

You have submitted your IRB Application. What happens next?

Assigning an ID#

IRB applications can be dropped off at our office, faxed in, or emailed from the PI's email address. Student PIs also need to "cc" their Faculty Advisors. After a new IRB protocol is received at our office, we assign a unique number and log it in our system.



Screening

After processing the protocol in the IRB system, an IRB staff member screens it based on the following criteria: Are all questions answered? Are all pertaining forms/documents attached? (e.g. list of research questions, consent/assent forms, training in Human Participants research protections, letter of cooperation, recruitment scripts, foreign language translations, etc...)



Screening – Questions

If items are missing and/or the screener has questions based on the information provided in the protocol, the PI and Co-PI/Faculty Advisor are contacted via email to ask for clarifications and/or the missing items. Once the application is complete, the staff member forwards the protocol to an IRB committee member for the primary review.



Review by IRB Committee Member – Exempt and Expedited

Minimal risk study protocols are forwarded to one IRB member for review. IRB members strive to complete the review within 2 weeks of receiving it.

Full Board Reviews ONLY!

If the protocol requires a full board review, the protocol is sent out to all IRB members to read before the monthly meeting. Therefore, all documents for full board reviews must be received by the IRB office at least two weeks before the next meeting date. In addition to IRB members, PI(s) and Faculty Advisors are also invited to attend the Full Board meeting.



Reviewer Feedback – Exempt and Expedited

If the Reviewer has questions, he or she emails the PI(s) directly to ask for clarifications. Once all concerns and questions are addressed to satisfaction, the Reviewer sends an approval email to the PI(s) (and Faculty Advisors, if applicable).



Reviewer Feedback - Full Board Reviews ONLY!

The primary reviewer facilitates the discussion during the Full Board meeting, and then emails the IRB's decision to the PI. This email also contains the Board's requests for changes and revisions, if any.



Approval

Once the review is complete and the protocol is approved, the Reviewer notifies the PI(s) in an email. This email contains the type and category of IRB approval, the date of approval and a reminder to notify the IRB of any modifications that may arise in the future. Study activities may commence upon the receipt of this email. Soon afterwards, a formal hard copy letter is sent to the PI as well.



Exempt

If a protocol is approved as Exempt – there is no need to submit continuing review forms. It is exempt from continuing review. PI(s) still need to submit a modification request for any changes to the protocol.

Expedited

If a protocol is approved as Expedited – PI(s) are required to submit a continuing review form annually. No research activity may take place – not even data analysis – beyond the date indicated on the approval letter, unless the protocol is renewed and approved through continuing review. PI(s) need to submit a modification request for any changes to the protocol.

Full Board

Protocols in this category are reviewed by multiple IRB members and approved during regular IRB meetings. If a protocol is approved as Full Board - the PI(s) are required to submit a continuing review form annually. No research activity may take place – not even data analysis – beyond the date indicated on the approval letter, unless the protocol is renewed and approved through continuing review. PI(s) need to submit a modification request for any changes to the protocol.