

GOVERNORS STATE UNIVERSITY
INSTITUTIONAL REVIEW BOARD

Guidance on the Types of IRB Submissions in Cayuse

Initial Review: The first submission always details the protocol and represents the initial approval/exemption process. Once the Initial Submission is approved, several new submission types become open to the research team: **Modification, Renewal, Incident, and Closure.**

Modification: The most common submission type, this is how you would request a change to your protocol. The same as your Initial submission, creating a modification will take you to the Submission Details screen of the newly created submission where you can click the **Edit** button or any of the task items to get into the actual forms.

Modifications are unique in that they present an editable version of your Initial submission, but with additional forms included at the beginning wherein you can offer some detail on the proposed changes. Essentially, it's the most recently approved version of your protocol, plus a coversheet. Keep in mind that changes made here do not take effect in real time. A Modification Submission is a request for a change, and so that change is nothing more than a request until the review process is completed with an affirmative decision.

This is most important to keep in mind for personnel changes, especially because certification by the PI (and potentially Co-PIs) is required for any submission to proceed to review. For this reason, if the certifier(s) on the research team are going to be unavailable, it often makes sense to submit a Modification changing who has the PI (and potentially Co-PI) role ahead of their departure, so that they will be able to certify that exchange of responsibility in case another Modification or a Renewal is required during their absence.

Renewal: If your study qualifies for continuing review according to your institutional policy, then you will periodically need to submit a Renewal Submission before the expiration date of your study. Completing a Renewal tends to be a pretty quick process so long as nothing has changed, though the review process of course depends entirely on the nature of the science. The PI for a study will receive email notifications ahead of the expiration date of their study requesting that they submit a Renewal.

If the expiration date passes you can still submit a Renewal Submission, however a project is considered out of compliance as soon as that line is crossed.

Incident: This submission type is meant for reporting any potentially risky events that arise over the course of a project. Every institution has its own policy about what qualifies as an event and

rules around the time-frame in which one must be reported-- but of course it's generally ideal to create and complete this type of submission as soon as one can. The decision outcomes for an Incident are a little different, meaning that review will often end either in suspension or the incident being "noted".

If your study is suspended then you will need to work with your IRB team to determine how to move forward.

Closure: This submission type officially ends a project. Be careful about creating a Closure as it will prevent the creation of any other submissions. If you create a Closure in error we recommend deleting it right away, as the research team loses the ability to delete it once someone certifies it. Once a Closure is routed to the IRB and approved, the study record is archived. An archived study and its submissions can still be viewed by everyone but it won't appear on the Dashboard or in regular search results and no changes can be made to the record.

Closures most often come up when a PI gets an expiration notification/request for continuing review, but the project has come to an end. In this case a Renewal isn't necessary since there is no ongoing project, a Closure would be used instead. Studies that are exempt from continuing review will not receive expiration notifications so it can be easy to forget to every officially close out a study. That said, if you are responsible for a project that has come to an end, it's best for the record of that project if you close it out with a Closure Submission-- and it greatly helps the IRB Office keep track of what's really active.