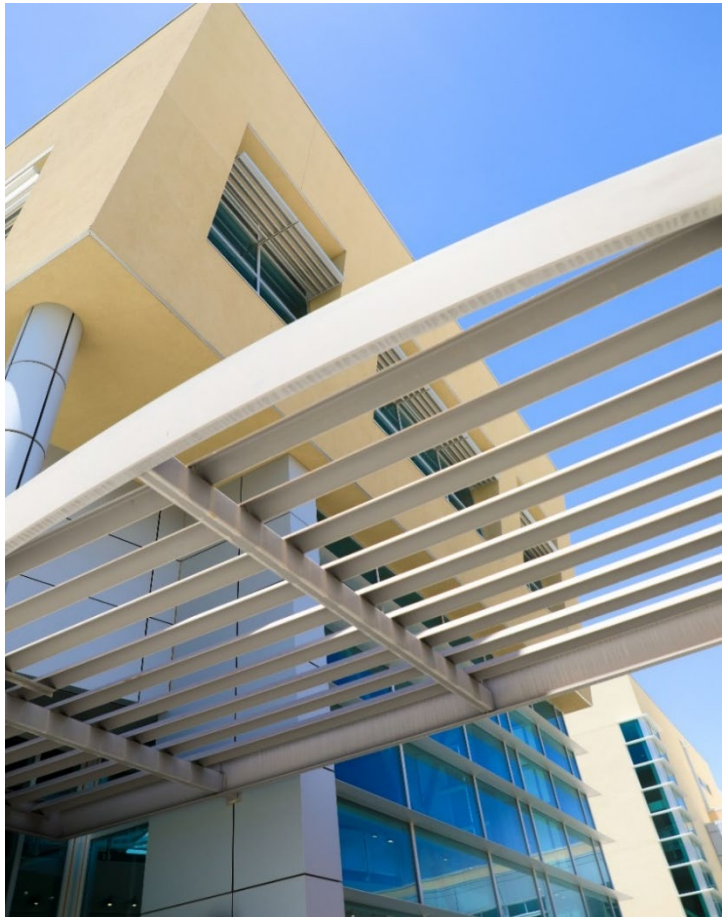
Huron IRB 10.1 Self-Guided Training for Investigators

- Overview of Huron IRB at the UNM Health Sciences
- Access, basic activities, navigation and workspaces
- Walk-through a new study submission
- IRB submission help and Huron IRB support
- Instructions to request an IRB account

Last updated: March 9, 2022

Begin

Overview of Huron IRB at the UNM Health Sciences



The **UNM Health Sciences Human Research Protections Office (HRPO)** uses Huron IRB to electronically process human subjects research applications (herein IRB submissions) for review by the **Human Research Review Committee (HRRC)**.

Huron IRB is intended to help investigators:

- Collaborate on the application process and reduce delays in routing and review.
- Receive notifications of important milestones and actions on a submission.
- Reduce errors and compliance risk.
- Manage the entire study cycle, end-to-end.

Next: Accessing Huron IRB

Accessing Huron IRB

- After you have completed this training and submitted the IRB account management request, an IRB account manager will send you an email that will contain your account information.
- The IRB account manager will set up your account with specific roles in the system:
  - **Study staff** – individual who is listed as a study team member; can create and edit a submission.
  - **Principal investigator (PI)** – individual who is listed as the principal investigator on a study; can submit a new study submission; receives communications about a submission.
    - This role is assigned to individuals that are eligible to be PI at the UNM Health Sciences. For first-time users, the individual must work with the HRPO to request the “Principal Investigator” role.
- You may access the Huron IRB system from any device that is connected to the internet.

Next: Basic Activities

Basic Activities

Your role in the system and affiliation with a submission will determine the information you may access as well as the level of activities you may perform.

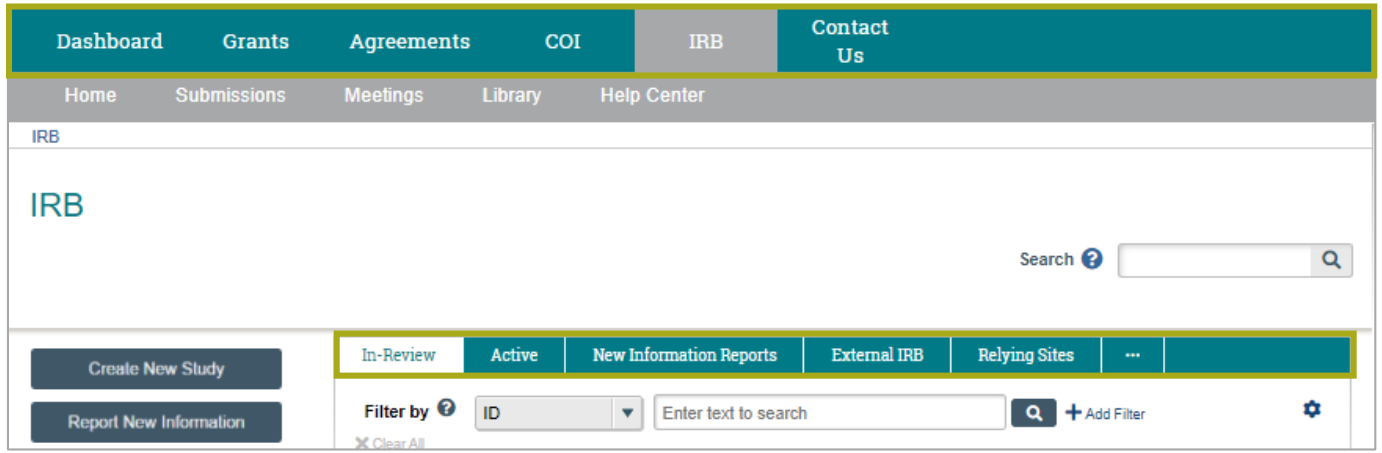
- As a **guest** on a study, you may view the study.
- As a **primary contact** on a study, you may view the study and receive notifications related to the study and follow-on submissions.
- As a **study team member**, you may create a new study submission, edit the submission, and attach documents. You may also create follow-on submissions for approved studies.
- As a **PI proxy**, you may submit follow-on submissions and respond to clarification requests on behalf of the principal investigator.
- As a **principal investigator** on a study, you may submit a submission to the HRPO for processing and respond to any requests for clarifications or modifications.
- For most submissions, you may add comments to communicate with study contacts and the HRPO staff, as well as run reports.

Next: Navigation and Workspaces

Navigation and Workspaces

Navigation

- The primary navigation menu contains links to system workspaces: **COI, Grants, Agreements,** and **IRB**.
- The **IRB** and the **Dashboard** are the primary tabs to perform many tasks.
  - The **IRB** tab allows you to toggle between IRB submission-specific workspaces: **Study**, **Submission**, and **Site**.
  - The **Dashboard** tab allows you to locate **My Inbox**, **My Reviews**, and pinned studies in the left hand navigation.



Workspaces

- IRB uses workspaces to organize information and activities.
- The following slides provide an overview of the workspaces you will see in the **IRB system** and the activities you may perform within each workspace.

Next: Home Workspace

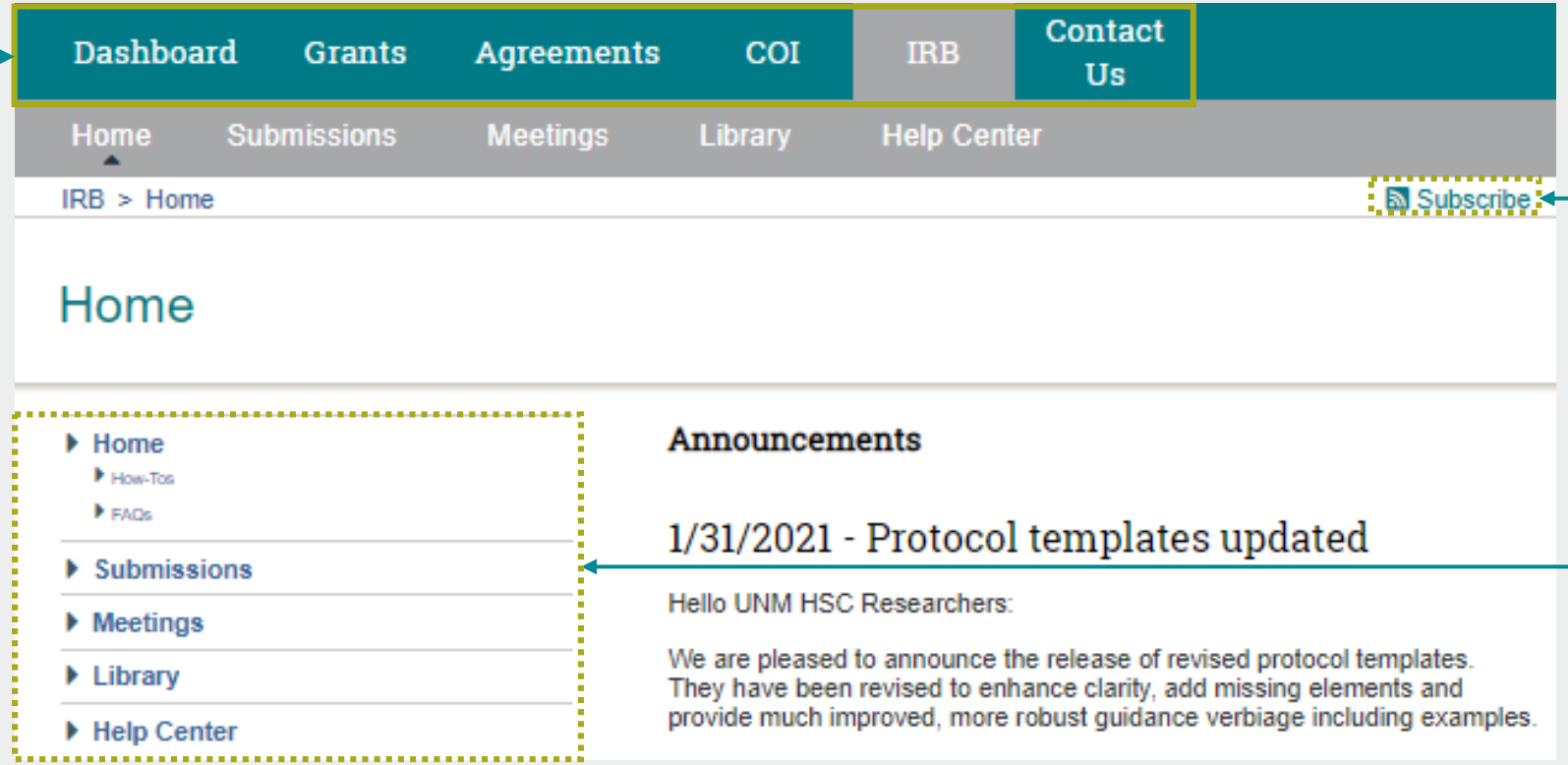
Home

The **Home workspace** provides access to posted announcements, training opportunities, and newsletters created by the HRPO.

Top navigation menu:

- **Dashboard**– Starting point for finding items and performing tasks
  - Subtabs - **My Inbox/ My Reviews**
- **Grants** – Grants submission system
- **Agreements** – Agreements submission system
- **COI** – COI submission system
- **IRB** – IRB submission system

Note: User can navigate between systems only if using the same User ID and has active account on each system.



Pictured: Sample rendering of the Home workspace

You have the option to subscribe to a page and receive an email anytime content is updated.

Shortcuts to access:

- **Home** – HRPO communications
- **How-Tos** – guides
- **FAQs** – frequently asked questions
- **Submissions** – all submissions
- **Meetings** – content visible to HRPO staff and HRRC members only
- **Library** – contains document templates
- **Help Center** – locate guides and videos

Next: Dashboard Workspace

Dashboard |

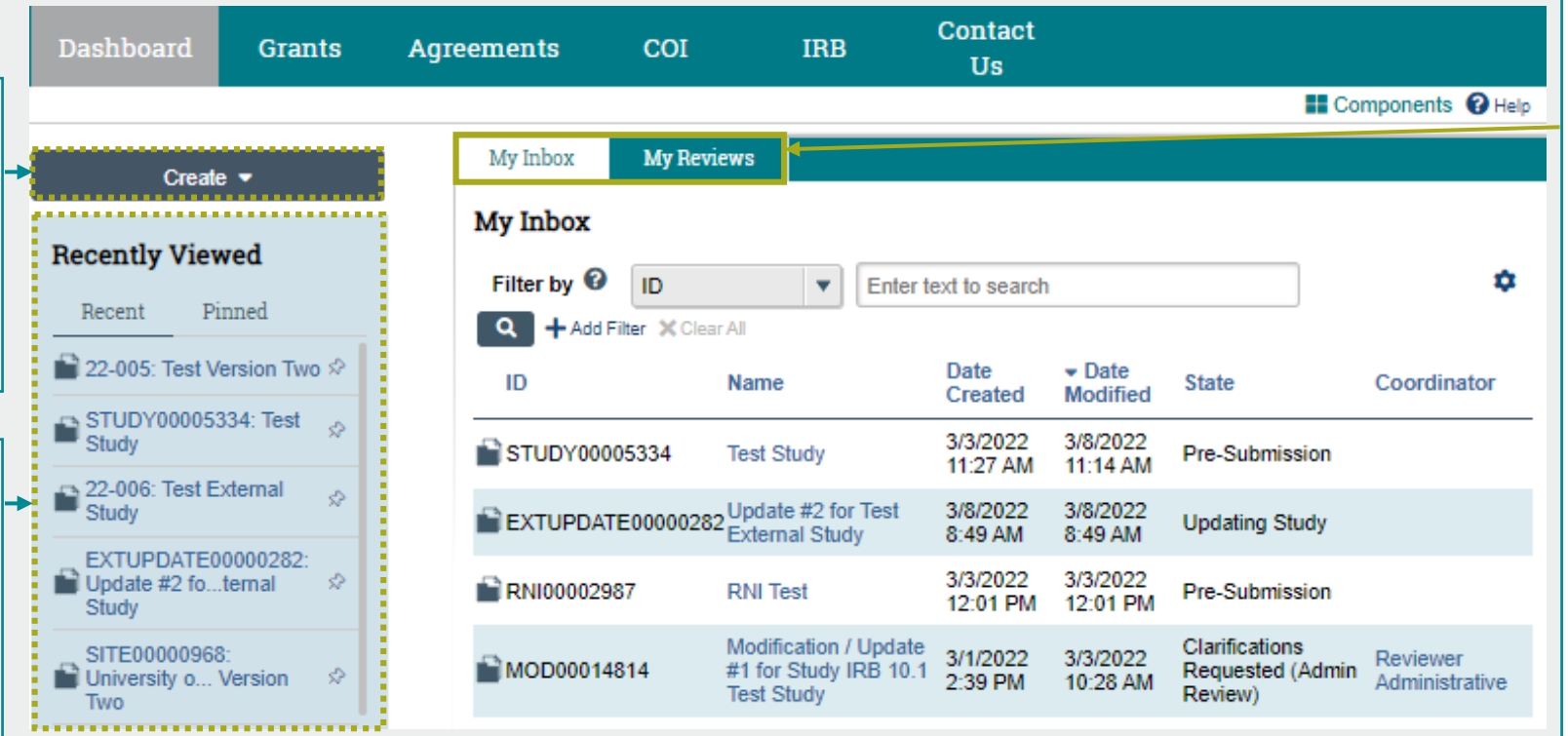
The **Dashboard workspace or "Dashboard tab"** is the starting point for finding items and performing many basic tasks.

Activities you may perform:

- **Create New Study** – activity to create a new submission
- **Report New Information** – activity to create a reportable new information submission

Shortcuts to access and recently viewed submissions:

- **Recent** – all recently viewed submissions
- **Pinned** – Pin submissions to the panel to revisit quickly



Pictured: Sample rendering of the Dashboard workspace in the IRB system

- **My Inbox** – studies that require your attention

A submission may be in any of the following project states:

- **Pre-submission** – finish editing the submission and submit it for review
- **Clarification requested (Admin Review, Pre-Review, or Designated Review)** – edit the submission to provide additional information and submit your response
- **Modifications required** – edit the submission to make the required changes and submit your response

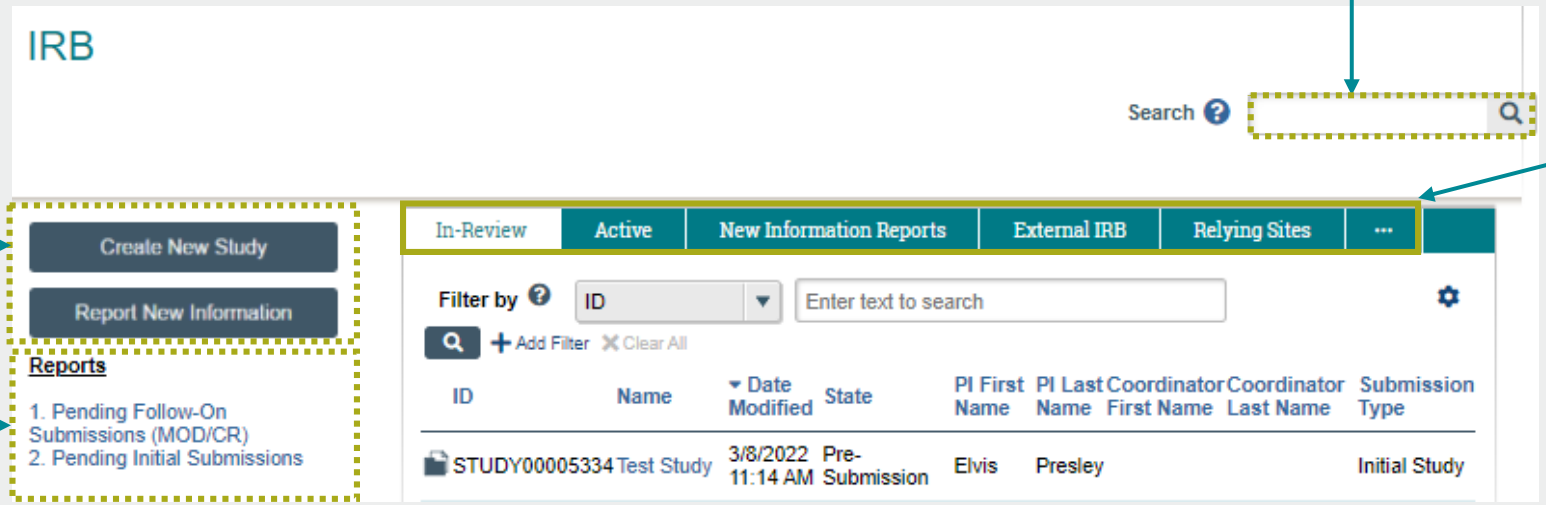
- **My Reviews**– content visible to ancillary reviewers, committee reviewers, and designated reviewers

Next: IRB Workspace

IRB |

The **IRB workspace** contains all IRB submissions that have been entered into the system and you have permission to access.

Search – use search to locate information by attributes e.g., ID, study title, protocol documents, research locations, study team members



Pictured: Sample rendering of the IRB workspace

Activities you may perform:

- **Create New Study**
- **Report New Information**

Reports you may run:

- **Pending Follow-On Submissions (MOD/CR)**
- **Pending Initial Submissions**

If you have many submissions, you may use the **Filter by** section to filter submissions by ID, name, date created or modified, state, or coordinator.

Submissions are sorted in the tabbed sections:

- **In-Review** – all submissions that are under-going HRRC review
- **Active** – all active HRRC studies
- **New Information Reports** – all reportable new information submissions
- **External IRB** – all studies managed by an external IRB
- **Relying Sites** – all participating sites relying on the HRRC as the single IRB of record

Click the ellipsis to see:

- **All Submissions** – all submissions and studies
- **Archived** – all submissions that are no longer active (e.g., closed, disapproved, discarded, and terminated).

Next: Submission Workspace

Submission |

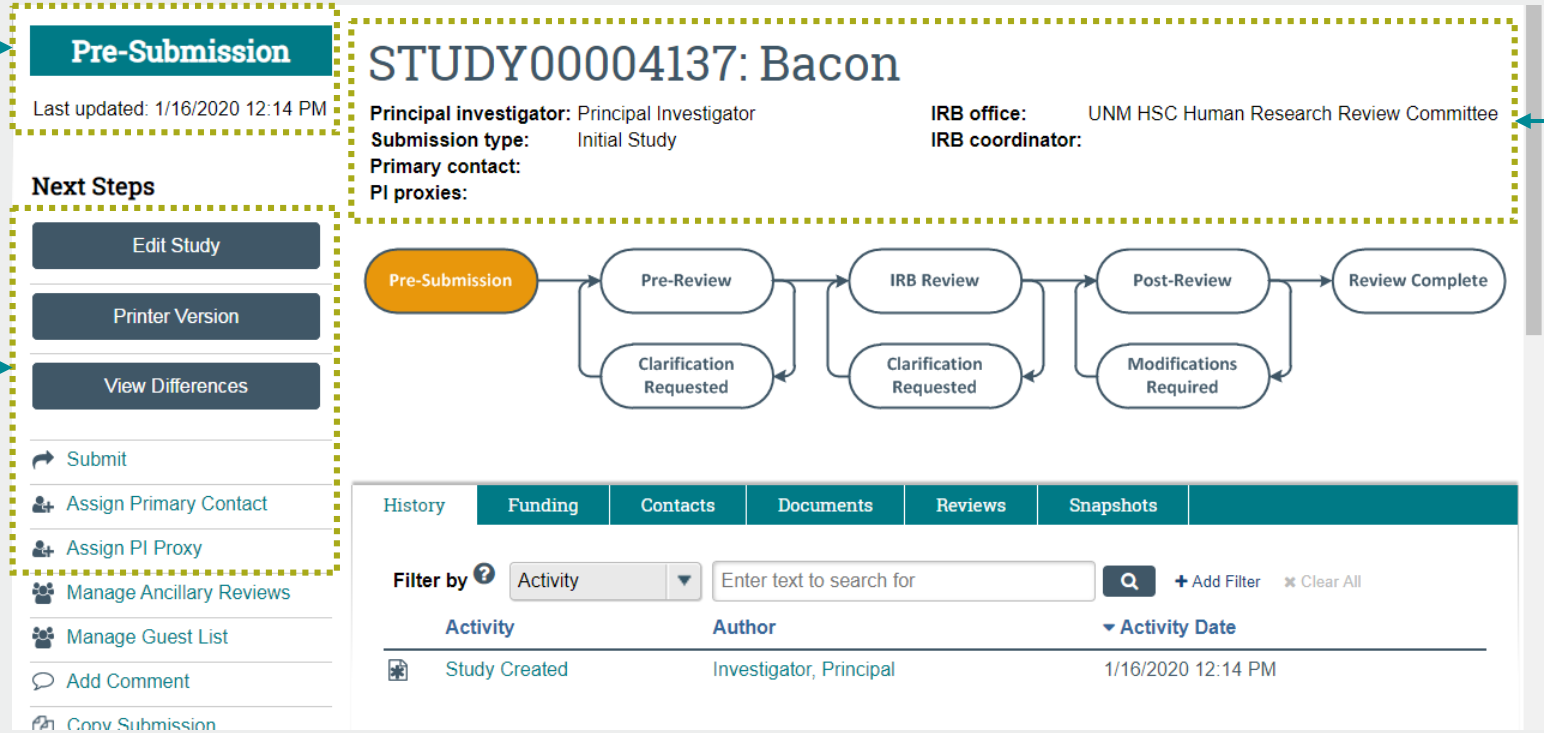
The **Submission workspace** appears for submissions that have been created and saved.

At a glance, you can see:

- **Project state** – state of the submission
- **Last updated** – date the submission was last updated

Activities you may perform:

- **Edit Study** – continue editing the submission
- **Printer Version** – open a printer-friendly view of the entire submission
- **View Differences** – review changes between versions of the submission
- **Submit** – available to PI to submit the submission to the HRPO
- **Assign Primary Contact** – available to PI to designate any user to receive communications related to the submission
- **Assign PI Proxy** – available to PI to grant study team member(s) to submit on behalf of the local principal investigator



Pictured: Sample rendering of a principal investigators Submission workspace for a single-site new study submission

- **Submission ID: Name** – automatically generated submission ID followed by the name of the submission
- **Principal investigator** – individual named as the principal investigator on the study
- **Submission type** – type of submission (e.g., Initial Study, Site, Follow-On, Reportable New Information, etc.)
- **Primary contact** – individual designated to receive communications
- **PI proxies** – study team member(s) delegated to act as PI proxy
- **IRB office** – UNM HSC Human Research Review Committee
- **IRB coordinator** – assigned HRPO staff member

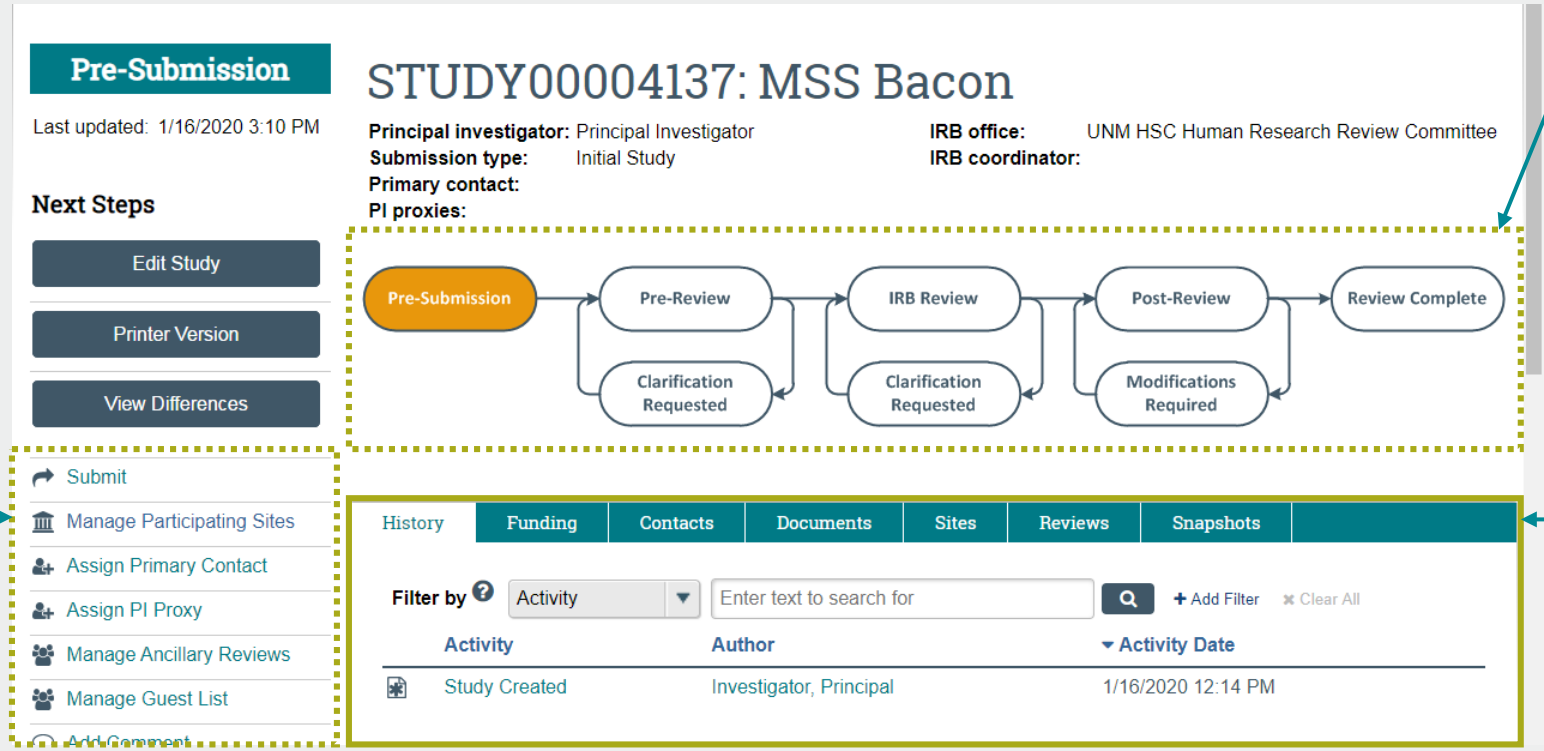
Next: Submission Workspace, continued

Submission |

The information, activities, and tabs in a **Submission workspace** will change based on the type and project state of a submission as well as your affiliation with the submission.

More activities you may perform:

- **Manage Participating Sites** – available on multi-site study submissions to add participating sites
- **Manage Ancillary Reviews** – grant department or scientific reviewers to review the submission
- **Manage Guest List** – grant non-study team members permission to view submission
- **Add Comment** – communication tool to be used by study team and HRPO staff
- **Copy Submission** – duplicate the submission
- **Discard** – remove the submission from IRB review
- **Manage Relationships** - add a related project, such as an agreement and/or grant



Pictured: Sample rendering of a principal investigators Submission workspace for a multi-site new study submission

- **Submission Tracker** – graphic that shows where your submission is in relation to the review process.

Submission tabs:

- **History** – lists activities taken on a submission
- **Funding** – lists the funding source(s) identified on the funding sources page
- **Contacts** – lists the study team member(s) identified on the study team page
- **Sites** – available on multi-site study submissions to list participating sites
- **Documents** – lists documents that have been attached to the study
- **Reviews** – lists ancillary reviews
- **Snapshots** – lists all versions of the submission

Next: Submission (Site) Workspace

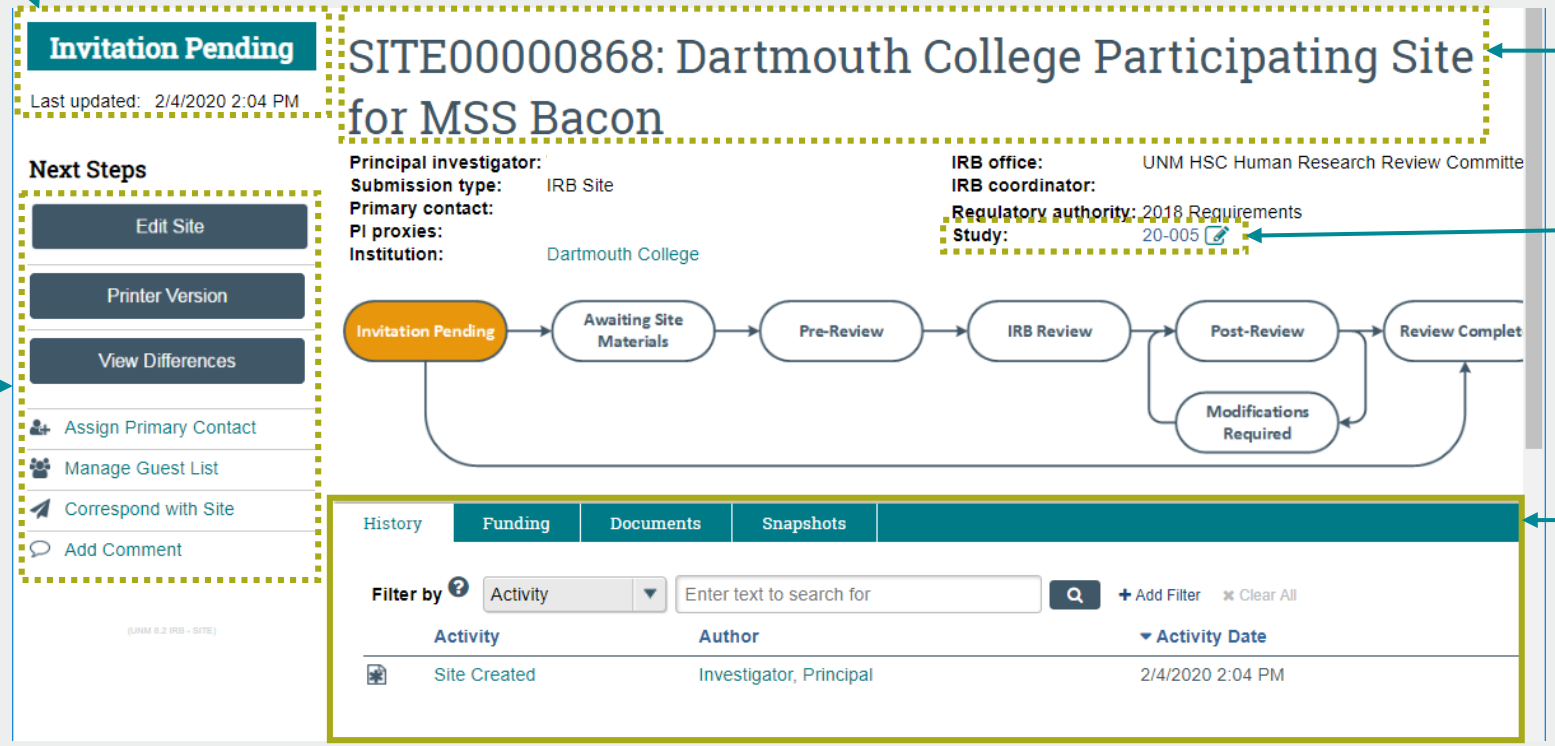
Submission (Site) | The **Submission (site) workspace** appears for site submissions that are associated with a multi-site study.

At a glance, you can see:

- **Project state** – state of the submission
- **Last updated** – date the submission was last updated

Activities you may perform:

- **Edit Site**– edit site record
- **Printer Version** – printer-friendly version of study record
- **View Differences** – changes between versions
- **Assign Primary Contact**
- **Manage Guest List**
- **Correspond with Site**
- **Add Comment**



- **Site ID: Name** – HRRC site number, followed by the site name for the study
- **Study** – Access the HRRC study workspace.

Site tabs:

- **History** – lists activities taken on a submission
- **Funding** – lists the funding source(s) identified on the funding sources page
- **Documents** – lists documents that have been attached to the study and site
- **Snapshots** – lists all versions of the submission

Pictured: Sample rendering of a principal investigators Submission (site) workspace for a new external participating site for a HRRC approved multi-site new study (i.e., UNM HSC is the lead sIRB).

Next: Study Workspace

Study |

The **Study workspace** appears for new study submissions that have received an official HRRC determination.

At a glance, you can see:

- **Project state** – state of the submission
- **Entered IRB** – date the submission submitted to the HRPO
- **Initial approval** – date the HRRC approved the study
- **Initial effective** – date the HRRC initially approved the study
- **Effective** – date the submission is effective
- **Approval end** – date the study approval expires
- **Last updated** – date the submission was last updated

Activities you may perform:

- **View Study** – view study record
- **Printer Version** – printer-friendly version of study record
- **View Differences** – changes between versions
- **Create Modification/CR** – create a modification or continuing review submission
- **Report New Information** – create a new reportable new information submission

Pictured: Sample rendering of a principal investigators Study workspace for a HRRC approved single-site new study

- **Study ID: Name** – HRRC study number, followed by the short title of the study

- **Letter** - View/download the HRRC determination letter.

Study tabs:

- **History** – lists activities taken on a submission
- **Funding** – lists the funding source(s) identified on the funding sources page
- **Contacts** – lists the study team member(s) identified on the study team page
- **Sites** – available on multi-site study submissions to list participating sites
- **Documents** – lists documents that have been attached to the study
- **Follow-on Submissions** – lists all modification, continuing review, and reportable new information submissions
- **Reviews** – lists ancillary reviews
- **Snapshots** – lists all versions of the submission

Next: IRB Site Workspace

IRB Site |

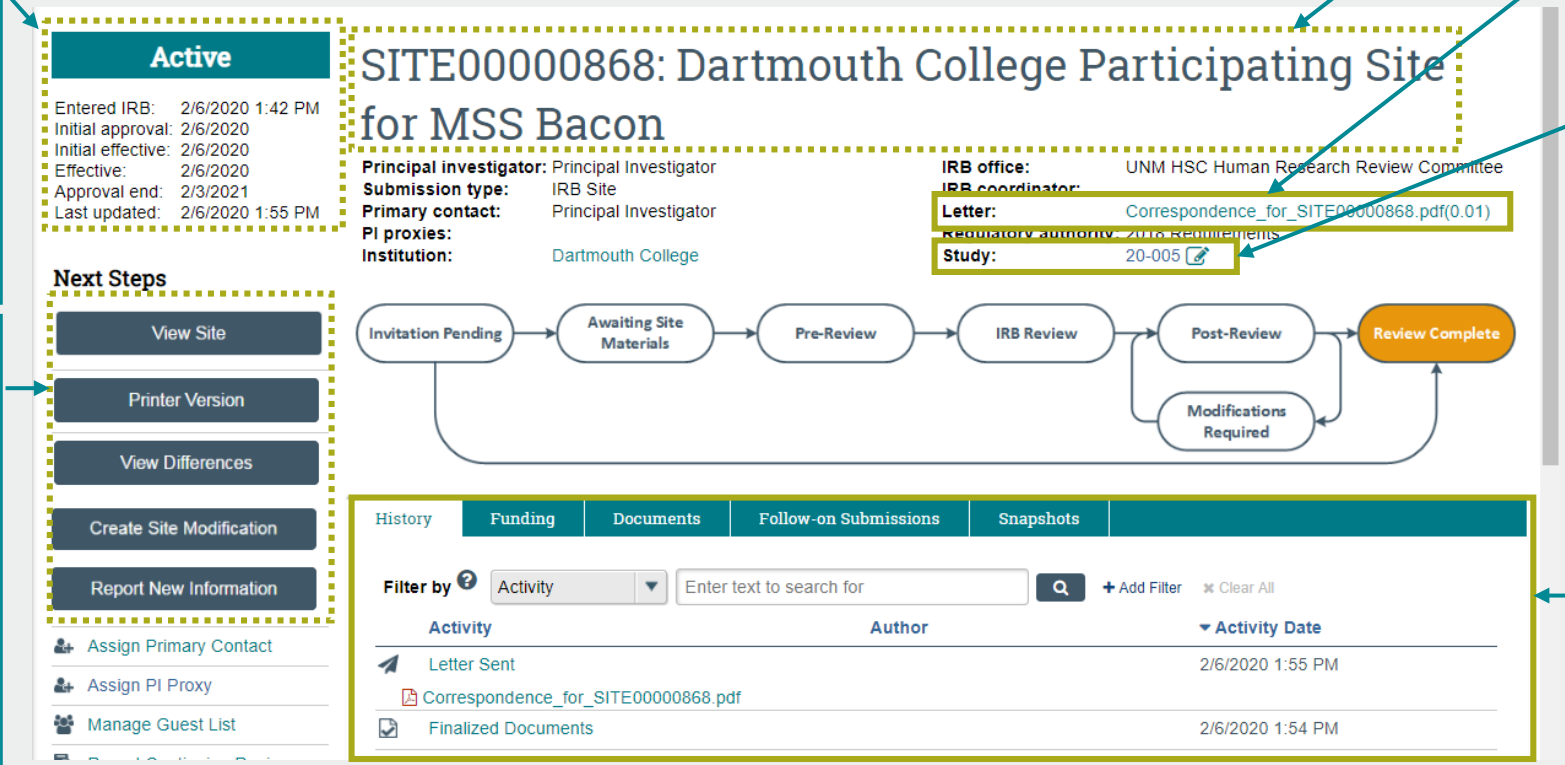
The **IRB Site workspace** appears for site submissions that have been activated.

At a glance, you can see:

- **Project state** – state of the submission
- **Entered IRB** – date the submission submitted to the HRPO
- **Initial approval** – date the HRRC approved the site
- **Initial effective** – date the HRRC initially approved the site
- **Effective** – date the submission is effective
- **Approval end** – date the site approval expires
- **Last updated** – date the submission was last updated

Activities you may perform:

- **View Site** – view site record
- **Printer Version** – printer-friendly version of site record
- **View Differences** – changes between versions
- **Create Site Modification** – create a modification submission
- **Report New Information** – create a new reportable new information submission



- **Study ID: Name** – HRRC site number, followed by the site name for the study
- **Letter** - View/download the HRRC determination letter.
- **Study** – Access the HRRC study workspace.

Site tabs:

- **History** – lists activities taken on a submission
- **Funding** – lists the funding source(s) identified on the funding sources page
- **Documents** – lists documents that have been attached to the study and site
- **Follow-on Submissions** – lists all modification and reportable new information submissions
- **Snapshots** – lists all versions of the submission

Pictured: Sample rendering of a principal investigators IRB Site workspace for an external participating site for a HRRC approved multi-site new study (i.e., UNM HSC is the lead sIRB).

Next: IRB Site Workspace, continued

IRB Site |

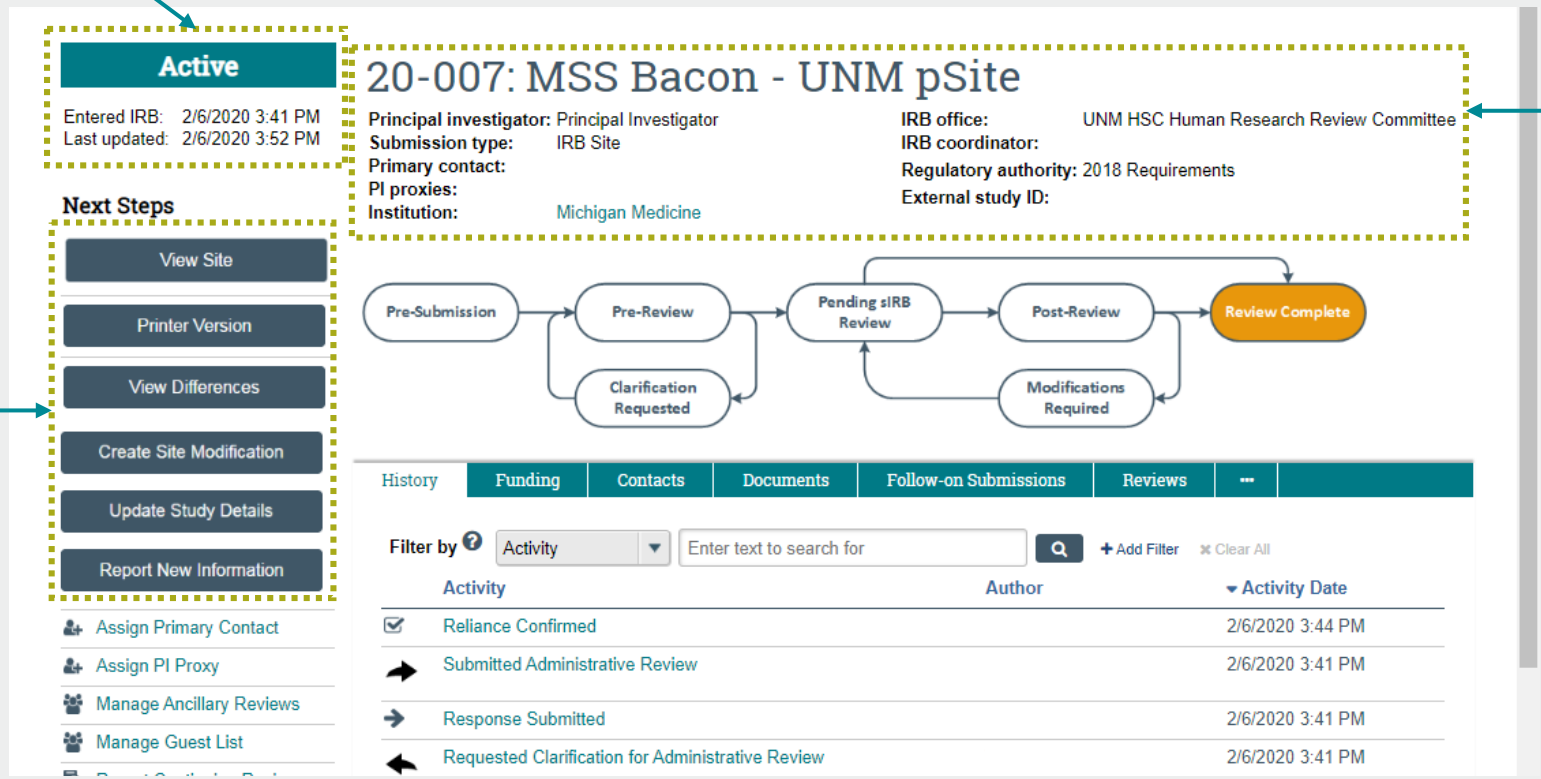
The information, activities, and tabs in the **IRB Site workspace** will change based on which institution is the lead.

At a glance, you can see:

- **Project state** – state of the submission
- **Entered IRB** – date the submission submitted to the HRPO
- **Last updated** – date the submission was last updated

Activities you may perform:

- **View Site** – view site record
- **Printer Version** – printer-friendly version of site record
- **View Differences** – changes between versions
- **Create Site Modification** – create a modification submission
- **Update Study Details**
- **Report New Information** – create a new reportable new information submission



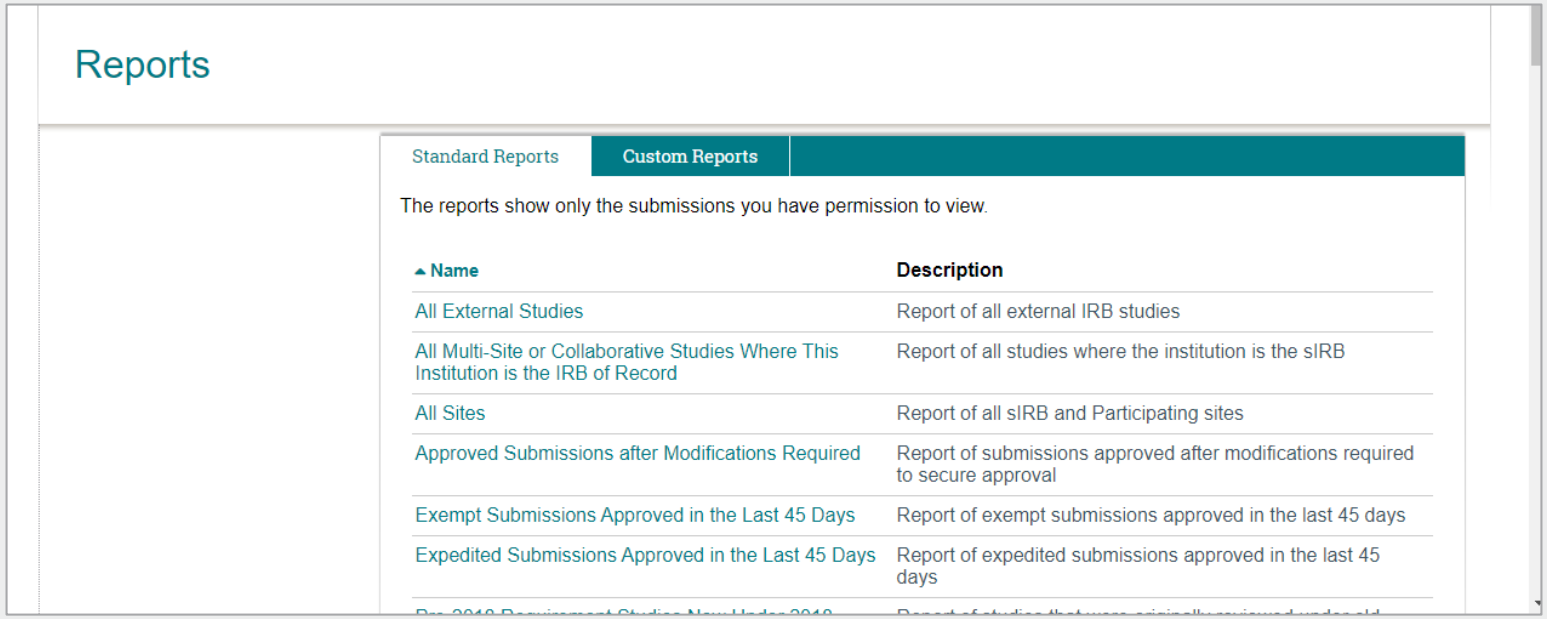
- **Study ID: Name** – HRRC site number, followed by the site name
- **Principal investigator** – individual named as the principal investigator on the study
- **Submission type** – type of submission (e.g., Initial Study, Site, Follow-On, Reportable New Information, etc.)
- **Primary contact** – individual designated to receive communications
- **PI proxies** – study team member(s) delegated to act as PI proxy
- **Institution** – lead institution
- **IRB office** – UNM HSC Human Research Review Committee
- **IRB coordinator** – assigned HRPO staff member
- **Regulatory authority**
- **External study ID** – appears for external IRB studies/sites

Pictured: Sample rendering of a principal investigators IRB Site workspace for an internal participating site (i.e., UNM HSC is the pSite) for an external approved multi-site new study.

Next: IRB Reports

IRB Reports |

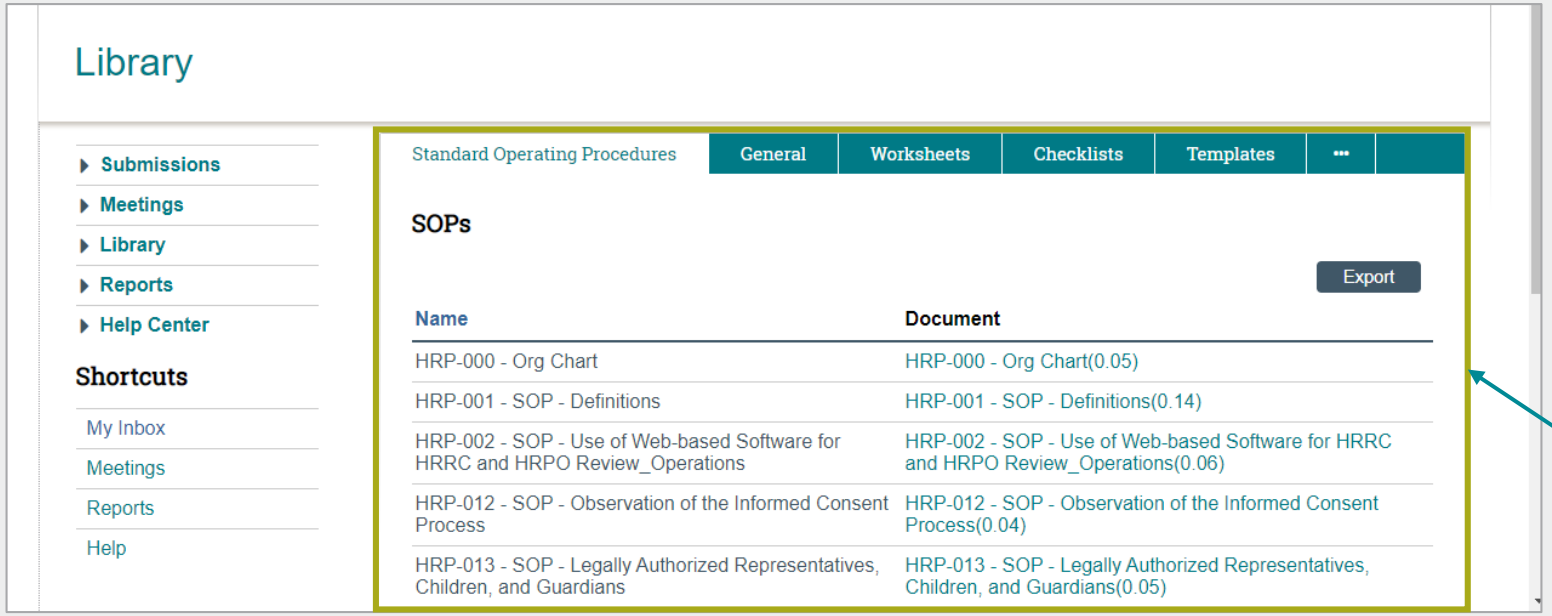
The **IRB Reports workspace** lists reports that allow you to query submissions you have permission to view.



Next: IRB Lbrary Workspace

IRB Library |

The **IRB Library workspace** contains downloadable materials specific to this institution and the IRB.



Library tabs:

- **Standard Operating Procedures** – lists documented processes
- **General** – lists documents specific to the human research protections program
- **Worksheets** – lists documents the HRPO and HRRC use to conduct reviews
- **Checklists** – lists documents the HRPO and HRRC use to conduct reviews
- **Templates** – lists templates for protocol, consent, HIPAA, etc.

Click the ellipsis to see:

- **Forms** – lists IRB submission attachments
- **HRRC Training Info** – lists training videos

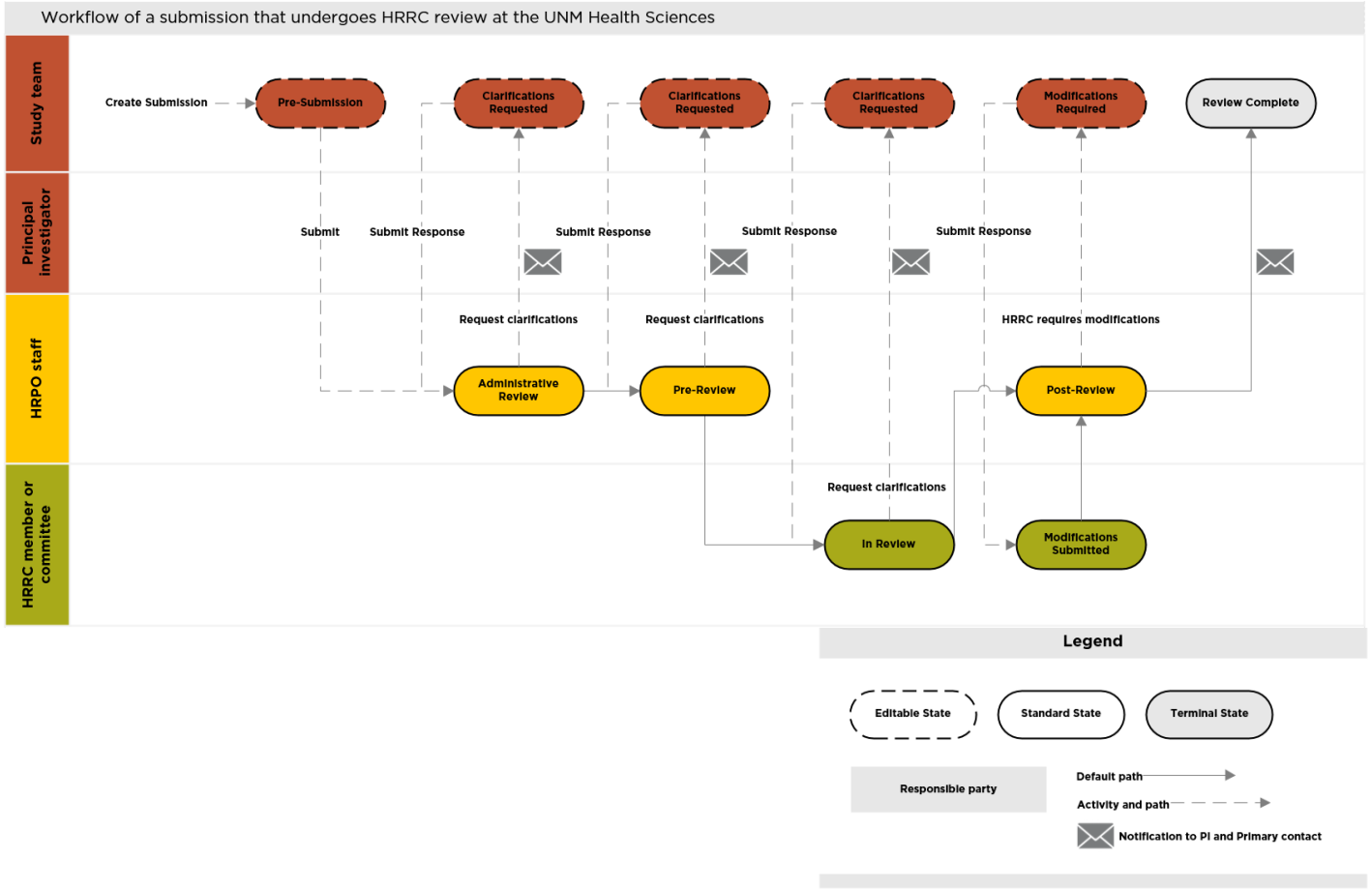
Next: Walk-through the submission process

Walk-through a new single-site study submission

As a submission moves through the process, the principal investigator and primary contact will receive email notifications regarding requests and status updates from:

HSC-HRPO@salud.unm.edu

The following slides demonstrate the submission and non-committee review process of a single-site new study submission using Huron IRB.



Pictured: Rendering of the workflow of a submission that undergoes HRRC review at the UNM Health Sciences

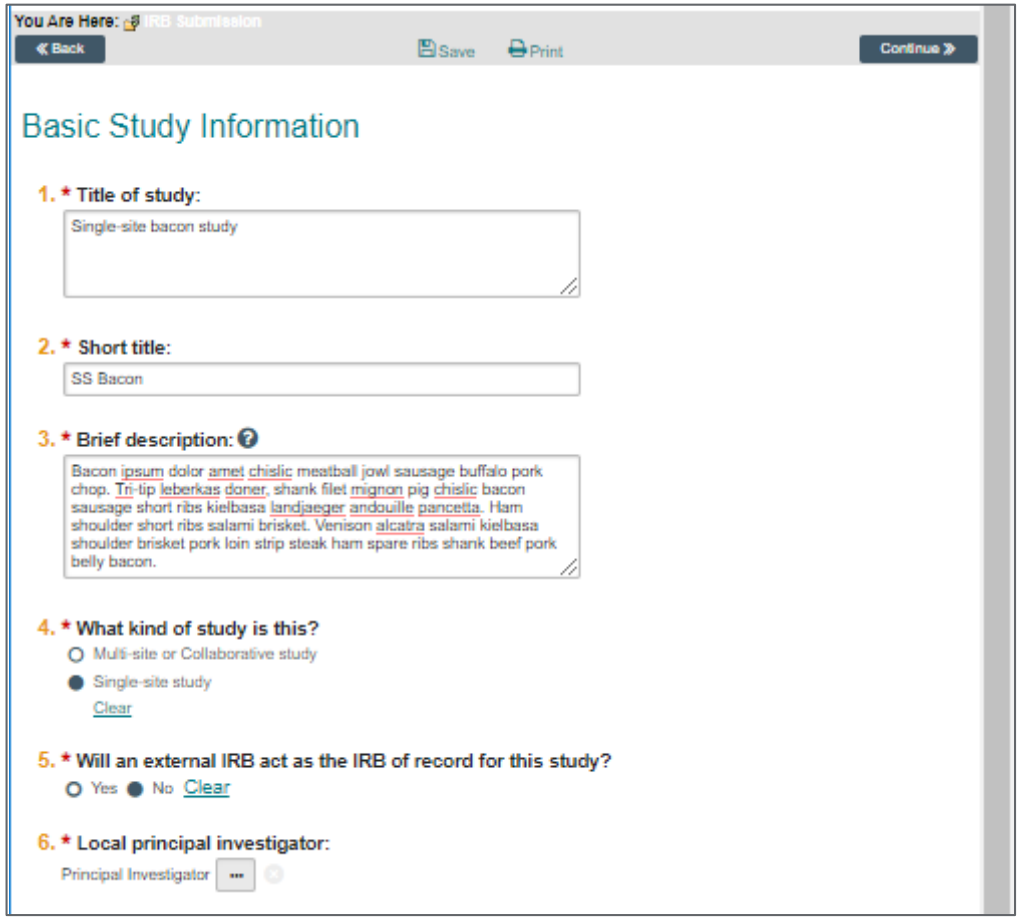
Next: Create a new study submission

Study Team

Create New Study → Pre-Submission

A study team member or principal investigator may create and edit a new study submission.

1. From the **My Inbox** or **IRB workspace**, click the **Create New Study** button.
   - This will open a draft IRB submission that you may edit.
2. Complete the pages and click the **Continue** button to advance to the next page.
3. On the final page, click the **Finish** button.
   - This will save the submission and return you to the **submission workspace**.



Pictured: Sample rendering of the Basic Study Information form

Next: Submit new study submission

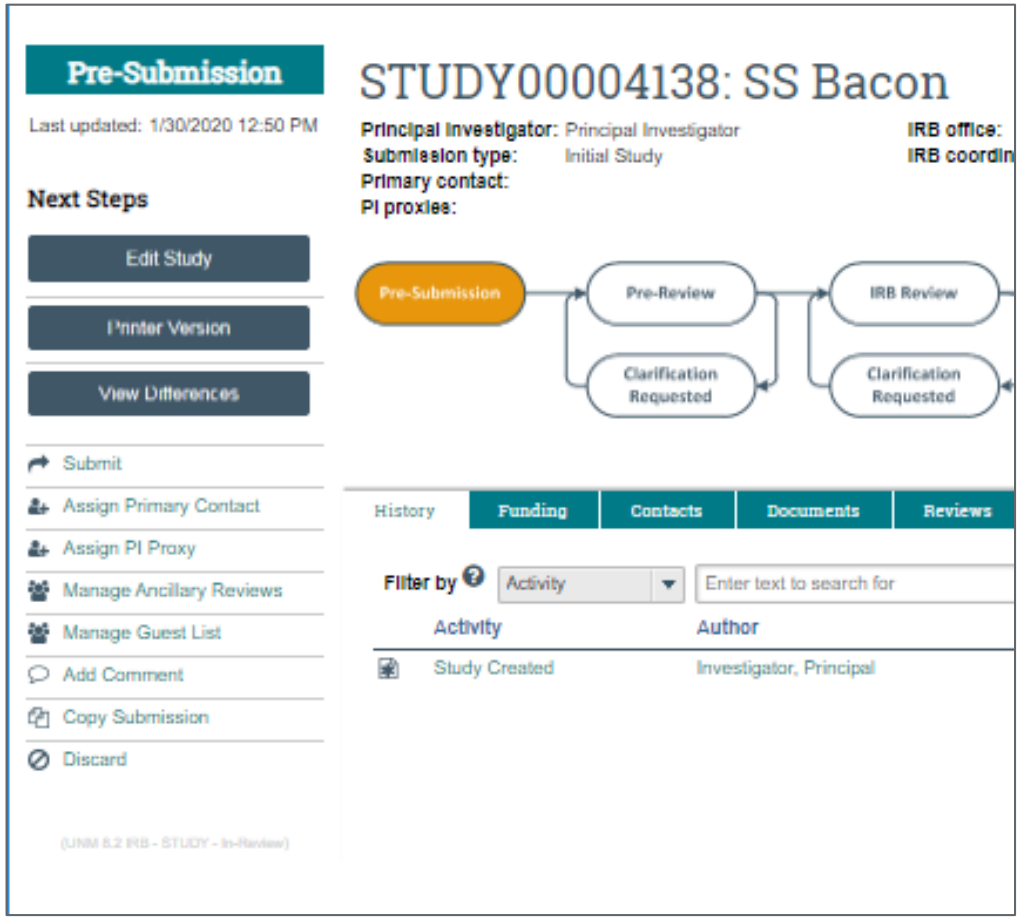
Principal investigator

Pre-Submission ---------- Submit ---------->

After the study team has completed all of the pages, the principal investigator may submit the submission.

4. From the **submission workspace**, click the **Submit** link.
   - The system will check the submission for errors and allow you to complete missing information.
5. Click the **OK** button to agree to the terms.
   - The system will advance the submission to the next project state, **Administrative Review**.

IMPORTANT: The listed principal investigator must have the "Principal Investigator" user role assigned to their IRB account in order to submit the study. This role requires PI eligibility verification by the HRPO.



Pictured: Sample rendering of a principal investigators Submission workspace in "Pre-Submission"

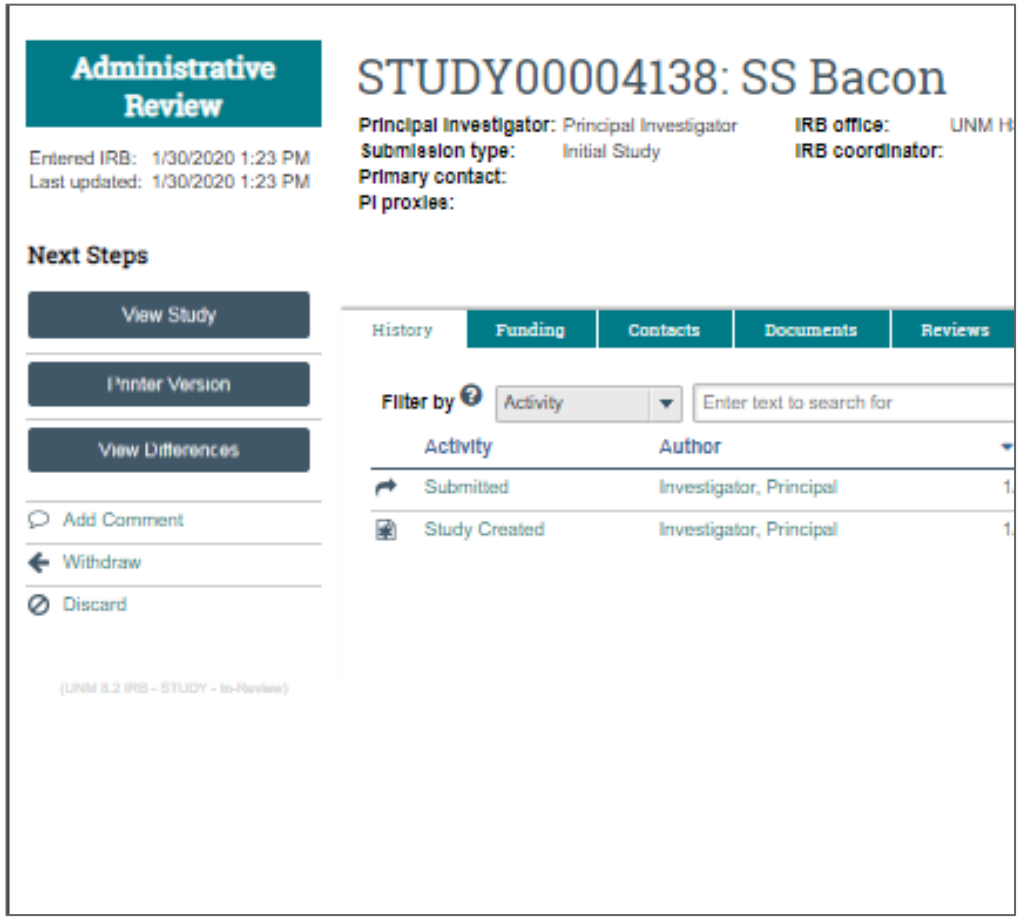
Next: Administrative Review

HRPO staff

Administrative Review — Request Clarifications →

During **Administrative Review**, a HRPO staff member conducts a cursory check of your submission to ensure minimum requirements have been met to begin pre-review.

When the submission is considered satisfactory, the submission will advance to the next state, **Pre-Review**.



Pictured: Sample rendering of a principal investigators Submission workspace in "Administrative Review"

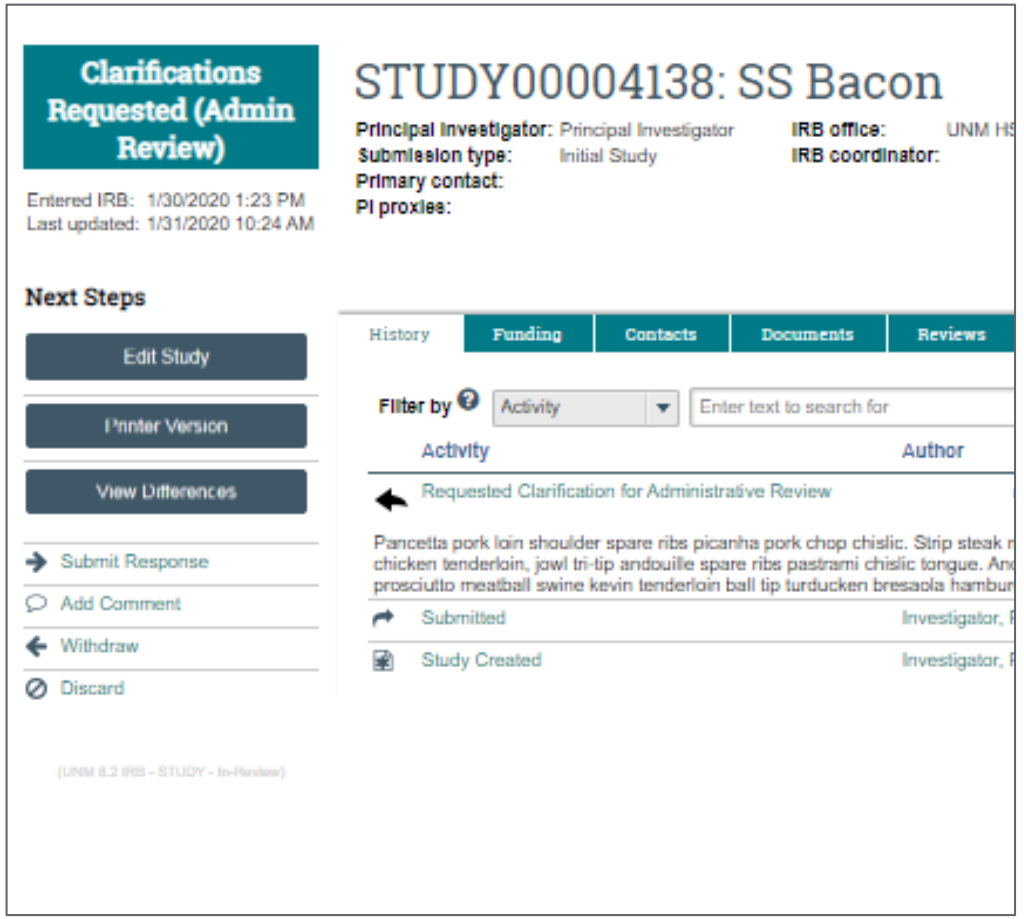
Next: Respond to requested clarifications

Principal investigator

Clarifications Requested (Admin Review) – – – – – – **Submit Response** – – – – – →

If the submission is considered incomplete, a notification will be sent to the principal investigator and the primary contact. The submission will be returned in a "clarifications requested" state so that you may address the issues.

1. Refer to the **History** tab to review the details of the request.
2. Click the **Edit Study** button to open the study record and make requested changes.
3. After you have addressed all issues, click the **Submit Response** link.
4. Click the **OK** button to submit your response.
   - The system will advance the submission to the previous project state, **Administrative Review**.



Pictured: Sample rendering of a principal investigators Submission workspace in "Clarifications Requested (Admin Review)

Next: Pre-Review

HRPO staff

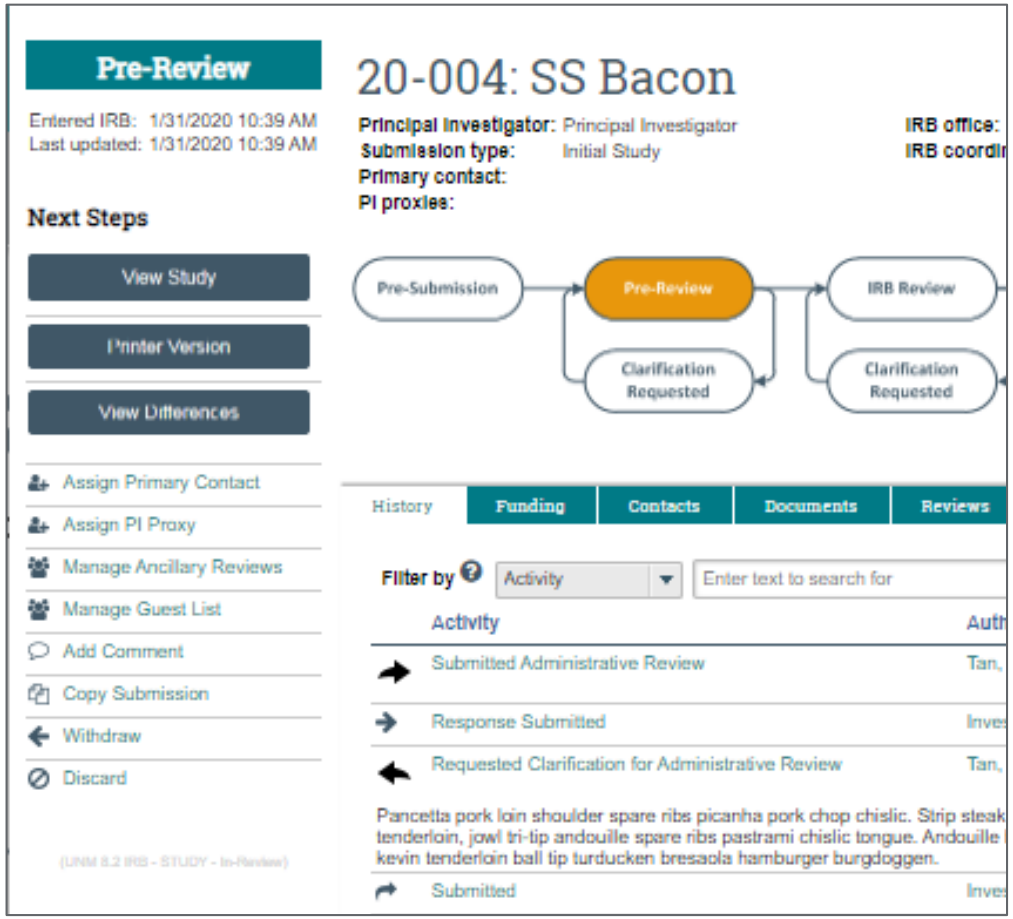
Pre-Review - - - - - - - **Request Clarifications** - - - - - - - →

During **Pre-Review**, a HRPO staff member conducts a preliminary review of your submission to ensure minimum requirements have been met to review.

When the submission is considered complete, the submission will advance to the next state, **Pre-Review Completed**.

The HRPO staff will then route your submission for the appropriate review:

- **Non-Committee Review** – review by a HRRC chair
- **Committee Review** – review by a convened HRRC committee



Pictured: Sample rendering of a principal investigators Submission workspace in "Pre-Review"

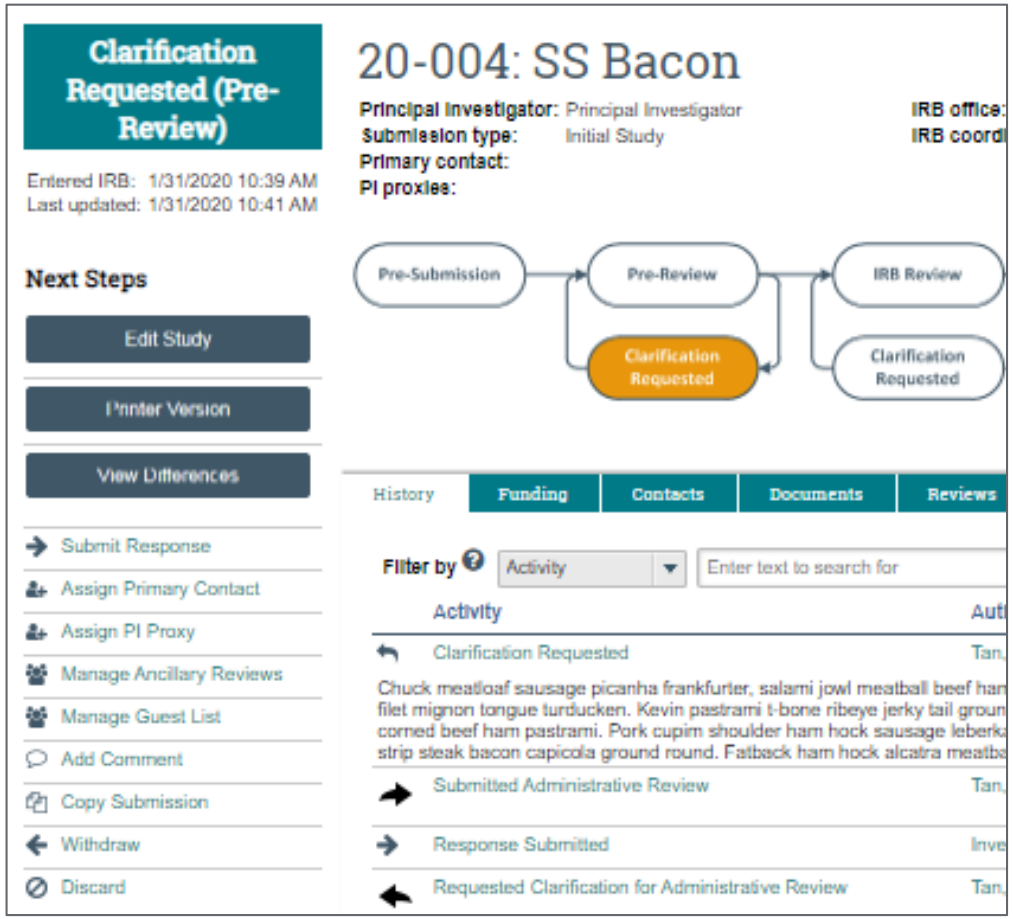
Next: Respond to requested clarifications

Principal investigator

Clarification Requested (Pre-Review) – – – – – – **Submit Response** – – – – – →

If the submission is considered incomplete, a notification will be sent to the principal investigator and the primary contact. The submission will be returned in a "clarifications requested" state so that you may address the issues.

1. Refer to the **History** tab to review the details of the request.
2. Click the **Edit Study** button to open the study record and make requested changes.
3. After you have addressed all issues, click the **Submit Response** link.
4. Click the **OK** button to submit your response.
   - The system will advance the submission to the previous project state, **Pre-Review**.

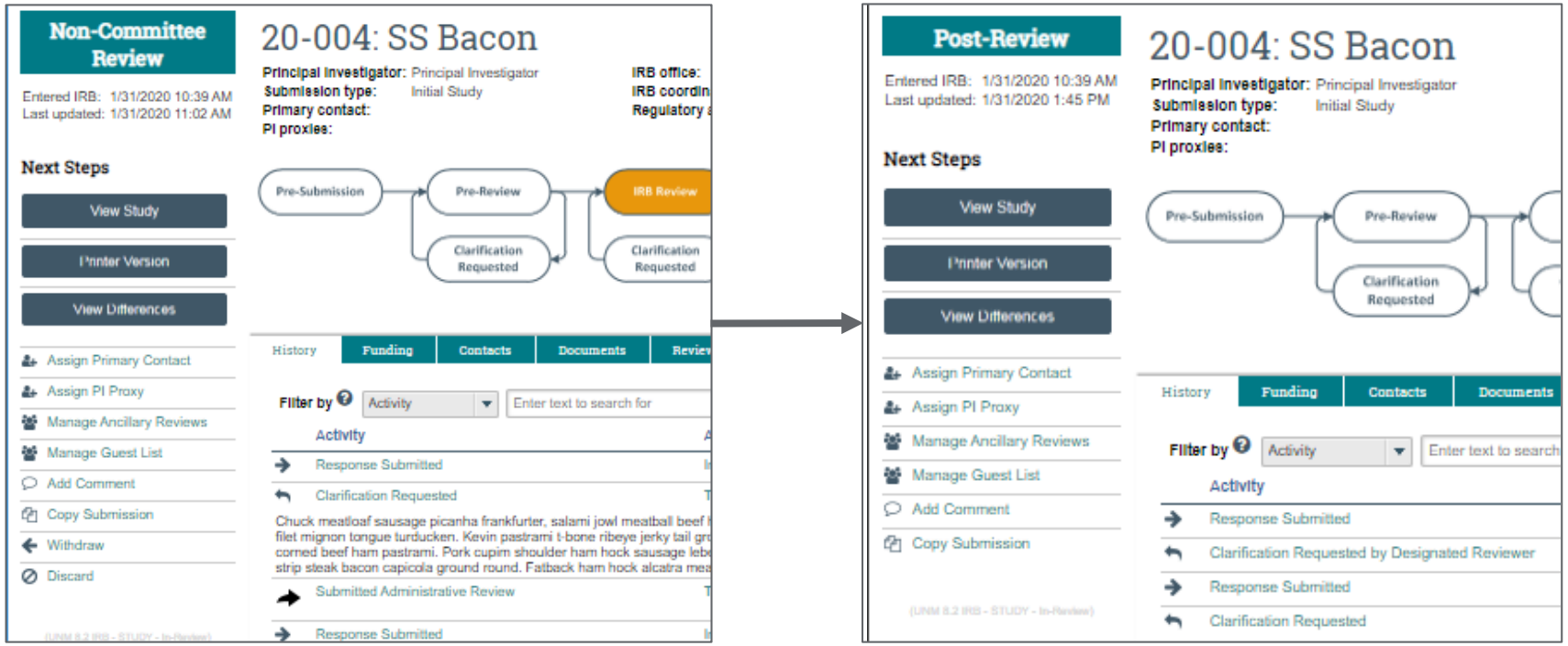


Pictured: Sample rendering of a principal investigators Submission workspace in "Clarification Requested (Pre-Review)"

Next: In-Review and Post-Review

HRRC | HRPO staff

During **In-Review**, the Human Research Review Committee chair or the convened committee, will review your submission and make a determination based on the information and materials submitted. Once a determination has been made, your submission will advance to the next state, **Post-Review**, where the HRPO staff will finalize the submission.



Pictured: Sample rendering of a principal investigators Submission workspace in “Non-Committee Review” and ”Post-Review”

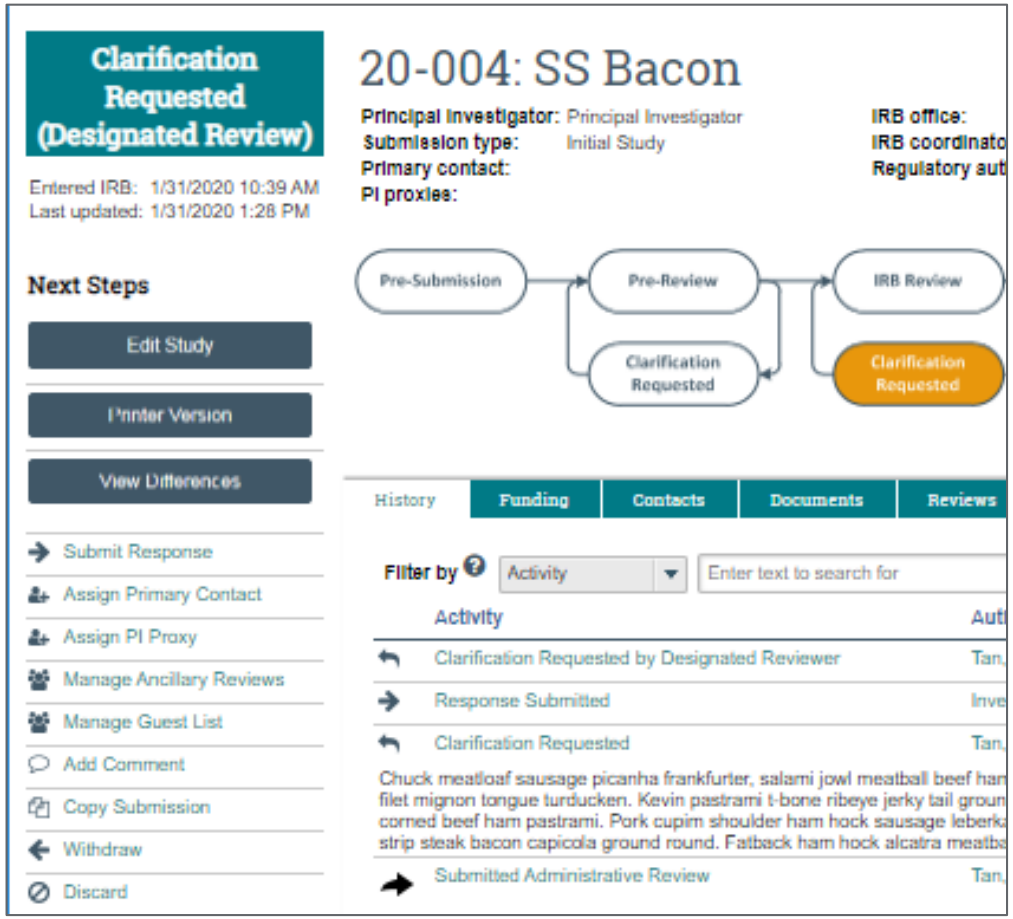
Next: Respond to requested clarifications

Principal investigator

Clarifications Requested (Designated Review) – – – – – – **Submit Response** – – – – – →

If the submission requires more information by a designated reviewer to make a determination, a notification will be sent to the principal investigator and the primary contact. The submission will be returned in a "clarifications requested" state so that you may address the issues.

1. Refer to the **History** tab to review the details of the request.
2. Click the **Edit Study** button to open the study record and make requested changes.
3. After you have addressed all issues, click the **Submit Response** link.
4. Click the **OK** button to submit your response.
   - The system will advance the submission to the previous project state, **Non-Committee Review**.



Pictured: Sample rendering of a principal investigators Submission workspace in "Clarifications Requested (Designated Review)"

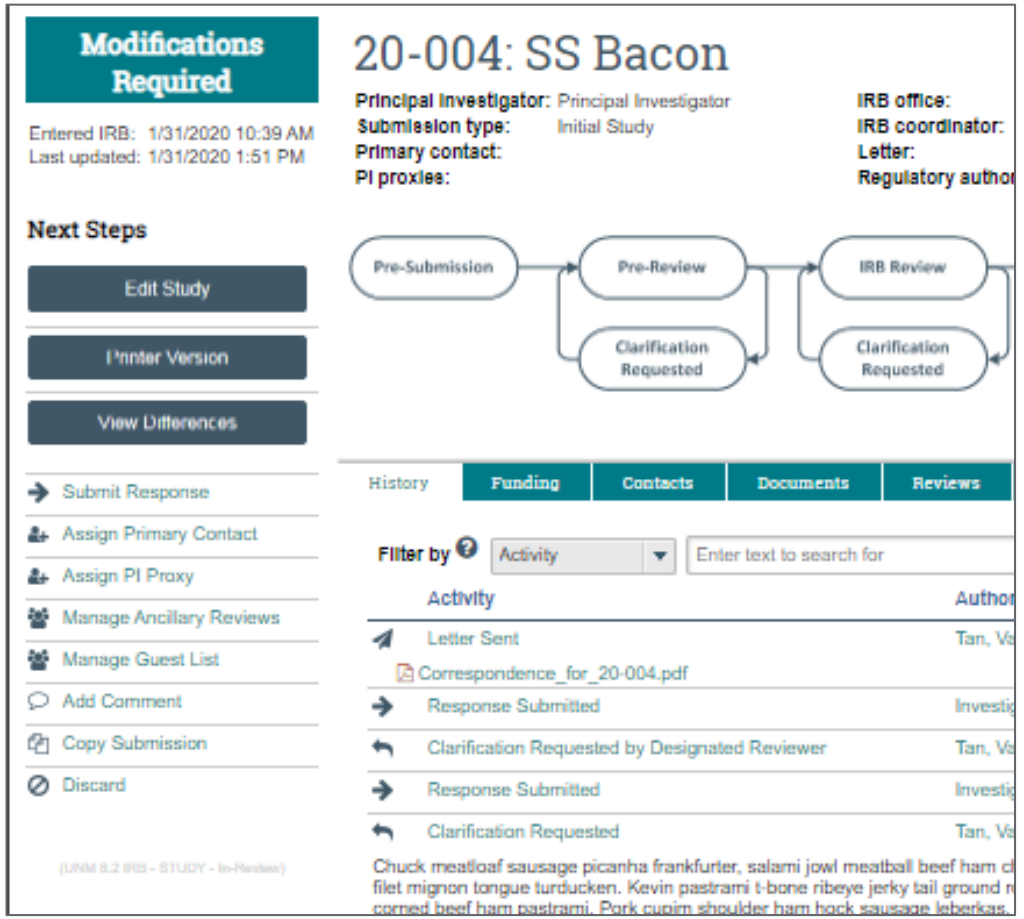
Next: Respond to required modifications

Principal investigator

Modifications Required — Submit Response →

If the submission requires modifications to secure approval, a notification will be sent to the principal investigator and the primary contact. The submission will be returned in a "modifications required" state so that you may address the issues.

1. Refer to the **History** tab to access the HRRC determination letter that outlines the details of the requirements.
2. Click the **Edit Study** button to open the study record and make required modifications.
3. After you have addressed all issues, click the **Submit Response** link.
4. Click the **OK** button to submit response.
   - The system will advance the submission to the next project state, **Modifications Submitted**.



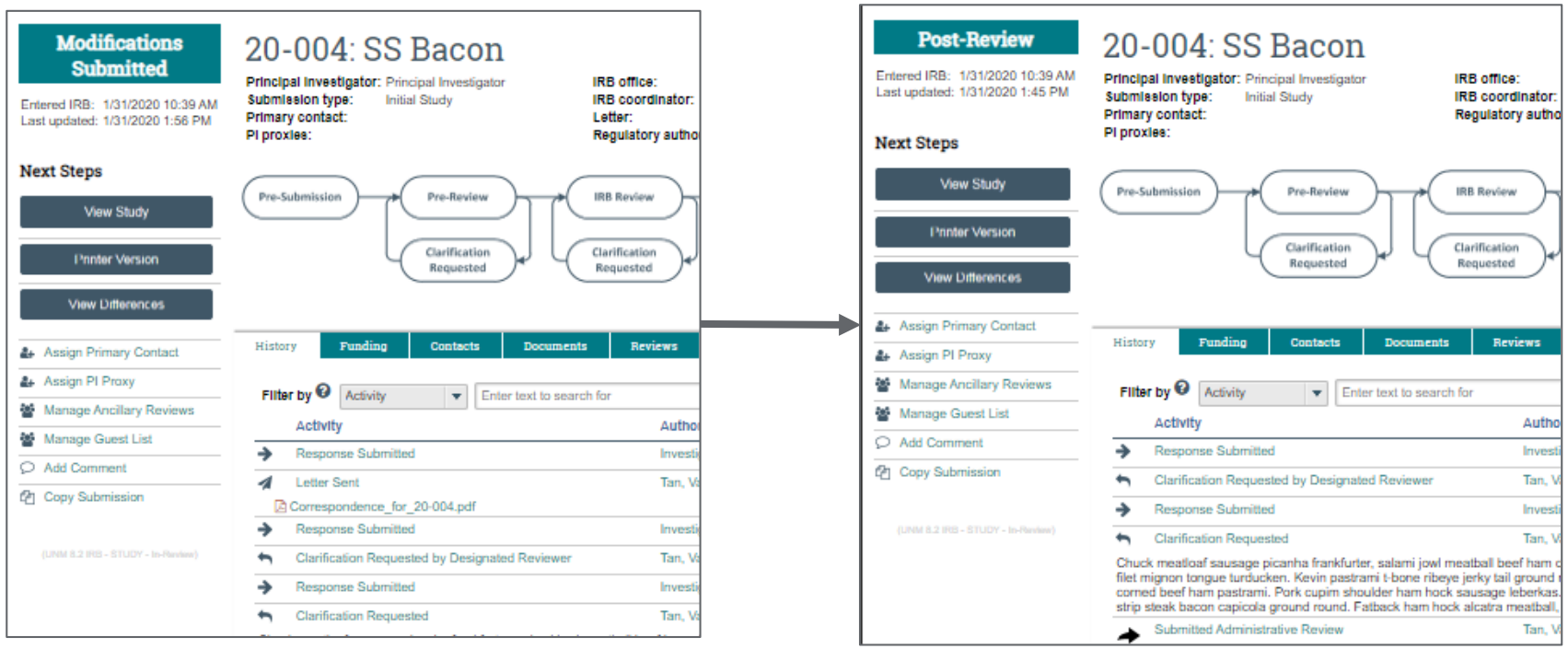
Pictured: Sample rendering of a principal investigators Submission workspace in "Modifications Required"

Next: Modifications Submitted and Post-Review

HRRC | HRPO staff

Modifications Submitted → **Post-Review**

During **Modifications Submitted**, the Human Research Review Committee chair will review your submission and make a determination based on the information and materials submitted. Once a determination has been made, your submission will advance to the next state, **Post-Review**, where the HRPO staff will finalize the submission.



Pictured: Sample rendering of a principal investigators Submission workspace in “Modifications Required” and ”Post-Review”

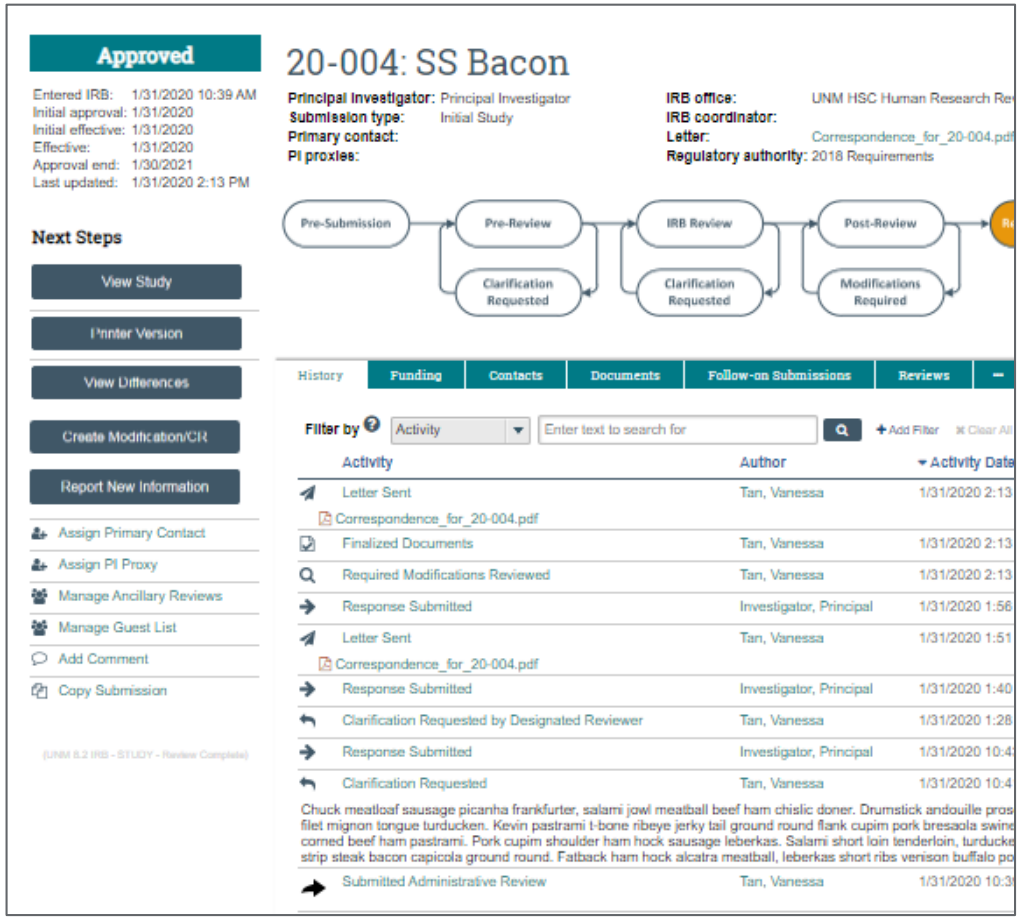
Next: Review complete

HRPO staff

Review Complete

After your submission has been finalized, a notification will be sent to the principal investigator and the primary contact. Your submission will enter a terminal "review complete" state (e.g., Approved, External IRB, Active, Disapproved, Deferred, etc.). In the study workspace:

1. Refer to the **History** tab to access the HRRC determination letter that outlines the details about the determination.
2. Click the **Documents** tab to download finalized study documents.
3. If the study is "Approved," the principal investigator may execute the **Assign PI Proxy** activity to delegate an approved study team member to act as PI proxy.



Pictured: Sample rendering of a principal investigators Study workspace in "Approved"

Next: IRB Submission Help

IRB Submission Help

Documents to download from the IRB Library:

Investigator Manual

Huron IRB Investigator Submission Guide

General questions and IRB consults, contact:

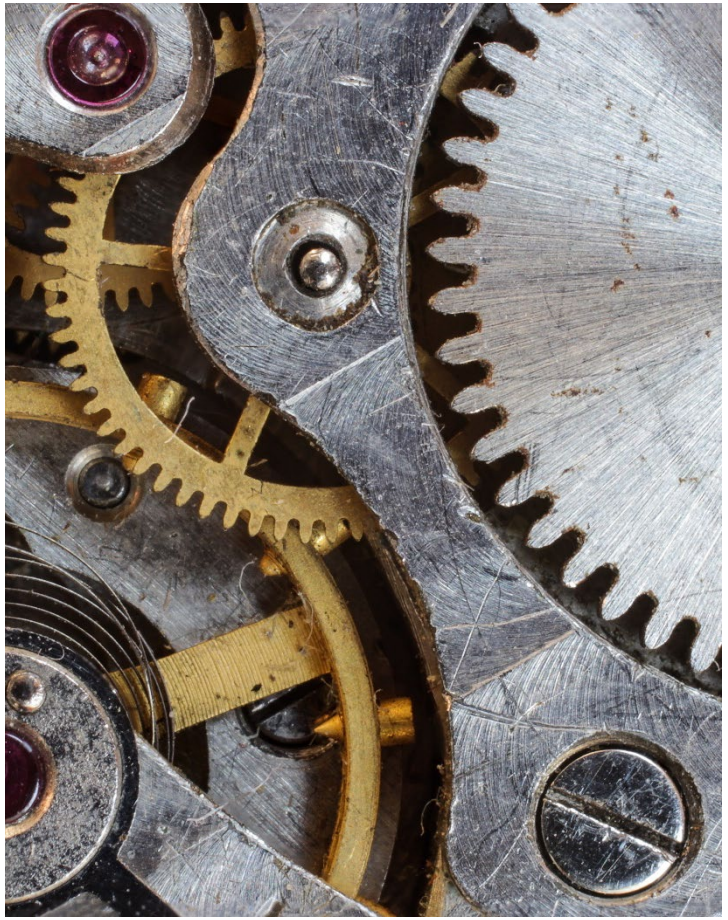
UNM Health Sciences Human Research Protections Office (HRPO)

HSC-HRPO@salud.unm.edu

(505) 272-1129

Next: Huron IRB Support

Huron IRB Support



If you experience technical issues with the system or a submission, contact:

HSC-ClickSupport@salud.unm.edu

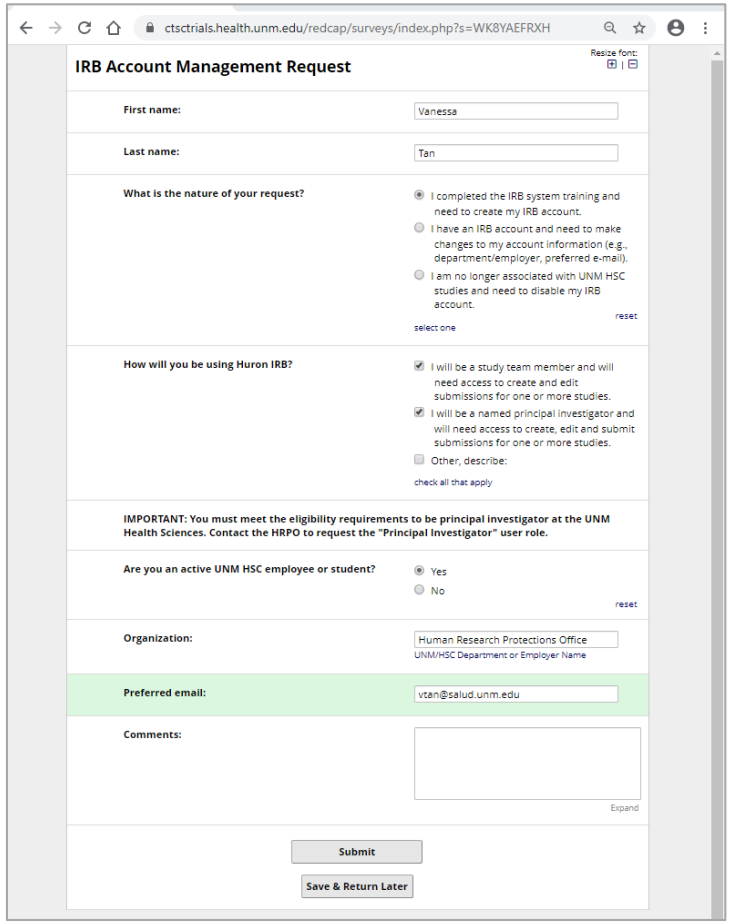
If you need help with an IRB account or cannot find an organization, contact:

Fabian Conant

FConant@salud.unm.edu

Next: Huron IRB Account Management Request

Huron IRB Account Management Request



Congrats on making it to the end of the Huron IRB 10.1 Self-Guided Training for Investigators!

Next step - Complete and submit the IRB Account Management Request form to have your IRB account created.

Important: Allow 1-2 business days for your account request to be processed. An IRB account manager will send you an email that will contain your login information, the website address, and instructions.

Finished