Reviewer Guide
Cayuse Human Ethics
Cayuse Orientation

Access
Home Screen
My Profile
Dashboard
Access to Cayuse Human Ethics

- Request a Cayuse Access for Non-Wright State Users
  - [https://www.wright.edu/research/research-and-sponsored-programs/cayuse-and-redcap-access-request-for-non-wright-state-users](https://www.wright.edu/research/research-and-sponsored-programs/cayuse-and-redcap-access-request-for-non-wright-state-users)
  - Normally granted in one week

- Request Cayuse Access (have existing w-number)
  - [https://www.wright.edu/research/research-and-sponsored-programs/cayuse-access-for-wsu-students-staff-and-faculty-form](https://www.wright.edu/research/research-and-sponsored-programs/cayuse-access-for-wsu-students-staff-and-faculty-form)
  - Normally granted within two days

Cayuse Human Ethics Link

VPN Not Required!
Cayuse Home

- Assign tasks to yourself
- Does not connect with individual products but will show up on this home task page and individuals assigned will receive e-mail notification to complete task.
- IRB may request non-review related tasks
To add Annual COI:
- Click My Profile
- Click COI Disclosures
- Click +New Disclosure
- Select Annual
  - Completed Every January
  - If outside this time frame, select Research Based.
Submission Details

To Start Review:

Complete Review
Submission Types

When you first create a study, you also create the initial submission outlining the purpose of that study. In addition to this initial submission, there are five other types of submissions that IRB Users may submit during the course of your research. The available submission types include:

- **Initial** - This is the first submission that you create when you enter a new study in the system. The initial submission describes the research you intend to do and the methodology you intend to use. The initial submission must be approved before any research can begin.

- **Modification** - If you wish to change any of the details of the study after it has been approved, you must submit a modification which must be approved before you can proceed with the changes.

- **Renewal** - When a study is nearing its expiration date, you must submit a renewal request in order to continue with the research. The renewal will need to be approved before you can continue with the study.

- **Incident** - You must submit an incident report to inform the Compliance Office of any adverse incidents, as required by your institution. Incident reports may be submitted at any time after a study has been approved, including after it has been closed. More than one incident report may be created for a given study, as needed.

- **Withdrawal** - A withdrawal submission notifies the 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 has been approved, you must create a closure submission in order to close the study if you no longer wish to conduct the research.

- **Closure** - A closure submission indicates that the research is complete and will not be continuing. Closed studies are marked as finalized and can no longer be modified.

- **Legacy** - Used for studies imported from previous systems. The legacy submission replaces the initial submission for imported studies. Once the legacy submission is finalized, you can create additional submissions such as modifications, renewals, etc. An IRB Analyst must create and publish a legacy template before users can create legacy submissions or work with studies that have been imported from other systems.

There are two additional submission types that are only available to IRB Analysts and Admins:

- **Admin Closure** - Allows a study to be administratively closed when needed, for example when the PI leaves the institution or chooses to let a study expire.

- **Admin Withdrawal** - Allows a study to be administratively withdrawn when needed, for example when the PI leaves the institution.
Reviewing & Commenting on Submissions

Commenting
Check Lists
Determinations
Notification

The Reviewer will receive:
- E-mail Message with Link
- Notification Bubble
- Task
- Added to Waiting Review Display

After all study reviewers have completed the IRB Analyst will be notified.
Starting a Review

- When you click on E-mail Link it will bring you to Cayuse Platform Home Screen – My Tasks.
- Select Human Ethics under Products.
- Select Reviewer Under Role

The Role you have starred will be the default role when you log in.
Select Study to Review:

Click on Study Number
Opens the Submission Details Screen

To Start Review:

Suggest going back to Study Details to View Regulatory Flags
Commenting

- Click to Add Comments

Comments:
- Formattable
- Upload Redlined Attachments
  - Not Anonymous. See instructions on how to anonymize before uploading.
  - Max Size: 20MB
Commenting

By default, new comments are visible only to IRB Analysts, Members, and Administrators. To make a comment visible to the research team, use the dropdown in the upper right of the comment to change the visibility from Restricted to Unrestricted. The IRB Analyst will verify this setting on your behalf during post-review processing.

Research Team will not be able to view identity of IRB Reviewers, only Analysts.
Checklists

Note: Cayuse does not require the checklist to be complete prior to finalizing the review.

Please don’t forget to complete the checklist.

The IRB Analyst has read-only access to the reviewers’ checklists, allowing the Analyst to see which items have or have not been completed during the review.
Checklists

Reviewer Checklist

If you opt to not complete the checklist, indicate all findings and determinations in this box.

Use the Flags on Study Details Page

Requires w-number login

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Make Decision

After making comments and completing the checklist, click on Submission Details.

Then, click on make decision task.
Make Decision

- Select appropriate decision from drop-down menu.
- Enter the Result Date.
- Select the Category, as appropriate.
- Document, if desired:
  - Findings (refer to checklist)
  - Researcher Notes
  - Internal Notes
  - The IRB Office will use the checklist as documentation for these.
- Amendments:
  - Summary will be documented in Researcher Notes section.
- Incidents:
  - Determination will be documented in Findings section.
  - Required investigator actions will be documented in Internal Notes section.
- Select Save.
- Select Review Complete.
# Available Decisions

<table>
<thead>
<tr>
<th>Decision</th>
<th>Explanation</th>
<th>Resulting Study Status</th>
<th>Routing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disapproved</td>
<td>The full board identified major issues with the study or submission and disapproved the research. In the case of a disapproved initial study, a new study and submission will need to be created. For disapproved renewal, modification, etc., submissions, the research team will need to create a new submission if they wish to proceed.</td>
<td>Disapproved</td>
<td>Approval is approved and no longer editable. The research team can add additional submissions to the study.</td>
</tr>
<tr>
<td>Deferred</td>
<td>The reviewer(s) identified major issues that the research team must correct before the submission can be approved.</td>
<td>Requires Changes</td>
<td>Submission is returned to the PI and reopened for editing.</td>
</tr>
<tr>
<td>Minor Stipulations</td>
<td>The reviewer(s) identified minor issues that the research team must correct before the submission can be approved.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Return to PI</td>
<td>The study is being returned to the research team to make changes because the IRB will not approve it as is.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not Expedited/Not Exempt</td>
<td>The study will be returned to the IRB Analyst to reassign it to the correct review type.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not Reviewed</td>
<td>Documents that the submission was unable to be discussed at the meeting. The &quot;Not Reviewed&quot; decision is logged in the decision history so that a new decision can be made at a subsequent meeting. This decision type is only available for full board reviews of initial, modification, incident, and renewal submissions.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Approved</td>
<td>The study is approved.</td>
<td>Approved</td>
<td></td>
</tr>
<tr>
<td>No Engagement in Research</td>
<td>The study does not constitute research and therefore does not require IRB approval.</td>
<td>No Engagement in Research</td>
<td>Submission is approved and no longer editable. The research team can add additional submissions to the study.</td>
</tr>
<tr>
<td>No Human Subjects Research</td>
<td>The study does not include human subjects research and therefore does not require IRB approval.</td>
<td>No Human Subjects Research</td>
<td>Submission is approved and no longer editable. The research team can add additional submissions to the study.</td>
</tr>
<tr>
<td>Noted</td>
<td>The incident report has been noted by the IRB.</td>
<td>Noted</td>
<td></td>
</tr>
<tr>
<td>Rely on External IRB</td>
<td>The study and submission were reviewed and approved by an external IRB and their decision has been recorded by the IRB.</td>
<td>Rely on External IRB</td>
<td>Submission is returned to the PI and is no longer editable.</td>
</tr>
<tr>
<td>Exempt</td>
<td>The study is exempt because it fits into one of the specified categories for exemption.</td>
<td>Exempt</td>
<td></td>
</tr>
<tr>
<td>Suspended</td>
<td>A study is suspended when the IRB decides that the research needs to stop until changes have been made to the research. A suspended decision is available on Incident Reports, Modifications, and Renewals. Suspension can only be lifted by selecting the “Suspension Removed” decision for a modification submission after it has had a full, expedited, or expedited review. Lifting the suspension changes the study’s status back to “Approved”. Note: Renewal submissions for an expired suspended study can receive a decision of “Approved” in order to extend the date without lifting the suspension, or “Suspension Removed” in order to extend the date and lift the suspension.</td>
<td>suspended</td>
<td>Submission is returned to the PI and is no longer editable.</td>
</tr>
<tr>
<td>Closed</td>
<td>A closure submission is created and submitted when the research is done and the study can be closed.</td>
<td>closed</td>
<td>The study is closed and no further research can be done.</td>
</tr>
<tr>
<td>Withdrawn</td>
<td>The research team decided not to proceed with the initial submission. This decision is only available for withdrawal submissions. The research team can choose to withdraw the study at any point until the initial submission has been approved. If the initial submission has been approved, the research team must create a closure submission instead.</td>
<td>withdrawn</td>
<td>The study is closed and no further research can be done.</td>
</tr>
</tbody>
</table>

**Wright State University**
Reviewing a Re-submission

How to review changes requested by the IRB
Open the Review

- Utilize the methods previously indicated to access and open the review.
- Bubbles will indicated where comments were made.
- Each comment will need to be marked as Addressed or Not Addressed. All must be marked in order to complete the review.
- Use Comparison Tool to identify changes in the application and attachments.
Comparison Tool

- Select COMPARE on Menu Bar
- Shows the changes made between this application version and previous one
- Can be used for uploaded documents
- Number indicators for number of differences
- Green for additions
- Red for deletions

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When the IRB Office is reviewing a submission, the IRB Analyst or Members may have questions regarding some of your answers. If the submission gets returned to you, you will see a comment icon in the sidebar next to each section that contains comments, and a similar icon underneath the questions that have comments on them. Click the **Expand Comments** link to see and respond to these comments.

**Primary Contact**

<table>
<thead>
<tr>
<th>Name</th>
<th>Organization</th>
<th>Address</th>
<th>Phone</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rob Rawley</td>
<td>School of Medicine</td>
<td>440 Exchange, Irvine, CA</td>
<td>714-265-7408</td>
<td><a href="mailto:brawley@visions.com">brawley@visions.com</a></td>
</tr>
</tbody>
</table>

**Collapse Comments**

**IRB Analyst**  Today at 2:15 PM
Are there any additional contacts for this study?
Reply

**IRB User**  Today at 2:59 PM
No, there are no additional contacts.
Addressed  Today at 5:30 PM by you.

**IRB Reviewer**  Today at 6:01 PM
I think there should be more contacts. What if the first one is out of the office?
Reply

When you have responded to a comment, change the dropdown from **Not Addressed** to **Addressed**. Unaddressed comments have a red bar to their left, and display the comment count in the comment bubble icon for that question. You can toggle comments between addressed and unaddressed as needed.
IRB Meeting

Agenda
Documents
Notice to Committee
The meetings tab allows IRB Analysts, Admins, and Committee Members to view the calendar of scheduled meetings and the agenda.
Board Members

Using the Calendar

You can browse the calendar by clicking the < and > buttons at the top of the calendar. Use the Boards dropdown in the upper right to filter the meetings shown on the calendar to only display meetings for the selected board.

When in "Month" view, selecting the month or year at the top of the calendar brings up a menu to allow you to select a new month and/or year.

Toggle Views
Meeting Details

9:00 AM - 1:00 PM
4 hours
University Hall - Room 101

View Details

View Agenda

9:00 AM  Wright State IRB
Meeting Details

Non-Review Items for this meeting
- Minutes
- Policies/Procedures
- Training
- Announcements

Study Review Agenda for this meeting

Notice to Committee Items
Protocol Review Agenda

Indicators for Primary & Secondary Reviewers

Primary Reviewer:
- Has most applicable scientific expertise in area of research.
- Focus is on Criteria for Approval.

Secondary Reviewer:
- Has additional Expertise and/or non-scientific members.
- Focus is on Informed Consent and Participant Facing Documents.

Note: Full Expedited Reviews are full board studies where changes were reviewed Expedited.
Full Board Review:

- All members should make comments using the comments feature on the application. These are viewable to all board members, not to investigators.
- Every board member will have an individual checklist they can complete. Only the IRB Analyst/Admin can view all checklists.
- Primary & Secondary Reviewers are REQUIRED to complete the checklist.
- Reviews should be completed two days prior to the meeting to allow the IRB office processing time.
Notable Changes in Initial Submission

Project Type Selection
Updated Sections
**Project Selection**

- All application types are in the initial submission
- Expanded Screening for NHS & Exempt Studies
- Streamlining for secondary and exempt studies
- If in doubt, start with Activities Not Regulated as Human Subjects Research.
  - Application will let you know if you need to change to a different type of application.
- Interaction/Interventional Research
- Secondary Research Only
- Activities Not Regulated as HSR
- HUD
- External Reliance Registration
- Collaborative Exempt Notification
- Umbrella Protocol
- Delayed Onset Determinations
- Single-Patient Expanded Access
Study Team

- Designate One Principal/Primary Investigator (PI)
- Designate at least one Primary Contact (PC)

If applicable:
- Designate one faculty mentor
- Add appropriate study site research coordinator

Qualifications:
- PI & Faculty Mentor provide CV’s to demonstrate oversight qualifications
- All other personnel qualification are designated as part of their role
Secondary Data

- IRB was very intentional when selecting sections to complete.
- In Research Plan section, you need to remember to check appropriate methods:
  - Medical Records Review
  - Data Repository
  - Biospecimens Collection/Repository
Exempt Studies

- IRB was very intentional when selecting sections to complete.
- Bare minimum required to make Exempt with Limited IRB review determination.
- Built in Exempt Category Decision Tree
Data Security & Management

- Aligned with CaTS Policies
- Questions aligned with recommendations presented in HIPAA presentation
  - Administrative
  - Physical
  - Technical
- Streamlining based on investigator comments

HIPAA Authorization

- Redesigned for ease including more multiple selection options verses free-text.

Not Regulated as HSR

- Some sections such as QA/QI have expanded decision tree options.

Clinical Trials

- Reworked the decision tree.
IRB Procedure Updates Summary

- CV Management
  - Only required for PI's & Faculty Mentors

- Project-Specific SFI
  - Signed forms no longer required
  - PI & Co-PI will certify submission
  - All others will be reported via application

- Modification cannot be made in Renewals/Continuing Reviews

- Routing Process
  - Co-PI’s will need to certify submissions
  - Chairs/Deans only need to sign off on initial study submission
  - Risk Management Review
    - COI, Biosafety, Laser/Radiation, IACUC, etc.

- Exempt & Expedited Check-Ins versus Updates
- Expedited & Full Board Consents need to be uploaded in PDF format
- New Incident Reporting Form
- New Application Types
- Biweekly IRB Meetings starting in September 2022
IRB Resources

**IRB Website:**
- Local Protocol & Consent Templates
- Check Lists
- Decision Trees
- Guidance Documents

**IRB SharePoint Group:**
- Calendar of Events
- Review Checklists & Worksheets
- IRB Metrics
- Workshop Slides & Videos
Get Help – IRB Staff Consultations

- Virtual Office Hours
  - Wednesdays at 11am – 12:30pm
  - By appointment
- IRB Chat via Teams
- IRB Help Line:
  - 937-775-4462
- Email: irb-rsp@wright.edu