ROAMWyo Human Ethics SOP:

IRB Reviewer

University of Wyoming
Research & Economic Development Division (REDD)
1000 E University Ave
Old Main Room 305
Laramie, WY 82071-3355

Title:	Process Owner:	Approved By:
ROAMWyo Human Ethics SOP: IRB Reviewer	Research and Economic Development Division, Compliance Office	Carolyn Brandt, Director Research Integrity and Compliance
Date Approved: XX/XX/XXXX	**Effective Date:** 6/15/2023	**Date of next review:** 6/14/2024

Purpose: To provide guidance and instructions to the University of Wyoming's IRB Reviewers, who are reviewing research protocols that involve human participants, on how to best utilize ROAMWyo and manage the IRB protocol.

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Scope: This guidance document applies to University of Wyoming's Institutional Review Board (IRB) members utilizing ROAMWyo Human Ethics module for IRB protocol reviews.

Responsibility: University of Wyoming's IRB members are responsible for adhering to this document to utilize ROAMWyo for various processes surrounding IRB Protocol review.

IRB Office – are staff of the University of Wyoming's REDD Compliance Office and are responsible for the administrative management of human subjects research oversight regulatory compliance and coordination of related work between the Institutional Review Board ("IRB") and researchers.

Institutional Review Board ("IRB") – is a group of experts from various backgrounds who are responsible for the review of IRB Protocols, modification submissions, annual renewals, and other submissions based on research activities. The committee is ultimately responsible for determining the approval or withholding status of a protocol.

Definitions:

Terms	Definitions
Administrative Check-in Date	This field will appear for expedited and exempt reviews guided by post-Common Rule 2018 policy with no expiration date. When an Administrative Check-In date for a review is set, it will trigger an email to the research team on that date.
Institutional Review Board ("IRB")	UW has one IRB responsible for conducting Human Subject Research project reviews and providing oversight for all Human Subjects Research activities conducted by faculty, staff, and students regardless of the source of funding. The IRB will conduct Initial and Renewal reviews of research activities according to Section 6 and Section 7 of the IRB Policies and Procedures Manual for Faculty, Staff, and Student Researchers. All review procedures will meet or exceed the requirements set forth in the regulations. The IRB has one regularly scheduled meeting per month during the academic year. IRB meeting dates and protocol submission deadlines can be found at the IRB Office webpage (https://www.uwyo.edu/research/compliance/human-subjects/index.html).
Analyst	An IRB Office staff member who conducts the initial review (or "Pre-Review") of the protocol submission and oversees it through the review process. When the protocol first routes to the IRB Office, an Analyst must be first assigned to conduct pre-review prior to the protocol moving forward in the review chain.
Dashboard	This is the ROAMWyo HE homepage that provides a summary of studies and submissions that are in different statuses: In-Draft, Awaiting Approval, Pre-Review, and Under Review. Also on display is "My Studies", "My Tasks", and "Submissions by Type".
Comments: Restricted and Unrestricted	Review comments are used by the Analyst and Reviewer when reviewing a protocol submission. If the Analyst decides that the PI should see these comments, he/she will have to adjust the comment settings to "unrestricted". "Restricted" comments will only be seen by the Analyst and Reviewer.

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Exempt Review	Federal regulations identify specific categories of research activities that are exempt from the federal regulations on the protection of human subjects in research. It is important to note that while a project may be exempt from the regulations, the ethical principles of conducting research with humans still apply: • All researchers and co-researchers are trained in the ethical principles, relevant federal regulations, and institutional policies governing human subject research; • Human subjects will voluntarily consent to participate in the research when appropriate and will provide subjects with pertinent information (e.g., risks and benefits, contact information for researchers and the IRB, etc.); • Human subjects will be selected equitably so that the risks and benefits of the research are justly distributed; • The IRB will be immediately informed of any unanticipated problems that would increase the risk to the human subjects and cause the category of review to be upgraded to expedited or full board review; • The IRB will be immediately informed of any complaints from participants regarding their risks and benefits; and • Confidentiality and privacy of the subjects and the research data will be maintained appropriately to ensure minimal risk to subjects. The researcher may not make the determination of exempt status. He/she may submit as an exempt, with the knowledge that the IRB may not consider the protocol as exempt and he/she may have to submit additional information. See the IRB Policy and Manual for additional details for exempt criteria and categories.
Expedited Review	These protocols are typically approved for up to 1 year and the PI must submit a renewal protocol 30 days prior to the protocol expiration date.
Full Board Review	All Submissions for Initial review of research determined by the IRB Analyst to not be eligible for exemption or review by expedited procedures must be reviewed and approved at a fully convened IRB meeting. Continuing Renewal and/or review of Modification(s) to previously-approved Full Board Studies may be reviewed by the IRB outside of convened Board meetings unless a request is made by an Analyst or Reviewer to discuss the proposed submission at a fully convened meeting.
Renewal	Expedited and Full Board Studies are generally approved for a one-year period but may be shorter. The Study expiration date for Expedited and Full Board protocols may be extended through approval of the Renewal Submission **prior** to the expiration of the project. Generally, the IRB Office requests that Renewal Submissions are completed and routed through ROAMWyo at least 30 days prior to expiration to allow adequate time for review.
Study	A ROAMWyo term that represents the overall research project describing the title, PI and key personnel, approval/expiration dates, and any key information (flags) for the project. A Study is the high-level description of a research endeavor, and will contain one or more Submissions to examine the Study. For

	a Study to be approved in ROAMWyo, the Initial Submission must be reviewed and approved. Additional Submissions may be added to alter, renew, report an adverse event related to, or close the Study. It is the overarching project (overall protocol) which could later have multiple follow-on submissions. When creating the Study, it is a two part process of creating the study first, and then the Initial Submission. Subsequent submissions could include modification, incident, renewal, withdrawal, or closure.
Submission	A ROAMWyo term for the forms that are completed by the researcher team and routed to the IRB Office and IRB to establish, alter, renew, report on, or close a Study. Submission types are: Initial, Modification, Renewal, Incident, Withdrawal, Closure, and Legacy.
Submission Type	The various forms available in ROAMWyo for a researcher to select to propose (Initial), continue (Renewal), alter (Modification), stop (Withdrawal, Closure), or report a concern (Incident) with their Study. The Study Details page will display any active Submissions in a Study.
Submission Type: Initial	A newly submitted IRB protocol related to a new study (or protocol). The system requires a "Study" to be created first and then an initial submission.
Submission Type: Incident	A PI Is responsible for reporting any type of problem related to the protocol. Reporting responsibilities of PI: a. Within 48 hours of knowledge of the unanticipated problem, the PI is asked to submit an Incident Submission. b. Expected adverse events (adverse events described in the risks section of the consent form) only have to be reported in the renewal submission (not as an unanticipated problem).
Submission Type: Modification	Any change or update to the approved protocol should be treated as a modification submission.
Submission Type: Renewal	A protocol that is nearing expiration is required to have a protocol renewal submission. To prevent research work from pausing, a renewal submission should be submitted at least 30 days in advance of the initial protocol submission expiration date.
Submission Type: Withdrawal	Submission that will notify the IRB Office that the submitter no longer wishes to submit his/her initial submission.
Submission Type: Closure	Researcher completes this submission to close the Study.
IRB Determinations	When an Initial, Renewal, or Modification Submission is discussed by the IRB, the Board may vote to (1) approve; (2) approve with explicit conditions; (3) table; or (4) disapprove the proposed item.
Decision: No Engagement in Research	The Study does not constitute research and therefore does not require IRB approval. Submission is approved and no longer editable; the research team can add additional Submissions to the Study (protocol).
Decision: No Human Subjects Research	The Study does not meet the federal definitions of Human Subjects Research and therefore does not require IRB approval. Submission is approved and no longer editable; research team can add additional changes to the Study (protocol) via Modification Submissions.
Decision: Approved	The study is approved and no longer editable within the system. The research team can add additional submissions to the study (protocol)

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Decision: Exempt	The study is exempt because it fits into one of the specified categories for exemption. Submission is approved and no longer editable; the research team can add additional submissions to the study (protocol).
Decision: Minor Stipulations	The reviewer(s) identified minor issues that the research team must correct before the submission can be approved. Submission is returned to the PI and reopened for editing.
Decision: Not Exempt/Not Expedited	The study will be returned to the IRB Analyst to reassign it to the correct review type.
Decision: Deferred	The reviewer(s) identified major issues that the research team must correct before the submission can be approved. Submission is then returned to the PI and reopened for editing.
Decision: Not Reviewed	Documents that the Submission was unable to be discussed at the monthly IRB 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.
Decision: 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. The submission and/or study are disapproved and no longer editable. Disapproving an initial submission archives the study.
Decision: Noted	The incident report has been noted by the IRB. Submission is approved and no longer editable; the research team can add additional submissions to the study (protocol).
Decision: 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. Submission is approved and no longer editable; the research team can add additional submissions to the study.
Decision: 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. Submission is approved and no longer editable; the research team can add additional submissions to the study
Decision: Return to PI	The study is being returned to the research team to make changes because the IRB will not approve it as-is. Submission is returned to the PI and reopened for editing.
Decision: Suspended	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, 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" to extend the date without lifting the suspension, or "Suspension Removed" to extend the date and lift the suspension.* Submission is returned to the PI and is no longer editable.
Decision: Withdrawn	The research team decided not to proceed with the initial submission. This decision is only available for withdrawal submissions. The research team can

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	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. The study is closed and no further research can be done.
Decision: Closed	A closure submission is created and submitted when the research is done, and the study can be closed. The study is closed, and no further research can be done.
Flags: Vulnerable Populations	• Adults unable to consent • AIDS/HIV+Children - 404 • Children - 405 • Children - 406 • Cognitively impaired • Economically and/or educationally disadvantaged Indigenous Peoples • K-12 • Minorities • Pregnant persons • Prisoners • Senior citizens • Students or employees • Terminally ill • Undocumented Persons Unhoused
Flags: Additional	• Biomedical • Broad Consent • CARES Act • Certificate of Confidentiality • Clinical trial • Community Advisory Board • Compassionate Use - Device • Conflict of Interest • COVID-19 • DoD • Emergency Use - Device • Emergency Use - Drug • EU General Data Protection Regulation • Expanded Access • External IRB reliance • FDA regulated • FDA Regulated - EFIC • FDA Regulated - IDE • FDA Regulated - IDE • FDA Regulated - IDE Abbreviated • FDA Regulated - IND (HE CAB) • FDA Regulated - NSR (non-significant risk device) • FDA Regulated - SR (significant risk device) • FDA Regulated – Drug

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	• Federally funded study • HIGH PRIORITY • HOLD • Institutional Biosafety Committee • International • IRB of record • Risk - Greater than Minimal Risk • Risk - Minimal Risk • SBER (Social Behavioral Education) • School-based Research • Sponsor-Investigator Initiated • Student-led research • Tribal Law • US Department of Education (ED) regulations • US Department of Energy (DOE) regulations • US Department of Health and Human Services (DHHS) regulations • US Department of Justice (DOJ) regulations • US Department of Veterans Affairs (VA) regulations • US Environmental Protection Agency (EPA) regulations • Waiver of Consent • Waiver-HIPAA - FULL Waiver-HIPAA - PARTIAL
Researcher Staff Member	A member of the Study team, oftentimes the project PI or Co-PI, or another member of the project, who creates and submits a form with ROAMWyo.
Principal Investigator (PI)	The lead individual for a research project involving human subjects. This may be a UW student, staff member, or faculty member. This individual (along with their faculty advisor, if a student or visiting researcher member) is ultimately responsible for the welfare of all human subjects involved in their projects and is responsible for the final review and submission of all protocols and other documents within ROAMWyo.
Co-Principal Investigator, aka Faculty Sponsor, aka Faculty Advisor	If the PI is non-UW faculty (i.e. a student, postdoctoral/visiting scholar, visiting/emeritus professor, etc.), then an active UW faculty member **must** be assigned to the study as a Faculty Sponsor, which effectively makes the Sponsor a Co-PI on the Study. This person is required to review and approve any ROAMWyo Submissions prior to certification and is ultimately responsible, along with the PI, for ensuring the safety and wellbeing of all human subjects involved in the Study (i.e. research subjects and research team personnel). If a Study has two faculty/staff UW researchers who are equally sharing in the project (typical definition of Co-PIs), a Research Staff Member may assign one person as the PI and the other individual can be listed as either a Primary Contact or a Co-Investigator (see below for differences).
Primary Contact	A member of the research personnel on a Submission who will have: view/edit access to the project, the ability to create follow-up Submissions after Initial approval (Renewal, Modification), and will be included in all automated Submission & Study communications.

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	A Primary Contact will **not** be required to review and approve a Submission prior to certification. You can have multiple Primary Contacts, but your Faculty Advisor (see Co-PI) above **must** be listed as a Primary Contact.
Co-Investigator	A member of the research personnel that will have view access to the project. A Co-Investigator will **not** have edit access, the ability to create follow-up Submissions after Initial approval (Renewal, Modification), and will not be included in any automated Submission or Study communications. You can have multiple Co-Investigators.
Other Personnel	All other members of a research Study. These individuals will have the same permissions as Co-Investigators (view access only).
Reviewer	An IRB member who is assigned to conduct the protocol review after the Analyst has conducted the initial review (or "pre-review").
Trigger Question	Questions within the module that when answered consequently trigger additional questions that appear in the form.
Status Banner: Unsubmitted	An in-draft submission that is open for editing and has not yet been routed to the IRB. Likely some required items still need to be completed before the submission can be declared complete and certified.
Status Banner: Awaiting Certification	Once a submission is declared complete, it informs the certifying researchers that they need to sign off on it. A submission cannot be edited once it reaches this point unless a certifier rejects it.
Status Banner: Reopened	This status is applied if a Certifier, Approver, Analyst, or Reviewer returns the submission at any point. It is functionally the same as the Unsubmitted status.
Status Banner: Under Pre-Review	Once all certifications and approvals are in, the submission routes to the IRB Office where an IRB Analyst will be assigned, determine the review level for the protocol, and begin a preliminary review. The Analyst may return a submission if they need additional information or clarification before sending the protocol to review.
Status Banner: Under Review	Regardless of the level of review or number of board members reviewing, this status indicates that the IRB review process is underway for a submission. For Full Board reviews, this can be expected to go through the Board's next meeting date, unless the submission has already been through a Full Board Review and needs only minor edits.
Status Banner: Under Post Review	This status is applied once the Reviewer's assessment of a submission is completed and they have come to a decision to either approve the protocol or ask for revisions. After a decision is made, the submission routes back to the assigned IRB Analyst for a final check before declaring the review complete, returning it, sending it to additional Reviewers (if needed).
Status Banner: Review Complete	Once an approval or exemption decision has been reached for a protocol and the IRB Office has signed off on it, this status becomes permanent for the submission and the Study Status may change to reflect it, as when an Initial

	Submission is first declared "Approved" or when an expired protocol finishes the continuing review process.
TOC (Table of Contents)	Table of Contents of the protocol form, located on the left side of the page, named "Sections". A successful completion of each section is indicated by a checkmark. For a protocol under review, a comment is indicated with a thought bubble icon next to each section title.

Related Policies:

- Institutional Review Board Policies and Procedures Manual for Faculty, Staff, and Student Researchers
- Investigator Data Retention Requirements
- Guidelines on Obtaining Child Assent
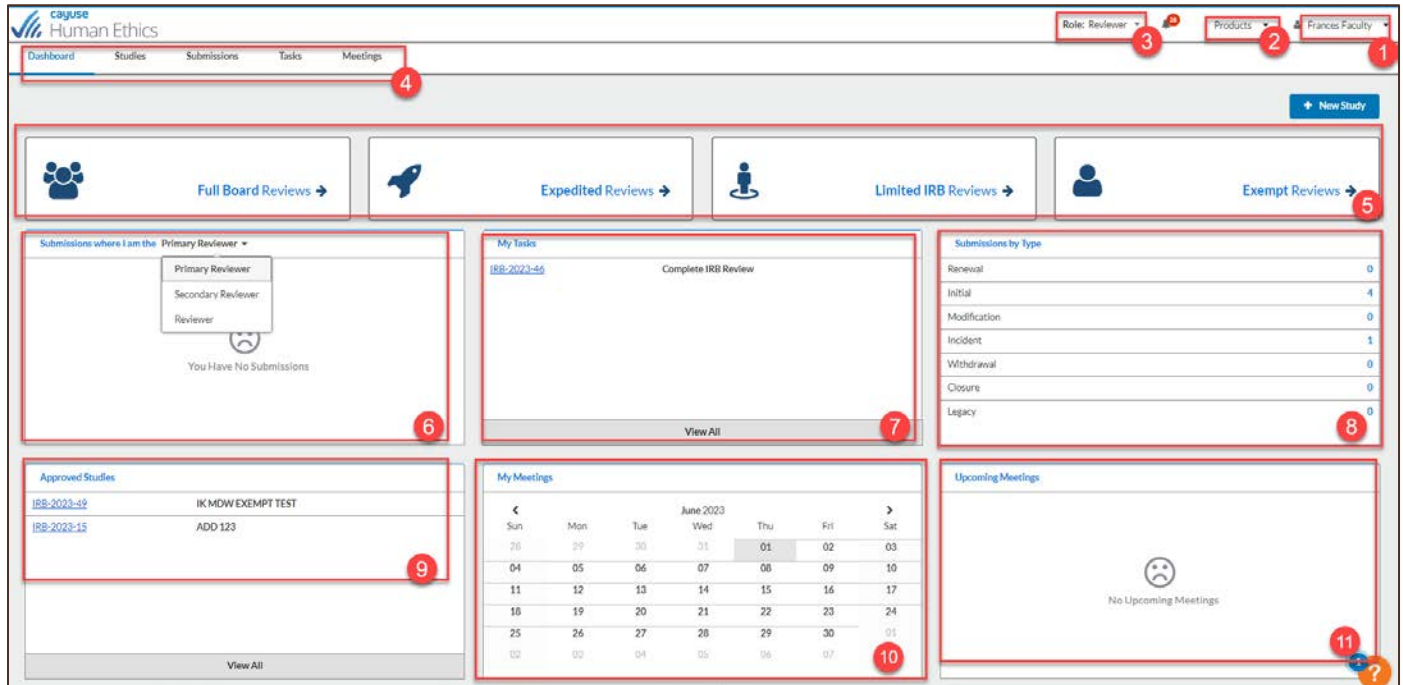- Human Subject Research Determination
- QA QI Program Evaluation Tool

Documents above and other detailed information is located at
http://www.uwyo.edu/research/compliance/human-subjects/index.html

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OVERVIEW AND NAVIGATION

Dashboard

Image 1. Dashboard View – IRB Reviewer

1. **Username** expands into a dropdown menu and includes the user's profile section
2. **Products** expands into a dropdown menu to toggle between ROAMWyo modules
3. **Role** selector dropdown toggles between roles within the module (e.g., **Reviewer** and **Researcher**)
4. **Menu of Tabs**
   a. **Dashboard** displays status tiles, Submissions by assignment, My Tasks, Submissions by Type, Submissions Under Review, Studies Expiring in 30 days, and My Meetings
   b. **Studies** lists all studies in various stages of the review lifecycle
   c. **Submissions** lists all submissions (e.g., initial, renewal, closure, withdrawal)
   d. **Tasks** displays what actions the user needs to take
   e. **Meetings** administrator manages the IRB meetings calendar, minutes, etc.
5. **Policy Review Category Tiles** protocols organized by policy type: Full Board reviews, Expedited Reviews, Limited IRB Reviews, and Exempt Reviews
6. **Submissions Where I am the Primary Reviewer/Secondary Reviewer** view of protocols assigned to you as a reviewer (Primary Reviewer, Secondary Reviewer, and/or Reviewer)
7. **My Tasks** actions that the reviewer must take on a protocol
8. **Submissions by Type** submissions list by type
9. **Approved Studies** lists approved studies
10. **My Meetings** displays a monthly view of your meetings
11. **Upcoming Meetings** displays an upcoming meeting

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Studies and Submissions

Image 2a. Study Details

The "Study Details" in blue is selected and shows the overall project information (or overall protocol). Related submissions are located on the right side, shown in image 2b.

1. **New Submission** start a new submission related to the study
2. **Study Details** an overview of the Study details, it is in blue when toggled to study details.
3. **Study Status** indicates study approval or submission status
4. **Study IRB protocol number and title**
5. **PDF** option to convert study into a PDF document
6. **Study Details includes**
   a. **Approval** date of the study
   b. **Expiration date** of the study
   c. **Organization** PI's department
   d. **Active submissions** the submissions related to the study (i.e., modification submission)
   e. **Population flags** indicates if study includes research on vulnerable populations
   f. **Additional flags** indicates if study includes additional flags (*see definition table for listing of additional flags*)
   g. **Admin check-in-date** date that protocol submission was accessed after it was submitted
   h. **Closed date** date when study was closed, if applicable
   i. **Current policy** type of study review
   j. **Sponsor** of the research project
7. **Key Personnel** active research members or staff involved in the research project
8. **Attachments** study attachments
9. **Flags** the vulnerable population and additional flag attributes of the study *(see listing of flags in definition table)*

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Image 2b. Study Details - Submissions

Submissions include the initial submission, and follow-on submissions on modification, incident, renewal, and closure.
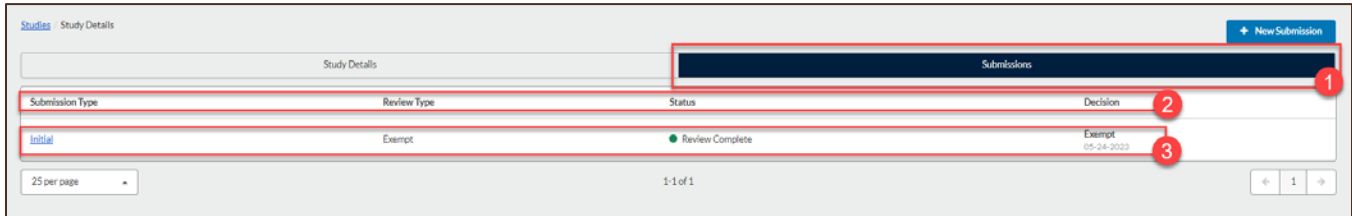
1. **Submissions** listing of submission related to the study
2. **Submission information categories**: Submission Type; Review Type; Status; Decision
3. **Submissions** associated to the overall study

Image 3a. Submissions Details (view as an IRB member, reviewer is a colleague)
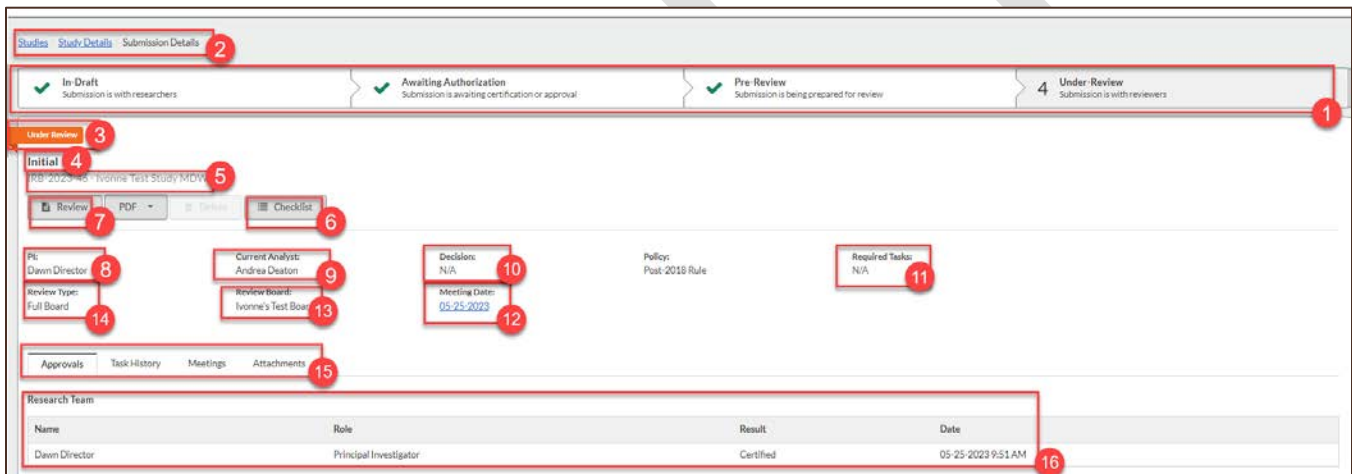
1. **Protocol Review Progress Status** organize submissions by the stage of the IRB protocol review lifecycle
   a. **In Draft:** Protocol Submission is in development and with the researcher
   b. **Awaiting Authorization:** A submission has been routed and is pending certification from the PI (or the IRB Office can "Administratively Certify" on behalf of the PI, if necessary).
   c. **Pre-Review**: A submission has been submitted to the IRB Office and is pending or under review by the IRB Office.
   d. **Under Review:** The IRB Office has reviewed the protocol and has assigned an IRB member(s) for review. This does not indicate an approval, however it indicates that it is in queue for review.
2. **Breadcrumb Mapping** displays hyperlinks to navigate to various part of the study or submission details
3. **Status Banner** the protocol review stage at a granular level (i.e., Unsubmitted, Awaiting Certification, Reopened, Under Pre-Review, Under Review, Under Post-Review, Review Complete; *see definition table for detailed status descriptions*)
4. **Submission Type** of the protocol is (i.e., initial, renewal, incident; *see definition table for descriptions*)
5. **IRB Protocol Number and Title**

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6. **Checklist** shows the review Checklist for protocol (a viewing checklist is available within the protocol)
7. **Review** starts the protocol review
8. **PI** name on protocol
9. **Current Analyst** is who conducts the IRB office pre-review
10. **Decision**
11. **Required Tasks** prompts the user to process the protocol review decision
12. **Meeting date** that the protocol submission is assigned to
13. **Review Board** is the IRB Board
14. **Review Type** is first determined during pre-review by the IRB Office
15. Protocol Information Tabs
    a. **Approvals** displays the protocol approval history
    b. **Task History** actions that have occurred on the protocol submission
    c. **Decisions** protocol decision outcomes
    d. **Attachments** related to the protocol submission
16. **Research Team** members involved in the protocol submission/work

Image 3b. Submission Details (as a primary or secondary reviewer)

Includes the same information as above with the addition of more tabs.

1. **Routing: Review Complete** to complete the review after the **Required Tasks** have been completed
2. **Routing: Change button** changes the Reviewers (or Review Type Board)
3. **Routing: Return to Investigators** if there are changes or questions
4. **Required Tasks** appear when a primary or secondary viewer is assigned and are required to make a decision

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Protocol Pathway

After PI submits the protocol, it is routed to the IRB Office "Analyst" for a preliminary review. At this time comments and questions may be added for the PI to address, which would result in a protocol being returned to the PI. Otherwise, the IRB Office Analyst will assign an IRB reviewer, if necessary, for a final decision. If there are no questions from the office "Analyst" or IRB reviewer, you will receive a notice of a final decision via letter sent by email. (Click here to see Appendix F: Decision Letters)

Review Tools

Image 4. Review Protocol Tools

Screen when starting a protocol review, along with the toolbar that has tools to assist with the review.
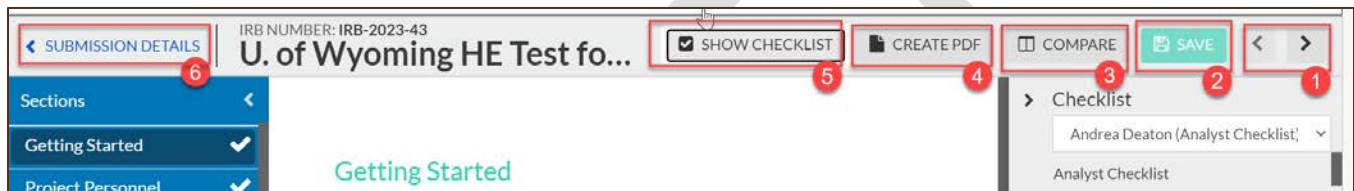
1. **Arrows** to navigate to the next or previous page of the protocol form (you may also select the page from the Table of Contents).
2. **Save** to save the review
3. **Compare** displays side by side views to highlight what has been changed in the protocol
4. **Create PDF** exports the protocol to a PDF
5. **Show Checklist** opens the checklist that provides review guidance to the reviewer
6. **Submission Details** returns the user to the main page of the submission

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Checklist

In ROAMWyo, analysts and administrators can create checklist templates for submissions. When creating a submission, users must check off the items on the checklist to make sure that their submission meets University of Wyoming's guidelines.

There are two types of checklist templates: Analyst Checklist and Reviewer Checklist. If no checklist is published for a user type, the **Show Checklist** button won't appear on a submission.

Image 5. Checklist View During Review

COMMENT FUNCTION OVERVIEW

Comments Overview

ROAMWyo has a commenting dialogue functionality created for the review process between the Analyst and the Researcher and the Analyst and IRB member.

Image 6. "Thought Bubble"

Icon in a section of the Table of Contents (TOC) indicates that a comment has been added to that protocol section. The number within the bubble represents the number of comments added.
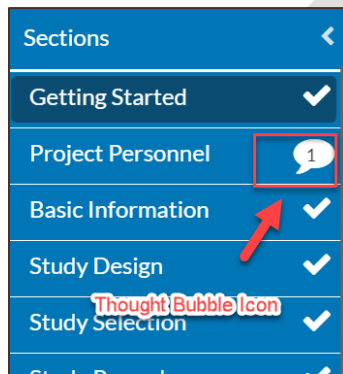
Image 7. Expanding and Collapsing Comments

Image 8. View of Expanded Comment and other comment functionality
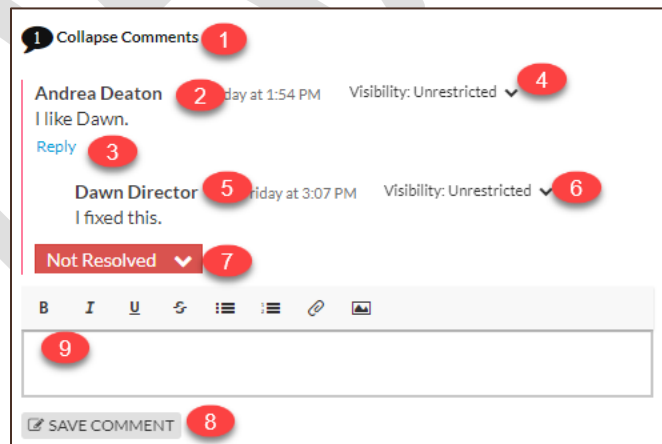
1. **Collapse Comments** (or Expand Comments) appears when the view is set to "Expand Comments". It is required to have expanded comments view to engage in comment dialogue.
2. Example of an initial comment from the Analyst to the PI.
3. **Reply** is used by the PI or IRB member to respond to the Analyst.

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4. If the Analyst wants the comments to be seen by the PI, this **Visibility: Restricted** dropdown must be switched to **Visibility: Unrestricted**
5. Example of a response from the PI to the Analyst
6. **Visibility: Unrestricted** must be selected for comments to be seen by the PI (or **Visibility: Restricted** to hide comments)
7. **Resolved/Not Resolved** is selected by the PI after entering a response
8. **Save Comment** should be selected after each comment is made
9. **Text field** where responses and comments are added and includes the functionality to attach a picture, a document, and various formatting options.

Review, Comment, and Response Scenarios

- **Scenario 1:** IRB Office (Analyst) has comments for the PI and returns the protocol to the PI prior to further review. PI is required to respond in the form prior to re-submitting the protocol.
  Involves: Creating comments; responding to comments, and marking comments as resolved
- **Scenario 2:** IRB Office (Analyst) has comments for the IRB Reviewer regarding the protocol, which then requires the Reviewer responding to the IRB Office. If these comments should be seen by the PI, the IRB Office is responsible for finalizing/editing comments prior to returning the protocol to the PI.
  Involves: Creating comments, responding to comments, editing comments, adjusting comment visibility, and marking comments as resolved
- **Scenario 3:** IRB Office (Analyst) and IRB Member (Primary Reviewer") use the comments function to communicate with each other (internally) and not for the PI to see.
  Involves: creating comments and responding to comments, marking them as resolved
- **Scenario 4:** IRB Office (Analyst) and IRB Member (Reviewer") include comments that request significant revisions to the protocol. The PI will receive the comments and suggested revisions and make the requested edits to the protocol and resubmit it to the IRB office. At this time the IRB Office and Reviewer will be able to use the "Compare" function to view the first protocol draft vs. the updated version to easily compare and see what the changes are.
  Involves: Creating Comments, responding to comments, making edits, using the Compare function, marking comments as resolved.

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COMPARISON TOOL

Overview

When you are reviewing a submission in ROAMWyo, you can compare different versions of the submission. This includes comparing different submission questions, as well as comparing versions of documents attached to the submission.

Comparing Submission and Attachment Versions

Image 9. Compare Button
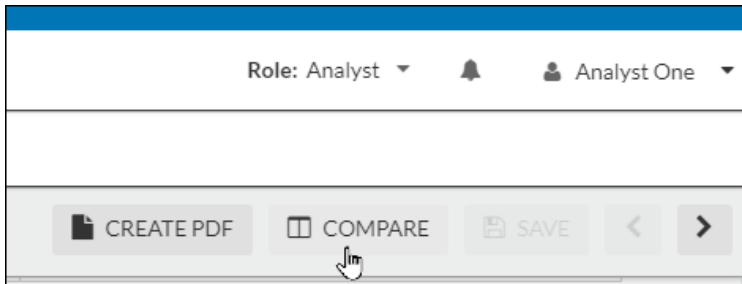
Image 10. Next Diff Button
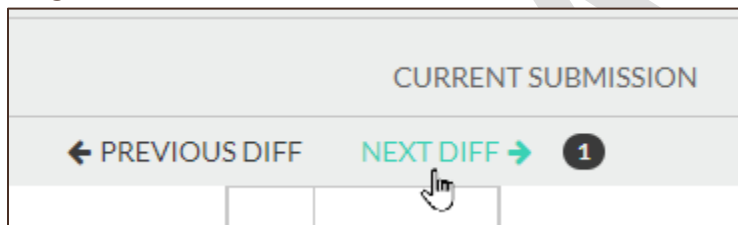
You will see the previous submission and the current submission side by side. Number of differences will be listed as a number next to **NEXT DIFF**. Click on the arrows to toggle between differences.

Image 11. Differences Highlighted in Blue for Visibility

A section that has been modified will be highlighted in blue.

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Image 12. Comparing Submission Text

Online Consent Form

Evaluating the Upgrade Enhancements to Document Compare

You are being asked to participate in a voluntary research study. The purpose of this study is to review document compare enhancements. Participating in this study will involve giving your opinion and your participation will last no more than 2 hours. Risks related to this research include going on the record; benefits related to this research include having a say. The alternative to participating in this study is to not participate.

What procedures are involved?
The study procedures are to look at compare.

This research will be performed online. You will need to participate 3 times over a 2 hour period. Each survey/activity will last 10 minutes.

Text that was added between submissions will be underlined green. Text that was deleted or replaced between submission will have a red triangle next to it.

Image 13. Comparing Submission Attachments Button

If an attachment has been revised or replaced, you will see a blue **Compare** button next to the attachment listing. Select **Compare** to see the two different versions of the attachment.

Image 14. Comparing Submission Attachment View
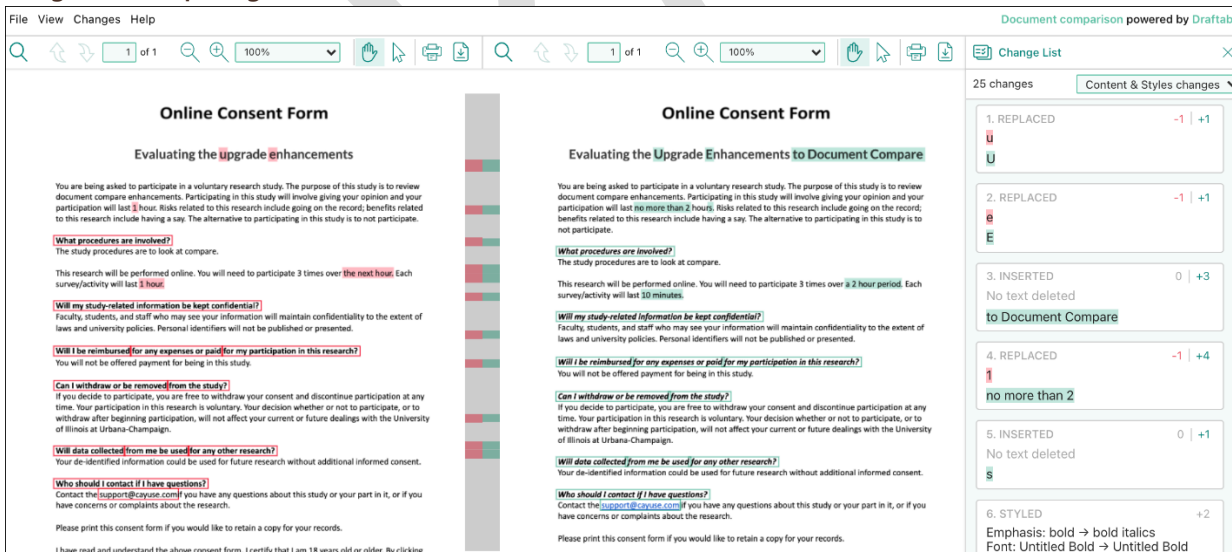
Like with submission text, red on the previous version means a section has been deleted or replaced. Green on the current version means the text was added.

ROAMWyo

IRB MEETINGS OVERVIEW

Calendar

Within ROAMWyo, an IRB member can view the IRB meeting schedule, agenda, meeting minutes, and attachments.

Image 15. IRB Meeting Schedule

Meeting date views can be adjusted to monthly, weekly, or a list. Select the meeting to view the details of the meeting, including the agenda, and to edit the meeting, and start and end the meeting.

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Meeting Details

Image 16. IRB Meeting Details
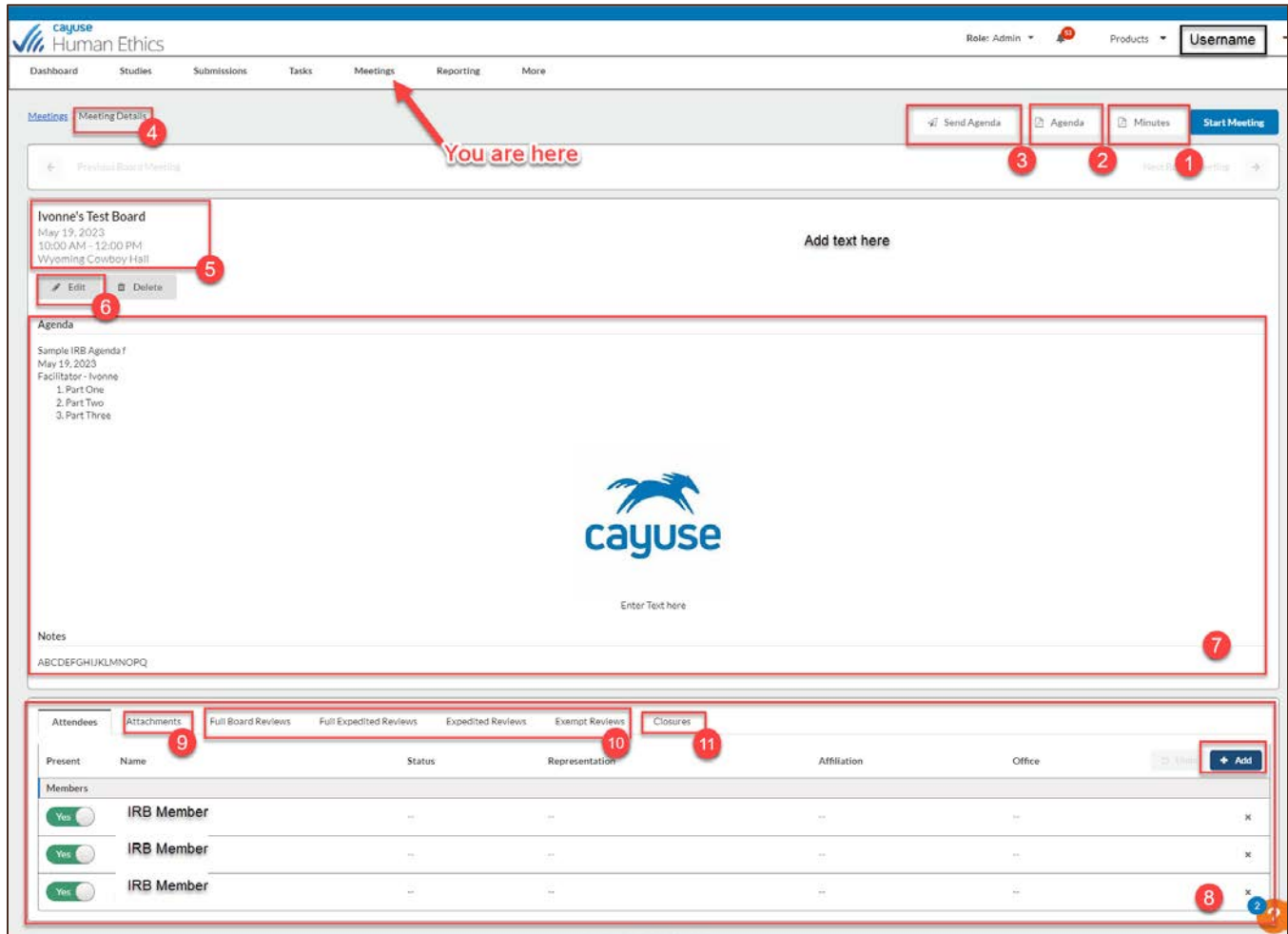
1. **Minutes:** location of Meeting Minutes
2. **Agenda:** view the agenda
3. **Send Agenda:** send the agenda to the committee
4. **Meeting Details:** breadcrumb mapping and each one can be selected if hyperlinked
5. **Meeting Information:** includes the Meeting name, date, time, and location
6. **Edit:** edit the details of the meeting, including the agenda
7. **Meeting Agenda:** preview of the agenda
8. **IRB Member Roster:** members can be viewed, added, removed, active or inactivated
9. **Attachments**: meeting documents
10. **Review Categories:** protocols organized by review category: Full Board Review, Full/Expedited Review, Expedited Reviews, Exempt Reviews
11. **Closures:** protocols with closure submissions

IRB PROTOCOL REVIEW

An initial submission is created for every new protocol, however, the submitter will be required to create an overall Study within ROAMWyo. The study is an overarching file folder, with the initial and follow-on submission(s) being housed within that folder.

1. Login to ROAMWyo
   a. Select **Human Ethics** from the **Products** dropdown
   b. Select **Role: Reviewer**
2. Select the hyperlinked IRB protocol number to review in **My Tasks**
3. Select **Review**
4. Select **Show Checklist** (if not already selected)

   Note: The review checklist will guide you through the review

5. Review each protocol section of the form using the **Checklist** as guidance
   a. Answer the **Checklist** questions while conducting the protocol review
6. Review any comments from the IRB Office which are displayed with a thought bubble icon on the Table of Contents section
   a. Select "**Expand Comments**" or "**Collapse Comments**" to view the comments or to collapse them (fields without comments will display "**+ Add Comment**").
7. IRB Office Pre-Review comments necessitate a response:
   a. Select **Expand Comments** (unless the comments are already expanded and "**Collapse Comments**" is displayed)
   b. Enter a comment in the **Reply** text field
   c. Select **Save Comment**
   d. Select **Edit** under your comment field to make changes
8. Continue completing the **Checklist**
   a. Complete the **Reviewer Certification** by selecting the radio button adjacent to the statement "**I certify that I have reviewed this submission and have completed the above Reviewer Checklist**."
   b. Select **Save Checklist** when the review is complete.

   Note: If there were modifications made to the protocol by the PI, select the "Compare" button to view a side-by-side comparison of modifications made.

9. Select **< Submission Details** (left top corner above the TOC)
10. If **Review Type** is **Full Board** – the process ends here, and step 11-19 below will be conducted by the IRB office following the meeting. If **Review Type** is **Exempt** or **Expedited,** move to the next step.
11. Select **Required Tasks: Make Decision**
    Click to see Submission Decision Matrices: Appendix A. Initial; Appendix B. Modification; Appendix C. Incident; and Appendix D. Renewal
    a. Select **Decision** from the Dropdown

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b. Enter **Result Date**

c. Enter **Administrative Check-In Date**

d. For an Expedited Review, select **Continuing review is mandatory**, if applicable

e. Select applicable categories under **Categories** section

12. Enter **Findings**

13. Enter **Researcher Notes**, if applicable

14. Enter **Internal Notes**, if applicable

15. Select **Save**

Note: Use the "Routing: Switch" button to switch the protocol type (i.e., exempt to expedited or expedited to exempt)

16. Route the protocol

a. Exempt: Select **Proceed**

b. Expedited: Select **Review Complete**

17. Select **Confirm**

Note: The protocol status banner will change from "Under Review" to "Under Post Review" which indicates that the submission has routed to the IRB Office for post-review, decision processing.

REPORTING

Study Information Report

1. Select **Reporting** from the menu toolbar
2. Select **Classic Reporting**
3. View a Report – move to steps 4 and 5; otherwise to step 6
4. Select ellipsis adjacent to the report **Name**
5. Select **Run**
6. Select **+ New Report**
7. Enter a **Report Name**
8. Select **Study Information** from the left side menu
9. Select desired **Report Filters** by selecting the **+** adjacent to the listed fields
10. Selected fields will be added to **Report Fields**
11. Select **Preview** to preview the report
12. Select **Save**

Audit Information Report

1. Select **Reporting** from the menu toolbar
2. Select **Classic Reporting**
3. View a Report – move to steps 4 and 5; otherwise to step 6
4. Select ellipsis adjacent to the report **Name**
5. Select **Run**
6. Select **+ New Report**

7. Enter a **Report Name**
8. Select **Audit Information** from the left side menu
9. Select desired **Report Filters** by selecting the **+** adjacent to the listed fields
10. Selected fields will be added to **Report Fields**
11. Select **Preview** to preview the report
12. Select **Save**

Note: 118 determinations are not reportable

APPENDIX A. INITIAL SUBMISSION DECISION MATRIX

INITIAL SUBMISSION				REVIEW TYPE			
Decision	**Explanation**	**Resulting Study Status**	**Routing**	**Exempt (Analysis & Reviewer)**	**Expedited**	**Full Board – Full Expedited (Analyst & Reviewer)**	**Full Board**
Exempt	The study is exempt because it fits into one of the specified categories for exemption.	Review Complete	Submission Approved: Not Editable; Follow-on Submissions Available	YES	YES	YES	YES
Approved	This study is approved	Review Complete	Submission Approved: Not Editable, Follow-on Submission Available		YES	YES	YES
No Engagement in Research	The study does not constitute research and therefore does not require IRB approval.	Review Complete	Submission Approved: Not Editable, Follow-on Submissions Available	YES	YES	YES	YES
No Human Subjects Research	Study does not include human subjects research and therefore does not require IRB approval.	Review Complete	Submission Approved: Not Editable, Follow-on Submissions Available	YES	YES	YES	YES
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.	Review Complete	Submission Approved: Not Editable, Follow-on Submissions Available	YES	YES	YES	YES
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.	Review Complete	Submission Approved: Not Editable, disapproving an initial submission archives the study			YES	YES
Deferred	The reviewer(s) identified major issues that the research team must correct before the submission can be approved.	In Draft	Submission returned to PI: Editable	YES	YES	YES	YES
Minor Stipulations	The reviewer(s) identified minor issues that the research team must correct before the submission can be approved.	In Draft	Submission returned to PI: Editable	YES	YES	YES	YES
Return to PI	The study is being returned to the research team to make changes	In Draft	Submission returned to PI: editable	YES	YES	YES	YES

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	because the IRB will not approve it as-is.						
Not [Selected Review Type]	The study will be returned to the IRB Analyst to reassign it to the correct review type.	Pre-Review	Submission returned to Analyst to reassign review type: ● Not Exempt decision returns to Post Review state, and analyst must use Change - Review Type to return to Pre-Review state. ● Not Limited IRB/Not Expedited decisions return to Post Review state, and analyst can use Reassign button to return to Pre-Review state (or Change button).	YES	YES		
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.	Under Review	Submission returned to Analyst to assign to new meeting.			YES	YES

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APPENDIX B. MODIFICATION SUBMISSION DECISION MATRIX

MODIFICATION SUBMISSION				REVIEW TYPE			
Decision	Explanation	Resulting Study Status	Routing	Exempt (Analysis & Reviewer)	Expedited	Full Board-Full Expedited (Analyst & Reviewer)	Full Board
Exempt	The study is exempt because it fits into one of the specified categories for exemption.	Review Complete	Submission Approved: Not Editable; Follow-on Submissions Available	YES	YES	YES	YES
Approved	This study is approved	Review Complete	Submission Approved: Not Editable, Follow-on Submission Available	YES	YES	YES	YES
No Engagement in Research	The study does not constitute research and therefore does not require IRB approval.	Review Complete	Submission Approved: Not Editable, Follow-on Submissions Available	YES	YES	YES	YES
No Human Subjects Research	Study does not include human subjects research and therefore does not require IRB approval.	Review Complete	Submission Approved: Not Editable, Follow-on Submissions Available	YES	YES	YES	YES
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.	Review Complete	Submission Approved: Not Editable, Follow-on Submissions Available	YES	YES	YES	YES
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.	Review Complete	Submission Approved: Not Editable, disapproving an initial submission archives the study			YES	YES
Deferred	The reviewer(s) identified major issues that the research team must correct before the submission can be approved.	In Draft	Submission returned to PI: Editable	YES	YES	YES	YES
Suspended	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.	Suspended	Submission returned to PI: Not editable	YES	YES	YES	YES
Suspension Removed	Suspension can only be lifted by selecting the "Suspension Removed" decision for a modification submission after it has had a full, full expedited, or expedited review. Lifting the	Review Complete	Submission Approved: Not editable, Follow-on submissions available		YES	YES	YES

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	suspension changes the study's status back to "Approved". *Note: Renewal submissions for an expired suspended study can receive a decision of "Approved" to extend the date without lifting the suspension, or "Suspension Removed" in order to extend the date and lift the suspension.*						
Minor Stipulations	The reviewer(s) identified minor issues that the research team must correct before the submission can be approved.	In Draft	Submission returned to PI: Editable	YES	YES	YES	YES
Return to PI	The study is being returned to the research team to make changes because the IRB will not approve it as-is.	In Draft	Submission returned to PI: editable	YES	YES	YES	YES
Not [Selected Review Type]	The study will be returned to the IRB Analyst to reassign it to the correct review type.	Pre-Review	Submission returned to Analyst to reassign review type: Not Exempt decision returns to Post Review state, and analyst must use Change - Review Type to return to Pre-Review state.; Not Limited IRB/Not Expedited decisions return to Post Review state, and analyst can use Reassign button to return to Pre-Review state (or Change button).	YES	YES		
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.	Under Review	Submission returned to Analyst to assign to new meeting.			YES	YES

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APPENDIX C. INCIDENT SUBMISSION DECISION MATRIX

INCIDENT SUBMISSION				REVIEW TYPE			
Decision	Explanation	Resulting Study Status	Routing	Exempt (Analysis & Reviewer)	Expedited	Full Board- Full Expedited (Analyst & Reviewer)	Full Board
Noted	The incident report has been noted by the IRB.	Review Complete	Submission Approved: Not editable, Follow-on submissions available	YES	YES	YES	YES
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.	Review Complete	Submission Approved: Not Editable, Follow-on Submissions Available	YES	YES	YES	YES
Deferred	The reviewer(s) identified major issues that the research team must correct before the submission can be approved.	In Draft	Submission returned to PI: Editable	YES	YES	YES	YES
Suspended	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.	Suspended	Submission returned to PI: Not editable	YES	YES	YES	YES
Minor Stipulations	The reviewer(s) identified minor issues that the research team must correct before the submission can be approved.	In Draft	Submission returned to PI: Editable	YES	YES	YES	YES
Return to PI	The study is being returned to the research team to make changes because the IRB will not approve it as-is.	In Draft	Submission returned to PI: editable	YES	YES	YES	YES
Not [Selected Review Type]	The study will be returned to the IRB Analyst to reassign it to the correct review type.	Pre-Review	Submission returned to Analyst to reassign review type: Not Exempt decision returns to Post Review state, and analyst must use Change - Review Type to return to Pre-Review state.; Not Limited IRB/Not Expedited decisions return to Post Review state, and analyst can use Reassign button to return to Pre-Review state (or Change button).	YES	YES		

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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.	Under Review	Submission returned to Analyst to assign to new meeting.			YES	YES

APPENDIX D. RENEWAL SUBMISSION DECISION MATRIX

RENEWAL SUBMISSION				REVIEW TYPE			
Decision	**Explanation**	**Resulting Study Status**	**Routing**	**Exempt (Analysis & Reviewer)**	**Expedited**	**Full Board – Full Expedited (Analyst & Reviewer)**	**Full Board**
Exempt	The study is exempt because it fits into one of the specified categories for exemption.	Review Complete	Submission Approved: Not Editable; Follow-on Submissions Available	YES	YES	YES	YES
Approved	This study is approved	Review Complete	Submission Approved: Not Editable, Follow-on Submission Available		YES	YES	YES
No Engagement in Research	The study does not constitute research and therefore does not require IRB approval.	Review Complete	Submission Approved: Not Editable, Follow-on Submissions Available	YES	YES	YES	YES
No Human Subjects Research	Study does not include human subjects research and therefore does not require IRB approval.	Review Complete	Submission Approved: Not Editable, Follow-on Submissions Available	YES	YES	YES	YES
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.	Review Complete	Submission Approved: Not Editable, Follow-on Submissions Available	YES	YES	YES	YES
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	Review Complete	Submission Approved: Not Editable, disapproving an initial submission archives the study			YES	YES

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Decision	Description	State	Outcome				
	will need to create a new submission if they wish to proceed.						
Deferred	The reviewer(s) identified major issues that the research team must correct before the submission can be approved.	In Draft	Submission returned to PI: Editable	YES	YES	YES	YES
Suspended	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.	Suspended	Submission returned to PI: Not editable		YES	YES	YES
Minor Stipulations	The reviewer(s) identified minor issues that the research team must correct before the submission can be approved.	In Draft	Submission returned to PI: Editable	YES	YES	YES	YES
Return to PI	The study is being returned to the research team to make changes because the IRB will not approve it as-is.	In Draft	Submission returned to PI: editable	YES	YES	YES	YES
Not [Selected Review Type]	The study will be returned to the IRB Analyst to reassign it to the correct review type.	Pre-Review	Submission returned to Analyst to reassign review type: ● Not Exempt decision returns to Post Review state, and analyst must use Change - Review Type to return to Pre-Review state. ● Not Limited IRB/Not Expedited decisions return to Post Review state, and analyst can use Reassign button to return to Pre-Review state (or Change button).	YES	YES		
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.	Under Review	Submission returned to Analyst to assign to new meeting.			YES	YES

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APPENDIX E. REQUIRED ATTACHMENTS

1. Training Certifications of Key Personnel (if not in the ROAMWyo system)
2. Training Documents for external collaborators
3. Reliance Agreements
4. Protocol Documentation if an external IRB is of record (or by Lead Site)
5. Recruitment Documents
6. Study Instruments (Surveys, scripts, personality scales, questionnaires, etc.)
7. Study Product Documents: Risk Documentation, FDA Approval Documentation, Formulation/Ingredient Information (for foods, supplements, etc.)
8. FDA Insurance Letter
9. International Research – Permission Documentation, Applicability of Research to Location; Community Consultation; Additional Local Context); Participant Protections (Literacy and Study Documents, Status of Women, Clarification of Research vs. Treatment)
10. Participant Protection Section – Debriefing Script
11. Consent and/or Assent Forms
12. Additional HIPPA documents
13. DSMP Documentation

APPENDIX F. DECISION LETTERS

Decision letters are created and issued by the IRB Office.

Types of Decision Letters

1. Administrative Closure
2. Administrative Withdrawal
3. Closure Submission
4. Incident – Full Board Review
5. Incident – Non-full Board Review
6. Initial – Exempt Review Approval
7. Initial – Expedited Review Approval
8. Initial – Full Board Review
9. Initial – Full Board Review Approval
10. Initial – Limited IRB Review Approval
11. Initial – Non-Full Board Review
12. Modification – Exempt Review Approval
13. Modification – Expedited Review Approval
14. Modification – Full Board Review Approval
15. Modification – Limited IRB Review Approval
16. Modification – Non-Full Board Review
17. Renewal - Exempt Review Approval

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18. Renewal - Expedited Review Approval
19. Renewal - Limited IRB Review Approval
20. Renewal – Non-Full Board Review
21. Renewal Submission – Full Board Review
22. Renewal Submission – Full Board Review Approval
23. Withdrawal Submission

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