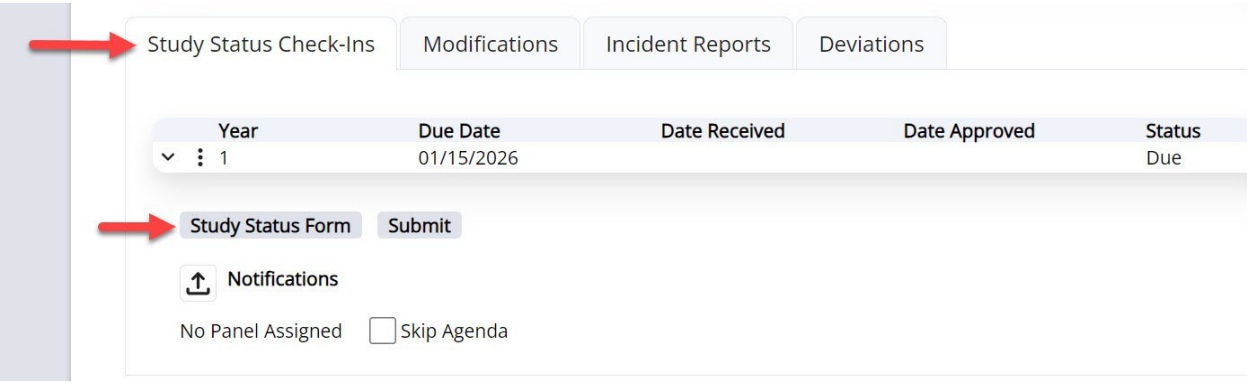
NAVIGATING IRB MENTOR
STUDY STATUS CHECK-INS OR CONTINUING REVIEWS

Approval Duration

The IRB office will determine whether and when your protocol approval expires. This information will be noted on the protocol information page.

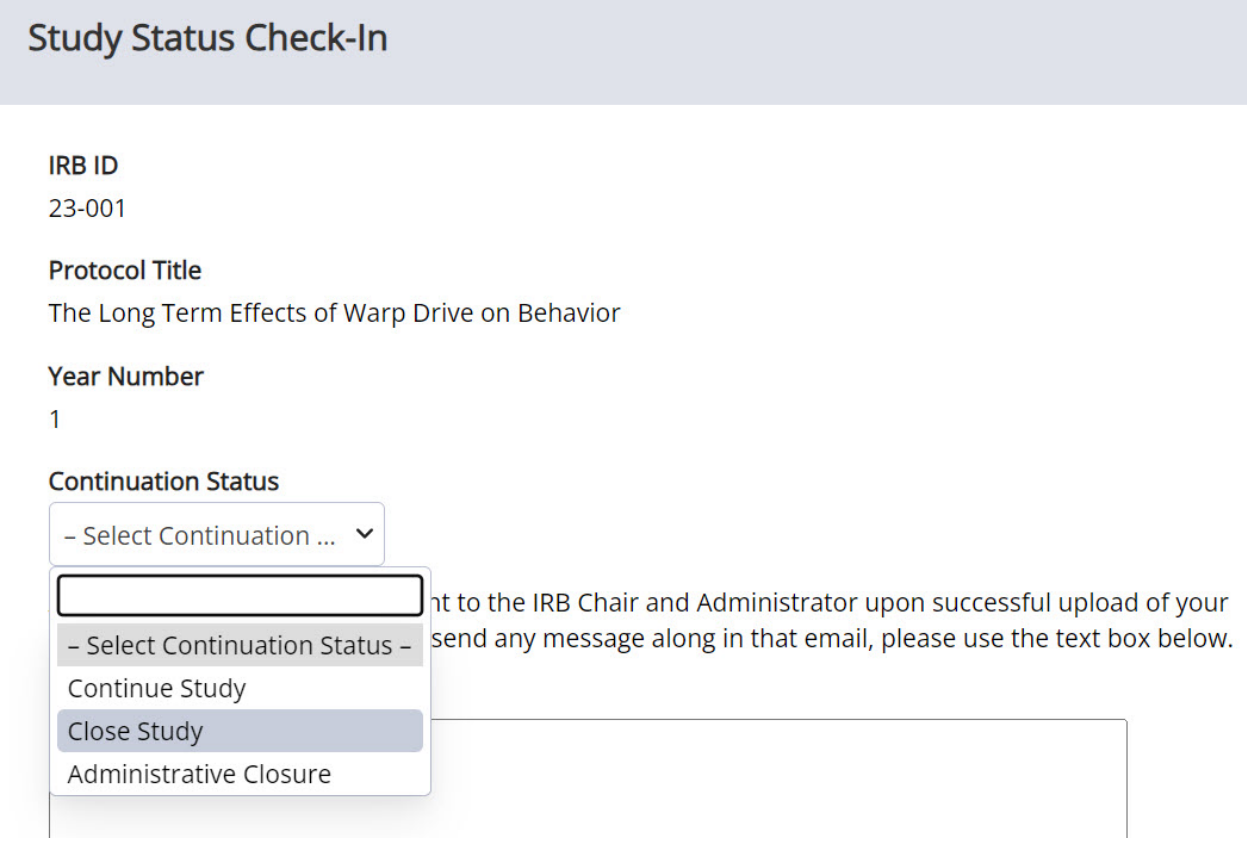
Exempt or Expedited Reviews

For most minimal risk research that went through either an exempt or expedited review, there will be a check-in requirement within 1-3 years (by default it is 3 years). Although this may be characterized as an "expiration date," the purpose of the check-in is to ensure that the IRB office has accurate information regarding active studies in the SJSU research portfolio. The approval for most research that undergoes exempt and expedited review does not actually expire. You will be sent an automated email reminder to log into IRB Mentor and report the status of your protocol. This is done via the post-approval reporting tab at the bottom of the protocol information page, which will not appear until your protocol is approved.



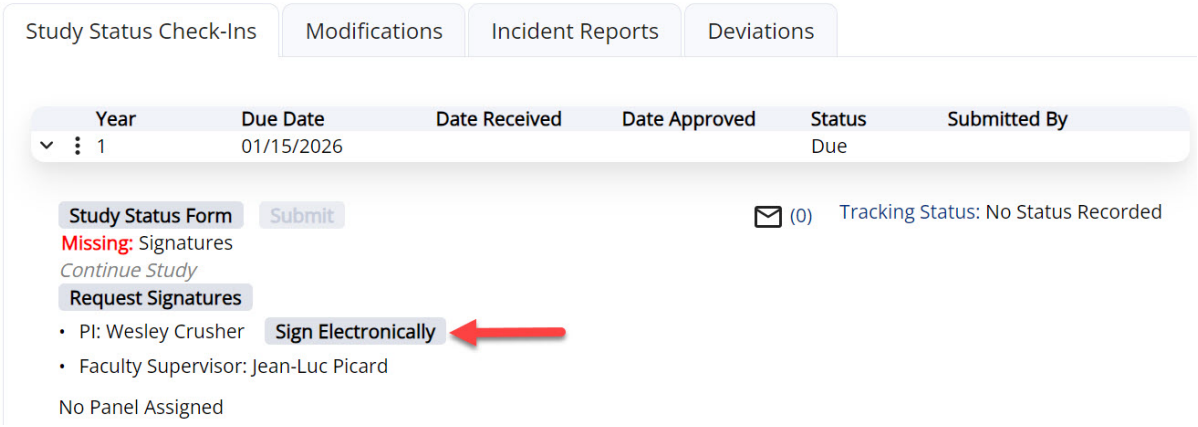
- After receiving the automated alert that your status check-in is due, click on the form under the Study Status Check-in tab and report whether or not the study is complete or is still ongoing. If it is ongoing, the IRB office will re-stamp your consent document if you were provided with a stamped version.

- If you complete the study before the check-in date, you can click on the Study Status Check-in Submission Form at any time, and select the Close Study option from the drop-down menu.



- Faculty supervisors are responsible for filing study status check-ins to close the study for students who have graduated and who have not closed their study within the system; automated alerts and reminders are copied to faculty supervisors of student research.

- Sign electronically by your name to submit the study status form and, if you are a student, request a signature from your faculty supervisor as well.

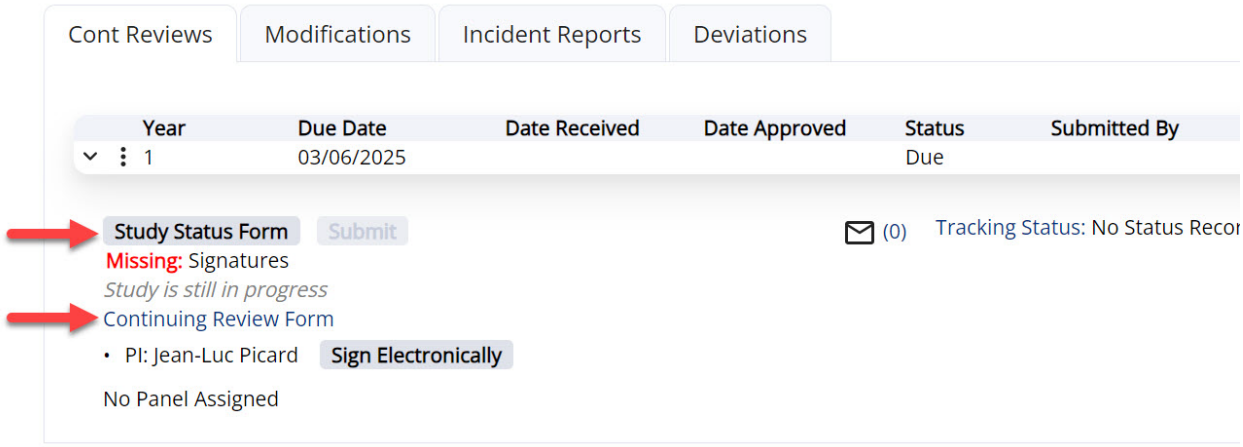


Continuing Reviews

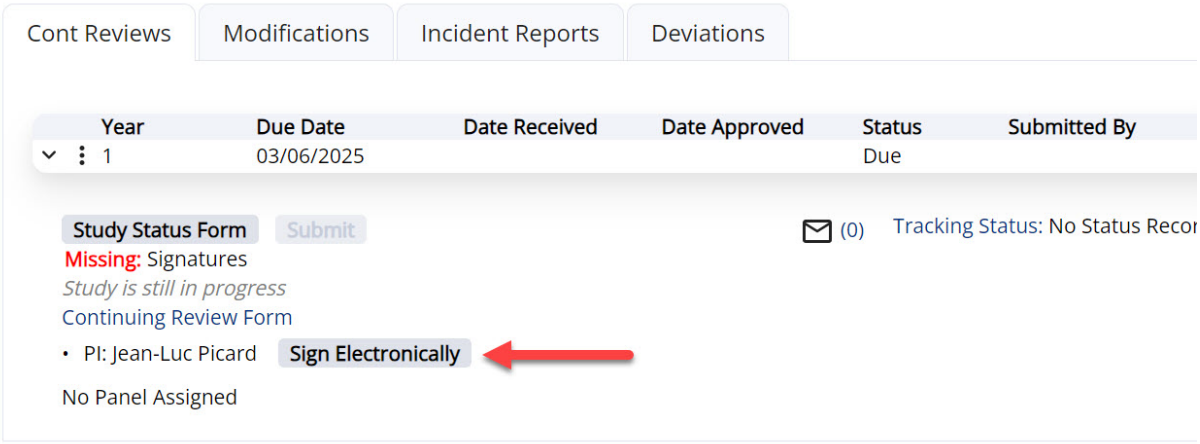
If your protocol went through a full-convened committee review, the tab at the bottom of the protocol information page will say “Cont Reviews” once your study is approved.

Approvals for continuing review protocols typically expire after one year, unless the IRB has decided on a shorter approval period (one year is the maximum duration of approval for protocols that undergo a full review).

- After receiving the automated alert that your continuing review is due, fill out the two forms under the Continuing Review Tab on the protocol information page:
  Study Status Form and Continuing Review Form.



- To submit the continuing review request to the IRB, click the “sign electronically” button next to your name. If the protocol was a student submission, the faculty supervisor will be required to sign as well.



- Your protocol will be placed on the next meeting agenda closest to your approval expiration date. If the meeting is scheduled after the approval expires, the system will automatically send you an expiration email alert even if the continuing review is upcoming. Once the approval expires, all study activities must stop until the IRB has reviewed the study and provided a renewal approval.

- You must file a continuing review request one last time when all study activities have been completed to notify the IRB of the completion of the study.

- Faculty supervisors are responsible for filing a final continuing review form to close the study for students who have graduated and who have not closed their study within the system; automated alerts and reminders are copied to faculty supervisors of student research.

Post-Approval Reporting

A separate guidance document has been prepared for investigators who need to submit modification requests, report incidents and unanticipated problems, and to report study deviations/protocol violations. Refer to the User Guide for Post-Approval Reporting for information on how to navigate these types of reporting mechanisms within IRB Mentor.