TWU IRB Cayuse and New Common Rule Implementation

Spring 2019

irb@twu.edu

https://twu.edu/institutional-review-board-irb/

Cayuse

Cayuse IRB is a cloud-based software system. With Cayuse IRB, we will be able to streamline IRB submission processes and provide greater access to your IRB records. Some benefits of Cayuse IRB include:

- Easy to use electronic forms with autofill and help features
- Ability to submit and certify protocols from your computer
- Real-time submission tracking
- IRB record management from initial submission through study closure

The Cayuse IRB platform was completed by the TWU implementation team on February 1 and was made available to the TWU campus on February 6. After this date, all new applications to the IRB will be submitted through Cayuse.

New Common Rule

Health and Human Services Office of Human Research Protections (OHRP) has issued the new federal Final Rule, referred to as the new Common Rule. These changes became effective January 21, 2019. The primary changes resulting from this new guidance are:

- changes in categories of review especially for exempt and expedited studies,
- modifications to consent requirements, and
- changes in continuing review requirements for expedited studies.

New Consent Requirements

The consent forms used for all new applications submitted after January 21 must comply with the new requirements. For approved studies that need modifications that affect the consent form after January 21, the consent forms must be updated to meet the new regulations if subjects are still being enrolled in the study. Consent forms must also be updated to meet new Common Rule requirements when a study is renewed / extended.

The new Common Rule consent requirements primarily include the addition of a concise and focused summary of 'key information' before the body of the consent and a statement clarifying the future use of any biospecimens or private identifiable information (if applicable).

New consent form guidance and sample documents has been posted to the IRB website at https://twu.edu/institutional-review-board-irb/informed-consent-guidance/.

Legacy Studies

Legacy data is defined as any study that was submitted to the IRB prior to February 1. This includes any studies that are pending, active, or closed as of February 1, 2019. Any studies submitted to the IRB after February 1, 2019, will be submitted using the Cayuse system.

Investigators will not be able to view legacy studies in Cayuse. The longterm plan (within the next six-twelve months) is to transition active legacy studies into Cayuse. In the interim, all activity on legacy studies will be processed using original IRB processes and forms.

Exempt Study Changes in Closure

Currently, all studies exempted prior to January 21, 2019, were closed at the time the exemption was issued and then shredded after three years. Because some studies are still active after three years, TWU modified this process. After January 21, 2019, exempt studies are no longer closed at the time of the exemption. Instead, an expiration date will be added to the study and the project must either be renewed or closed at the time the study expires.

Expiration / Continuing Review

Per the new Common Rule, exempt and expedited studies no longer require continuing annual review by the IRB. However, all studies in Cayuse are assigned an expiration date regardless of the level of review. For exempt and expedited studies, the end date completed by the investigator on the application will be used to determine the expiration date. Full board studies require annual review and the expiration will be one-year from the approval / renewal date.

A notification will be sent from the IRB 45 days prior to the expiration requesting that the investigator either close or renew the study. If a response to this request is not received by the investigator, the IRB will administratively close the study and the investigator will have to submit a new application in order to continue.

Cayuse Accounts and Login

To access Cayuse, a user must have a Cayuse account. TWU provided Cayuse with a list of all TWU investigators, faculty advisors, and research team members on active studies. Accounts have already been created for these TWU personnel and these investigators should be able to login to Cayuse using their Portal account login information.

In order to add any TWU PI, faculty advisor, co-investigator, or research team member, they must have a Cayuse account. If a person needs an account, an email should be sent to the IRB with the person's name, TWU email address, and department. The IRB staff will then create an account in Cayuse. Please note that this process may take 1-2 days. Non-TWU research personnel are not assigned TWU Cayuse IRB accounts; these research team members must be handled differently.

Cayuse Notifications and Emails

Cayuse will send automatic emails to investigators and organizational approvers. These emails are sent when an action must be performed by a user (such as to certify a submission, makes necessary changes to an application, or prior to a study expiring). Emails may also sent to inform the investigators that an application has been received by the IRB office and other review progress.

Similar to the email notifications are alerts within the Cayuse system. These alerts appear at the top of the dashboard page and serve as a shortcut to access an action.

Cayuse Submissions

All new studies submitted to the IRB after February 1, 2019, will be submitted and managed through Cayuse. A new application submitted in Cayuse is referred to as an *Initial Submission*. Once this submission is made in Cayuse, all types of submissions related to this study will also be submitted using Cayuse (i.e., *Renewal, Closure, Modifications, and Incident Reports).*

Cayuse Approval Routing

An initial submission in Cayuse must be certified by the principal investigator and all co-investigators (including the faculty advisor). Once the PI and the Co-Investigators have certified the submission, the application must then be certified by the department chair / unit administrator. Cayuse generates an email to all investigators and unit administrators alerting them that the new submission requires their certification.

Once the submission is certified by all investigators and the unit administrator, the application is received by the IRB and will be assigned to the appropriate review process.

Cayuse Dashboard

All Cayuse users will have a dashboard which is a snapshot of all their studies and activity. The next slide shows a sample of this dashboard. It should be noted that the dashboard is "role-driven" meaning that **if a user has more than one role** (i.e., researcher, reviewer, organization approver), then they will have a separate dashboard for each role. Most users in Cayuse only have the researcher role.

≡ Menu

Dashboard

▦ ♠ 👤 Tracy Lindsay

My Role: Researcher ▾

+ **New Study**

	0 In-Draft		0 Awaiting Authorization		0 Pre-Review		0 Under Review

My Studies

My Tasks

Submissions by Type

Initial	0
Withdrawal	0
Modification	0
Renewal	0
Incident	0
Closure	0
Legacy	0

☹
You Have No Studies

✓
All Tasks Complete

Approved Studies

Studies Expiring in 30 days ▾

Expired Studies

Training Requirements

TWU training requirements for studies have not changed. CITI will link to Cayuse using the email addresses in both systems. We are still working on linking TWU's CITI trainings to TWU's users in Cayuse and expect this system to operational within the next few weeks.

Training certificates other than CITI and training certificates for non-TWU users will be uploaded to new applications and renewal submissions as attachments.

Updating Materials and Website

We are in the process of updating all materials on the website. In addition, the TWU policies and procedures will be updated within the next few weeks to reflect changes resulting from the Cayuse implementation and the new Common Rule requirements. Written materials and the website are being updated as quickly as possible, so please keep checking back for updated materials.

The Cayuse Implementation Team

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We greatly appreciate your patience as we make these two major transitions.