Cayuse IRB User Guide

Office of Research and Sponsored Programs
ORSP@acu.edu

Before You Start…

- If you receive this "Forbidden" message at log-in, please reach out to orsp@acu.edu

- Once the office creates an account, the system needs to update overnight before that user can access his/her account in Cayuse IRB.

Cayuse IRB Submission Types – Create an Initial Submission

- Log in to **Cayuse**. If you cannot, email ORSP@acu.edu and request an account
- From the Product drop-down menu, select **Human Ethics**
- Select the "+ New Study" button.
- Enter the study title and select the check mark button.
- Select the "+ New Submission" button.
- Select the type "Initial."
- Select the "Complete Submission" link and follow the instructions to fill out the submission after all the sections have been completed (indicated by the checkmarks), and you have reviewed your application,

After completing the submission

- We recommend allowing ample time for IRB review and responding promptly to IRB feedback.
- A submission's approval/exempt determination is dependent on your timely and sufficient response to comments.
- Ensure you update the application as well as responding to comments.

Cayuse IRB Submission Types

In addition to the Initial Submission, there are five other types of submissions that you may submit during the course of your study. The additional submission types include:

- **Withdrawal (**Select "Withdrawal" from the "New Submission" dropdown menu): A withdrawal submission notifies the Research Compliance Office that you no longer wish to submit your initial submission and want to withdraw the study. Withdrawn studies are marked as finalized and can no longer be modified. You may create a withdrawal submission at any point once an initial submission has been created, until it has been approved. If the initial submission had been approved, you must create a closure submission in order to close the study if you no longer wish to conduct the research.

- **Modification** (Select "Modification" from the "New Submission" dropdown menu): For any study that was previously approved by expedited or full board review, any and all proposed changes to the study, no matter how minor (including changes to personnel, methodology, or consent forms), must receive prior approval by the IRB before being implemented (Investigator Responsibilities) (except when the change was made to eliminate an apparent immediate hazard to the participants, in which case an unanticipated problem report should be filed in addition to the amendment form).

  For studies previously determined to be non-research, non-human research, or exempt, if the changes to the study may cause a classification change, such that it no longer qualifies for exemption, please submit a Modification Request.

Cayuse IRB Submission Types (Continued)

- **Incident (**Select "Incident" from the "New Submission" dropdown menu): If you have an unexpected event that is probably related to the research and potentially increases the risk profile of the study, there is a complaint from a participant that suggests there may be an increased risk to the study, or there is a breach of confidentiality, then you must report this to the IRB. Unanticipated problems that are serious UPIRSOs (Unanticipated Problems Involving Risk to Subjects or Others) should be reported within 7 days of learning of the event, unless the UPIRSO is potentially lethal, then it should be reported within 2 days. Other unanticipated problems should be reported within 14 days of learning of the event. UPIRSOs may require an amendment to the protocol to reduce risk, notification to current and/or past participants of the new risk, and/or, in some serious cases, inactivation of the protocol. Please include these materials with your report, as applicable.

  In addition, any deviation from the approved protocol, no matter how small, must be reported to the IRB using the same timeline as above, with the exception that minor deviations that do not affect safety, increase risk, or violate rights and welfare of participants may be reported on the continuing review. If the reported deviation is a permanent change, it must be accompanied by an amendment request form.

* Any persons with concerns regarding human research may bring these concerns in writing or in person to the IRB Chair. Concerns may be reported anonymously, and there will be no repercussions for personnel reporting policy violations. Whistleblower protections are posted in the Employee Handbook. If you need to report a human research concern, please complete the form below. You may email this form to orsp@acu.edu or to the IRB Chair directly at qxh22a@acu.edu. You may also hand deliver this form to the ORSP Office in 328 Hardin Administration Bldg. You may send the form anonymously through campus mail to ACU Box 29103 c/o Qi Hang. Finally, you may place an anonymous phone call to the ORSP Office at 674-2885.

Cayuse IRB Submission Types (Continued)

- **Closure** (Select "Closure" from the "New Submission" dropdown menu): All studies that were previously approved by expedited or full board review must be inactivated upon completion of the study and records stored by the investigator for at least 3 years (**45 CFR #46.115(b)**; **Investigator Responsibilities**). Inactivation should be completed when enrollment is closed, data is no longer being collected, and analysis is complete or involves only de-identified data.

- **Renewal** (Select "Renewal" from the "New Submission" dropdown menu): All studies that were previously approved by full board review and that continue beyond one year must submit a Renewal Request once per year until inactivated (45 CFR #46.109(e); Investigator Responsibilities). Studies with a high degree of risk may be reviewed more frequently at the IRB's discretion. Please submit a renewal request at least 30 days (but no sooner than 60 days) prior to expiration

  If your study expires before you obtain re-approval, you must halt all research activity on that protocol until approval is received or unless the IRB determines it is in the interest of participant safety to continue.