ROAMWyo

Research Organization
Administration and Management

ROAMWyo Human Ethics SOP:

Principal Investigator

University of Wyoming
Research & Economic Development Division (REDD)
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Title:	Process Owner:	Approved By:
ROAMWyo Human Ethics SOP: Principal Investigator	Research and Economic Development Division, Compliance Office	Carolyn Brandt, Director, Research Integrity and Compliance
Date Approved:	**Effective Date:**	**Date of next review:**
12/1/2023	1/1/2024	7/1/2024

Purpose: To provide guidance and instructions to the University of Wyoming's investigators, who are conducting research that involves human subjects, on how to best utilize ROAMWyo and manage their IRB protocol(s).

Contents

Scope: This guidance document applies to all relevant University of Wyoming investigators/researchers utilizing the ROAMWyo Human Ethics platform for IRB protocol submission and management.

Responsibility: University of Wyoming's investigators and researchers are responsible for adhering to and following this document to utilize ROAMWyo Human Ethics ("HE") module for various processes surrounding IRB protocol submission. In cases where students and/or outside researchers are involved on a protocol, it is the responsibility of the Principal Investigator and/or faculty advisor to ensure that all members of the research team are adequately trained and adhering to the University of Wyoming Institutional Review Board Policies and Procedures Manual for Faculty, Staff, and Student Researchers ("Policy"). Additional responsibilities include:

Principal Investigators (PIs)/Investigators/Researchers – are to utilize ROAMWyo's Human Ethics ("HE") module to submit and maintain accurate & up-to-date IRB protocols and to inform the IRB if any unanticipated problems arise.

Institutional Review Board ("IRB", "Board") – is a group of experts from various backgrounds who are responsible for the review and approval of Human Subjects Research conducted at the University of Wyoming. In relation to this SOP, the IRB reviews new IRB protocol Submissions, including the initial experimental proposal, study modifications, annual renewals, closures, and other submissions based on the research activities. The Board is ultimately responsible for determining the approval or withholding status of a protocol.

IRB Office – includes staff of the University of Wyoming's Research and Economic Development Division's Office of Research Integrity & Compliance, and is responsible for the administrative management of Human Subjects Research oversight regulatory compliance and coordination of related work between the IRB and researchers.

Definitions:

Terms	Definitions
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).
Exempt Review	Human Subjects Research that is classified as "exempt" indicates that the research qualifies as no risk or minimal risk to subjects and is therefore exempt from most of the requirements of federal regulations of Human Subjects Research, but is still considered research requiring IRB review and approval prior to any initiation of the research process. An IRB Analyst, not the researcher, will determine if a Submission is exempt. A researcher with questions about their

	research and its classification may reach out to the IRB Office at IRB@uwyo.edu. See the IRB Policy and Manual for additional details for exempt criteria and categories. Exempt Submissions do not expire, but may have periodic Administrative Check-Ins to ensure that the work is continuing as proposed and with no ethical concerns.
Expedited Review	These protocols are typically approved for up to one year and the PI must submit a Renewal Submission at least 30 days prior to the Study 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. Full Board protocols are typically approved for up to one year and researchers must submit a Renewal Submission at least 30 days prior to the Study expiration date if they wish to continue this work. Full Board Studies that pass their expiration date **MUST** stop all data collection and experimental interventions and/or recruiting until the Renewal is approved.
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.
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. 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 to the IRB via the Incident or Modification Submission forms. Reporting responsibilities of PI: a. Within 48 hours of knowledge of the unanticipated problem, the PI is asked to complete and certify 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 the Incident Submission.
Submission Type: Modification	Any desired change or update to an approved protocol is completed via Modification Submission.
Submission Type: Renewal	A Study that is nearing expiration is required to have a Renewal Submission. To prevent research work from pausing, a Renewal Submission should be submitted at least 30 days in advance of the Study expiration date.
Submission Type: Withdrawal	Submission that will notify the IRB Office that the researcher no longer wishes to submit their 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: Not Exempt/Not Expedited	The Study will be returned to the IRB Analyst to reassign it to the correct review type.
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: Noted	The Incident Submission/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 UW 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 (National Cancer Institute – Central Institutional Review Board) and their decision has been recorded by the UW 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 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 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.
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. 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 Submission review after the Analyst has conducted the initial review (or "pre-review").
Trigger Question	Questions within the module that when answered will consequently create additional curated questions that appear in the form.
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 IRB 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 each 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 Renewal 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:

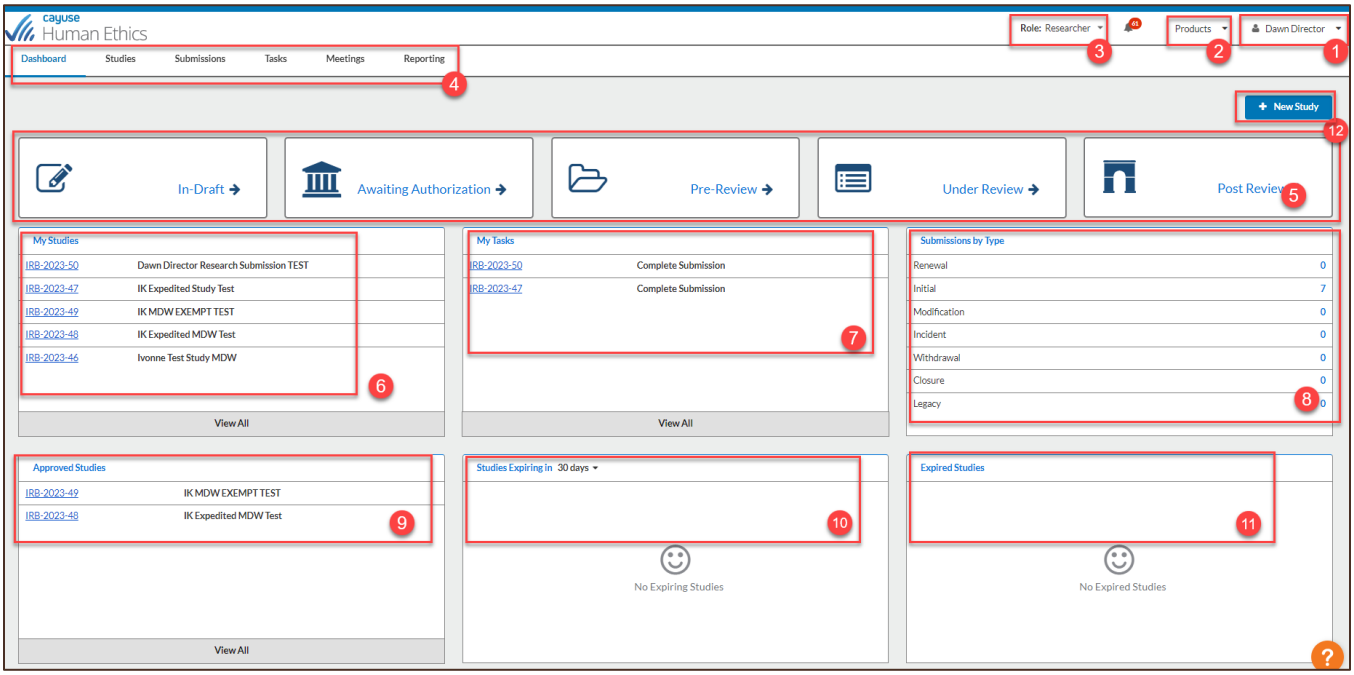
- Institutional Review Board Policies and Procedures Manual for Faculty, Staff, and Student Researchers
- Investigator Data Retention Requirements
- Guidelines on Obtaining Child Assent
- Human Subject Research Determination
- QA/QI Program Evaluation Tool

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

OVERVIEW AND NAVIGATION

Dashboard

Image 1. Dashboard View – Researcher



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 **(5)**, My Studies **(6)**, My Tasks **(7)**, Submissions by Type **(8)**, Approved Studies **(9)**, Studies Expiring in 30/60/90 days **(10)**, and Expired Studies **(11)**
    b. **Studies** lists all Studies in various stages of the review lifecycle
    c. **Submissions** lists all Submissions (Initial, Renewal, Closure, Withdrawal) and their status
    d. **Tasks** displays what actions the user needs to take
    e. **Meetings** administrator manages the IRB meetings calendar, minutes, etc.
    f. **Reporting** create reports of Studies/Submission (use "classic" option)
5. **Status Tiles** organize Submissions by the IRB protocol review lifecycle stage
    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.

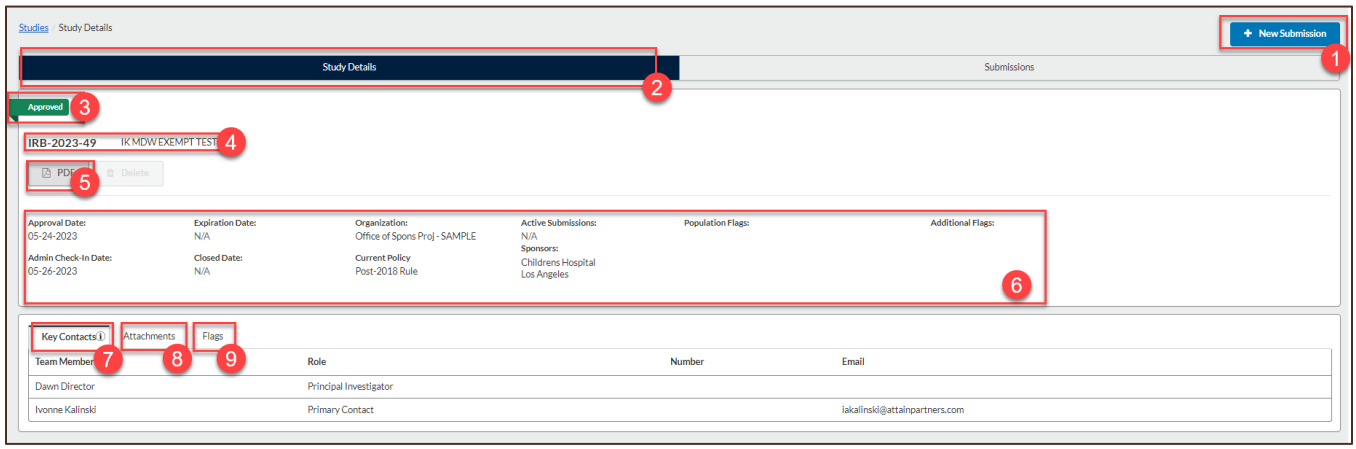
e. **Post-Review**: These are Submissions that have been reviewed and a decision has been determined.

6. **My Studies** lists the account user's Studies
7. **My Tasks** displays what actions the account user needs to take
8. **Submissions by Type** Submissions list by type
9. **Submissions Under Review** Submissions under review separated by review category of Full Board Review, Expedited, and Exempt. This is when the protocol is in the IRB member reviewer's hands.
10. **Studies Expiring** lists all Studies expiring in 30/60/90 days as a reminder to complete and certify Renewal Submissions to prevent a pause or closure of ongoing work.
11. **My Meetings** shows upcoming IRB Meetings by a monthly calendar view (adjustable to weekly or list view)
12. **New Study** is used to create a new protocol that does not already exist in the system

Studies and Submissions

Image 2a. Study Details

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

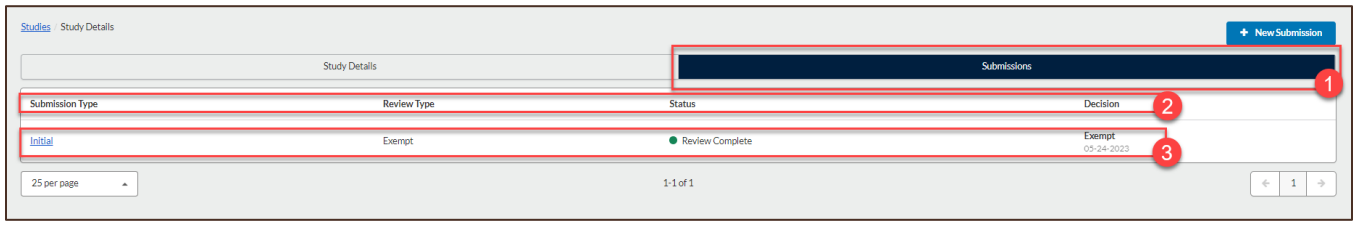


1. **New Submission** start a new Submission related to the Study
2. **Study Details** an overview of the Study details, it is in blue when toggled to study details. Conversely, clicking 'Submissions' will toggle that section blue (see Image 2b below)
3. **Study Status** indicates Study approval or Submission 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 (e.g., a Modification Submission or an Incident Submission)

e. **Population flags** indicates if Study includes research on vulnerable populations (*see definitions above)*
f. **Additional flags** indicates if Study includes additional flags (*see definitions above)*
g. **Admin check-in-date** date that protocol Submission was accessed after it was submitted
h. **Closed date** is the date when a Study was closed, if applicable
i. **Current policy** type of Study review
j. **Sponsor** of the research project

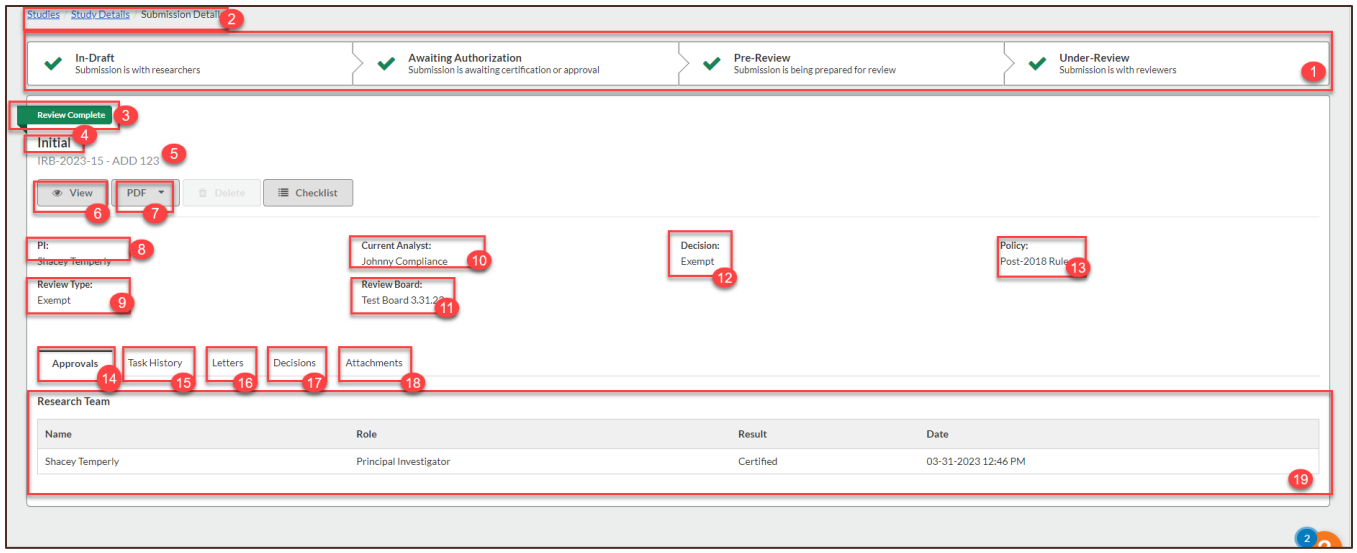
7. **Key Personnel** active research members involved in the research project
8. **Attachments** Study attachments
9. **Flags** the vulnerable population and additional flag attributes of the study *(see listing of flags in definition table)*

Image 2b. Study Details - Submissions



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 3. Submissions Details



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** hyperlinks to navigate to various part of the Study or Submission details
3. **Status Banner** the granular protocol review stage (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, Modification, Incident; *see definition table for descriptions*)
5. **IRB Protocol Number and Title**
6. **View** your protocol; or **Edit** if the protocol is "In-Draft" stage (this button changes depending on protocol review stage)
7. **PDF** create a PDF version of the protocol
8. **PI Name**
9. **Review Type** determined by IRB Office and supported by IRB Board; option types are Exempt, Expedited, or Full IRB (*see definitions for more details*)
10. **Current Analyst** an IRB Office staff member who conducts the pre-review, shepherds the protocol review and comment process between the PI and IRB member and conducts the post-review.
11. **Review Board** name of the IRB reviewing the protocol
12. **Decision** final review determination by the Analyst and/or Reviewer *(see decision types in the definition table)*
13. **Policy** indicates if protocol is Pre- or Post-2018 Rule
14. **Approvals** is the protocol approval history
15. **Task History** actions that have occurred on the protocol Submission (i.e., creation, certification, etc.)
16. **Letters** that have been distributed regarding protocol Submission decisions; hyperlinked for viewing
17. **Decisions** protocol decision outcomes, hyperlinked for viewing the details
18. **Attachments** related to the Study
19. **Research team** members involved in the protocol Submission

Protocol Pathway

After the 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 B: Decision Letters)

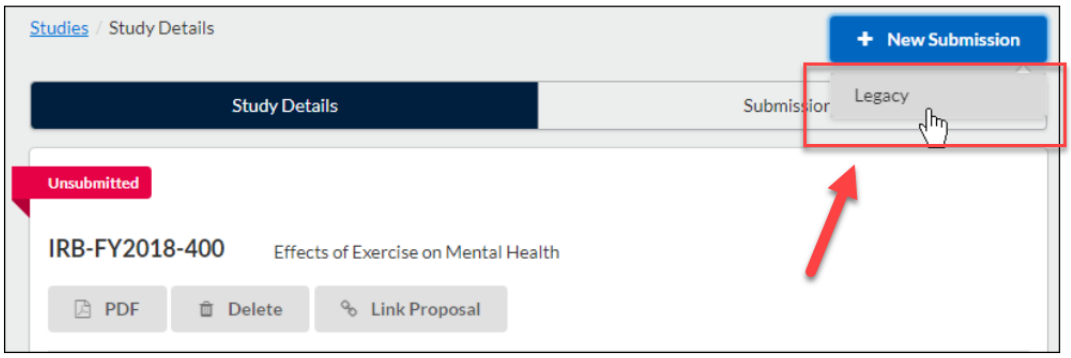
CREATING A PROTOCOL LEGACY SUBMISSION

Overview

At the time of the ROAMWyo launch, researchers with an active IRB protocol are required to complete a "Legacy" submission (a ROAMWyo term) to assist with the transition from the old system into ROAMWyo. Shell versions of all existing IRB protocols (known as a Legacies) have already been added into the system. These Legacy Studies contain only the most basic information- PI name, project title, and approval date. Researchers are required to complete a Legacy Submission for each of their active projects by inserting their original protocol information into the Legacy Submission form. Once submitted and approved by an IRB Analyst, the researcher will be able to complete follow-up Submissions (Renewals, Modifications, Incident Reports, and Closures). When selecting + New Submission, the option will be listed as "Legacy Submission." You will not be able to complete a follow-up Submission to a protocol without first completing a Legacy Submission, nor with the IRB Office allow any paper forms to be submitted for protocol updates or renewals

Note: the IRB Office will accept the paper form Unanticipated Problem Report Form in situations where an event has occurred on a study that has yet to be converted.

Image 13. Legacy Data Submission



Creating a Legacy Submission

1. **Login** to ROAMWyo (using SSO credentials)
    a. Select **Products** to reveal a dropdown menu (top right of the screen)
    b. Select **Human Ethics** from the drop down menu
    c. Select **Role: Researcher** from the dropdown menu on the toolbar (this menu will only appear if you have multiple roles within this module, such as an IRB member and a researcher).

Note: You will be directed to your ROAMWyo HE Dashboard (see Image 1)

2. Find the study in the **Dashboard** (This can be done by following the directions for a or b below)
    a. Search for the Protocol Study
        i. Select **Studies** from the toolbar menu

ii. Click in the search bar to initiate the search by revealing a dropdown of search filter options
iii. Select **PI**
iv. Enter the PI's name that is related to the protocol
v. Select the protocol by clicking on the hyperlinked protocol number

b. Locate the Legacy under the **My Studies** tile
i. Select the relevant Study to open

***Note**: if you are unable to locate an active, previously-approved IRB protocol in ROAMWyo, please contact the IRB Office immediately.*

3. Select **+ New Submission**
4. Select **Legacy Submission**
5. Review **Key Contacts** to ensure accuracy
6. Review **Attachments**
    a. Select **+ Upload Attachments**
    b. If desired, you can upload any attachments from the original protocol (consent forms, recruiting materials, survey materials, etc. Otherwise you can add these later)
    c. Confirm that the file has uploaded to the tab
7. Review and complete **Flags**
    a. Select all applicable items
    b. Select **Save**
8. Select **+New Submission**
9. Select **Legacy**
10. Select **Edit** or **Complete Submission** to open the form
11. Complete the first Section in the form, **Getting Started**

Note: Checkmarks appear in the Table of Contents when a section has been successfully completed

12. Complete section **Project Personnel**
    a. Select **Find People** to add an individual
    b. Enter the individual's name in the search bar
    c. Select the **magnifying glass** to start the search
    d. Select the individual's name
    e. Select **Save** to complete adding them to the protocol

Note: All UW employees (including paid part-time students) should be in the ROAMWyo system. If you need to add additional personnel to ROAMWyo (unpaid students, outside collaborators, etc.), please contact the IRB Office at IRB@uwyo.edu.

Note: Delete personnel by selecting the x on the right side of the table with the relevant personnel's name

Note: To navigate to the next section, use the arrows in the top right of the screen, or select the section in the Table of Contents.

Note: Training certifications are housed in key personnel's user profile – select "View" under Trainings to view certifications. If the personnel's training is not listed, scroll down to attach training documentation.

13. Complete section **Basic Information**

Note: Questions answered may reveal one or more new section(s) for additional detail entry and relevant document uploads

Note: Documents to upload include reliance agreements for External Collaborators or US External Sites; Training Documentation for External Collaborators

    a. Enter the Sponsor/Funder
        i. Select **Find Sponsors**
        ii. Enter the name of the company/agency to search
        iii. Select the **magnifying glass** to start the search
        iv. Select the + to select the sponsor (a checkmark will appear to indicate that you have selected that sponsor)
        v. Select **Save**
        vi. If Sponsor is not listed, enter the sponsor name in the field **If your funding entity is not in the list, please name them here**
        vii. Select **Save**
14. Complete section **Study Design**
15. Complete section **Study Selection**

Note: Questions answered affirmatively may reveal additional section(s)

16. Complete section **Study Procedures**

Note: if Study Products are selected as Yes, the Study Products section will appear

17. Complete section **Study Products** (if applicable)
18. Complete section **International Research** (if applicable)
19. Complete section **Participant Protection** (If applicable)

Note: If Data & Safety Monitoring is answered as Yes, the Data and Safety Monitoring section will appear

Note: If both questions are answered as Yes in the HIPPA section, a HIPPA section will appear

20. Complete section **HIPPA** (if applicable)
21. Complete section **Data Safety and Monitoring** (if applicable)
22. Review uploaded attachment in the section **Attachments**

23. Select **Save**
    a. Select **Create PDF** if a hard copy is desired
24. Select **Complete Submission** (last option in the Table of Contents)
25. Select **Confirm**
26. Certify the Submission
    a. Select **Certify**
    b. Select **Confirm**

Note: Once the protocol has been certified, it will route to the IRB Office for pre-review. You may view the protocol information in the tabs: Approvals, Task History, and Attachments. An "Under Review" status indicates that the protocol is ready for IRB member review (either under review or in the queue for under review).

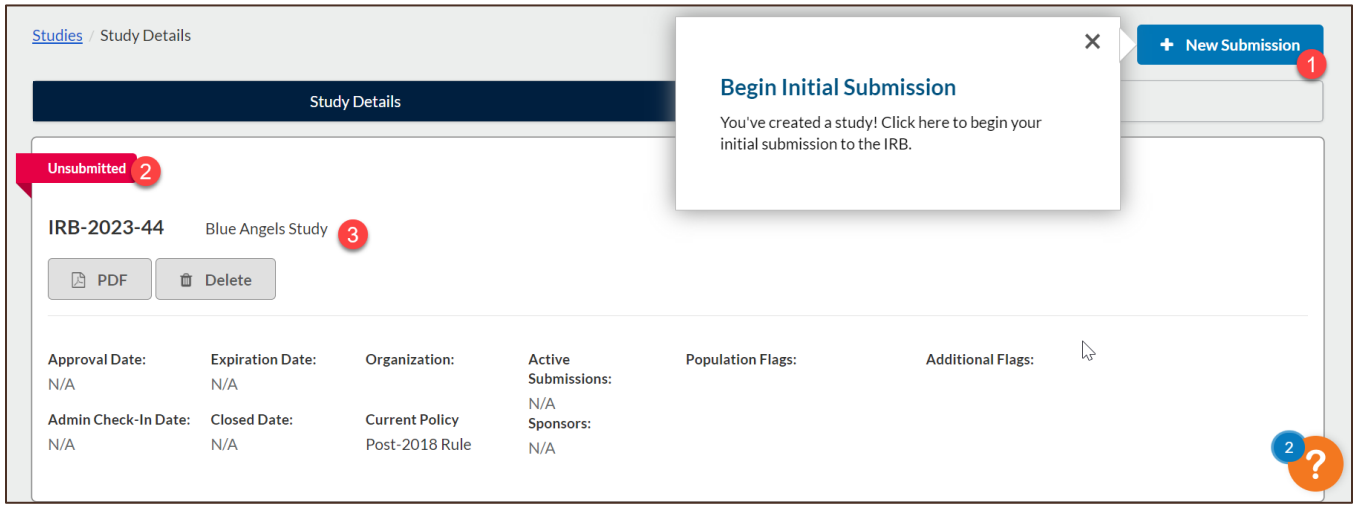
CREATING A NEW STUDY & INITIAL SUBMISSION

Overview

The Initial Submission is the first major description of a research project, and this form contains all of the required details to inform the IRB and IRB Office about the research project in order for them to make a fair assessment of the ethical risks, benefits, and protections involved in this work. ROAMWyo requires a "Study" to be created prior to an "Initial Submission" for a new protocol. Once you have created a new Study, then you can create a new Submission, which is called the "Initial Submission."

Note: Only one Initial Submission is created for a Study. If you need to make any changes to an approved Study/ Initial Submission, please see the Modification Submission section of this document.

Image 14. Newly Created Study and Initial Submission



1. **+ New Submission** to create a protocol submission
2. **Status Banner** the protocol review stage at a granular level (i.e., Pre-Review could have different sub-status such as "Reopened")
3. Location of the **IRB number** and **Study Title**

Creating a New Study and Initial Submission

1. **Login** to ROAMWyo (using SSO credentials)
    a. Select **Products** to reveal a dropdown menu (top right of the screen)
    b. Select **Human Ethics** from the drop down menu
    c. Select **Role: Researcher** from the dropdown menu on the toolbar (this menu will only appear if you have multiple roles within this module, such as an IRB member and a researcher).
1. Select + **New Study**
2. Enter **Study Title**
3. Select **Checkmark** button

Note: You will see the Study Details page with key personnel, attachments, and flags

a. Navigate to **Flags** tab
b. Select **Flags** that apply (**Vulnerable Population** and/or **Additional Flags)**
c. Select **Save**

4. Select **+New Submission** and **Initial**

Note: The "+New Submission" dropdown will display the next logical submission option, in this case it is the initial submission as it is a new study.

5. Select **Edit** from the **Submission Details** page
6. Complete section **Getting Started** – Select **Yes** to acknowledge your review and understanding of the content (after acknowledgement, additional table of contents sections will appear).

Note: Depending on how certain questions are answered, additional sections will appear for completion that are specific to the type of the protocol. The form begins with the following standard sections: Getting Started; Project Personnel; Basic Information, and Attachments.

7. Complete section **Project Personnel**
   a. Select **Find People** to add an individual
   b. Enter the individual's name in the search bar
   c. Select the **magnifying glass** to start the search
   d. Select the **+** adjacent to the individual's name
   e. Select **Save**
   f. Enter **Co-Investigator(s),** if applicable
   g. Enter **Other Personnel**, if applicable
   h. **Attach** required training documentation for personnel that do not have training certificates listed
   i. A white checkmark beside the **Project Personnel** Section of the Table of Contents will indicate that you have completed all required questions in this Section. If the checkmark is missing, please re-review the page and ensure that all questions with a red asterisk(*) are completed
   j. You may save your progress on any incomplete page by selecting **Save** at the top right of the form. If you navigate away from an incomplete page you may lose your progress
   k. Use the forward/right arrow at either the top or bottom of the screen to navigate to the next section, or select the next Section in the Table of Contents on the left-hand side.

Note: All UW employees (including paid part-time students) should be in the ROAMWyo system. If you need to add additional personnel into ROAMWyo (unpaid students, outside collaborators, etc.), please contact the IRB Office at IRB@uwyo.edu.

Note: As a reminder, ALL IRB STUDIES LED BY A STUDENT PI MUST include a Faculty Sponsor in the Project Personnel Section.

Note: Training certifications are housed in key personnel's user profile – select "View" under Trainings to view certifications. If the personnel's training is not listed, scroll down to attach

training documentation. Submissions will not be approved without proof of Training for each member of the research team.

Note: The individual creating the submission will automatically be listed under Primary Contact and this can be modified.

8. Complete section **Basic Information**

   Note: Project type will trigger additional TOC sections based on how it is answered

9. Steps 10-18 are trigger sections, which only appear if certain questions are answered in the Basic Information section and may not be applicable to all protocols.
10. Complete section **Study Design**
11. Complete section: **Study Selection**
12. Complete section: **Study Procedures**
13. Complete section: **Study Products**
14. Complete section: **International Research**
15. Complete section: **Participant Protection**
16. Complete section: **HIPPA**
17. Complete section: **Data Safety and Monitoring**
18. Review section**: Attachments** (click here to see Appendix A: Required Attachments)

    Note: There is a location to upload a document under each required section. Additionally, this section compiles all of the attachments for final review.

19. Select **Save**

    Note: Select Create PDF if a hard copy is desired for your records

20. Select **Complete Submission**
21. Select **Confirm**

    Note: The Submission automatically updates to the" Awaiting Authorization" status, which prompts the PI to certify the Submission

22. Certify the submission
    a. Select **Certify**
    b. Select **Confirm**
    c. Alternatively, you may certify the submission later by following the steps below:
        i. Navigate to **HE Dashboard**
        ii. Select the tile **Awaiting Authorization** or **My Tasks**
        iii. Select the relevant protocol
        iv. Select **View** to review the submission once more for accuracy
        v. Select **Certify**
        vi. Select **Confirm**

Note: The Submission automatically updates to "Under Pre-Review" status, which indicates that the Submission is routed to the IRB Office.

You may view the protocol's status in the Pre-Review tile and sort by PI name (or "My Studies" or "My Submissions"). If an "Analyst" has been assigned, this indicates that the IRB Office is reviewing the protocol; if a "Primary Reviewer" is assigned, this indicates that an IRB member is either conducting a review or in the review queue and the status will be "Under Review."

CREATING A PROTOCOL MODIFICATION SUBMISSION

Whenever a change is required for an approved research protocol, the Study must have a Modification Submission completed, reviewed, and approved **PRIOR** to that change taking place. This includes, but is not limited to: changes in recruiting materials/dissemination, new survey questions, addition of new research personnel, changes in subject inclusions/exclusions/numbers, or any other change in the research project.

Note: You can only have one active/unapproved Modification at a time. Multiple changes across several sections may be made to a Study in a single Modification Submission, but you must wait for a Modification to be approved before being able to initiate a new Modification Submission.

1. **Login** to ROAMWyo (using SSO credentials)
    a. Select **Products** to reveal a dropdown menu (top right of the screen)
    b. Select **Human Ethics** from the drop down menu
    c. Select **Role: Researcher** from the dropdown menu on the toolbar (this menu will only appear if you have multiple roles within this module, such as an IRB reviewer and a researcher).
2. Navigate to **My Studies**
3. Select the relevant **Study** (also known as the protocol)
4. Select + **New Submission** to reveal a dropdown menu from the **Study Details** page
5. Select **Modification**
6. Select **Edit** or **Complete Submission** to open the Modification form
7. Select **Yes** to "Are you making changes to the project"

    Note: The only way to make changes to the research protocol is through a Modification Submission. If you are looking to renew an approved project, a Renewal Submission is required. If you are looking to report an incident or event with the study, an Incident Submission is required. If the study is complete, a Closure Submission is required.

8. Complete the **Justification** field for modification(s)
9. Select **Save**
10. Select **next arrow**
11. Continue to complete the relevant section(s) for corresponding modification(s)
12. **Attach** relevant documents
13. Select **Complete Submission**
14. Select **Confirm**
15. Select **Certify**
16. Select **Confirm**
17. Select **Routing: Proceed**
18. Select **Confirm**

CREATING A PROTOCOL INCIDENT SUBMISSION

Whenever a PI becomes aware of an unanticipated problem, they have 48 hours to fill out and submit an Incident Submission in order to inform the IRB.

You may have multiple Incident Submissions for the same Study.

Note: You will be unable to complete an Incident Submission for any Study that has not had a completed, reviewed, and approved Legacy Submission. If you experience an unanticipated problem for an incomplete Legacy then please contact the IRB Office immediately at IRB@uwyo.edu.

1. **Login** to ROAMWyo (using SSO credentials)
    a. Select **Products** to reveal a dropdown menu (top right of the screen)
    b. Select **Human Ethics** from the drop down menu
    c. Select **Role: Researcher** from the dropdown menu on the toolbar (this menu will only appear if you have multiple roles within this module, e.g. an IRB member and a researcher).
2. Navigate to **My Studies**
3. Select the relevant **Study** (also known as the protocol)
4. Select + **New Submission** to reveal a dropdown
5. Select **Incident**
6. Select **Edit**
7. Select the appropriate incident type
8. Complete all fields and questions in the Incident Report
9. **Attach** relevant documents
10. Select **Save**
11. Select **Complete Submission**
12. Select **Confirm**
13. Select **Certify**
14. Select **Confirm**

CREATING A PROTOCOL RENEWAL SUBMISSION

Some protocols have expirations or Administrative Check-ins which require the PI or a member of the research team to provide a Study update via the Renewal Submission.

Note: Failure to submit a Renewal Submission prior to the deadline will result in non-compliance and all experimental work and recruiting must pause.

1. **Login** to ROAMWyo (using SSO credentials)
    a. Select **Products** to reveal a dropdown menu (top right of the screen)
    b. Select **Human Ethics** from the drop down menu
    c. Select **Role: Researcher** from the dropdown menu on the toolbar (this menu will only appear if you have multiple roles within this module, such as an IRB member and a researcher).
2. Navigate to **My Studies**
3. Select the relevant **Study** (also known as the protocol)
4. Select + **New Submission** and **Renewal**
5. Select **Edit**
6. Select **Yes**
7. Complete the renewal form **Check-in & Continuing Review**
8. Select **Save**
9. Select **Complete Submission**
10. Select **Confirm**
11. Select **Certify**
12. Select **Confirm**

CREATING A PROTOCOL CLOSURE SUBMISSION

Upon the completion of a Study, the PI or another key personnel must inform the IRB via a Closure Submission.

1. **Login** to ROAMWyo (using SSO credentials)
    a. Select **Products** to reveal a dropdown menu (top right of the screen)
    b. Select **Human Ethics** from the drop down menu
    c. Select **Role: Researcher** from the dropdown menu on the toolbar (this menu will only appear if you have multiple roles within this module, such as an IRB member and a researcher).
2. Navigate to **My Studies**
3. Select the relevant **Study** (also known as the protocol)
4. Select + **New Submission**
5. Select **Closure**
6. Select **Edit**
7. Select **Yes**
8. Complete the form **Project Closure**
9. Attach relevant documents (Final Progress Report and Additional information)
    a. Select **Attach**
    b. Select the **+** sign
    c. Select **Add File**
    d. Select **Apply**
10. Select **Save**
11. Select **Complete Submission**
12. Select **Confirm**
13. Select **Certify**
14. Select **Confirm**

CREATING A WITHDRAWAL SUBMISSION

A Withdrawal Submission allows a PI to retract an Initial Submission, effectively canceling the Submission prior to IRB review and approval. You may create a Withdrawal Submission at any point once an Initial Submission has been created up until it has been approved. If the Initial Submission has been approved, you must create a Closure Submission to close the Study if you no longer wish to conduct the research.

1. **Login** to ROAMWyo (using SSO credentials)
    a. Select **Products** to reveal a dropdown menu (top right of the screen)
    b. Select **Human Ethics** from the drop down menu
    c. Select **Role: Researcher** from the dropdown menu on the toolbar (this menu will only appear if you have multiple roles within this module, such as an IRB member and a researcher).
2. Navigate to **My Studies**
3. Select the relevant study to open
4. Select **+New Submission** and **Withdraw**
5. Select **Withdraw**
6. Select **Confirm**
7. Select **Required Tasks: Complete Submission**
8. Select **Yes** to **Do you want to withdraw your Initial Submission?**
9. Complete the **Justification** field for withdrawal reason(s)
10. Select **Save**
11. Select **Complete Submission**
12. Select **Confirm**
13. Select **Certify**
14. Select **Confirm**

Note: Withdrawn studies are marked as finalized and can no longer be modified.

CREATING AND RESPONDING TO COMMENTS

Comments Overview

ROAMWyo has a commenting dialogue function that can be utilized during the review process- for discussions between the Analyst and Researcher, as well as between the Analyst and IRB member.

Viewing and Responding to Comments

Image 4. 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.

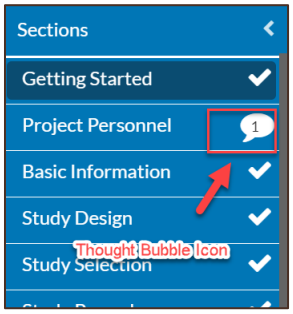
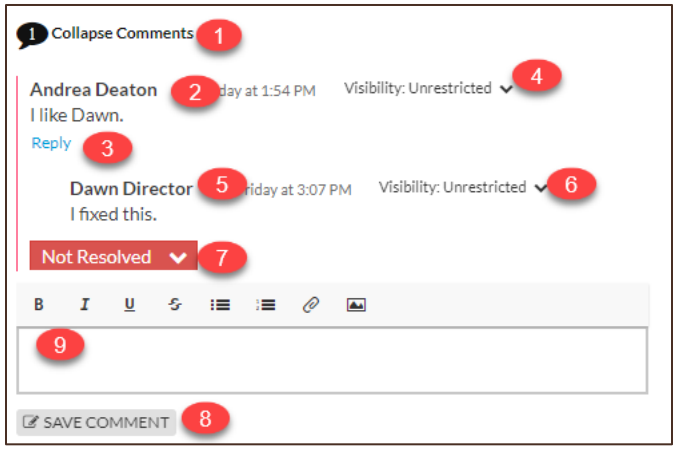


Image 5. Expand Comments

Is selected to display the comments (if you do not see this, that is because the comments are already expanded and in this case you will see **Collapse Comments**).

Image 6. Collapse Comments

To truncate the comments; or see the view below with comments expanded using **Expand Comments** option.



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 to respond to the Analyst.
4. **Visibility: Unrestricted** must be selected by the Analyst for the PI to view the comments
5. Example of a response from the PI to the Analyst
6. **Visibility: Unrestricted** must be selected for comments to be seen
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.

Receiving Comments from the IRB Office

A PI is required to respond to comments from the IRB office prior to routing the submission.

1. **Login** to ROAMWyo (UW researchers can log in to uwyo.app.cayuse.com using SSO credentials; guest accounts can be set up for non-UW research members by contacting the IRB Office).
    a. Select **Products** to reveal a dropdown menu (top right of the screen)
    b. Select **Human Ethics** from the drop down menu
    c. Select **Role: Researcher** from the dropdown menu on the toolbar (this menu will only appear if you have multiple roles within this module (e.g. IRB member and researcher).
2. Navigate to the **HE Dashboard**
3. Select relevant protocol in **My Tasks**
4. Select **Edit**
5. Navigate to the section that has a comment (indicated by a thought bubble icon)
6. Select **Expand Comments**
7. Select **Reply**

8. Enter a response
9. Select **Address** from the dropdown
10. Repeat steps 6-9 per comment
11. Select **Complete Submission**
12. Select **Confirm**
13. Select **Certify**
14. Select **Confirm**

USING THE COMPARISON TOOL

Comparison Tool Overview

When adding edits to a protocol 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 7. Compare Button

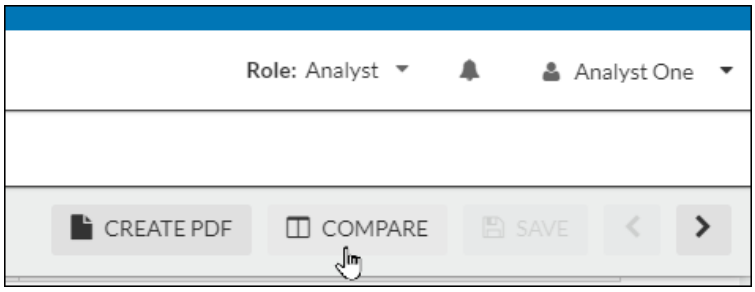
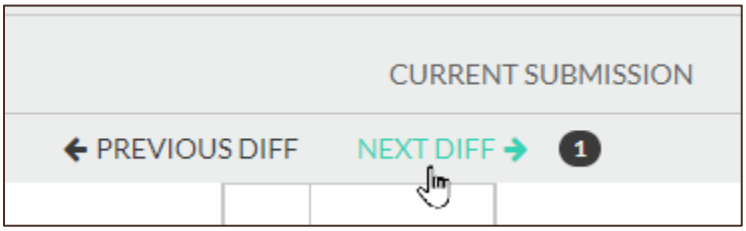
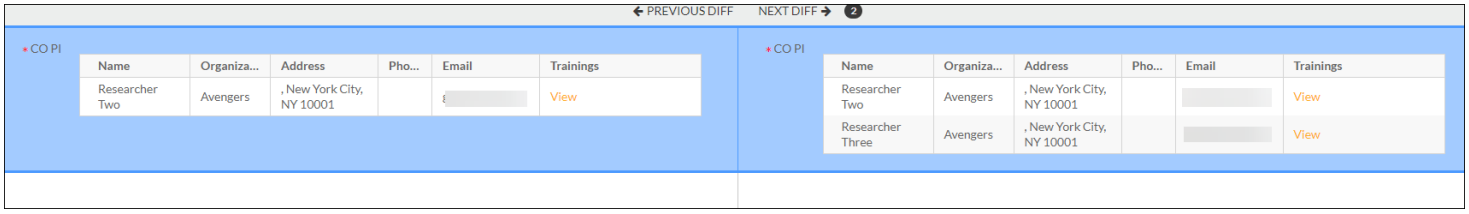


Image 8. Next Diff Button



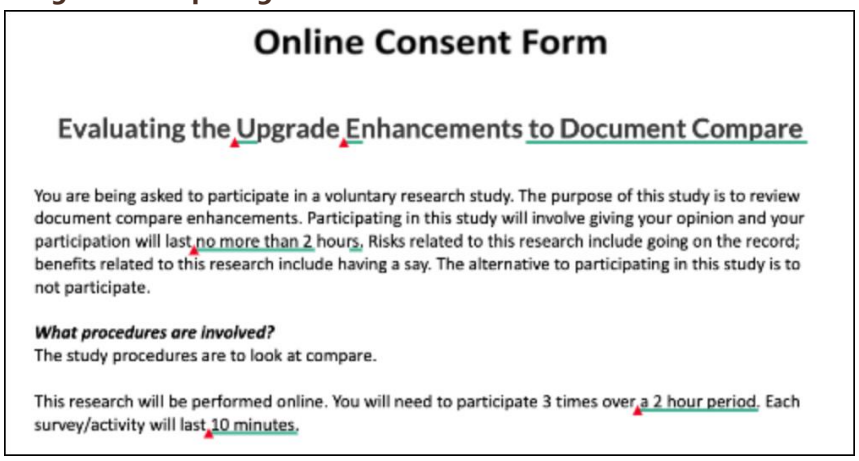
You will see the previous Submission draft and the current Submission draft side by side. Number of differences will be listed as a number next to **NEXT DIFF**. Click on the arrows to toggle between differences.

Image 9. Differences Highlighted in Blue for Visibility



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

Image 10. Comparing Submission Text



Online Consent Form

Evaluating the Upgrade Enhancements to Document Compare

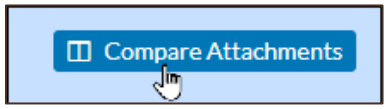
You are being asked to participate in a voluntary research study. The purpose of this study is to review document compare enhancements. Participating in this study will involve giving your opinion and your participation will last no more than 2 hours. Risks related to this research include going on the 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.

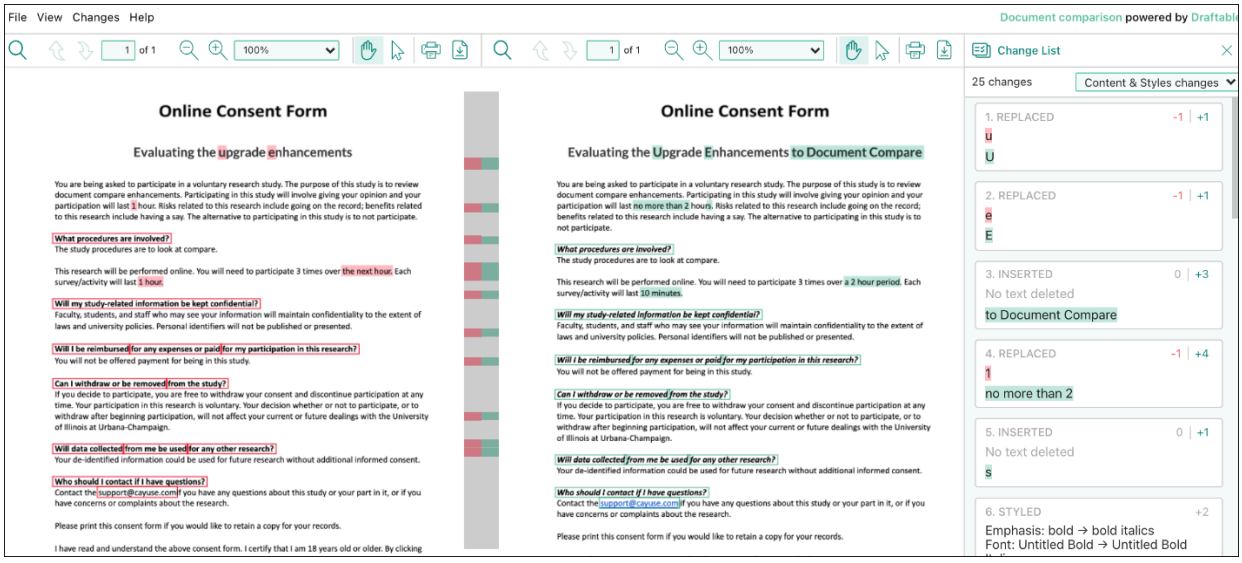
Text that was added between Submissions will be underlined green. Text that was deleted or replaced between Submission will have a red triangle next to it.

Image 11. 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 12. 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.

APPENDIX A. REQUIRED ATTACHMENTS

1. Training Certifications of Personnel (e.g., CITI Training for non-UW researchers and/or if not in the ROAMWyo system, other relevant proof of training)
2. Reliance Agreements
3. Protocol Documentation if an External IRB is of record (or by Lead Site)
4. Recruitment Documents
5. Study Instruments (Surveys, scripts, personality scales, questionnaires, etc.)
6. Study Product Documents: Risk Documentation, FDA Approval Documentation, Formulation/Ingredient Information (for foods, supplements, etc.)
7. FDA Insurance Letter
8. 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)
9. Participant Protection Section – Debriefing Script
10. Consent and/or Assent Forms
11. Additional HIPPA documents
12. DSMP Documentation

APPENDIX B. DECISION LETTERS

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
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