Samlabasu.com
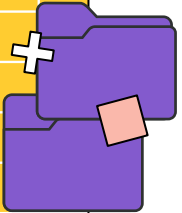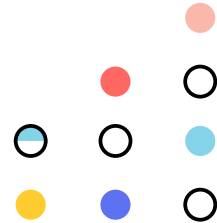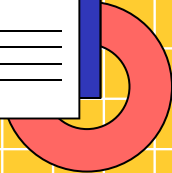
SAM LAB WEBINAR

Learn how to submit a successful IRB

Streamlining your experience with the IRB

Objectives:

- CITI Training

- Access the IRB Website

- Propose a new study to the IRB
  - Navigate the social-behavior IRB application form

- Responding to clarifications requested in ERA

- Submitting an IRB Modification

Before You Submit an IRB…

IDK: If you have taken PSY 290, you should have already completed this.
(last for 5 years)

NO: you need to go to www.citiprogram.org

Yes

Have you received a certification for the human subjects research?

IDK/No

Have your certificate handy for the application, if you don't have it, go to www.citiprogram.org

CITI PROGRAM

Instructions to access CITI training

01	Go to the website, and select "**Log in**"
02	Choose "**Log in through my institution**"
03	Select "**Arizona State University**"
04	Log in using your **ASURITE user ID** and **password**
05	After logging in, select "**I don't have a CITI program account**" **UNLESS** you already have an account or had a CITI account through another institution.
06	Select "**Arizona State University Courses**" tab

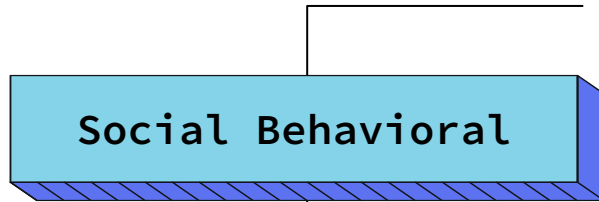From there, you will take the "**IRB – Social & Behavioral Research Course**"

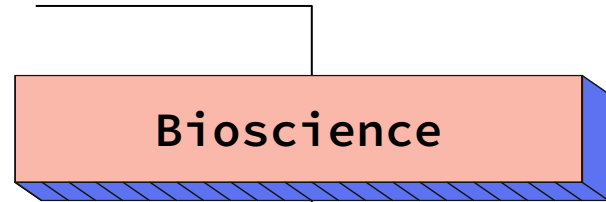# After training

What's next?...

IRB Protocol

What kind of Protocol?

Two protocols

Social Behavioral

Bioscience

Used for

Any research that is not biomedical in nature

✔️

Used for

Any research that contains biomedical elements

❌

IRB Protocol Steps 1 & 2

INSTRUCTIONS
Complete each section of the application. Based on the nature of the research being proposed some sections may not apply. Those sections can be marked as N/A. Remember that the IRB is concerned with risks and benefits to the research participant and your responses should clearly reflect these issues. You (the PI) need to retain the most recent protocol document for future revisions. Questions can be addressed to research.integrity@asu.edu. **PIs are strongly encouraged to complete this application with words and terms used to describe the protocol is geared towards someone not specialized in the PI's area of expertise.**

IRB: 1. Protocol Title:

IRB: 2. Background and Objectives
2.1 List the specific aims or research questions in 300 words or less.
2.2 Refer to findings relevant to the risks and benefits to participants in the proposed research.
2.3 Identify any past studies by ID number that are related to this study. If the work was done elsewhere, indicate the location.

TIPS for streamlining the review time:
✓ Two paragraphs or less is recommended.
✓ Do not submit sections of funded grants or similar. The IRB will request additional information, if needed.

Response:

Title

Background objectives

- Use abstract as a guide
- About 2 paragraphs

IRB Protocol Step 3

IRB: 3. Data Use - What are the intended uses of the data generated from this project?
Examples include: Dissertation, thesis, undergraduate project, publication/journal article, conferences/presentations, results released to agency, organization, employer, or school. If other, then describe.

Response:

Data Use

- How will the data be used?
- Ex: Dissertation, journal article, thesis,etc.

IRB Protocol Step 4

IRB: 4. Inclusion and Exclusion Criteria

4.1 List criteria that define who will be included or excluded in your final sample.
Indicate if each of the following special (vulnerable/protected) populations is included or excluded:

- Minors (under 18)
- Adults who are unable to consent (impaired decision-making capacity)
- Prisoners
- Economically or educationally disadvantaged individuals

4.2 If not obvious, what is the rationale for the exclusion of special populations?
4.3 What procedures will be used to determine inclusion/exclusion of special populations?

TIPS for streamlining the review time.

✓ Research involving only data analyses should only describe variables included in the dataset that will be used.
✓ Course evaluation data: if there is any intent to use the course evaluation data for research, submit to the IRB to get approval.
✓ For any research which includes or may likely include children/minors or adults unable to consent, review content [here]
✓ For research targeting Native Americans or populations with a high Native American demographic, or on or near tribal lands, review content [here]
For research involving minors on campus, review content [here]
✓ Research involving broader ASU student community where students are recruited outside IRB Principal Investigator's unit requires Provost Committee Approval. Please reach out to shelly.potts@asu.edu for questions regarding this process.

Response:

Inclusion & Exclusion

Must specifically address these populations:

- Minors
- Adults unable to consent
- Pregnant women
- Prisoner
- Native Americans
- Undocumented individuals

IRB Protocol Steps 5 & 6

IRB: 5. Number of Participants
Indicate the total number of individuals you expect to recruit and enroll. For secondary data analyses, the response should reflect the number of cases in the dataset.

Response:

IRB: 6. Recruitment Methods
6.1 Identify who will be doing the recruitment and consenting of participants.
6.2 Identify when, where, and how potential participants will be identified, recruited, and consented.
6.3 Name materials that will be used (e.g., recruitment materials such as emails, flyers, advertisements, etc.) Please upload each recruitment material as a separate document, Name the document: recruitment_methods_email/flyer/advertisement_dd-mm-yyyy
6.4 Describe the procedures relevant to using materials (e.g., consent form).
✓

Response:

Number of Participants

Recruitment Methods

- Who
- When
- Where
- Materials

qualtrics XM

Prolific

amazon mechanical turk

IRB Protocol Step 7

IRB: 7. Study Procedures
7.1 List research procedure step by step (e.g., interventions, surveys, focus groups, observations, lab procedures, secondary data collection, accessing student or other records for research purposes, and follow-ups). Upload one attachment, dated, with all the materials relevant to this section. Name the document: supporting documents dd-mm-yyyy.
7.2 For each procedure listed, describe **who** will be conducting it, **where** it will be performed, **how long** is participation in each procedure, and **how/what data** will be collected in each procedure.
7.3 Report the total period and span of time for the procedures (if applicable the timeline for follow ups).
7.4 For secondary data analyses, identify if it is a public dataset (please include a weblink where the data will be accessed from, if applicable). If not, describe the contents of the dataset, how it will be accessed, and attach data use agreement(s) if relevant.

TIPS for streamlining the review time.
✓ Ensure that research materials and procedures are explicitly connected to the articulated aims or research questions (from section 2 above).
✓ In some cases, a table enumerating the name of the measures, corresponding citation (if any), number of items, sources of data, time/wave if a repeated measures design can help the IRB streamline the review time.

Response:

Study Procedures

- Research procedure (step by step)
- All materials being used in procedure (survey, video/audio recordings, ECG monitor, ect.)

IRB Protocol Steps 8 & 9

IRB: 8. Compensation

8.1 Report the amount and timing of any compensation or credit to participants.
8.2 Identify the source of the funds to compensate participants.
8.3 Justify that the compensation to participants to indicate it is reasonable and/or how the compensation amount was determined.
8.4 Describe the procedures for distributing the compensation or assigning the credit to participants.

TIPS for streamlining the review time.
✓ If partial compensation or credit will be given or if completion of all elements is required, explain the rationale or a plan to avoid coercion
✓ For extra or course credit guidance, see "Research on educational programs or in classrooms" on the following page: https://researchintegrity.asu.edu/human-subjects/special-considerations.
✓ For compensation over $100.00 and other institutional financial policies, review "Research Subject Compensation" at: https://researchintegrity.asu.edu/human-subjects/special-considerations for more information.

Response:

IRB: 9. Risk to Participants

List the reasonably foreseeable risks, discomforts, or inconveniences related to participation in the research.

TIPS for streamlining the review time.
✓ Consider the broad definition of "minimal risk" as the probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
✓ Consider physical, psychological, social, legal, and economic risks.
✓ If there are risks, clearly describe the plan for mitigating the identified risks.

Response:

Compensation or Credit

- SONA - Credit

Risk to participants

- Includes physical, psychological, social, legal, and economic risks

IRB Protocol Steps 10 & 11

IRB: 10. Potential Direct Benefits to Participants
List the potential direct benefits to research participants. If there are risks noted in 9 (above), articulated benefits should outweigh such risks. These benefits are not to society or others not considered participants in the proposed research. Indicate if there is no direct benefit. A direct benefit comes as a direct result of the subject's participation in the research. An indirect benefit may be incidental to the subject's participation. Do not include compensation as a benefit.

Response:

IRB: 11. Privacy and Confidentiality
Indicate the steps that will be taken to protect the participant's privacy.

11.1 Identify who will have **access to the data**.
11.2 Identify where, how, and how long data will be **stored** (e.g. ASU secure server, ASU cloud storage, filing cabinets).
11.3 Describe the procedures for **sharing, managing and destroying data**.
11.4 Describe any special measures to **protect** any extremely sensitive data (e.g. password protection, encryption, certificates of confidentiality, separation of identifiers and data, secured storage, etc.).
11.5 Describe how any **audio or video recordings** will be managed, secured, and/or de-identified.
11.6 Describe how will any signed consent, assent, and/or parental permission forms be secured and how long they will be maintained. These forms should separate from the rest of the study data.
11.7 Describe how any data will be **de-identified**, linked or tracked (e.g. master-list, contact list, reproducible participant ID, randomized ID, etc.). Outline the specific procedures and processes that will be followed.
11.8 Describe any and all identifying or contact information that will be collected for any reason during the course of the study and how it will be secured or protected. This includes contact information collected for follow-up, compensation, linking data, or recruitment.
11.9 For studies accessing existing data sets, clearly describe whether or not the data requires a Data Use Agreement or any other contracts/agreements to access it for research purposes.
11.10 For any data that may be covered under FERPA (student grades, etc.) additional information and requirements is available at https://researchintegrity.asu.edu/human-subjects/special-considerations.
11.11 If your study is sponsored by HHS: NIH, you will need to comply with the revised 2023 NIH Data Management and Sharing policy. Additional information and requirements are available at https://libguides.asu.edu/NIH-2023. Please be aware, per 2023 NIH DMS policy, DMS plan is required at the time of proposal submission

Response:

Benefits to participants

- Should NOT include societal or other benefits

Privacy & Confidentitality

- Where will data be stored?
- How long will it be stored?
- How will data be tracked (ID's)?

IRB Protocol Step 12

IRB: 12. Consent
Describe the procedures that will be used to obtain consent or assent (and/or parental permission).

12.1 Who will be responsible for consenting participants?
12.2 Where will the consent process take place?
12.3 How will the consent be obtained (e.g., verbal, digital signature)?
12.4 If your study is sponsored by HHS: NIH, you will need to comply with the revised 2023 NIH Data Management and Sharing policy. Additional information and requirements are available at https://libguides.asu.edu/NIH-2023. To comply with this policy, the informed consent should explain how data will be managed and shared. This sharing should be consistent with the DMS plan.

TIPS for streamlining the review time.
✓ If participants who do not speak English will be enrolled, describe the process to ensure that the oral and/or written information provided to those participants will be in their preferred language. Indicate the language that will be used by those obtaining consent. For translation requirements, see Translating documents and materials under https://researchintegrity.asu.edu/human-subjects/protocol-submission
✓ Translated consent forms should be submitted after the English is version of all relevant materials are approved. Alternatively, submit translation certification letter.
✓ **If a waiver for the informed consent process is requested, justify the waiver in terms of each of the following: (a) The research involves no more than minimal risk to the subjects; (b) The waiver or alteration will not adversely affect the rights and welfare of the subjects; (c) The research could not practicably be carried out without the waiver or alteration; and (d) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.** Studies involving confidential, one time, or anonymous data need not justify a waiver. A verbal consent or implied consent after reading a cover letter is sufficient.
✓ ASU consent templates are [here].
✓ Consents and related materials need to be congruent with the content of the application.

Response:

Consent

- Who will be obtaining consent?
- How will it be obtained?
- Protocol for participants who don't speak English (if applicable)

IRB Protocol Steps 13 & 14

IRB: 13. Site(s) or locations where research will be conducted.
List the sites or locations where interactions with participants will occur-
- Identify where research procedures will be performed.
- For research conducted outside of the ASU describe:
  - Site-specific regulations or customs affecting the research.
  - Local scientific and ethical review structures in place.
- For research conducted outside of the United States/United States Territories describe:
  - Safeguards to ensure participants are protected.
- For information on international research, review the content [here].

For research conducted with secondary data (archived data):
- List what data will be collected and from where.
- Describe whether or not the data requires a Data Use Agreement or any other contracts/agreements to access it for research purposes.
- For any data that may be covered under FERPA (student grades, etc.) additional information and requirements is available [here].
- For any data that may be covered under FERPA (student grades, homework assignments, student ID numbers etc.), additional information and requirements is available [here].

Response:

IRB: **14. Human Subjects Certification from Training.**

Provide the names of the members of the research team.

ASU affiliated individuals do not need attach Certificates. Non-ASU investigators and research team members anticipated to manage data and/or interact
with participants, need to provide the most recent CITI training for human participants available at www.citiprogram.org. Certificates are valid for 4 years.

TIPS for streamlining the review time.
- ✓ If any of the study team members have not completed training through ASU's CITI training (i.e. they completed training at another university), copies of their completion reports will need to be uploaded when you submit.
- ✓ For any team members who are affiliated with another institution, please see "Collaborating with other institutions" [here]
- ✓ The IRB will verify that team members have completed IRB training. Details on how to complete IRB CITI training through ASU are [here]

Response:

Research conducted

- Where will it be performed?

CITI training

- Enter the training you completed and the date when you completed it.

Now...

IRB
Submission

Gather all documents before submitting
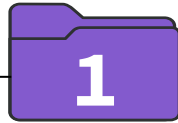
1 Research materials (survey, consent form, ect.)

Will ask for these as you are going through application.

2 Funding approval forms

3 CITI certificate

IRB Submission

1. Start by accessing the ERA website
2. Click IRB

IRB Submission

3. Click on Create
4. Click on Create new study

IRB Submission

5. Complete the application
   - Follow it step by step.
   - Will ask you to attach all your other documents

6. Reach out to your advisor (PI) and let them know you completed the application, and they will submit it.
   - Application doesn't go through until your advisor submits it.

Creating New: IRB Submission

Basic Study Information ❓

1. * Title of study: ❓

2. * Short title: ❓

3. * Brief description: ❓

4. * What kind of study is this? ❓
   - ○ Multi-site or Collaborative study
   - ○ Single-site study
   Clear

5. * Will an external IRB act as the IRB of record for this study? ❓
   ○ Yes ○ No Clear

IRB Process

Pre-Submission → Pre-Review → IRB Review → Post-Review → Review Complete

Clarification Requested | Clarification Requested | Modifications Required

- You will get clarifications requested and need to change those and re-submit.
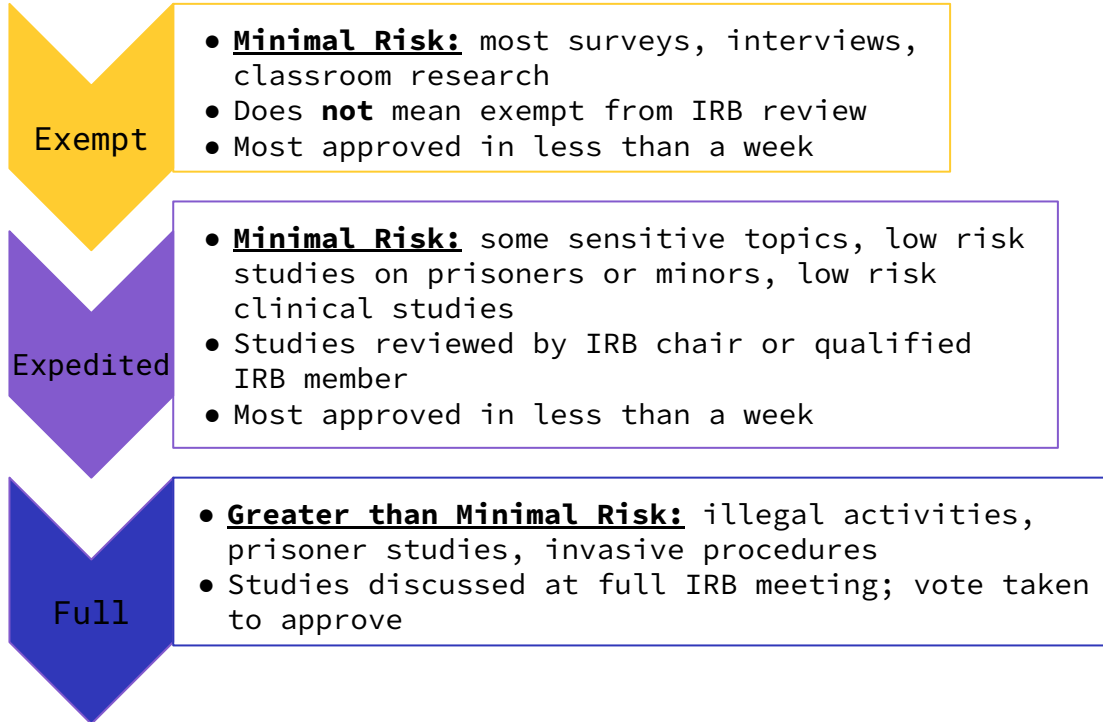- "Exempt" or "Expedited" move along quickly.

Responding to Clarifications
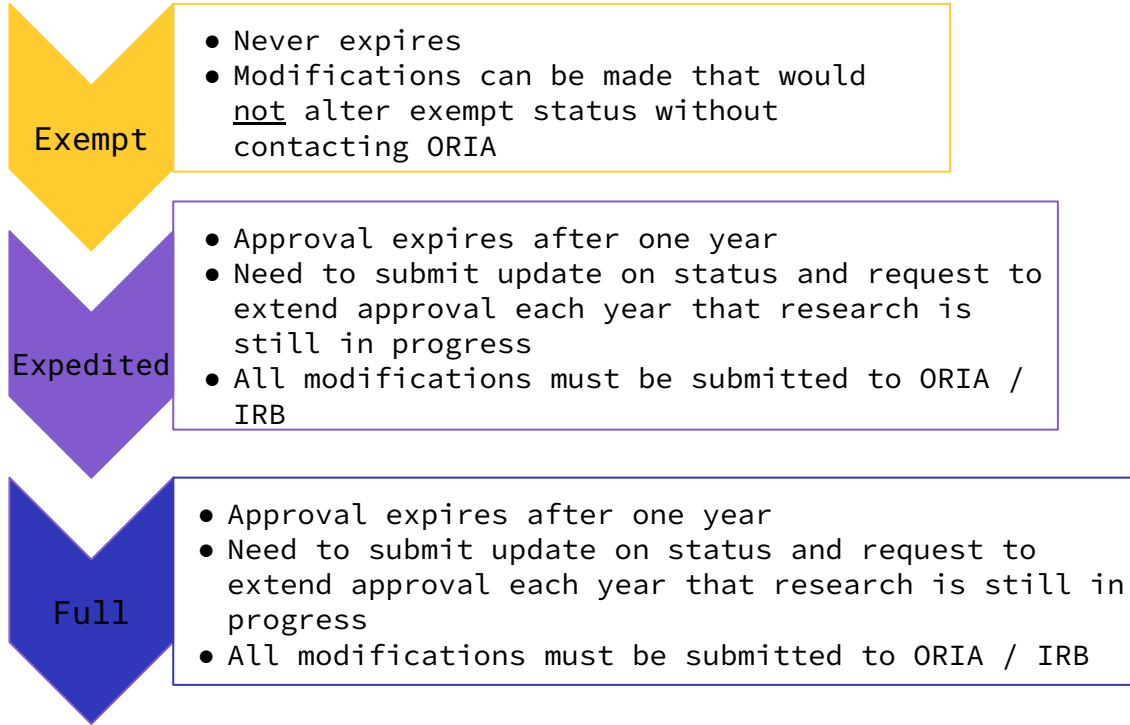
Tips to accelerate the process:

- They respond quickly; you should too

- Be concise

- Provide supplementary documents

- Your advisor has to re-submit when the clarifications are made.

- Might get clarifications again.

Types of Reviews

Exempt
- **<u>Minimal Risk:</u>** most surveys, interviews, classroom research
- Does **not** mean exempt from IRB review
- Most approved in less than a week

Expedited
- **<u>Minimal Risk:</u>** some sensitive topics, low risk studies on prisoners or minors, low risk clinical studies
- Studies reviewed by IRB chair or qualified IRB member
- Most approved in less than a week

Full
- **<u>Greater than Minimal Risk:</u>** illegal activities, prisoner studies, invasive procedures
- Studies discussed at full IRB meeting; vote taken to approve

Types of Reviews

Exempt
- Never expires
- Modifications can be made that would <u>not</u> alter exempt status without contacting ORIA

Expedited
- Approval expires after one year
- Need to submit update on status and request to extend approval each year that research is still in progress
- All modifications must be submitted to ORIA / IRB

Full
- Approval expires after one year
- Need to submit update on status and request to extend approval each year that research is still in progress
- All modifications must be submitted to ORIA / IRB

Committee Review

- SB IRB committee meets once a month to discuss applications and vote on them.
- Deadline for submitting applications for full review is 12 **BUSINESS** days prior to the next scheduled IRB meeting.

Make sure to submit in time!

Social Behavioral IRB	
Meeting date	Submission deadline
July 21, 2023	July 5, 2023
August 18, 2023	August 2, 2023
September 15, 2023	August 30, 2023
October 20, 2023	October 4, 2023
November 17, 2023	November 1, 2023
December 15, 2023	November 29, 2023

Submitting an IRB Modification

Go to IRB Website
Go to IRB records
Click "Active"
Click on the title of study you want to make a modification
Click "Create Modification"
Proceed through questions on application
Once complete, you will have your advisor submit the modification

Helpful Resources

Learn more at the ASU IRB website: https://researchintegrity.asu.edu/human-subjects/protocol-submission

ASU Office of Research
Integrity &
Assurance
Phone: (480) 965-6788
Email:
research.integrity@asu.edu
Website:
researchintegrity.asu.edu

SAM Lab can provide general
assistance with
preparation of IRB applications
Statistics and Methods (SAM)
Lab
Phone: (602) 543-6045
Email: samlabasu@gmail.com
Website: samlabasu.com

Thank you!

Any questions?