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1. Accessing Cayuse Human Ethics (HE)

In order to submit to the Health Sciences North Research Ethics Board, you will need to access our Cayuse HE website, which is available here. If you do not have account, please reach out to reb@hsnsudbury.ca to request one.

Note: We recommend you clear your preferred browser cache to avoid any page loading issues. Click Ctrl + Shift + R to reload page ignoring cache, or Ctrl + Shift + Delete to clear cache.

a) *Cayuse Human Ethics Dashboard*

Once you have logged in, click on "Products" on the top right corner, then click on "Human Ethics." This will bring you to the Dashboard.
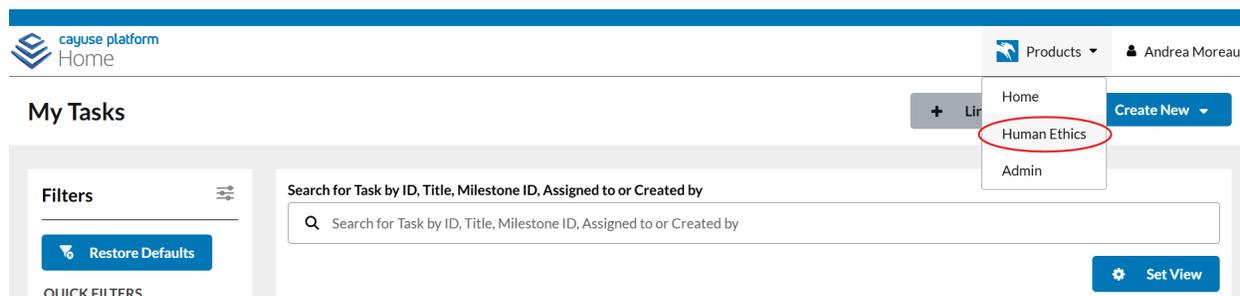
The Dashboard includes at a glance information and tabs such as "Studies," "Submissions," and "Tasks."

Studies
This section highlights all of the studies that you are attached to, as either a Principal Investigator, Co-Investigator or Primary Contact. There is also an "Archive" tab, where past completed, withdrawn or closed studies can be viewed.

Submissions
The "Submissions" tab contains all submissions regardless of the current status (ex. unsubmitted, pre-review, complete, etc.).

Tasks
This tab allows you to see at a glance your outstanding tasks.

2. Creating Submissions

This can be done through the Dashboard or the "Studies" tab, by selecting "New Study". **Note:** the study title is required at this stage before proceeding to the initial submission.
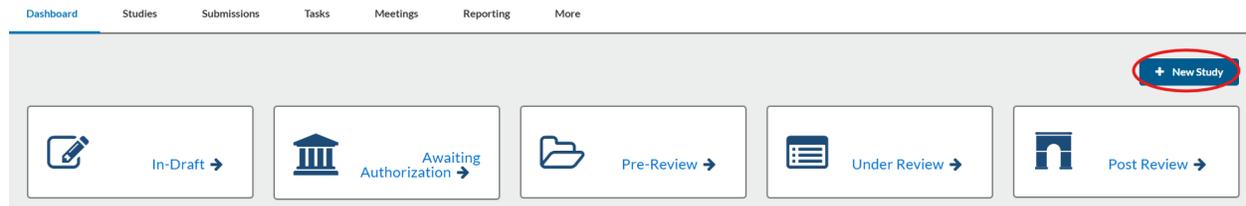
The Study Details page displays all of the important study information.

The individual who created the study will be added as the Primary Contact of the study by default, but this can be changed while completing the Initial Submission.

a) *Initial Submission*
Click on + New Submission in the upper right-hand corner of the Study Details page. This will bring down the option to fill out an Initial Submission.

Once you have clicked on "Initial," you may now click on "Edit" on the left-hand side to begin filling out your Initial submission.

To navigate the submission, use the arrow buttons on the top right or select a section name using the left-hand menu.

Person Finder
Every initial submission will require you to add a Primary Contact and a Principal Investigator, along with other members of the research team as needed. Any study team member who will need access to the Cayuse HE submission must be added as a "Primary Contact" under "Contact Information". If you cannot find an individual within the Person Finder, please email the Research Ethics Office at reb@hsnsudbury.ca and request that a Cayuse account be created for them.

Attachments
Upload one or more files to the study by clicking on the "Attach" button.
The Cayuse HE System supports the following file types:

File Type	Extension
Text	txt
Adobe	pdf
Raster image formats	png, bmp, gif, tif, tiff, jpg, jpeg, jp2, jpx
Vector image formats	wmf, emf, svg
Microsoft Word	doc, docx, docm
Microsoft Excel	xls, xlsx, xlsm
Microsoft PowerPoint	ppt, pps, pptx, pptm, ppsx, ppsm, sldx, sldm

Required Fields
A red asterisk indicates that a question is required. Incomplete sections will also have a red asterisk next to the section name.

Completing a Submission

Once there are check marks next to all of the sections listed on the left-hand menu, and the submission form is complete, then you are able to proceed to certification. If one of your sections does not contain a check mark, click on the section to search for any required questions that you may have missed.

Certification

The PI will be notified via email that the submission is awaiting their confirmation that the submission is accurate and complete.

Once the submission has been routed for certification, you will see the status of your submission change to "Awaiting Certification" on the Submission Details page. The PI can then proceed to certify the project by clicking the Certify button. **Please note that submissions will not be routed to the REB for review until the PI has certified them**. If you require assistance with this step, or would like confirmation that the submission has been received, reach out to the Research Ethics Office at reb@hsnsudbury.ca.

Pre-Review

Once the submission is certified, it is automatically sent to the Analyst for pre-review. The pre-review includes confirming all required elements of the submission are complete.

An Analyst may return the submission to the researcher with feedback on any deficiencies. The Analyst will email the researcher to inform them of any requested changes. There may be comments attached to questions that require a response. Please navigate to the section with the comments and provide updates/responses as needed.

If documents are being updated in response to pre-review comments, be sure to delete the previously attached version and attach the new version.

Board Review

Next, the Research Ethics Board will receive and review your submission. This can be done either via Full Board or Delegated (Expedited) review.

Decision Letters

When the Research Ethics Board has completed their review of your submission and reached a decision, a decision letter will be issued through Cayuse HE, from the

reb_hsnsudbury@cayuse.com email address. Please note that the Research Ethics Office does not receive any emails sent to this email address, but can be reached at reb@hsnsudbury.ca if you have any questions or concerns regarding the letter. On the "Submission Details" page, there is a "Letters" tab that contains all REB decision letters. Click on the link associated with the letter you wish to view. We recommend you save a copy of your Approval Letters for your records. To save documents from Cayuse, use the print to PDF feature.

b) *Submitting Subsequent Submissions*

In addition to the initial submission, there are five other types of submissions that may be submitted during the course of any research project. To create subsequent submissions, choose the study on the Dashboard and click on the study number. On the top right-hand corner of the Study Details page, click on New Submission, and select the appropriate submission type. Once selected, click on Edit to begin the submission. Once complete, click Complete Submission and follow the certification steps. Once certified, the submission will go through the required review process and you will be notified of the decision.

The subsequent submissions types are as follows:

- Modification: If the study requires amendments after it has been approved, a modification must be submitted and approved before the study can proceed with the updated information.
  - "Section 1: Type of Modification" and "Section 2: Attachments" are directly related to the modification submission, and all of the information below (from "Instructions" through "Section 11: Attachments") is related to the study's initial submission, and can be updated or added to if a change is being made that impacts the content in that section. For example, if a project's consent form has been updated, the researchers should delete the old version and attach the updated version under "Section 7: Consent". This ensures that the most recent versions of study materials carry over into future submissions.
  - Please note that modifications cannot be submitted until a study's initial submission is approved. Modifications can be submitted while other types of submissions (i.e. Renewal, Incident) are under review, but two modification submissions cannot be submitted at once- any previous modifications must be approved first.

- Renewal: When a study is nearing its expiration date, the research team must submit a renewal request in order to continue with the research for another year.
  - Annual renewal submissions are an opportunity to inform the Research Ethics Board of how a project is progressing, including what study activities have taken place since the last renewal or approval, any notable occurrences or findings, and what is left to do before the study concludes.
  - Cayuse will send email notifications 30, 60, and 90 days prior to a project's expiration, reminding you to submit a renewal. **Please note that these reminders will be sent up until the renewal is reviewed and approved, even if the submission has already been completed and certified.**
  - If a renewal submission is not received by the study's expiry date, you will receive an automated email from Cayuse alerting you that all study activities must be stopped. In order to resume the research, a renewal must be submitted and approved. If no renewal or closure submission is received 2 months after the expiry date, the study will be terminated by the REB.

- Incident: An incident report must be submitted when a reportable event occurs. A reportable event can include privacy breaches, local adverse events, and other unanticipated problems. Incident reports can be submitted any time, including after the study has been closed.

- Withdrawal: A withdrawal can only be completed for an initial submission, after it has been submitted for pre-review. The REB will be notified of the withdrawal and the study can no longer be modified. **Note:** If the initial submission has been approved, a closure must be submitted in order to close the study.

- Closure: A closure indicates that the study is complete. Closed studies are marked as finalized and can no longer be modified.

  Researchers may submit a closure when there is no further participant involvement at the site, all new data collection is complete, and the sponsor closeout activities, if applicable, have been completed.

  Additional guidance documents are available on our website:
  www.hsnsudbury.ca/en/Research/Research-Ethics-Board-REB

c) *Legacy Studies*
Studies that were approved prior to April 2024 will be imported into the Cayuse HE system via a Legacy submission. The legacy submission form mirrors the initial submission. Once the legacy submission is finalized, additional submissions may be created, such as modifications, renewals, etc.

3. Deleting a Study or Submission

a) *Deleting a Study*
A study can only be deleted when the initial submission has not been submitted. To delete a study, click on Delete on the Study Details page.

b) *Deleting a Submission*

A submission can only be deleted when the submission (ex. renewal, modification, etc.) has not been submitted. To delete a submission, click on Delete on the Submission Details page.

Please reach out to reb@hsnsudbury.ca **with any inquiries, or for assistance with completing an ethics submission.**