research" course
- Good Clinical Practice: investigators conducting a clinical trial are generally required to take the "Good Clinical Practice" course (either behavioral or biomedical)
- Health Information Privacy & Security: covers HIPAA and related concerns
- Conflict of Interest Course
- Lab Animal Courses

Checklist Before Starting AURA Application

- ✓ Find a Principal Investigator (faculty member)
- ✓ Plan ahead
 - Exempt: 1-2 weeks
 - Expedited: 2-3 weeks
 - Full Board: up to 2 months
- ✓ Human Subjects Protection Training
- ✓ Design study procedures, recruitment
- ✓ Prepare documents and have them ready to upload
 - e.g., recruitment materials, consent forms, data collection instruments, questionnaires, interview questions, debriefing forms, etc.
- ✓ Secure any site permissions you may need
- ✓ Talk with IT if data is sensitive
- ✓ Work with URA if data use agreements needed (DUAs)

Common Reasons for Delays

- The PI did not endorse the application online
- Vague, general, or incomplete description of study procedures
- Documents not attached: recruitment, consent (verbal consent still requires a document), debriefing, surveys or other study materials
- Materials missing required elements (consider using templates for consent, parental permission)
- Details in the application (procedures, time commitment, compensation) do not match details in the recruitment or consent documents
- Inadequate data security procedures
- CITI training not completed

Once You are Approved...

- Submit an **amendment** if there are ANY changes to procedures, funding, materials used with subjects (recruitment, consent, questionnaires, interview questions, etc.), study team, etc.
 - The amendment must be reviewed and approved prior to implementing the changes
- Submit continuing reviews, if required
- Alert IRB to any adverse or unexpected events
- Submit a termination request when the project is complete

Additional Questions???

Social & Behavioral Sciences (SBS) IRB:

- Email: sbs-irb@uchicago.edu
- Web: <https://voices.uchicago.edu/sbsirb/>

