

**Rowan IRB**

**Progress Report**

**Frequently asked questions**

1. **How do I know when my study has expired?**

The CIRB system will send 60 and 30 days reminder before the protocol expires. When such notices are received, the PI must submit either a continuing review application (only when the IRB has required Continuing review at the time of initial review) or progress report unless the study is complete. In which case, you are required to submit a final report.

1. **How do I obtain continued approval for my research study?**

All IRB studies are approved for one year. A continuing review application or a progress report is required for continuing the study.

1. **What do I have to do if my study is complete?**

You must submit a Final report through CIRB.

1. **What if I did not submit a continuing review or progress report before the study has expired?**

IRB office will send an email to the principal investigator and the student 60 and 30 days before the expiration alerting them to the impending approval expiration. If no response is received to the reminders, a notice indicating the approval for the study expired may be sent after the approval expiration date. If approval is allowed to expire, all research on the study must cease until renewed approval is granted.

1. **What if my study is complete and I am only analyzing data for publication or other purposes?**

Data analysis does not require continuing review or annual progress report. In the final report the PI should indicate that the study is in the data analysis phase.

1. **What do I do if have to make modifications to my approved study?**

Investigators with approved projects must submit an Amendment/Modification application if there are significant changes involving any of the study protocols, study design, informed consent procedures, advertisements or principal investigator team. The administrator and chair of IRB review all amendment applications, and assign them for review and approval.

1. **Do I have to complete a Financial Conflict of Interest Form with my annual progress report?**

It is not required for progress report unless there is a change. If there is a change, a request for modification should be submitted through CIRB for review and approval. If the modification is for change in personnel, then a conflict of interest form is required. New personnel must complete CITI training.

1. **In the case of a potential unanticipated problem involving risks to participants or others, when is the principal investigator expected to report this occurrence to the IRB?**

Serious adverse events must be reported to the IRB immediately, with a written report by the PI following within 24 hours of the PI's becoming aware of the event. Serious adverse events are (1) death of a research participant; or (2) serious injury to a research participant.

All other non-serious unanticipated problems should be reported to the IRB within 2 weeks of the first awareness of the problem by the Protocol PI or another researcher, ORIA, or a member of the IRB. Prompt reporting is important, as unanticipated problems often require some modification of study procedures, protocols, and/or informed consent processes. Such modifications require the review and approval of the IRB.

The Unexpected Event Report form is available on the IRB website

Please note that unanticipated problems may result in revisions to the approved research study and the consent form may need to be revised.