

Cayuse Orientation

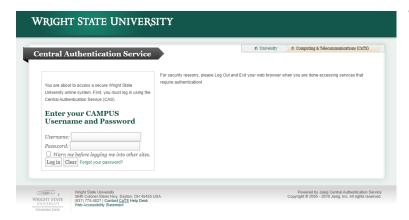
Access

Home Screen

My Profile

Dashboard

Access to Cayuse Human Ethics



Cayuse Human Ethics Link

VPN Not Required!

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

Cayuse and REDCap access request for non-Wright State users

First name * REQUIRED

Last name * REQUIRED

Email * REQUIRED

E.g., Dayton VA, Clinical Neuroscience Institute

Why do you need Cayuse or REDCap access (check all that apply)? * REQUIRED

To submit an animal use protocol

I need access to REDCap

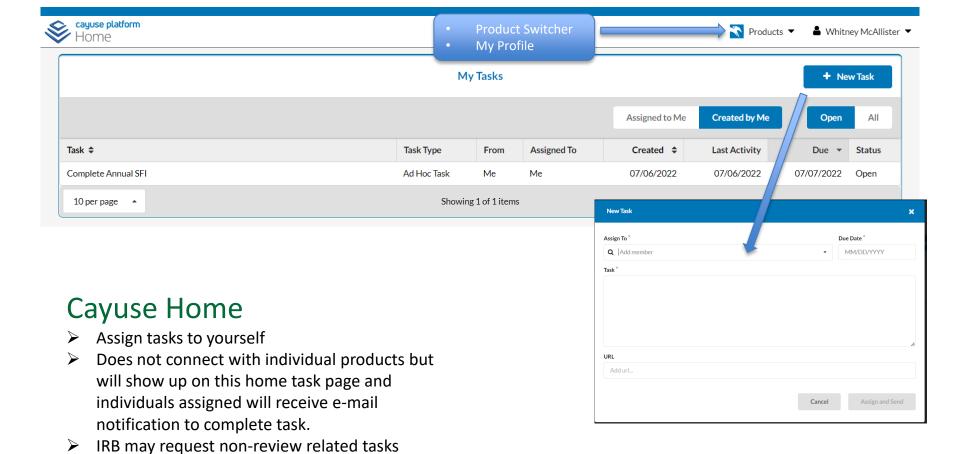
To submit or locate a grant or proposal

To submit a human subjects study

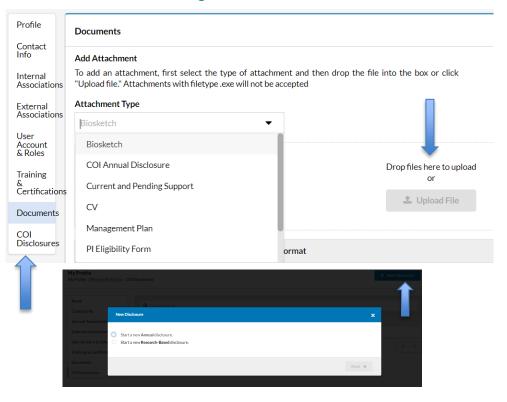
To submit a biosafety protocol

To complete a significant financial interest (SFI) disclosure

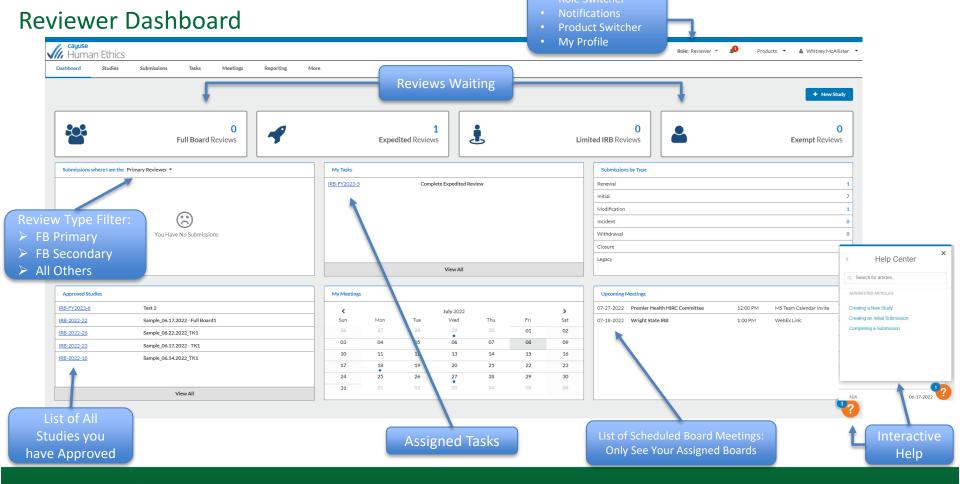
Other...



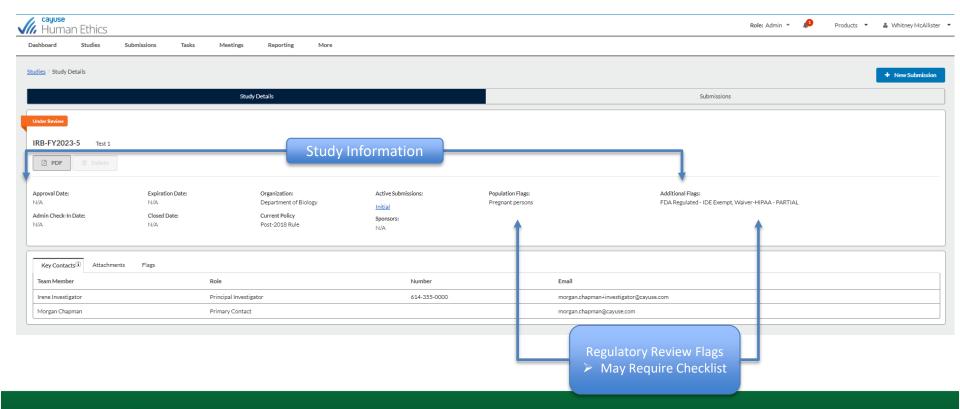
My Profile



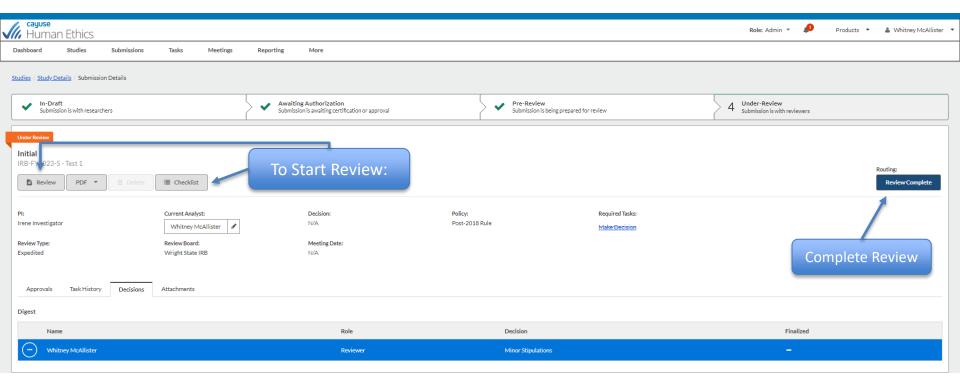
- > To add Annual COI:
 - ➤ Click My Profile
 - > Click COI Disclosures
 - ➤ Click +New Disclosure
 - Select Annual
 - ➤ Completed Every January
 - ➤ If outside this time frame, select Research Based



Study Details



Submission Details



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:

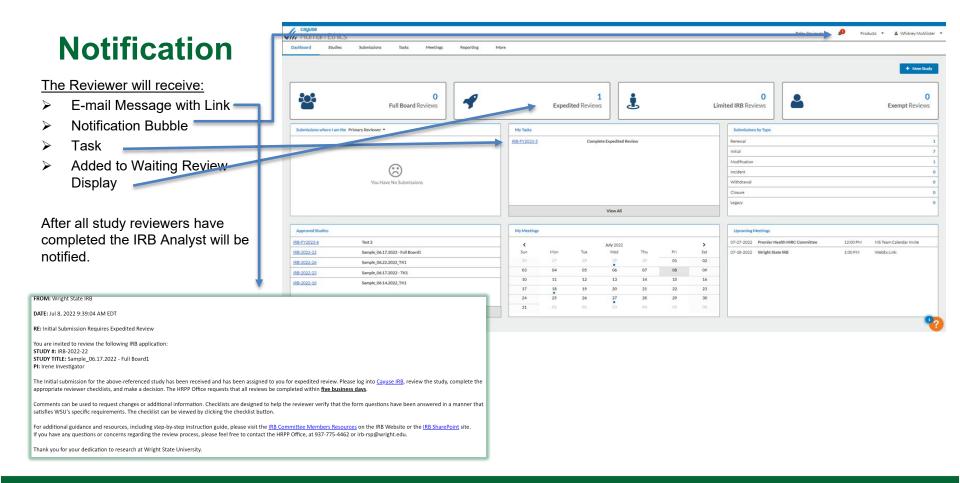
- Admin Closure Allows a study to be administratively closed when needed, for example when the PI leaves the institution or chooses
 to let a study expire.
- Admin Withdrawal Allows a study to be administratively withdrawn when needed, for example when the PI leaves the institution.

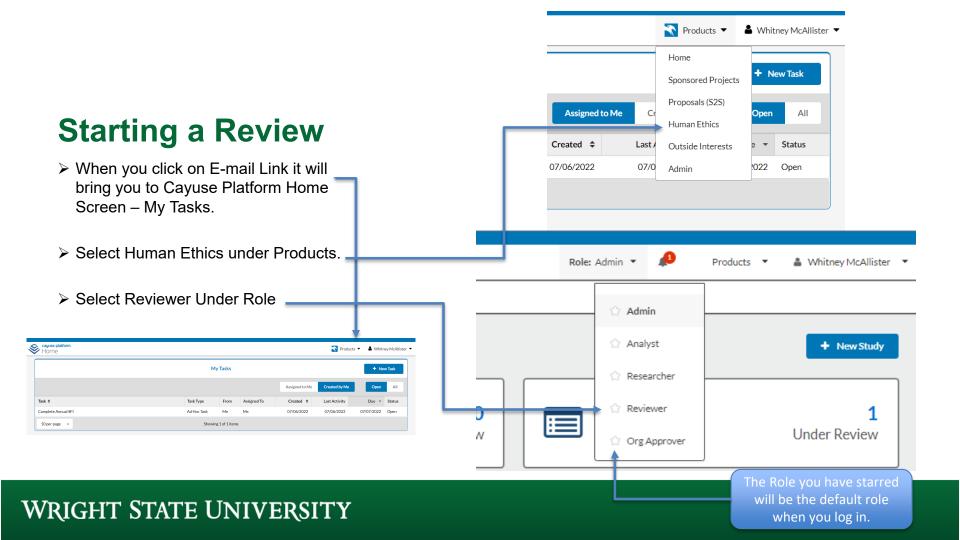
Reviewing & Commenting on Submissions

Commenting

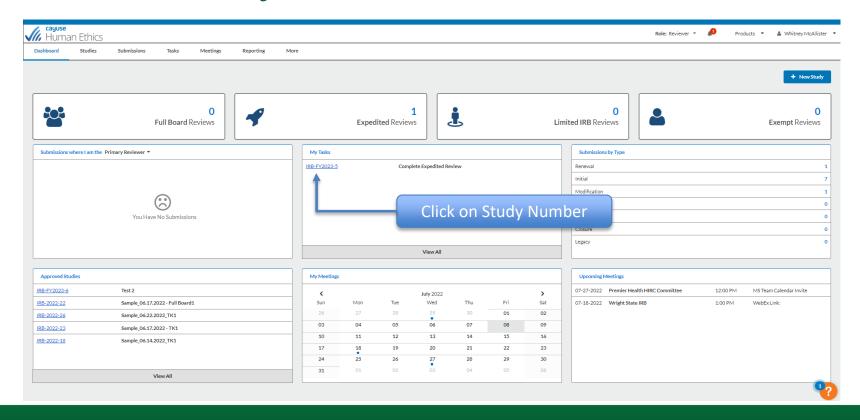
Check Lists

Determinations

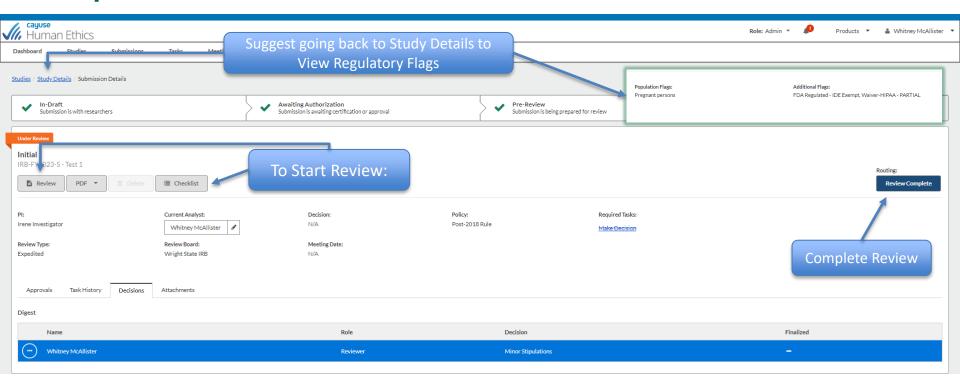




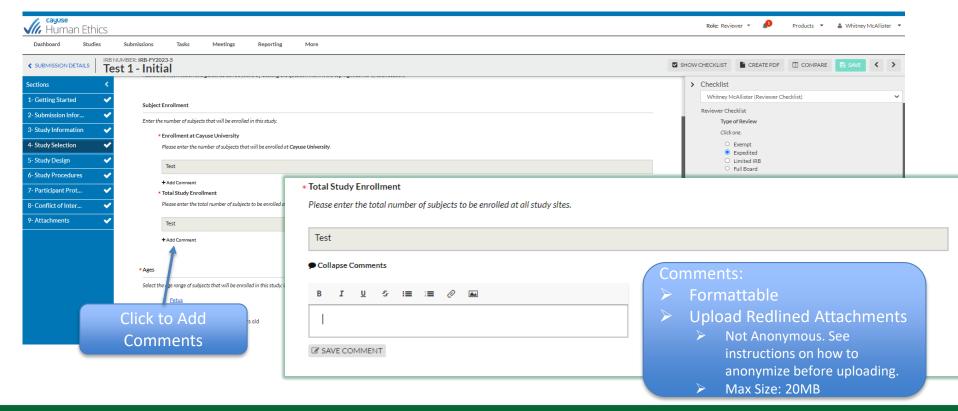
Select Study to Review:



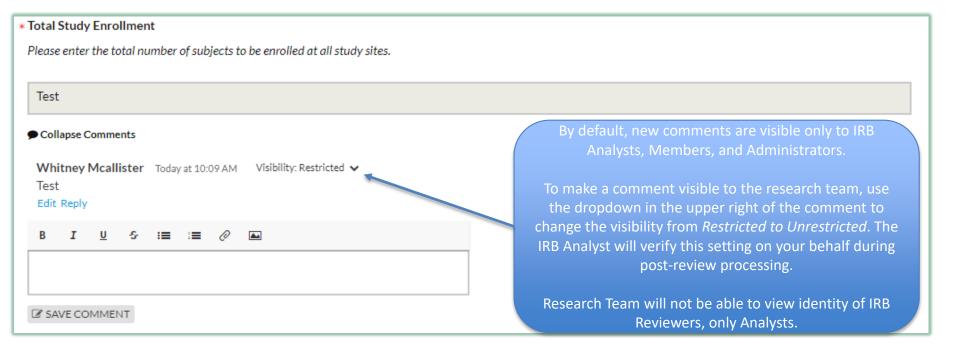
Opens the Submission Details Screen



Commenting



Commenting



Checklists

Using Checklists

Checklists are designed to help the analyst or reviewer verify that the form questions have been answered in a manner that satisfies your institution's specific requirements. IRB Analysts and Administrators can configure the checklist questions via the <u>Settings</u> menu. There are two different checklists used for all submissions—one checklist for the IRB Analyst, and a different checklist used by each of the submission's reviewer(s).

cayuse IRB **≪** STUDY SHOW CHECKLIST 🔽 CREATE PDF Social Effects of Early Onset Hair Loss - Initial Checklist Sections Assignments IRB Analyst (Analyst Checklist) Address Name Organization Phone Email IRB Member 3 (Reviewer Checklist) Is this a new study that has not Joe Smith School of Medicine 440 Exchange, Irvine, CA 714 265 7841 ismith@evisions.com been previously submitted? + Add Comment Is the PI approved for research? Does the PC have sufficient Primary Contact contact information? Name Organization Address Phone Email 52 Other Items **Bob Rawley** School of Medicine 440 Exchange, Irvine, CA 714 265 7498 brawlev@evisions.cor Is Form 3B attached? + Add Comment 53 Optional Forms Are all additional forms completely filled out? SAVE CHECKLIST

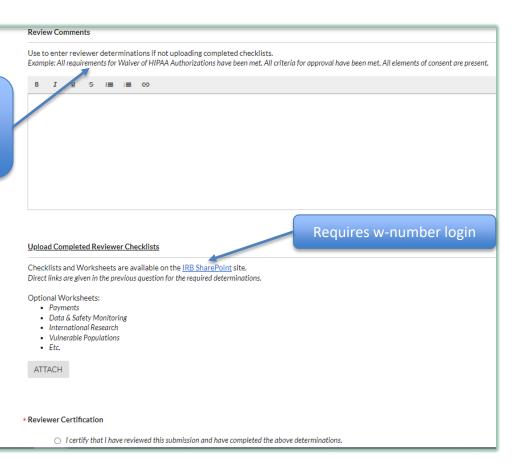
Note: Cayuse does not require the checklist to be complete prior to finalizing the review.

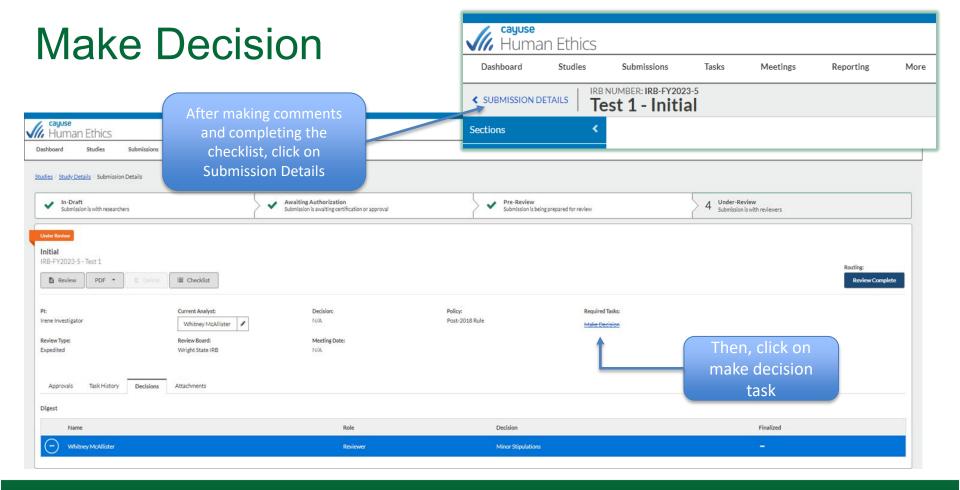
Please don't forget to complete the checklist.

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

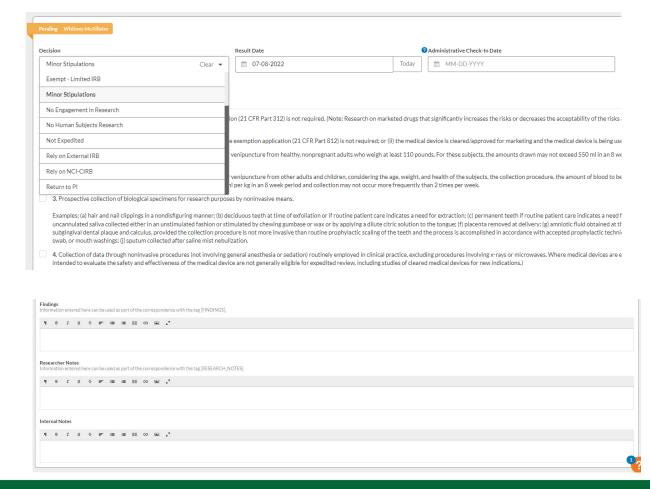
Reviewer Checklist If you opt to not complete Type of Review the checklist, indicate all findings and determinations Select the appropriate review level. in this box. Non-Human Subjects Research ○ Exempt Exempt with Limited IRB Review Expedited Full Board Use the Flags on Study Details Page Additional Required Determinations: Select if any of the following determinations need to be made for this study. Download the reviewer checklist ☐ Children □ Prisoners Pregnant Women Download the Reviewer Checklist: HRP-412 - CHECKLIST - Pregnant Women □ Waiver of Documentation of Consent ☐ Waiver of HIPAA Authorization Adults with Impaired Decision Making □ FDA Device Risk Determination Humanitarian Use Device ☐ Emergency Use





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

Decision	Explanation	Resulting Study Status	Routing
Disapproved	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.	Disapproved	The submission and/or study are disapproved and no longer editable. Disapproving an initial submission archives the study.
Deferred	The reviewer(s) identified major issues that the research team must correct before the submission can be approved.		
Minor Stipulations	The reviewer(s) identified minor issues that the research team must correct before the submission can be approved.	Requires Changes	Submission is returned to the PI and reopened for editing.
Return to PI	The study is being returned to the research team to make changes because the IRB will not approve it as-is.		
Not Expedited/Not Exempt	The study will be returned to the IRB Analyst to reassign it to the correct review type.		Submission is returned to the Analyst to reassign the review type and reviewers.
Not Reviewed	Documents that the submission was unable to be discussed at the meeting. The "Not Reviewed" 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.		Submission is returned to the Analyst to assign to a new meeting.

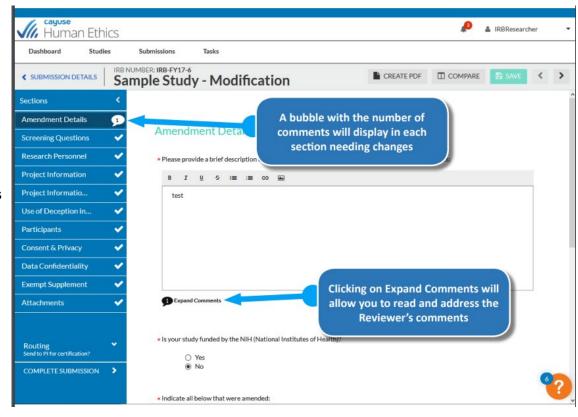
Decision	Explanation	Resulting Study Status	Routing
Approved	The study is approved.		
No Engagement in Research	The study does not constitute research and therefore does not require IRB approval.		
No Human Subjects Research	The study does not include human subjects research and therefore does not require IRB approval.	Approved	Submission is approved and no longer editable.
Noted	The incident report has been noted by the IRB.		
Rely on External IRB	The study and submission were reviewed and approved by an external IRB and their decision has been recorded by the IRB.		The research team can add additional submissions to the study.
Rely on NCI-CIRB	The study and submission were reviewed and approved by an NCI-CIRB and their decision has been recorded by the IRB.		
Exempt	The study is exempt because it fits into one of the specified categories for exemption.	Exempt	
	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		Submission is
Suspended	Removed" decision for a modification submission after it has had a full, 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	Suspended	returned to the PI and is no longer editable.
	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.		
Closed	A closure submission is created and submitted when the research is done and the study can be closed.	Closed	The study is closed and no further research can be done.
Withdrawn	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.	Withdrawn	The study is closed and no further research can be done.

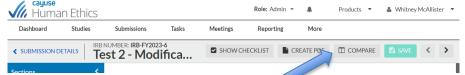
Reviewing a Re-submission

How to review changes requested by the IRB

Open the Review

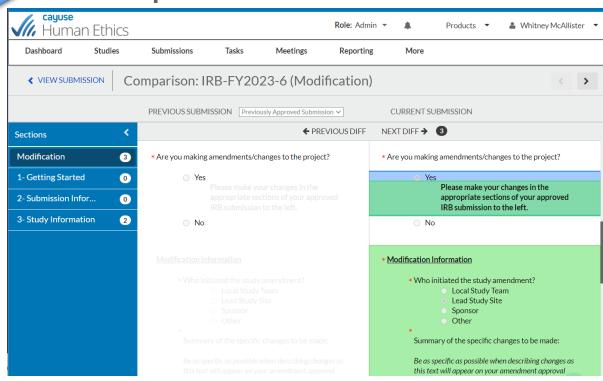
- Utilize the methods previously indicated to access and open the review.
- ➤ Bubbles will indicated where comments were made.
- Each comment will need to be marked as Addressed or Not Addressed. All must be marked in order to complete the review.
- Use Comparison Tool to identify changes in the application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





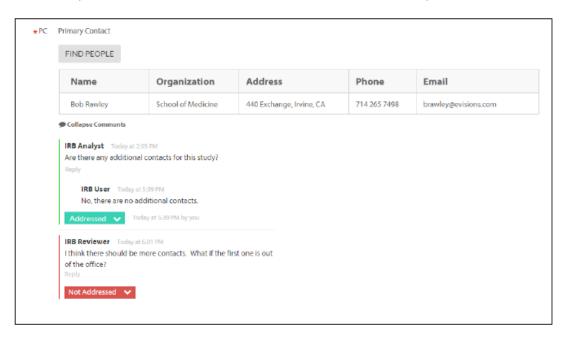
Comparison Tool

- 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



Comments

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



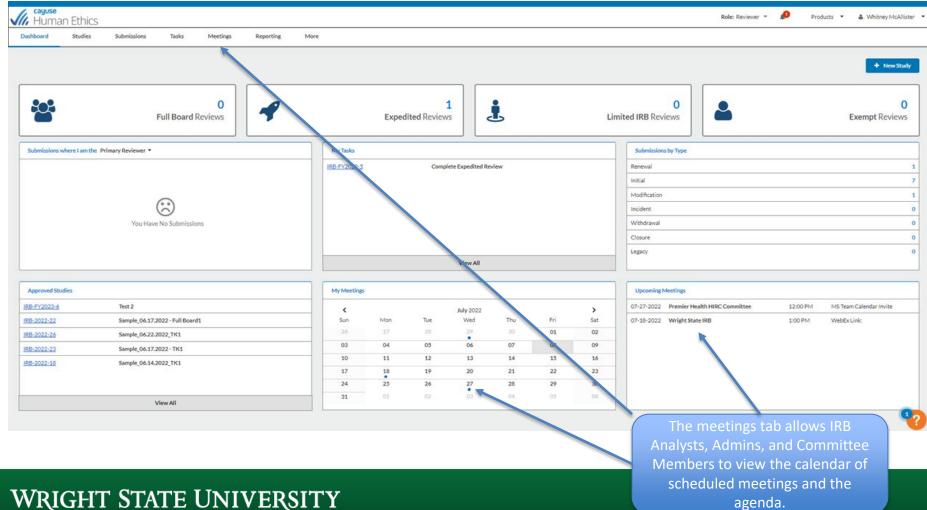
When you have responded to a comment, change the dropdown from Not Addressed to Addressed Unaddressed comments have a red bar to their left, and display the comment count in the comment bubble icon for that question. You can toggle comments between addressed and unaddressed as needed.

IRB Meeting

Agenda

Documents

Notice to Committee

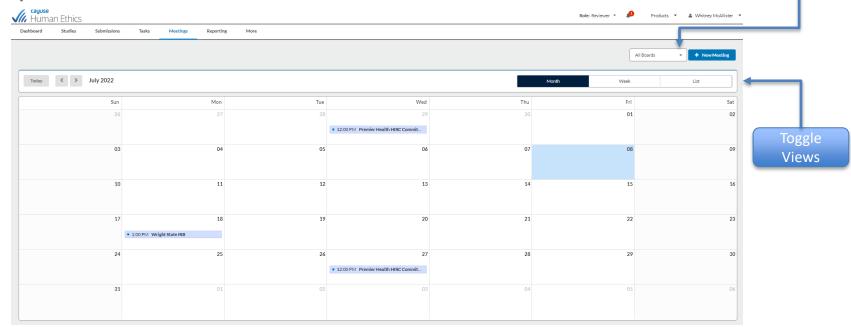


Board Members

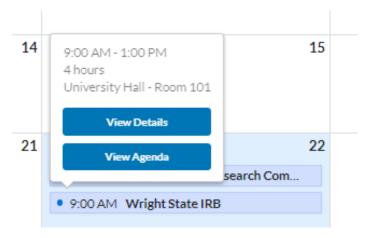
Using the Calendar

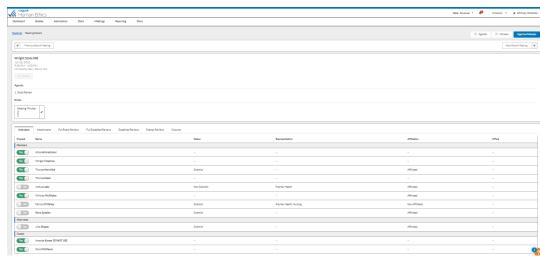
You can browse the calendar by clicking the < and > buttons at the top of the calendar. Use the **Boards** dropdown in the upper right to filter the meetings shown on the calendar to only displays meetings for the selected board.

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.

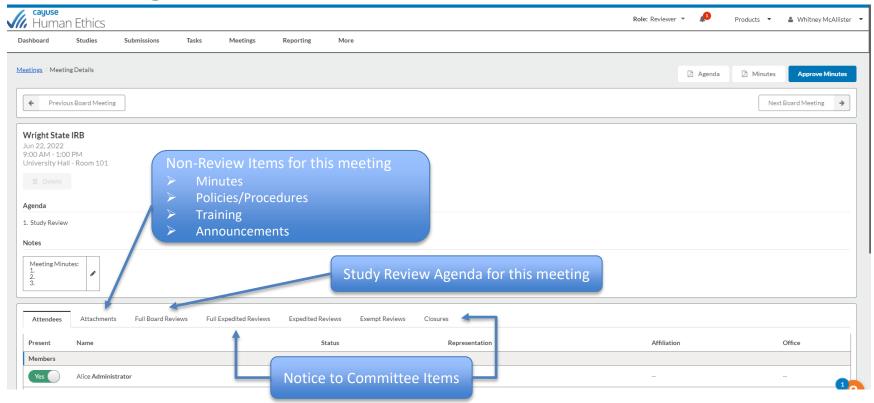


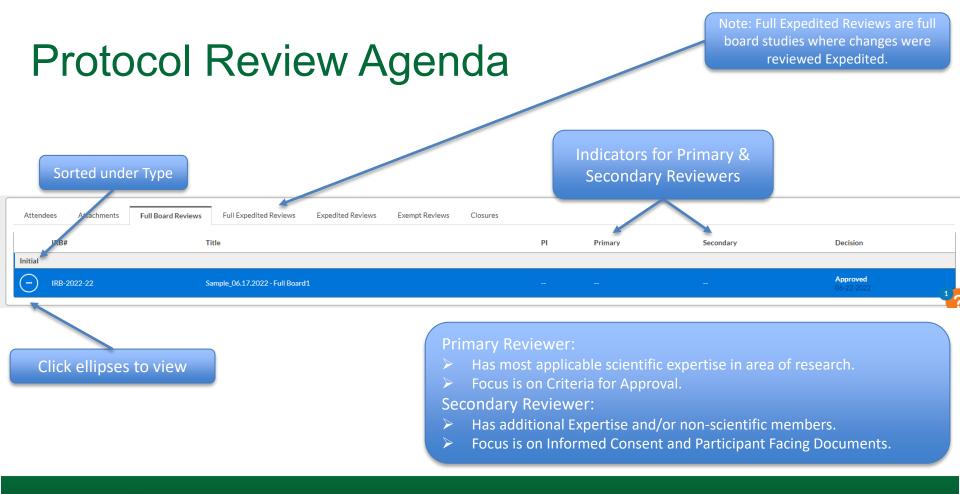
Meeting Details





Meeting Details



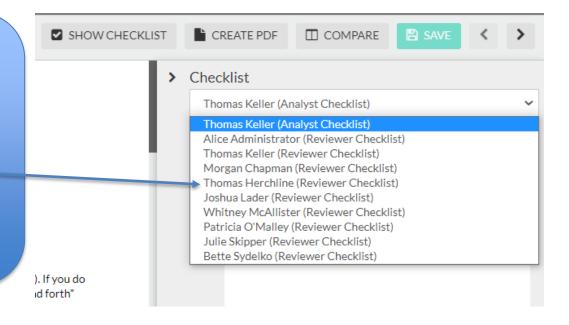


Full Board - Checklists

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 <u>two days</u> 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

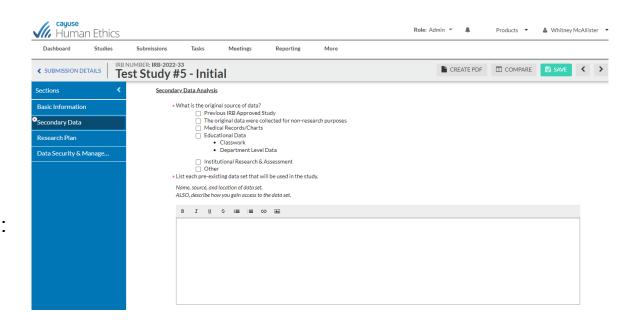
* Other Personnel & Qualifications

CV's are required for the PI and Faculty Mentor. Upload in the Documents section in My Profile or attach in the Upload Supporting Document section.

For all other study roles, select the study team role and corresponding qualifications and/or training to fulfill their role on the study and perform study procedures. Research Coordinators/Research Assistants/Research Nurses Individuals who are/will be working in a research position that involves patient contact and has undergone training specific to conducting research studies and patient procedures such as vital signs, phlebotomy or similar level invasive procedures. Research Administrators Individuals who processes research paperwork such as IRB correspondence and has no patient contact. Research Pharmacist Individuals who are qualified pharmacists and maintain and/or prepare investigational medications. Medical Technicians/Medical Staff Individuals who perform technical procedures according to their specialty (MRI, CT, Ultrasound, DXA, Mammogram, Respiratory Therapist, phlebotomist, Medical Assistant, Nurse, etc.) that is consistent with their role as an employee. ☐ Undergraduate or Graduate Students Students enrolled at WSU or other institution who is engaged in research including recording data, entering data, conducting non-invasive patient procedures, and processing specimens. Medical Students Students who are actively enrolled in medical school at WSU or other institution who will be engaged in research including recording data, entering data, conducting patient procedures, and processing specimens. Residents Individuals who are actively enrolled in a Residency Program (WSU or other). * Add the appropriate personnel: Full Edit Rights to Study Requires Certification FIND PEOPLE Physicians Individuals who have completed medical school and residency and have maintained appropriate licensing for their field. ☐ Honest Broker A neutral third party, who is not part of the research team in any way. The honest broker cannot be one of the investigators, study coordinators, or statisticians on the study and cannot serve as a co-author on any publication. This individual must have registered as an Honest Broker with the WSU IRB. Other Personnel No additional personnel on the project.

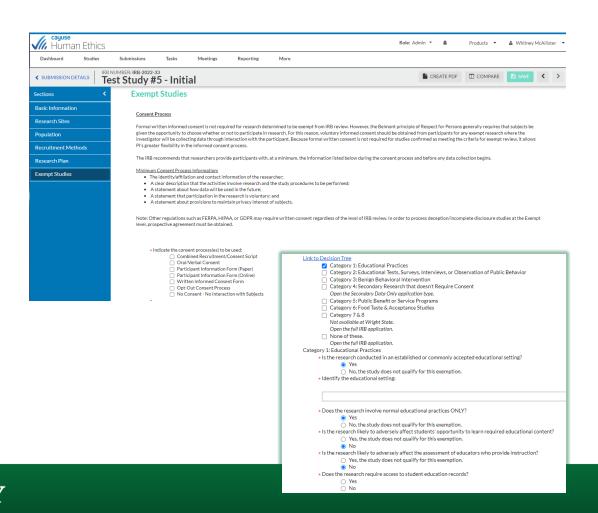
Secondary Data

- ➤ 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
 - BiospecimensCollection/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-In verses Updates
- Expedited & Full Board Consents need to be upload in PDF format
- New Incident Reporting Form
- New Application Types
- Biweekly IRB Meetings starting in September 2022



WRIGHT STATE UNIVERSITY

IRB Resources

IRB Website:

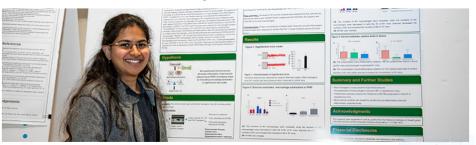
- Local Protocol & Consent Templates
- Check Lists
- Decision Trees
- Guidance Documents

IRB SharePoint Group:

- Calendar of Events
- Review Checklists & Worksheets
- > IRB Metrics
- Workshop Slides & Videos

Welcome to Wright State University's Institutional Review Board (IRB) website. Here, you will find everything you need to submit a human subjects research study for ethical review.

Office of Human Research Protections Program



ELECTRONIC SUBMISSION & PI RESPONSIBILITIES



New to Human Subjects Research? Start Here!

Activities Requiring IRB Submission

How to Submit

Common IRB Submission Errors

RSP Gateway Login

PI Roles & Responsibilities

Training & Education

IRB Meeting Dates & Deadlines

PREPARING PROTOCOL SUBMISSIONS



Initial Application

Amendments to Approved Research

Continuing/Administrative Review

Event Reporting

Closing a Study

Emergency Use & Expanded Access

Understanding Submission Types

Informed Consent

Collaborative Research & External IRBs

TEMPLATES, GUIDANCE & RESOURCES



COVID-19 Procedures

Templates & Checklists

Guidance Documents

Policies & Procedures

Researcher Resources

IRB Committee Member Resources

Get Help - IRB Submission

<u>Consultations</u>

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: <u>irb-rsp@wright.edu</u>

