What does the IRB require of student researchers?

The IRB requires student researchers to:

- **Work under the supervision of a UA faculty member or research staff member.** Students may identify themselves as principal investigators but a faculty member must always be named as second investigator.

- **Complete the human research training requirements for students** before submitting an application to IRB.
  
  - Undergraduate students who are conducting small research projects simply for learning experience must complete the non-medical training specified on the IRB website.
  
  - Master’s and Doctoral students conducting human subjects research at UA must complete the National Institutes of Health (NIH) training or the Collaborative Institutional Training Initiative (CITI training) available on the IRB website. This is **regardless of whether the research will be a part of their thesis or dissertation or not.**

- **Prepare an IRB application describing the research and the protection of human research participants that meets IRB requirements.** You may use e-PROTOCOL (our electronic submission guide) or write your own.
  
  - Please read and follow the advice contained in GUIDANCE: IRB Application Guide.
Depending on the nature of your research, identify and read any other policies on the IRB website that are relevant to your research and follow any additional instructions in those policies. For example, if your research uses prisoners, you are requesting use of a vulnerable population entitled to special protection. See POLICY: Research Involving Prisoners and attach supplementary FORM: Application for Research Involving Prisoners.

The IRB also recommends that you read GUIDANCE: General Responsibilities of Investigators, POLICY: Investigator Responsibility for Informed Consent Process and Documentation, and POLICY: Investigator Assurance of Participant Comprehension. These deal with issues relevant to all research and will help you to write an adequate application and learn how to conduct research responsibly.

Prepare appropriate consent documents.

Read GUIDANCE: Informed Consent Template and GUIDANCE on Assent if that is relevant. “Assent” refers to cases where you must first obtain permission from a parent or legal representative for a child, prisoner, person with cognitive impairment, etc., to participate in research and then must obtain assent—verbal agreement—to participate from the actual research participant.

If you are using deception/concealment or wish to alter the usual consent information or documentation in some way, you must request a waiver of consent, a waiver of alteration of consent, or a waiver of written documentation of consent. See POLICY: Waivers, Alteration, and Exceptions to Informed Consent or its Written Documentation; GUIDELINES: Use of Deception/Concealment in Research; and complete and attach the form for the appropriate waiver.

REVIEW YOUR APPLICATION against FORM: IRB Checklist for Reviewers and Investigators. This is the document reviewers will use to evaluate your application. While not all of it will be relevant to every application, performing this check will increase your chances of a complete application.

Complete the Signature Assurance Sheet and include with the application.

Hint: Check on the availability of your faculty supervisor well before the date you hope to submit the application, as faculty are sometimes away or otherwise unavailable on a given day. The IRB will accept your proposal without this page but it will not be reviewed until the Signature Assurance
Sheet or other departmental documentation of awareness of the study is submitted.

- **Submit your application.**
  
  o If using e-PROTOCOL, click “Submit”. (Be sure to identify your faculty supervisor and attach the FORM: Signature Assurance Sheet.) Or you can e-mail it or hand-deliver it to Rose 358.

**OTHER QUESTIONS**

**How do I choose a faculty supervisor?**

All student researchers must have a faculty supervisor. Sometimes this is the professor teaching the course that requires research; sometimes, you have a choice. Common advice:

- Choose a faculty supervisor who has expertise and interest in your topic, preferably, a person who has actually done research in your area.

- Ask former students who have worked with this professor about their experiences with him or her.

- Choose a faculty supervisor who works well with you. S/he will provide you with valuable advice about your design and minimizing risks to human participants and is your chief contact for concerns and questions.

- Ask about the potential supervisor’s availability during your study timeframe. If s/he is going on sabbatical, this may impact your communication and response.

**How long does IRB review take?**

The first factor in this answer depends on the completeness of your initial application. Our Research Compliance Specialists review your application for completeness and any issues they believe reviewers will want to know more about and request this information from you before scheduling the application for review. **HINT:** Asking your faculty adviser to review your application before submitting it will often result in a more complete application and will save you time.
Once the application is complete, the time for review depends in part on the level of review appropriate to your research. Some applications qualify for exempt status. These are reviewed by the Director of Research Compliance and you will receive feedback within 7-10 working days of receipt of the application. Applications submitted as part of course learning—not a thesis pilot, thesis, or dissertation—often qualify for exempt status and we try to provide rapid turn-around time in recognition of the semester demands.

Some minimal risk applications qualify for expedited review and do not have to wait for the next scheduled IRB meeting. You can expect to hear a decision about an expedited project within 7 to 10 days of submission. Applications requiring full board review will be reviewed at the next scheduled meeting of the appropriate board and you will receive a response within 5-7 working days of the IRB meeting.

The IRB may approve your application as submitted, approve it with minor revisions that can be approved by a designated person or subcommittee, or request that you revise and resubmit the proposal for the next full board review. The latter will increase the time needed for IRB approval. Again, try very hard to submit a complete, detailed application the first time around, and use the given application guide and consent form template. The IRB has found that consent forms using our template are both clearer for participants and more complete for IRB purposes, hence saving you valuable time.

How long does IRB approval last? What if it expires while I am still working on the study?

IRB typically grants approval for a study for a maximum period of one year. If your study takes more than one year (or lasts longer than a shorter period of approval) you must file FORM: IRB Renewal Application with the IRB. This is like a report on what has been accomplished thus far and any problems you have encountered. You will receive a notice from the IRB 90 days ahead of the date your approval expires to warn you that renewal is needed.

What if I need to make changes in my procedures?

This happens fairly often. If you need to make a change in your procedures, file the FORM: Modification of an Approved Protocol. Here, you will describe what change(s) is needed and why, and whether the change will alter the risk to participants. Do not implement changes until the IRB has approved them, even if you must stop collecting data for a time.
Are there certain events that I should report to the IRB?

Yes. See GUIDANCE: Reportable Events for a list of things that must be reported to the IRB if they happen.

Do I need to tell the IRB when my study is done?

YES! File FORM: Request for Closure (Investigator) when the study is finished or you leave the university or if you transfer the study to a UA faculty member for additional work.