



Guide to “Study Status” in the eIRB

“The study” refers to the initial submissions and “other activities”, including modification requests (MR), continuing reviews (CR), unanticipated problems (UP), protocol deviations (PD) and terminations that are created within the eIRB system. Throughout this document, “The activity” refers to all the above study-related activities.

In the states listed below, the study or other activity is in the Principal Investigator’s (PI) inbox and requires the PI and/or study staff to complete an action.

Researcher Preparation	The PI has not submitted the activity and so the IRB (Institutional Review Board), CI (Cancer Institute) or OCTRI (Oregon Clinical and Translational Research Institute) have not received or reviewed any such activity.
Pre-board Revisions	The PI has submitted the activity to the IRB, and the IRB has returned it for revisions, often prior to an IRB Chair’s review, and always before going to a full Board meeting.
Researcher Revision	The full Board has reviewed an activity and returned it for revision.
PI Review	The full board has reviewed the activity and has approved it after having made some minor changes. The chair sends the activity back to the PI for review to either agree or disagree with the minor changes. PI agreement grants IRB approval of the activity; disagreement allows the PI to make further revisions prior to his/her resubmission to the IRB.
Lapsed	The study’s IRB approval has expired and the PI must complete an action (termination or CR) in a timely manner. Prior to receiving this notice, the eIRB system has generated three CR notices by email to the PI and study team. When the study expires, the eIRB system sends an email on the day the study expires and another one 10 days later. A CR or termination request must be received within those 20 days post-expiration or the Research Integrity Office will administratively terminate the study, and the department will be charged \$500.

In the following states, the IRB has not yet received the study and requires review by these committees prior to being forwarded to the IRB for review.

OCTRI Review	Review to be conducted by OCTRI (Oregon Clinical and Translational Research Institute) conducts the preliminary review and then sends the study on to the IRB for review.
CI review	Cancer Institute (CI) conducts the review. The IRB does not receive the study for review until the CI Clinical Research Review Committee (CRRC) review is complete and they have granted approval, or if deemed appropriate, the study may be passed on to the IRB for concurrent review.

The following states are when the activity has been approved and no action is required or requested.

Active	The study is open for subject enrollment.
Closed to Enrollment	Subject enrollment is complete. Subjects can still be in follow-up and data analysis is ongoing.
Terminated	The study is complete. All subjects have completed all study-related activities, including follow-up. Data analysis is complete and the study has been accepted for publication. If it is a sponsored study, the data has been locked and nothing else is required of the OHSU PI.

Reminder: The PI is the only person who can submit a study or other activity.

In the following state, the IRB has reviewed and approved the activity and requires additional oversight committee review.

<p>Ancillary Approval Pending</p>	<p>The IRB has approved the activity and it is awaiting approval from the Radiation Safety Committee, Biosafety Committee, and/or Conflict of Interest in Research.</p>
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In the following states, the activity is in the IRB inbox and action is required from an analyst, a Chair or the IRB.

<p>Documents Pending</p>	<p>The study staff or PI have indicated that a hard copy document has been or will be sent to the IRB. In this state the IRB is not reviewing the activity and will not review it until the IRB administrative staff receives the document, and scans and uploads it. Often times study staff checks this in error, so be careful and call (503) 494-7887 if you discover an activity in this state that should not be.</p>
<p>Pending Docket</p>	<p>The PI has submitted the study but an IRB analyst has not yet claimed it. This only applies to initial submissions.</p>
<p>Analyst Review</p>	<p>The activity is in an IRB analyst's inbox.</p>
<p>Draft Agenda</p>	<p>The activity has been placed on a tentative Board meeting agenda which has not yet been approved by a Chair.</p>
<p>Board Review</p>	<p>The activity is on an approved Board meeting agenda. Study staff receive an email after the agenda has been approved informing them of the date of the board meeting.</p>
<p>IRB Chair Screening</p>	<p>The activity has been submitted to the IRB Chair for review and/or approval.</p>
<p>Analyst Revision</p>	<p>The IRB Chair has rejected the approval for the activity, and is waiting for the analyst to make revisions and send it back for approval.</p>
<p>Chair Revision approval</p>	<p>The IRB analyst has corrected the activity's approval and has submitted it to the IRB Chair for approval.</p>
<p>Chair Response Approval</p>	<p>The activity has been submitted to the Chair for approval. A convened IRB has reviewed the activity, which was approved with minor changes, and the managing analyst completed the revisions. See PI Review.</p>
<p>Chair Confirm Approval</p>	<p>The activity has been submitted to the Chair for approval after being approved as presented by a convened IRB.</p>
<p>Triage Review</p>	<p>The analyst has a question regarding the study and has submitted it to an IRB Chair for assistance.</p>
<p>Analyst Response Prep</p>	<p>The Chair has requested changes in an approval memo or review communication that an analyst has drafted after the Board has met and reviewed the activity. The managing analyst will revise the memo and resubmit it to an IRB Chair for approval.</p>