



ECSU

ELIZABETH CITY STATE UNIVERSITY

FOUNDED 1891

Office of Sponsored Programs, Contracts and Grants

Cayuse Human Ethics Module for IRB Submission/Approval

Annemarie Delgado
Director of Sponsored Programs

George Cox
Research Compliance Officer

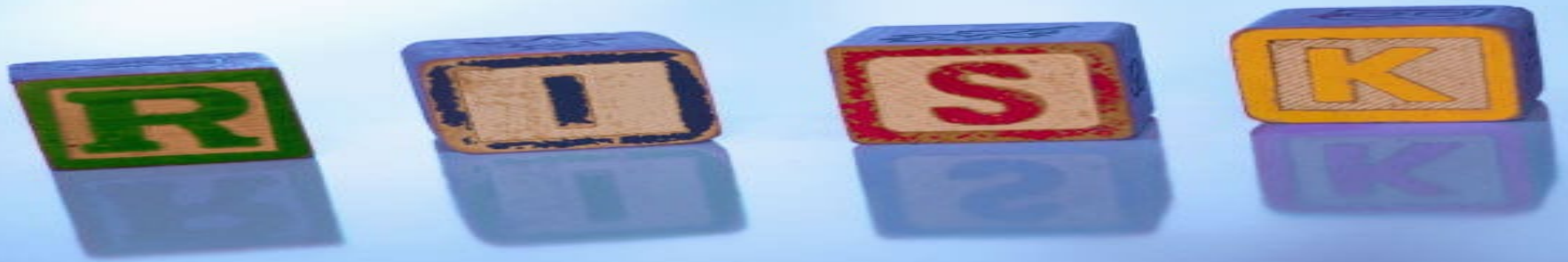
<https://www.ecsu.edu/academics/sponsored-programs.php>



IRB Responsibilities

All research involving human subjects conducted by researchers (ECSU faculty, staff, or students) or sponsored by ECSU, must be reviewed and approved by the IRB prior to start of the project; and then conducted in full compliance with IRB guidelines and procedures regardless of funding.





Types of Reviews

Exempt Review – little or no risk

Expedited Review – minimal risk

Full Board Review – greater than minimal risk



IRB Application Process

- Emailed or paper submissions have been used for many years. Several challenges have persisted.
- Beginning July 1, 2024, Cayuse Human Ethics will be used for all IRB applications, modifications, and event reporting.
- All drafts/revisions and related documents will be housed in Cayuse.
- Approvals will be sent from Cayuse with copies stored in the system.

CITI Training

Before beginning an IRB Submission, be sure you have completed required CITI Training

Go to www.citiprogram.org

- You will not have to enter any payment information or pay for anything while completing these courses. Your participation is covered under ECSU's subscription.
- If you already have an account, click on login. Skip to the directions for registering for courses.
- If you do not have an account, click on Register at the top right of the page.

CITI Requirements

To satisfy IRB training requirements, register for:

- Social and Behavioral Research Investigators and Key Personnel
- Responsible Conduct of Research Investigators and Key Personnel

Save a pdf of your certificate for upload in Cayuse.

Getting Prepared

Other documents to prepare for upload:

- Data Collection Instruments
 - Surveys/questionnaires
 - Interview/focus group protocol
- Consent/assent documents or information sheet
- Recruitment materials (emails, flyers, scripts, etc.)

Accessing Cayuse

- ECSU Faculty and Staff will be prompted to login using ECSU credentials using SSO.
- ECSU Students will need to request Cayuse access by sending an email to irb@ecsu.edu requesting Cayuse access.
 - Include a brief description of planned research.
 - Copy research advisor and ghcox@ecsu.edu on the email.
- An automated email from Cayuse will be sent to your ECSU address with instructions.

Accessing Cayuse

To access Cayuse Human Ethics, go to

<https://ecsu.cayuse.com>

Click on Products in the upper right corner and select “Human Ethics”.

The screenshot displays the Cayuse Human Ethics dashboard. At the top, the browser address bar shows the URL ecsu.cayuse.com/rs/rb#dashboard. The dashboard header includes the Cayuse logo, the text "Human Ethics", and user information: "Role: Researcher", "Products", and "George Cox". A navigation menu contains "Dashboard", "Studies", "Submissions", "Tasks", "Meetings", "Reporting", and "More". A "New Study" button is located in the top right corner.

The main content area features five status cards with icons and arrows:

- In-Draft**: Represented by a pencil icon.
- Awaiting Authorization**: Represented by a classical building icon.
- Pre-Review**: Represented by a folder icon.
- Under Review**: Represented by a calendar icon.
- Post Review**: Represented by a graduation cap icon.

Below these cards are several summary panels:

- My Studies**: Shows "You Have No Studies" with a sad face icon.
- My Tasks**: Shows "All Tasks Complete" with a checkmark icon.
- Submissions by Type**: A list of submission types: Renewal, Initial, Modification, Incident, Withdrawal, Closure, and Legacy.
- Approved Studies**: Shows "No Approved Studies" with a sad face icon.
- Studies Expiring in 30 days**: Shows "No Expiring Studies" with a happy face icon.
- Expired Studies**: Shows "No Expired Studies" with a happy face icon.

A red notification bubble with the number "5" and a question mark icon is visible in the bottom right corner.

Starting an IRB Application

Click on “New Study” in the upper right corner.

The screenshot displays the Cayuse Human Ethics dashboard. At the top, the browser address bar shows 'ecsu-t.cayuse.com/rs/irb#dashboard'. The dashboard header includes the Cayuse logo, the text 'Human Ethics', and user information: 'Role: Reviewer', 'Products' (with a notification badge), and 'George Cox'. A navigation menu contains 'Dashboard', 'Studies', 'Submissions', 'Tasks', 'Meetings', 'Reporting', and 'More'. A prominent blue '+ New Study' button is located in the upper right corner of the main content area.

The main content area is divided into several sections:

- Review Types:** Five cards with icons and arrows pointing to different review categories: 'Full Board Reviews', 'Expedited Reviews', 'Limited IRB Reviews', 'Exempt Reviews', and 'Admin Level Reviews'.
- Submissions where I am the Primary Reviewer:** A panel showing 'You Have No Submissions' with a sad face icon.
- My Tasks:** A panel showing 'All Tasks Complete' with a checkmark icon.
- Submissions by Type:** A table listing submission types and their counts:

Submissions by Type	Count
Renewal	0
Initial	1
Modification	0
Incident	0
Withdrawal	0
Closure	0
Legacy	0
- Approved Studies:** A panel showing 'No Approved Studies' with a sad face icon.
- My Meetings:** A calendar view for April 2024. The current date is the 8th (Monday).

April 2024						
Sun	Mon	Tue	Wed	Thu	Fri	Sat
31	01	02	03	04	05	06
07	08	09	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
- Upcoming Meetings:** A panel showing 'No Upcoming Meetings' with a sad face icon.

A red notification badge with the number '5' and a question mark icon is visible in the bottom right corner of the dashboard.

Starting an IRB Application

Add study title and then click on the blue check mark on the right side of the screen.

This creates the study in which the application and any follow-on submissions will be housed.

The screenshot displays the Cayuse Human Ethics web application interface. At the top, the logo for Cayuse Human Ethics is visible on the left, and the user's role (Reviewer), a notification bell with 23 alerts, and the user's name (George Cox) are on the right. A navigation menu includes Dashboard, Studies, Submissions, Tasks, Meetings, Reporting, and More. The main content area is titled 'Studies / Study Details' and features a '+ New Submission' button. A dark blue bar highlights the 'Study Details' tab, with 'Submissions' as an alternative view. A text input field contains 'Cayuse Training Submission', with a blue checkmark button and a close button to its right. Below the input field are 'PDF' and 'Delete' buttons. A table of metadata is displayed below:

Approval Date:	Expiration Date:	Organization:	Active Submissions:	Population Flags:	Additional Flags:
N/A	N/A	N/A			
Admin Check-In Date:	Closed Date:	Current Policy	Sponsors:		
N/A	N/A		N/A		

In the bottom right corner, there is a red notification bell with the number 4 and a blue question mark icon.

Starting an IRB Application

Studies may have multiple submissions. Select “New Submission” and then choose “initial” in the upper right corner to begin the application.

The screenshot displays the Cayuse Human Ethics web application. The top navigation bar includes the logo, user role (Researcher), notification count (23), and user name (George Cox). A secondary navigation bar lists menu items: Dashboard, Studies, Submissions, Tasks, Meetings, Reporting, and More. The main content area is titled 'Studies / Study Details' and features a '+ New Submission' button. A dark blue header bar indicates the current view is 'Study Details'. A red 'Unsubmitted' badge is present. The study information for 'IRB-2024-20' (Cayuse Training Submission) is shown, including PDF and Delete buttons. A table of metadata follows, and a 'Key Contacts' section is currently empty.

Role: Researcher | 23 Products | George Cox

Dashboard | Studies | Submissions | Tasks | Meetings | Reporting | More

Studies / Study Details + New Submission

Study Details | Submissions

Unsubmitted

IRB-2024-20 Cayuse Training Submission

PDF Delete

Approval Date: N/A	Expiration Date: N/A	Organization: Current Policy Post-2018 Rule	Active Submissions: N/A Sponsors: N/A	Population Flags:	Additional Flags:
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Key Contacts ⓘ | Attachments | Flags

Team Member	Role	Number	Email
No Key Study Contacts.			

Starting an IRB Application

- Read and complete the Getting started acknowledgement.
- Use the menu on the left to click to the next page of the form – Submission Information.
- Save (upper right) frequently.

The screenshot shows the Cayuse Human Ethics web application interface. The top navigation bar includes the logo, user role (Researcher), and notification icons. The main navigation menu on the left lists Dashboard, Studies, Submissions, Tasks, Meetings, Reporting, and More. The current page is titled 'SUBMISSION DETAILS' for 'Cayuse Training Submission - Initial' (IRB NUMBER: IRB-2024-20). The left sidebar shows 'Getting Started' as the active section. The main content area contains a 'Getting started' section with a list of requirements for the submission. At the bottom, there is a checkbox for 'I have read the information above and I am ready to begin my submission.' which is currently checked.

Additional Information has been added throughout the form for guidance and clarity. This additional information can be found by clicking the question mark in the top-right corner of each section.

For more information about the IRB submission Process, please contact us at irb@ecsu.edu.

Getting started

Throughout the submission, you will be required to provide the following:

- A complete account of all of the study details, including (but not limited to) all study procedures, risks and benefits, inclusion/exclusion criteria, privacy/confidentiality protections, etc.
- Data collection instruments, including (but not limited to): questionnaires, observation guides, interview guides, etc.
- All participant-facing research materials, including (but not limited to): informed consent materials, research recruitment materials, instructions for participants, information sheets, etc.

Elizabeth City State University IRB

- You cannot begin data collection until you have received formal approval or an official exemption determination from the IRB.
- Please allow at least for 2 weeks from the final revision of your application for IRB review of your submission. Studies that require full board review will require longer review times. The ECSU IRB meets on a monthly basis to discuss studies requiring full board review.
- If your study is funded, please provide the Sponsored Programs record number.
- For more information regarding the ECSU IRB, consent form templates, and FAQs, visit our [website](#).

I have read the information above and I am ready to begin my submission.

Yes

IRB Application

- Insert a Brief summary of the study and then proceed to add personnel.
- The PI must be an ECSU faculty or staff member.
- Student researchers should be listed as co-PI.
- Use the find people tool to search.
- If a researcher cannot be found, email irb@ecs.edu.

The screenshot displays the Cayuse Human Ethics web application. The top navigation bar includes the logo, user role (Researcher), and notification icons. A secondary navigation bar lists menu items like Dashboard, Studies, Submissions, Tasks, Meetings, Reporting, and More. The main content area is titled 'Cayuse Training Submission - Initial' with the IRB number 'IRB-2024-20'. A left sidebar shows 'Submission Information' as the active section. The main form area is divided into sections: 'Brief Summary' with a text editor and a 'Project Personnel' section containing three questions with radio button options.

Brief Summary

Provide a short non-technical description of the study in 50-100 words, which will be used in IRB documentation as a description of the study. You will be asked for more specifics around background/rationale and research question(s) further in the application. This should only serve as a brief synopsis and not the full description of your study.

Project Personnel

- Will this project be led by a STUDENT (undergraduate, graduate) or TRAINEE (fellow or postdoc)?
 Yes
 No
- Please identify the Principal Investigator (PI) for this project.
If you are a student researcher, you must select your faculty advisor as the PI for the study.
- Do you want to identify a primary contact other than the PI?
If you choose not to identify a primary contact for this submission, it will default to the person who created and began filling out this Initial Submission.
 Yes
 No

Please select all Co-PIs affiliated with Elizabeth City State University. Only complete this section if there are additional personnel not previously identified.

IRB Application

- Continue answering required questions (red asterisk) until a check mark appears in the left-hand menu.
- Individual Investigator Agreements only need to be completed for collaborators outside of ECSU (template will be on OSP website).
- If the information for a required text box is not known, type N/A in the box or make a note about what questions you have.
- When a check appears by the current form, use the right arrow at the bottom or the menu at the left to proceed to the next page of the form.

IRB Application

- Once all forms are complete, the Routing and Certification sections will appear.
- Click on these to complete submission. Follow the on-screen prompts to return to submission details.

The screenshot shows the Cayuse Human Ethics web application interface. At the top, the logo for Cayuse Human Ethics is visible. Below the logo is a navigation menu with options: Dashboard, Studies, Submissions, Tasks, Meetings, Reporting, and More. The main header area displays the IRB NUMBER: IRB-2024-20 and the title Cayuse Training Submission - Initial. A left sidebar contains a list of sections with checkmarks indicating completion status: Sections, Getting Started, Submission Inform..., Exemptions, Study Design and P..., Study Design and P..., Research Subjects..., Risks and Benefits, Data Protections, Data and Safety mo..., Consent Process, Routing, and COMPLETE SUBMISSION. The main content area is divided into sections for waivers. The first section is titled "Waiver of written documentation of informed consent / parental permission" and includes a paragraph explaining the default requirement for a signed consent form. Below this is a question: "Are you requesting a waiver of written (signed) documentation of informed consent / parental permission?" with radio button options for Yes and No. The second section is titled "Full or partial waiver of consent / parental permission" and includes a paragraph explaining the default requirement for informed consent. Below this is a question: "Are you requesting any of the following:" with three checkbox options: a waiver of informed consent / parental permission in its entirety, a waiver or alteration of some of the elements of informed consent / parental permission, and a waiver of parental permission for college students under the age of majority.

IRB NUMBER: IRB-2024-20
Cayuse Training Submission - Initial

Sections

- Getting Started ✓
- Submission Inform... ✓
- Exemptions ✓
- Study Design and P... ✓
- Study Design and P... ✓
- Research Subjects ... ✓
- Risks and Benefits ✓
- Data Protections ✓
- Data and Safety mo... ✓
- Consent Process ✓

Waiver of written documentation of informed consent / parental permission

The default is for subjects to sign a written document that contains all the elements of informed consent. Under limited circumstances, the requirement for a signed consent form may be waived or internet surveys, when a signed consent form is either impractical or unnecessary, or in circumstances where a signed consent form creates a risk for the subject.

* Are you requesting a waiver of written (signed) documentation of informed consent / parental permission?

Yes
 No

Full or partial waiver of consent / parental permission

The default is for subjects to give informed consent. A waiver of informed consent, or of certain elements of informed consent, might be warranted in certain circumstances.

Are you requesting any of the following:

- a waiver of informed consent / parental permission in its entirety
- a waiver or alteration of some of the elements of informed consent / parental permission
- a waiver of parental permission for college students under the age of majority

IRB Application

- Click “Certify” on the right-hand side of the screen.
- When prompted, click “confirm”.
- The PI’s department chair or division head will get an email requesting approval.
- You can monitor the status of a submitted application from your dashboard.

The screenshot displays the Cayuse Human Ethics dashboard for a user with the role of 'Researcher' (George Cox). The dashboard is organized into several sections:

- Navigation:** Top bar includes 'Role: Researcher', 'Products', and 'George Cox'. Below it are tabs for 'Dashboard', 'Studies', 'Submissions', 'Tasks', 'Meetings', 'Reporting', and 'More'.
- Status Filters:** A row of five filter cards: 'In-Draft', 'Awaiting Authorization', 'Pre-Review', 'Under Review', and 'Post Review', each with an icon and a right-pointing arrow.
- My Studies:** A table listing studies with columns for ID and description.

Study ID	Description
IRB-2024-20	Cayuse Training Submission
IRB-2024-19	Cayuse Training Submission
IRB-2024-13	Test 2/6/24 After Initial Revisions
IRB-2024-12	IRB Chair Demo
IRB-FY2024-9	testing study
- My Tasks:** A table listing tasks with columns for ID and description.

Task ID	Description
IRB-2024-12	Complete Submission
IRB-FY2024-9	Complete Submission
- Submissions by Type:** A table showing counts for different submission types.

Submission Type	Count
Renewal	0
Initial	3
Modification	0
Incident	0
Withdrawal	0
Closure	0
Legacy	0
- Approved Studies:** A section with a sad face icon and the text 'No Approved Studies'.
- Studies Expiring in 30 days:** A section with a happy face icon and the text 'No Expiring Studies'.
- Expired Studies:** A section with a happy face icon and the text 'No Expired Studies'.

IRB Application

- Applicants will receive emails as the application proceeds in the review process.
- New tasks will show on the dashboard as input is needed.
- If an amendment is needed or if any adverse events need to be reported, this is done through the “new submission” button in the upper right of the study.

The screenshot displays the Cayuse Human Ethics dashboard. At the top, the user is logged in as George Cox, a Researcher. The dashboard is divided into several sections:

- Navigation:** Dashboard, Studies, Submissions, Tasks, Meetings, Reporting, More.
- Status Cards:** In-Draft, Awaiting Authorization, Pre-Review, Under Review, Post Review.
- My Studies:** A table listing studies with their IDs and descriptions.
- My Tasks:** A table listing tasks with their IDs and descriptions.
- Submissions by Type:** A table showing the count of submissions for various types.
- Approved Studies:** A section showing no approved studies.
- Studies Expiring in 30 days:** A section showing no expiring studies.
- Expired Studies:** A section showing no expired studies.

My Studies	
IRB-2024-20	Cayuse Training Submission
IRB-2024-19	Cayuse Training Submission
IRB-2024-13	Test 2/6/24 After Initial Revisions
IRB-2024-12	IRB Chair Demo
IRB-FY2024-9	testing study

My Tasks	
IRB-2024-12	Complete Submission
IRB-FY2024-9	Complete Submission

Submissions by Type	
Renewal	0
Initial	3
Modification	0
Incident	0
Withdrawal	0
Closure	0
Legacy	0

Other Comments

- This presentation, templates, and other helpful documents will be available on the ECSU OSP website.
- The Cayuse application process will begin on July 1, 2024.
- I am available to do an individual zoom sessions to support the application process.

Questions?