Revised Cayuse IRB Initial Submission Form FAQ

As of 12:00 am on May 1, 2025, the Office of Research Integrity - Human Subjects (ORI-HS) will be releasing a revised version of the submission form used for Initial Submissions in Cayuse for IRB review. Review the following frequently asked questions to learn more about the revised submission form.

Why is the Initial Submission Form Being Changed?

In the years following the implementation of Cayuse, ORI-HS has identified common challenges researchers and their teams face when completing the Initial Submission form in Cayuse for IRB review. The current Initial Submission form is not structured to capture all necessary information needed by the IRB to conduct efficient and effective reviews of new studies. The experience of researchers, IRB Member Reviewers, and ORI-HS Staff indicated a need for an overhaul of the existing initial submission form in Cayuse, in order to streamline the review process for all parties.

What are the Main Changes to the Initial Submission Form?

The key change to the initial submission form is the introduction of review "pathways." Upon creating a new study and opening an initial submission form, study teams will be presented with four possible review "pathways," which should be selected based on the nature of the study, and the level of IRB review required.

The initial submission form will then adapt to the review pathway selection, populating a submission form that is designed to be comprehensive, but targeted towards the nature of the research project being submitted.

What are these Possible Review "Pathways," and How do they Differ?

There are four review pathways in the revised initial submission form. They include:

- 1. A pathway for exclusion (Not Human Subjects Research [NHSR]) determinations that consists of one page
- 2. A pathway for exempt studies that collects the minimum information necessary to conduct exempt reviews, with a specific pathway for secondary data only studies that consists of one page
- 3. A combined pathway for expedited/full board research that collects more detailed information, in keeping with what is required for both expedited and full board studies. This pathway still leverages branching logic to only display certain questions/pages when applicable to a study. Branching logic is also deployed to display explanatory/instructional text to assist in completion of the form
- 4. A pathway for submitting a request for an external IRB of record to review on behalf of UNLV that consists of one page

What Opportunities Will I Have to Receive Training on the New Submission Form?

ORI-HS will be offering several training opportunities and resources to the research community to support the rollout of the revised Initial Submission form. Researchers and study teams can find training opportunities and resources in the following places:

- Announcements on the Division of Research Page
- Sign up for the Research Weekly newsletter
- Find Live trainings on the <u>UNLV Events Calendar</u>, and the <u>Division of Research Events</u> page
- Announcements on UNLV Today
- Register for our <u>training course in REBELearn</u> to access live training sessions, recordings, and other guidance documents and resources
- Register for the UNLV IRB Researcher Resource Center in WebCampus (great for student researchers!) To self-enroll in the WebCampus organization, first <u>follow the self-enrollment link</u>.

After clicking the link, users will be prompted to click the "Enroll in Course" button. Once that is complete, users can click the "Go to Course" button to be taken directly to the resource center immediately. Log into <a href="https://www.university.com/www.u

Book a group training for up to 50 attendees to learn about the revised Initial Submission form. Book us for your next department meeting or research team meeting! (Note: events must be scheduled a minimum of 4 days in advance.)

Will Other Submission Forms in Cayuse be Affected, such as the Modification or Renewal Submission Forms?

No, at present, ORI-HS is only rolling out a revised Initial Submission Form in Cayuse. While ORI-HS is likely to update and revise other submission forms in Cayuse in the future, the May 1, 2025 update will not affect other submission form types such as Modifications, Renewals, Incidents, or Closures.

What Will Happen to Initial Submissions Opened or Currently Under Review On the Rollout Date?

At 12:00 am May 1, 2025, ORI-HS will publish the new Initial Submission form in Cayuse. Only Initial Submissions created on or after this implementation date will use the revised Initial Submission Form. If you have opened an Initial Submission before 12:00 am May 1, 2025, then the Initial Submission will remain on the previous version of the Initial Submission Form.

My Initial Submission was Approved Prior to the Rollout Date. Will I Need to Convert to the New Initial Submission Form When I Next Submit a Modification?

No. Cayuse does not overwrite previous versions of submission forms when new versions are made. This means, if your Initial Submission was approved prior to 12:00 am May 1, 2025,

when you submit a Modification, your study will retain the previous version of the Initial Submission form, and will not be forced to adapt the study submission to the revised version of the Initial Submission form.

However, this means that, for researchers who have studies approved prior to May 1, 2025, and who plan to open *new* studies after 12:00 am May 1, 2025, they will have some studies on the previous version of the Initial Submission form, and some studies using the updated version of the Initial Submission form.

How Can I Share Feedback on the Revised Initial Submission Form?

We welcome feedback on the Initial Submission form after rollout! ORI-HS conducted thorough testing of the revised Initial Submission form, and gathered feedback from stakeholders and researchers during the design process. However, we recognize that ongoing feedback is key to ensuring the success of the revised Initial Submission Form. Please email irb@unlv.edu to provide feedback on the initial submission form, or to request assistance if you encounter any problems or issues requiring troubleshooting.

Where Else Can I Find Helpful Information?

ORI-HS suggests bookmarking the following pages for easy access to other helpful information:

- ORI-HS Cayuse webpage. Log into Cayuse and access guidance documents on using Cayuse on this page
- ORI-HS Forms and Templates. Find helpful templates and forms
- ORI-HS Training website. Learn about training opportunities and required CITI training here.
- <u>PI Eligibility Webpage.</u> Learn about PI Eligibility requirements for conducting human subjects research, and find forms relating to PI Eligibility.

Whom Can I Contact with Questions?

Use the following email addresses to get help with various topics:

- IRB@unlv.edu General IRB questions, to request a consultation, or to contact your study's assigned IRB Analyst
- <u>HSComp@unlv.edu</u> questions about compensation for participants in human subjects research
- PIE@unlv.edu for guestions and submitting forms relating to PI Eligibility