Life Cycle of an IRB Protocol

This document is intended to guide Cornell researchers through the process of submitting, modifying, and closing a human participant research project that requires Institutional Review Board (IRB) oversight. It is addressed to Principal Investigators (PIs) but can provide guidance for anybody involved in the human participant research process.

While specific websites and resources will be linked where appropriate, a few central resources are:

- irbhp@cornell.edu – the e-mail address for the Institutional Review Board team.
- Microsoft Bookings – the page to make an appointment with IRB Administrators or RASS-IRB support.
- RASS-IRB – the protocol management system used for all Cornell University IRB protocols.
- RASS Guides Site – a website containing walk-throughs for many essential processes in the protocol life cycle process.
- IRB Guidance and Policies – a page on the IRB website listing all guidance and policies regarding human participant research projects at Cornell University.

1. Determine whether or not your project requires a submission to the IRB.

Not every project involving human information or biospecimens needs IRB oversight - the IRB only has oversight over activities that meet the regulatory definition of 'human subjects research.' This guidance document is a decision tree that leads you through the many factors that determine whether or not a particular activity requires IRB review - but if you have any questions about it, or if you would like to confirm the decision, you can reach out to our office at irbhp@cornell.edu or make an appointment to meet with an IRB Administrator. For a more detailed overview of this topic, you can read through Policy #1.

2. Prepare your protocol.

If you have determined that your project meets the definition of human subjects research, you should prepare the materials needed for your IRB protocol. These materials are dependent on your research protocol, but we will be looking for:

- The full text of any **data collection instruments** (ex. surveys, interview questions, stimuli, other forms or documents utilized with human participants) included in your research. You can make changes to these documents after the protocol is approved, but will need to submit an amendment and have it approved before any changes can be instituted in your protocol.
- **Informed consent** forms (We have templates available on our website.)
- **Recruitment materials** (How will participants be finding out about your research? We will want to see any posters/e-mails/social media posts that you will

be using to advertise your study. For more information about what information is required in recruitment materials, you can look at Policy #9.)
- The human subject research ethics **training records** of everybody on your research team, including yourself. (People with Cornell NetIDs who have taken a Cornell IRB course through the online CITI Program will have their training automatically synched with the RASS-IRB system. Otherwise, you should upload the Training Completion Reports to the protocol. For more information about our training requirements, please visit the IRB Training page on our website.)
- Anything else providing **insight into the participant experience** (ex. standard operating procedures for biological specimen collection, debriefing scripts if you are using deception, letters of permission or approval from a hosting institution, etc.)

We may want to see additional information based on the specifics of your research protocol - the IRB Administrator assigned to review your protocol will communicate this to you and is available by appointment to discuss.

You should upload documents to the relevant sections on your protocol in RASS-IRB, and only need to add documents that are relevant to your research. (For instance, if your project only involves a survey, you would not need to provide a standard operating procedure for the collection of specimens.)

If you are a student, you should also ensure that you have a faculty member ready to serve as your advisor for this project. The duties of the faculty advisor are to provide a student PI with guidance on human participant research topics and take responsibility for overseeing the compliance with IRB policies and procedures. The faculty advisor does not need to be involved in the actual conduct of the research; however, they should offer some oversight or guidance. You should discuss this project with any potential faculty advisors to make sure they are willing to take on these responsibilities.

The earlier you submit your protocol, the better. If you are under a tight timeline, please let the IRB staff know as soon as possible. Please be aware, though, that the IRB office is small and very busy. Each Administrator manages the review of 30-40 protocol submissions each month, on average. Protocols are usually reviewed first come, first served, so prioritizing your protocol over someone else's will be done at the discretion of the staff.

3. Submit a protocol through RASS-IRB.

The Cornell IRB only accepts new protocol applications through the RASS-IRB portal. We have a RASS Guides website containing a multitude of detailed walk-throughs for any number of processes, including this guidance document explaining how to submit a new application.

While you are entering information about your protocol into the system, it will automatically assign your protocol a review level based off of regulatory definitions.

These levels are: Exempt (subject to administrative review), Expedited (reviewed by a single designated committee member rather than the entire committee) and Full Board (also called "Convened Committee," reviewed by the entire IRB Committee).

As part of this process, all members of your research team (except for students) will be required to complete a Conflict of Interest Project-Specific Disclosure. Additionally, the PI – and the Faculty Advisor, if there is one – are required to attest that they are willing to take on the responsibilities associated with those roles. These are considered 'pre-approval requirements' and you can check on their status in the Requirements table at the bottom of your protocol. If you are required to provide an attestation, you will receive an email notification, as well as a task on your "My Tasks" list in RASS.

If you have any questions that have not been addressed by the RASS Guides site, our team is available to provide assistance. For questions related to technical workings of the RASS site (i.e. login troubles, documents not uploading) you can contact our System Administrator colleagues at rass@research.cornell.edu, or make an appointment for support. For questions related to the content of the protocol (i.e. training documentation, requirements for certain application sections) please reach out to IRB staff via irbhp@cornell.edu, or make an appointment with an IRB Administrator.

4. **IRB Administrators/Members will review, make comments, ask questions.**

During this step, the IRB Administrators will be reviewing your protocol to ensure that the research you are conducting is compliant with human participant research regulations and protections. An IRB Member may also review your protocol at this point, depending on the review level.

The timeline by which you should expect comments to be returned varies based on the review level, the completeness of your initial application, the complexity of the research, and the workload of the IRB Administrator assigned to review your protocol. Our goal is to complete initial review and return a protocol with feedback **within two to three weeks of attestation**. If it has been longer than this time period for your protocol and you have not heard from an IRB Administrator or received the protocol back, please feel free to reach out to irbhp@cornell.edu for any updates.

Please note that Administrators cannot begin reviewing protocols while there is an attestation pending from the PI or Faculty Advisor.

While your protocol is under review, you cannot edit it. If during this period you need to make a change to the protocol, please write in to irbhp@cornell.edu, and we can return the protocol to you for you to make changes and re-submit.

5. **You take feedback into account, reviewing and responding to comments**

When the initial review is complete, the IRB Administrator will return the protocol with any feedback. You will receive an e-mail when this occurs, and will be able to access and

edit the protocol again. We have a RASS Guides document that explains how to view and address any questions or requests for changes. If you need clarification about any of these comments, you can write in to irbhp@cornell.edu or make an appointment to meet with the IRB Administrator to discuss.

Once you have made the requested edits, you re-submit the protocol so that the Administrator can re-review. Typically, this re-review process is shorter than the initial review, and our Administrators and reviewers try to get additional feedback or a decision regarding approval back within one to two weeks of this re-submission.

If your protocol is receiving Expedited or Full Board review, once the IRB Administrator conducting the initial review is satisfied, they will send it to IRB Committee members, who will also provide feedback and may request additional changes to the protocol. If your protocol is receiving Full Board review, it will be discussed at one of the monthly committee meetings.

6. **Approval.**

Expect Exemption determinations to take 3-4 weeks from start to finish, Expedited approvals 4-6 weeks, and Full Board approvals 4-8 weeks. The more complete your application is from the start, and the quicker you respond to review comments, the faster you will receive your approval.

When the reviewers (the IRB Administrator, the IRB Committee members, or the entire IRB Committee) are satisfied with the protocol, the PI and anyone else with editing permissions on the protocol will be sent a notice that your protocol was approved, or was determined to be exempt (the equivalent of approval for Exempt review). **You cannot conduct any human participant research, including recruitment, before you have received IRB approval**.

7. **Amendments, unanticipated problems, and continuing reviews.**

If you are changing any of the information that you have told the IRB in your initial protocol – surveys, procedures, research team personnel, informed consent documents, recruitment, etc. – you should submit an amendment for the protocol. We have a RASS Guides document detailing the steps in RASS to submit an amendment.

For Exempt protocols, you do not need to amend the protocol for changes to the research team, excluding the roles of PI or Faculty advisor. This is the only change to a protocol that does not require an amendment. If you are unsure if your change requires an amendment, you can reach out to irbhp@cornell.edu.

Researchers are required to submit a report if there is an unanticipated/adverse event or a protocol deviation. We have more information regarding IRB policies around unanticipated/adverse events and instances of noncompliance (including protocol deviations) in Policies #4 and #5 respectively. You should submit these reports via

RASS-IRB. We have RASS Guides for submitting protocol deviation and unexpected event reports.

Additionally, the IRB is required to review every Full Board protocol annually via the continuing review process. You will receive an e-mail notification about 60 days before your protocol's expiration date. If you are still enrolling participants, interacting with participants, and/or obtaining and analyzing personally identifiable information, you must submit a continuing review request. Our RASS Guides website contains a walk-through for submitting the continuing review request.

8. Closing the protocol.

When your protocol is complete – if the study is permanently closed to enrollment, all participants have completed all study-related interventions, the collection and analysis of private identifiable information is complete, and any remaining study activities are limited to analysis of de-identified data only– you should submit a closure request for your protocol. You can also close the protocol if you do not plan to complete the study, or if the protocol is continuing under the purview of a different IRB.

If you do not have access to a protocol but need to close it, you can reach out to irbhp@cornell.edu for assistance.

Please be sure to maintain your human participant research records—including signed and dated consent documents—for at least three years following completion of the study. Records may need to be kept longer per funders' or other regulators' requirements. See Cornell University Policy 4.21, Research Data Retention for additional information.