

Post Approval Reports and Submissions

Types of Submission after Approval:

Modification – you must receive approval from the IRB before implementing changes to your data collection tool, informed consent form, inclusion/exclusion criteria, incentives, subject population, methods, etc.

Renewal – to continue your study for another year, you must submit a renewal and receive approval before activity can continue. Cayuse IRB will automatically remind you of upcoming expirations.

Closure – when your study is complete, use this submission to close the study. Cayuse IRB will automatically remind you of upcoming expirations.

Incident – if a participant is injured or has a negative reaction due to their participation in your study, please report the incident to the IRB with this submission type.

Withdrawal – Only use this submission type if research has not begun and will not be conducted in the future. Withdrawn studies cannot be recovered once deleted!

Making a New Submission:

1. If you need to make one of the submission types listed above, login to Cayuse IRB using your SacLink username and password (<https://csus.cayuse424.com/rs/irb>) and select your study under *My Studies*.

The screenshot displays the Cayuse IRB dashboard for a user with the role of 'Researcher'. At the top right, there is a '+ New Study' button. Below this, four summary cards show submission counts: 'In-Draft' (0), 'Awaiting Approval' (1), 'Pre-Review' (0), and 'Under Review' (1). The 'Awaiting Approval' card features a building icon. Below the summary cards are three main sections: 'My Studies', 'My Tasks', and 'Submissions by Type'. The 'My Studies' section is circled in red and contains a table with three entries: 'TR-15-16-19' with the description 'Study Title Goes Here', 'TR-15-16-17' with 'April test', and 'TR-15-16-16' with 'try again'. The 'My Tasks' section shows one task: 'TR-15-16-16' with a 'View Submission' link. The 'Submissions by Type' section is a table showing counts for various submission types: Initial (3), Withdrawal (0), Modification (0), Renewal (0), Incident (0), Closure (0), and Legacy (0). A dark blue sidebar on the left contains navigation icons for home, documents, checkmarks, calendar, list, settings, and help.

Submission Type	Count
Initial	3
Withdrawal	0
Modification	0
Renewal	0
Incident	0
Closure	0
Legacy	0

2. Select *New Submission* and choose the appropriate application for your circumstance.

The screenshot shows the 'Study Details' page for study TR-15-16-17. The 'New Submission' button is circled in red, and its dropdown menu is open, showing options: Renewal, Modification, Incident, and Closure. The page also displays study information such as Approval Date (04-14-2016), Expiration Date (04-30-2016), and Organization (Office of Research Affairs, Physical Therapy).

3. Just like the initial submission, your new submission will have a list of Required Tasks for you to complete before you can submit.

The screenshot shows the 'Submission Details' page for a submission in the 'In-Draft' stage. The 'Required Tasks' section is circled in red, showing a single task: Complete Submission. The page also displays submission information such as PI (Diane Director), Current Analyst (N/A), and Review Type (N/A).

4. Enter the required information and select COMPLETE SUBMISSION >

The screenshot shows the 'Renewal Report' form for study TR-15-16-18. The 'COMPLETE SUBMISSION' button is circled in red. The form contains three questions for the user to answer:

- Please provide a brief summary of the work accomplished to date:
- Please provide a brief summary of the work to be accomplished in the next approval period:
- Did any participants experience a negative and unexpected reaction from your study?
 No
 Yes

5. You will need to confirm the submission and will be brought back to your Submission Details. Click Certify to “sign” the submission and send it to the IRB.

The screenshot shows the IRB Submission Details page. At the top, the title is "Submission Details" and the user is identified as "Diane Director". The page displays a four-step workflow: 1. In-Draft (Submission is with researchers), 2. Awaiting Approvals (Submission is awaiting certification or approval), 3. Pre-Review (Submission is being prepared for review), and 4. Under-Review (Submission is with reviewers). The current status is "Awaiting Certification". Below this, the submission is titled "Renewal" with the description "TR-15-16-18 - RRC routing test". There are buttons for "View", "PDF", and "Delete". On the right, under "Routing:", there are "Return" and "Certify" buttons, with "Certify" circled in red. At the bottom, there is a table of submission details:

PI: Diane Director	Current Analyst: N/A	Decision: N/A	Required Tasks: N/A
Review Type: N/A	Review Board: N/A	Meeting Date: N/A	

6. These submission types only require confirmation from any listed Co-PIs/Faculty Advisors and will not be routed through the Department Chair/Head signature process.

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