

Cayuse – Human Ethics Full Board Legacy Study Guidance

- This document covers what your full board protocols will look like in our IRB submission platform Cayuse – Human Ethics. We will be going over what has been transferred over from IRB Wise and what steps the study team will need to take to review the information that has been transferred and how to update the study information accordingly.
- The images included in this document are for Example Only, please be sure to read and review all sections of the submissions and respond according to your submission.
- Please contact the Office of Research Integrity Assurance at irb@gatech.edu if you have any questions.

Landing Page – Dashboard

This is the main page that allows you to see your different studies, tasks, and submission statuses. Your dashboard will also show you your approved studies, studies expiring within 30 days, and currently expired studies.

For further information please watch [Human Ethics Researcher Dashboard Overview Video](#)

The dashboard interface includes a top navigation bar with a 'Menu' icon, the title 'Dashboard', a notification bell, and the user name 'Bruce Banner'. A '+ New Study' button is located in the top right corner.

The dashboard features four main status cards at the top:

- In-Draft:** 29 studies (represented by a pencil icon)
- Awaiting Authorization:** 7 studies (represented by a building icon)
- Pre-Review:** 4 studies (represented by a folder icon)
- Under Review:** 3 studies (represented by a checklist icon)

Below these cards are three main sections:

- My Studies:** A list of studies with details such as IRB number and title. Visible entries include:
 - IRB-FY2019-1479: Bone-anchored hearing aids: a clinical study
 - IRB-FY2019-1473: Strengthening habitual behaviors with sucrose rewards
 - IRB-FY2019-1407: Personality changes after frontal lobe operations
 - IRB-FY2019-912: An analysis of spinal muscular atrophy
 - IRB-FY2019-911: Clinical practice of anemia and bloodA 'View All' link is at the bottom.
- My Tasks:** A list of tasks with IRB numbers and actions. Visible entries include:
 - IRB-FY2019-1407: View Submission
 - IRB-FY2019-1407: Certify Submission
 - IRB-FY2019-354: Complete Submission
 - IRB-FY2019-912: Complete Submission
 - IRB-FY2019-911: Complete SubmissionA 'View All' link is at the bottom.
- Submissions by Type:** A table showing the count of submissions for each type:

Submission Type	Count
Initial	25
Withdrawal	5
Modification	4
Renewal	10
Incident	1
Closure	1
Legacy	0

At the bottom, there are three more sections:

- Approved Studies:** Shows a list of approved studies, including IRB-FY2019-1473: Strengthening habitual behaviors with sucrose rewards.
- Studies Expiring in 30 days:** Shows a list of studies expiring soon, including IRB-FY2019-1473: Strengthening habitual behaviors with sucrose rewards.
- Expired Studies:** A section for studies that have expired.

Locating your Legacy Study

- You can search for your protocol using your Protocol (Study) title or Protocol (Study) Number under the Studies Tab.

The screenshot displays the Cayuse Human Ethics interface. At the top, the logo and navigation menu are visible. The 'Studies' tab is selected. A search bar contains the text 'Legacy-2'. Below the search bar, a table lists the study details. The table has columns for IRB#, Study Title, Status, PI, Exp Date, Admin Check-in Date, and Create Date. The data row shows 'Legacy-2' as the IRB#, 'Legacy Title - 2' as the Study Title, 'Approved' as the Status, 'Irene Investigator' as the PI, '10-31-2024' as the Exp Date, 'N/A' as the Admin Check-in Date, and '04-01-2021' as the Create Date. Below the table, there is a pagination control showing '1-1 of 1' and a '25 per page' dropdown menu.

Navigation: Dashboard | **Studies** | Submissions | Tasks

Search: All: Legacy-2

IRB#	Study Title	Status	PI	Exp Date	Admin Check-in Date	Create Date
Legacy-2	Legacy Title - 2	Approved	Irene Investigator	10-31-2024	N/A	04-01-2021

1-1 of 1

25 per page

Legacy Study Details

- You will be able to review a snapshot of the study under the details section after clicking on the study.

The screenshot displays the 'Legacy-2' study details page. At the top, the 'cayuse Human Ethics' logo is on the left, and a notification bell with '186' and a user profile for 'Irene Investigator' are on the right. Below the header is a navigation bar with 'Dashboard', 'Studies', 'Submissions', and 'Tasks'. The main content area shows the study title 'Legacy-2' and 'Legacy Title - 2'. There are 'PDF' and 'Delete' buttons. A metadata table lists: Approval Date (04-01-2023), Expiration Date (10-31-2024), Organization (Biological Sciences), Active Submissions (N/A), Admin Check-In Date (N/A), Closed Date (N/A), Current Policy (Post-2018 Rule), and Sponsors (N/A). Below this is a 'Key Contacts' section with a table:

Team Member	Role	Number	Email
Irene Investigator	Principal Investigator		thomas.keller+investigator@cayuse.com
Irene Investigator	Primary Contact		thomas.keller+investigator@cayuse.com
Frances Faculty	Co-Principal Investigator		thomas.keller+faculty@cayuse.com

Legacy Study Submissions

- You will be able to review the Legacy Submission completed by the IRB Team for your convenience.

The screenshot shows the 'Legacy Study Submissions' page. The header and navigation are identical to the previous screenshot. The main content area has a breadcrumb 'Studies / Study Details' and a '+ New Submission' button. Below is a tabbed interface with 'Study Details' and 'Submissions' tabs. The 'Submissions' tab is active, showing a table with one submission:

Submission Type	Review Type	Status	Decision
Legacy	Unassigned	● Review Complete	--

Below the table is a pagination control showing '1-1 of 1' and a '25 per page' dropdown menu.

Legacy Submission Details

- You will be able to review all Legacy documents uploaded by the IRB Team once you are under the Legacy Submission.
 - Uploaded Documents: PDFs of the IRB Wise Submissions excluding personnel only amendments, IRB approved study documents, and the most recent approval letter.
 - Should the study team want to add any documents you will be able to include them in the required modification.
- The study team will be asked to submit a modification to add in any missing information for your Study.

The screenshot shows the 'Submission Details' page in the Cayuse Human Ethics system. The top navigation bar includes 'Dashboard', 'Studies', 'Submissions', and 'Tasks'. The user is logged in as 'Irene Investigator'. The submission is in the 'Under-Review' stage, with a progress bar showing four stages: 'In-Draft' (Submission is with researchers), 'Awaiting Authorization' (Submission is awaiting certification or approval), 'Pre-Review' (Submission is being prepared for review), and 'Under-Review' (Submission is with reviewers). A 'Review Complete' notification is visible. The submission is titled 'Legacy-2 - Legacy Title - 2' and has options to 'View', 'PDF', and 'Delete'. Key information includes: PI: Irene Investigator, Current Analyst: Alyssa Cabrera, Decision: N/A, Policy: Post-2018 Rule, Review Type: N/A, and Review Board: N/A.

The screenshot shows the 'Attachments' page in the Cayuse Human Ethics system. The top navigation bar includes 'Dashboard', 'Studies', 'Submissions', and 'Tasks'. The user is logged in as 'Irene Investigator'. The page has tabs for 'Approvals', 'Task History', and 'Attachments'. A search bar is present with the text 'Click to search'. Below the search bar is a table listing uploaded documents.

Filename	Uploaded By	Date Uploaded
Legacy Document - Training - Protocol.docx	Alyssa Cabrera	10-24-2024 2:08 PM
Legacy Document - Training - AM.docx	Alyssa Cabrera	10-24-2024 2:08 PM
Legacy Document - Training - CR.docx	Alyssa Cabrera	10-24-2024 2:08 PM
Legacy Document - Training.docx	Alyssa Cabrera	10-24-2024 2:08 PM
Legacy Document - Training - Most Recent IRB Approval Letter.docx	Alyssa Cabrera	10-24-2024 2:08 PM

1-5 of 5

Legacy Submission - View

- Once you have selected your Legacy Submission and click View, you will see the Getting Started Page, Project Personnel, Basic Information, and Legacy Attachments.

The image displays four sequential screenshots of the 'Legacy Submission - View' interface, each showing a different section of the submission details for 'Legacy Title - 2 - Legacy' (IRB NUMBER: Legacy-2). Each screenshot includes a top navigation bar with 'SUBMISSION DETAILS', 'CREATE PDF', 'COMPARE', and 'SAVE' buttons, and a left sidebar with a 'Sections' menu.

- Getting Started:** The main content area displays the title 'Getting Started' and a warning: 'THIS IS A LEGACY STUDY FORM. SELECT STUDY INFORMATION HAS BEEN TRANSFERRED FOR YOU. PLEASE BE SURE TO REVIEW YOUR ENTIRE SUBMISSION TO CONFIRM TRANSFERRED INFORMATION IS ACCURATE AND COMPLETE.' It also provides contact information for the Georgia Institute of Technology Office of Research Integrity Assurance (irb@gatech.edu).
- Project Personnel:** The main content area displays the title 'Project Personnel' and a question: 'What affiliation does the PI have with Georgia Tech?'. It includes a note about student eligibility and a list of radio button options: Faculty (selected), Staff, and Other.
- Basic Information:** The main content area displays the title 'Basic Information' and a 'Project Type' section with the question 'What type of project is this submission for?'. It includes radio button options for 'Research Study' and 'Reliance Agreement/IRB Deferral Request', and a section for 'Is this a student class project?' with 'No' and 'Yes' options.
- Legacy Attachments:** The main content area displays the title 'Legacy Attachments' and two sections: 'Legacy Protocol' and 'Legacy Amendments'. Each section contains a file upload box with a document icon and a file name (e.g., 'Legacy Document - Training - P...').

Legacy Study – Modification Instructions

- Once you have reviewed the attached documents and submissions details, please go to the Study Details Page and select New Submission – Modification.

Study Details

Approved

Legacy-2 Legacy Title - 2

PDF Delete

Approval Date:	Expiration Date:	Organization:	Active Submissions:
04-01-2023	10-31-2024	Biological Sciences	N/A
Admin Check-In Date:	Closed Date:	Current Policy	Sponsors:
N/A	N/A	Post-2018 Rule	N/A

Submission Workflow

- 1 In-Draft**
Submission is with researchers
- 2 Awaiting Authorization**
Submission is awaiting certification or approval
- 3 Pre-Review**
Submission is being prepared for review
- 4 Under-Review**
Submission is with reviewers

Unsubmitted

Modification

Legacy-2 - Legacy Title - 2

Edit PDF Delete

PI:	Current Analyst:	Decision:	Policy:	Required Tasks:
Irene Investigator	N/A	N/A	Post-2018 Rule	Assign-PI
Review Type:	Review Board:	Meeting Date:		Assign-PC
N/A	N/A	N/A		Complete Submission

Legacy Study – Modification Instructions Cont.

- Select Edit and you will be able to make changes to the study information that has been uploaded. This includes project personnel, basic information, and legacy attachments. We request the study team refrains from removing any uploaded approved documents unless they are no longer being used in the study.

The screenshot shows the Cayuse Human Ethics interface. The top navigation bar includes the logo, 'Products' dropdown, and 'Irene Investigator' dropdown. Below the navigation bar are tabs for 'Dashboard', 'Studies', 'Submissions', and 'Tasks'. The main content area is titled 'SUBMISSION DETAILS' and 'Legacy Title - 2 - Modification'. On the left, a sidebar lists sections: 'Modification Information' (selected), 'Getting Started', 'Project Personnel', 'Basic Information', and 'Legacy Attachments'. The main content area displays 'Modification Information' with an 'IMPORTANT REMINDER' section. The reminder states: 'The only way to make changes to the study protocol is to make them in a modification submission.' It lists three bullet points: 'If you are looking to renew study approval, a Renewal submission is needed.', 'If you are looking to report an event or incident with the study, an Incident submission may be needed.', and 'If the study is complete, a Closure submission may be needed.' Below the reminder is a question: '* Are you making changes to the project?' with radio buttons for 'Yes' and 'No'.

The screenshot shows the Cayuse Human Ethics interface. The top navigation bar includes the logo, 'Products' dropdown, and 'Irene Investigator' dropdown. Below the navigation bar are tabs for 'Dashboard', 'Studies', 'Submissions', and 'Tasks'. The main content area is titled 'SUBMISSION DETAILS' and 'Legacy Title - 2 - Modification'. On the left, a sidebar lists sections: 'Basic Information' (selected), 'Modification Information', 'Getting Started', 'Project Personnel', 'Basic Information', and 'Legacy Attachments'. The main content area displays 'Basic Information' with a 'Project Type' section. The 'Project Type' section asks 'What type of project is this submission for?' and has two radio buttons: 'Research Study' and 'Reliance Agreement/IRB Deferral Request'. Below this is a question: 'Is this a student class project?' with radio buttons for 'No' and 'Yes'. At the bottom, there is a 'Study Site(s)' field.

Should the study team have any additional questions or concerns regarding modifications, please visit [Creating a Modification Submission in Human Ethics](#).