



HEALTH
SCIENCES
OFFICE OF RESEARCH

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

Human Research Protections

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.



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.



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.

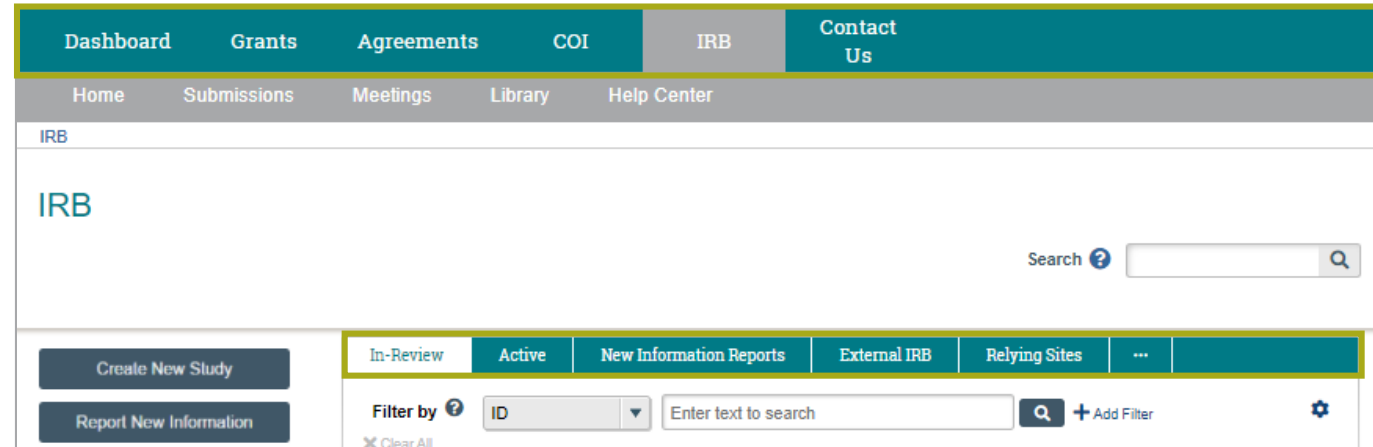
- As a **guest** on a study, you may view the study.
- As a **primary contact** on a study, you may view the study and receive notifications related to the study and follow-on submissions.
- As a **study team member**, you may create a new study submission, edit the submission, and attach documents. 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.



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.



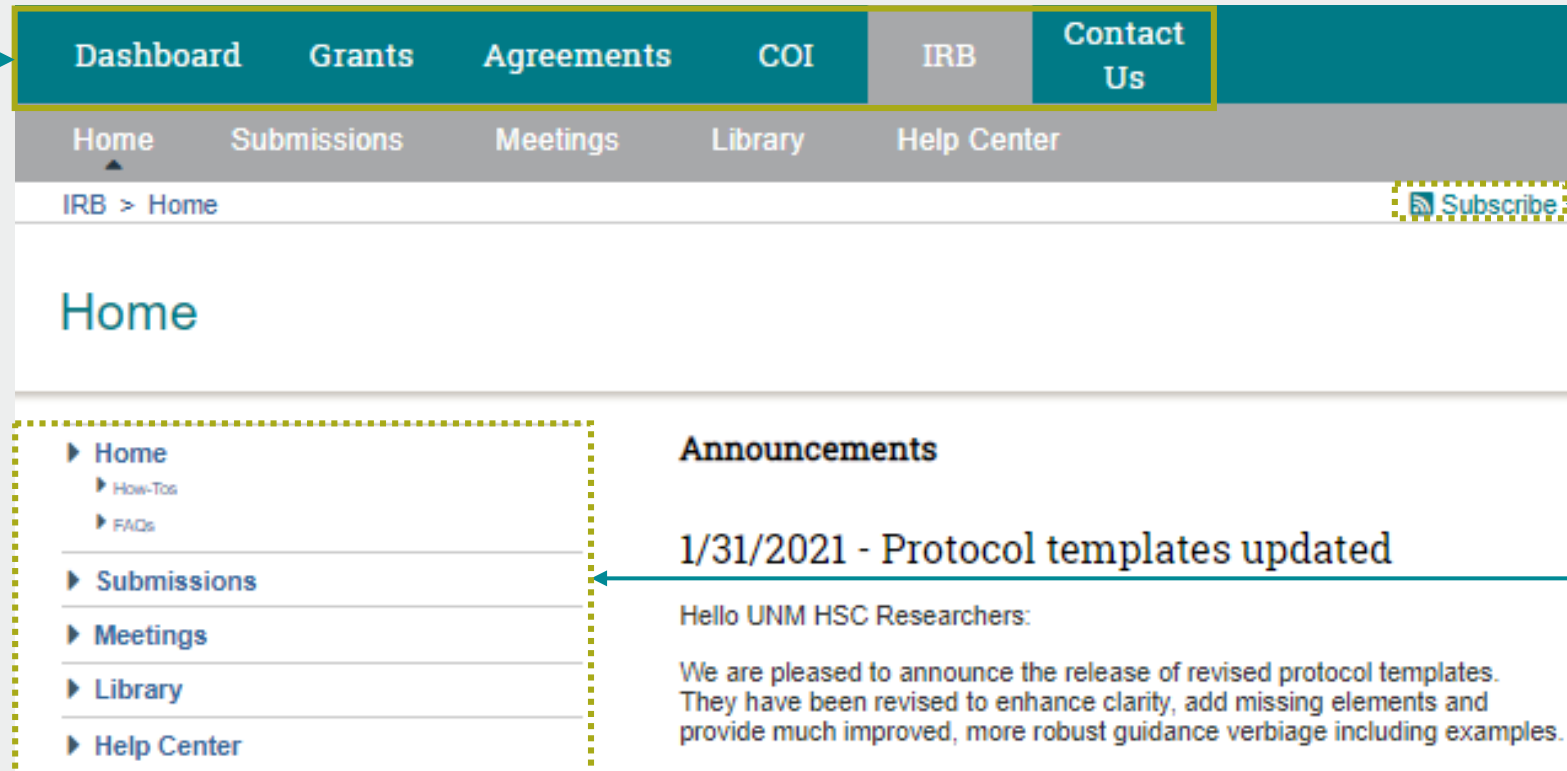
Home

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



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

Dashboard | Grants | Agreements | COI | IRB | Contact Us

Components ? Help

My Inbox | **My Reviews**

My Inbox

Filter by ? ID [v] Enter text to search

+ Add Filter X Clear All

ID	Name	Date Created	Date Modified	State	Coordinator
STUDY00005334	Test Study	3/3/2022 11:27 AM	3/8/2022 11:14 AM	Pre-Submission	
EXTUPDATE00000282	Update #2 for Test External Study	3/8/2022 8:49 AM	3/8/2022 8:49 AM	Updating Study	
RNI00002987	RNI Test	3/3/2022 12:01 PM	3/3/2022 12:01 PM	Pre-Submission	
MOD00014814	Modification / Update #1 for Study IRB 10.1 Test Study	3/1/2022 2:39 PM	3/3/2022 10:28 AM	Clarifications Requested (Admin Review)	Reviewer Administrative

Recently Viewed

Recent Pinned

- 22-005: Test Version Two
- STUDY00005334: Test Study
- 22-006: Test External Study
- EXTUPDATE00000282: Update #2 for Test External Study
- SITE00000968: University o... Version Two

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

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

Activities you may perform:

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

Reports you may run:

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

IRB

Search ?

Create New Study

Report New Information

Reports

1. Pending Follow-On Submissions (MOD/CR)

2. Pending Initial Submissions

In-Review Active New Information Reports External IRB Relying Sites ...

Filter by ? ID Enter text to search

+ Add Filter X Clear All

ID	Name	Date Modified	State	PI First Name	PI Last Name	Coordinator First Name	Coordinator Last Name	Submission Type
STUDY00005334	Test Study	3/8/2022 11:14 AM	Pre-Submission	Elvis	Presley			Initial Study

Pictured: Sample rendering of the IRB workspace

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 |

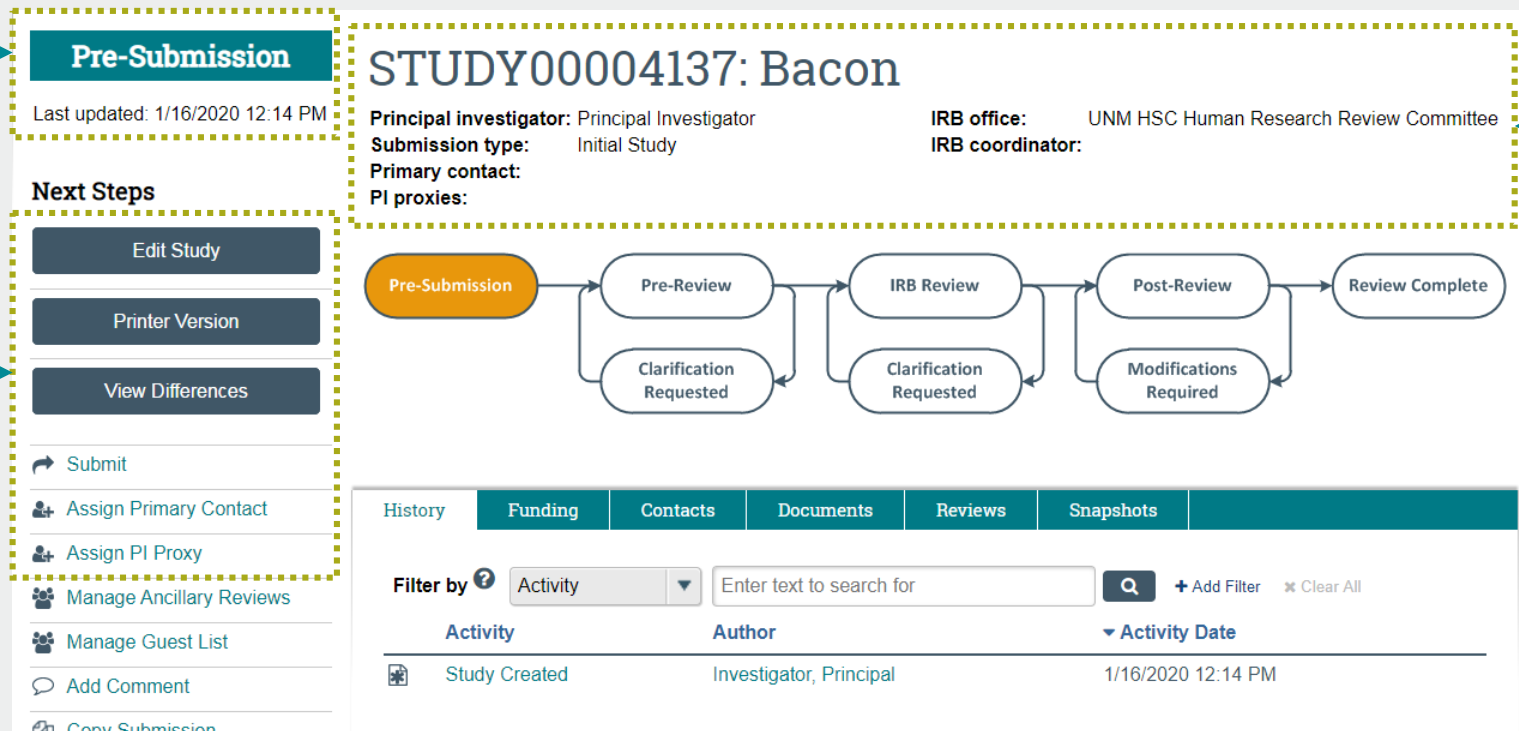
The **Submission workspace** appears for submissions that have been created and saved.

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

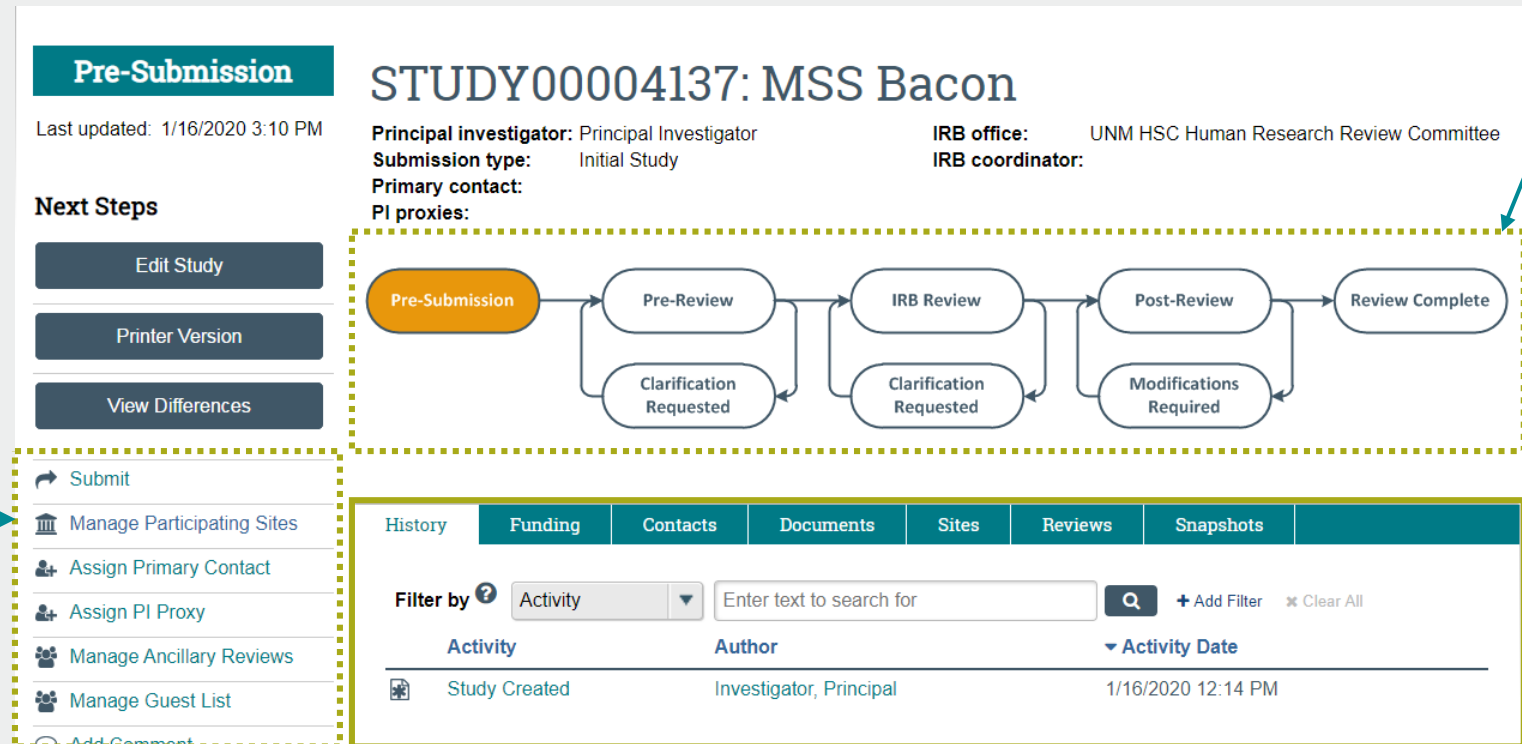


Submission |

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**

The screenshot displays the 'Submission (Site) workspace' for a new external participating site. The main header shows the site ID 'SITE00000868' and the site name 'Dartmouth College Participating Site for MSS Bacon'. The status is 'Invitation Pending', with a last updated date of '2/4/2020 2:04 PM'. The workspace is divided into several sections: 'Next Steps' with buttons for 'Edit Site', 'Printer Version', and 'View Differences'; a list of activities including 'Assign Primary Contact', 'Manage Guest List', 'Correspond with Site', and 'Add Comment'; a flowchart showing the submission process from 'Invitation Pending' to 'Review Complete'; and a table with tabs for 'History', 'Funding', 'Documents', and 'Snapshots'. The 'History' tab is active, showing a table with columns for 'Activity', 'Author', and 'Activity Date'. The first entry is 'Site Created' by 'Investigator, Principal' on '2/4/2020 2:04 PM'.

Invitation Pending
Last updated: 2/4/2020 2:04 PM

SITE00000868: Dartmouth College Participating Site for MSS Bacon

Principal investigator: IRB Site
Submission type: IRB Site
Primary contact:
PI proxies:
Institution: Dartmouth College

IRB office: UNM HSC Human Research Review Committee
IRB coordinator:
Regulatory authority: 2018 Requirements
Study: 20-005

Next Steps

- Edit Site
- Printer Version
- View Differences

Assign Primary Contact
Manage Guest List
Correspond with Site
Add Comment

Flowchart: Invitation Pending → Awaiting Site Materials → Pre-Review → IRB Review → Post-Review → Review Complete. A loop exists from Post-Review to Modifications Required, which then leads back to IRB Review.

History Table:

Activity	Author	Activity Date
Site Created	Investigator, Principal	2/4/2020 2:04 PM

- **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

- **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

The image shows a screenshot of a study workspace for a study titled "20-004: SS Bacon". The workspace is divided into several sections:

- Approved:** A teal box containing submission details: Entered IRB: 1/31/2020 10:39 AM, Initial approval: 1/31/2020, Initial effective: 1/31/2020, Effective: 1/31/2020, Approval end: 1/30/2021, Last updated: 1/31/2020 2:13 PM.
- Next Steps:** A list of actions: View Study, Printer Version, View Differences, Create Modification/CR, and Report New Information.
- Submission Details:** Principal investigator: Principal Investigator, Submission type: Initial Study, Primary contact: PI proxies.
- IRB office:** UNM HSC Human Research Review Committee.
- Letter:** Correspondence_for_20-004.pdf(0.02).
- Regulatory authority:** 2018 Requirements.
- Workflow:** A flowchart showing the process: Pre-Submission → Pre-Review → IRB Review → Post-Review → Review Complete. There are also loops for Clarification Requested and Modifications Required.
- History:** A table with tabs for History, Funding, Contacts, Documents, Follow-on Submissions, Reviews, and Snapshots. The History tab is active, showing a list of activities with columns for Activity, Author, and Activity Date.

Activity	Author	Activity Date
Letter Sent		1/31/2020 2:13 PM
Correspondence_for_20-004.pdf		
Finalized Documents		1/31/2020 2:13 PM
Required Modifications Reviewed		1/31/2020 2:13 PM
Response Submitted		1/31/2020 1:56 PM
Letter Sent		1/31/2020 1:51 PM
Correspondence_for_20-004.pdf		
Response Submitted		1/31/2020 1:40 PM
Clarification Requested by Designated Reviewer		1/31/2020 1:28 PM
Response Submitted		1/31/2020 10:43 AM

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

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

Active

Entered IRB: 2/6/2020 1:42 PM
Initial approval: 2/6/2020
Initial effective: 2/6/2020
Effective: 2/6/2020
Approval end: 2/3/2021
Last updated: 2/6/2020 1:55 PM

SITE00000868: Dartmouth College Participating Site for MSS Bacon

Principal investigator: Principal Investigator
Submission type: IRB Site
Primary contact: Principal Investigator
PI proxies:
Institution: Dartmouth College

IRB office: UNM HSC Human Research Review Committee
IRB coordinator:
Letter: Correspondence_for_SITE00000868.pdf(0.01)
Regulatory authority: 2005 Requirements
Study: 20-005

Next Steps

- View Site
- Printer Version
- View Differences
- Create Site Modification
- Report New Information

Assign Primary Contact
Assign PI Proxy
Manage Guest List

Workflow: Invitation Pending → Awaiting Site Materials → Pre-Review → IRB Review → Post-Review → Review Complete (with a loop to Modifications Required).

History Table:

Activity	Author	Activity Date
Letter Sent		2/6/2020 1:55 PM
Correspondence_for_SITE00000868.pdf		
Finalized Documents		2/6/2020 1:54 PM

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

Active

Entered IRB: 2/6/2020 3:41 PM
Last updated: 2/6/2020 3:52 PM

Next Steps

- View Site
- Printer Version
- View Differences
- Create Site Modification
- Update Study Details
- Report New Information

20-007: MSS Bacon - UNM pSite

Principal investigator: Principal Investigator
Submission type: IRB Site
Primary contact:
PI proxies:
Institution: Michigan Medicine

IRB office: UNM HSC Human Research Review Committee
IRB coordinator:
Regulatory authority: 2018 Requirements
External study ID:

Workflow Diagram:

```
graph LR; A[Pre-Submission] --> B[Pre-Review]; B --> C[Pending sIRB Review]; C --> D[Post-Review]; D --> E[Review Complete]; C --> F[Clarification Requested]; F --> B; D --> G[Modifications Required]; G --> C;
```

History

Activity	Author	Activity Date
Reliance Confirmed		2/6/2020 3:44 PM
Submitted Administrative Review		2/6/2020 3:41 PM
Response Submitted		2/6/2020 3:41 PM
Requested Clarification for Administrative Review		2/6/2020 3:41 PM

- **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.

Reports

Standard Reports

Custom Reports

The reports show only the submissions you have permission to view.

Name	Description
All External Studies	Report of all external IRB studies
All Multi-Site or Collaborative Studies Where This Institution is the IRB of Record	Report of all studies where the institution is the sIRB
All Sites	Report of all sIRB and Participating sites
Approved Submissions after Modifications Required	Report of submissions approved after modifications required to secure approval
Exempt Submissions Approved in the Last 45 Days	Report of exempt submissions approved in the last 45 days
Expedited Submissions Approved in the Last 45 Days	Report of expedited submissions approved in the last 45 days
Pre-2010 Research Studies Now Under 2010	Report of studies that were originally reviewed under old



IRB Library |

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

Library

► Submissions
► Meetings
► Library
► Reports
► Help Center

Shortcuts

My Inbox
Meetings
Reports
Help

Standard Operating Procedures

General Worksheets Checklists Templates ...

SOPs

Export

Name	Document
HRP-000 - Org Chart	HRP-000 - Org Chart(0.05)
HRP-001 - SOP - Definitions	HRP-001 - SOP - Definitions(0.14)
HRP-002 - SOP - Use of Web-based Software for HRRC and HRPO Review_Operations	HRP-002 - SOP - Use of Web-based Software for HRRC and HRPO Review_Operations(0.06)
HRP-012 - SOP - Observation of the Informed Consent Process	HRP-012 - SOP - Observation of the Informed Consent Process(0.04)
HRP-013 - SOP - Legally Authorized Representatives, Children, and Guardians	HRP-013 - SOP - Legally Authorized Representatives, Children, and Guardians(0.05)

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



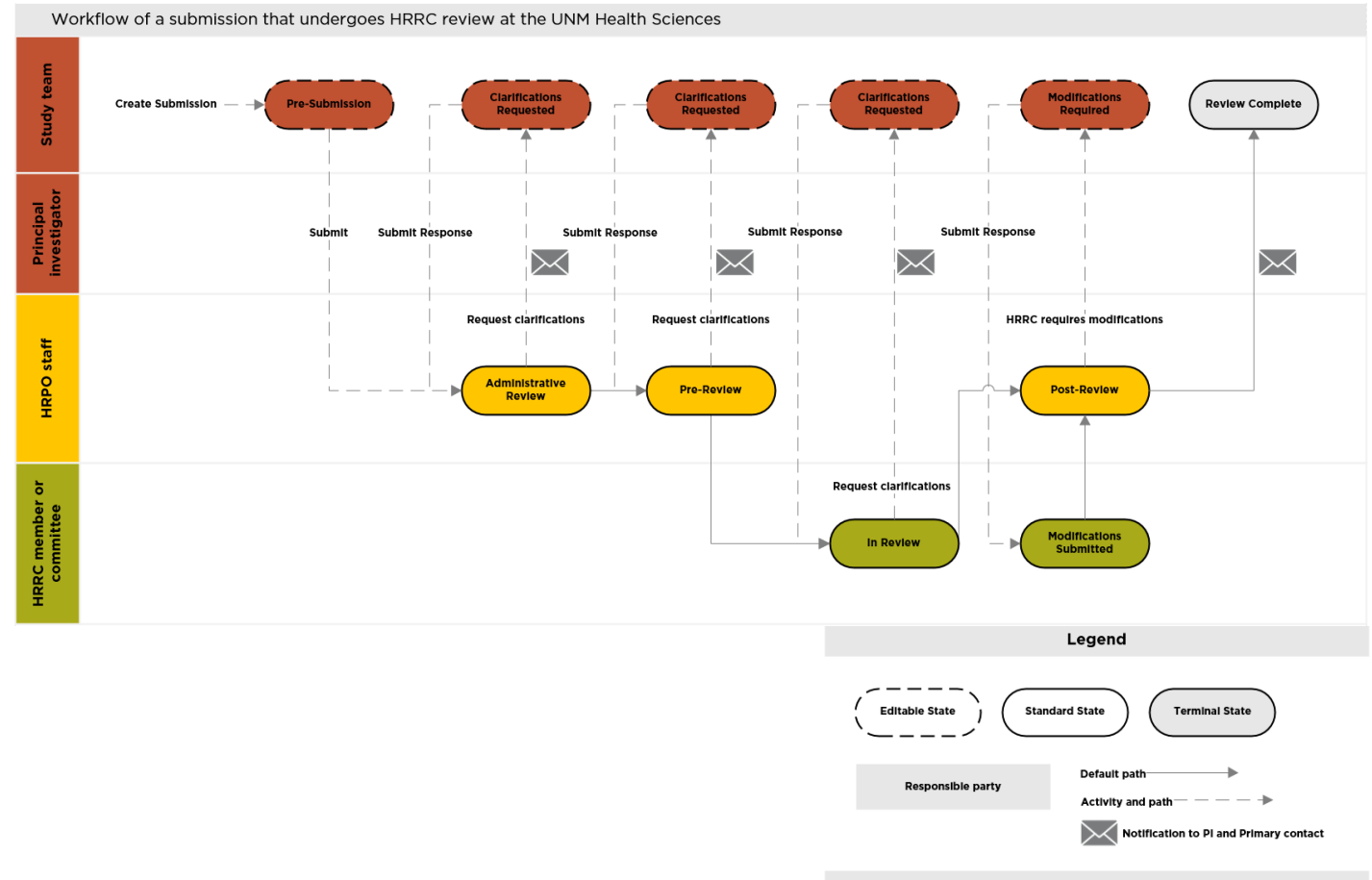
Walk-through a new single-site study submission

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



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**.

The screenshot shows a web interface for an IRB submission. At the top, it says 'You Are Here: IRB Submission' with navigation links for 'Back', 'Save', 'Print', and 'Continue'. The main heading is 'Basic Study Information'. The form contains six numbered sections:

- 1. * Title of study:** A text input field containing 'Single-site bacon study'.
- 2. * Short title:** A text input field containing 'SS Bacon'.
- 3. * Brief description:** A text area containing a paragraph of placeholder text: 'Bacon ipsum dolor amet chislic meatball jowl sausage buffalo pork chop. Tri-tip leberkas doner, shank filet mignon pig chislic bacon sausage short ribs kielbasa landjaeger andouille pancetta. Ham shoulder short ribs salami brisket. Venison alcañra salami kielbasa shoulder brisket pork loin strip steak ham spare ribs shank beef pork belly bacon.'
- 4. * What kind of study is this?** Radio buttons for 'Multi-site or Collaborative study' and 'Single-site study' (which is selected). A 'Clear' link is below.
- 5. * Will an external IRB act as the IRB of record for this study?** Radio buttons for 'Yes' and 'No' (which is selected). A 'Clear' link is below.
- 6. * Local principal investigator:** A dropdown menu labeled 'Principal Investigator' with a three-dot icon and a radio button.

Pictured: Sample rendering of the Basic Study Information form

Next: Submit new study submission



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.

Pre-Submission

Last updated: 1/30/2020 12:50 PM

STUDY00004138: SS Bacon

Principal Investigator: Principal Investigator
Submission type: Initial Study
Primary contact:
PI proxies:

IRB office:
IRB coordin

Next Steps

Edit Study

Printer Version

View Differences

Submit

Assign Primary Contact

Assign PI Proxy

Manage Ancillary Reviews

Manage Guest List

Add Comment

Copy Submission

Discard

(UNM 5.2 IRB - STUDY - In-Review)

Flowchart:

```
graph LR; A[Pre-Submission] --> B[Pre-Review]; B --> C[IRB Review]; C --> D[Clarification Requested]; D --> B;
```

History | Funding | Contacts | Documents | Reviews

Filter by [?] Activity

Activity	Author
Study Created	Investigator, Principal

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

Next: Administrative Review



**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**.

Administrative Review

Entered IRB: 1/30/2020 1:23 PM
Last updated: 1/30/2020 1:23 PM

STUDY00004138: SS Bacon

Principal Investigator: Principal Investigator
Submission type: Initial Study
Primary contact:
PI proxies:

IRB office: UNM H
IRB coordinator:

Next Steps

- View Study
- Enter Version
- View Differences
- Add Comment
- Withdraw
- Discard

(UNM 8.2 IRB - STUDY - In-Review)

History | **Funding** | Contacts | Documents | Reviews

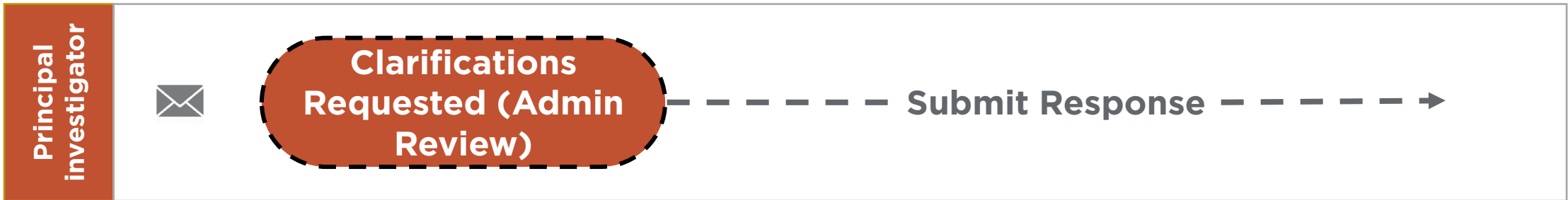
Filter by [?] Activity

Activity	Author	
Submitted	Investigator, Principal	1.
Study Created	Investigator, Principal	1.

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

Next: Respond to requested clarifications





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**.

The screenshot shows a web interface for a study titled "STUDY00004138: SS Bacon". The top left has a teal header "Clarifications Requested (Admin Review)". Below it, it says "Entered IRB: 1/30/2020 1:23 PM" and "Last updated: 1/31/2020 10:24 AM". To the right, it lists "Principal Investigator: Principal Investigator", "Submission type: Initial Study", "Primary contact:", "PI proxies:", "IRB office: UNM HS", and "IRB coordinator:". Below this is a "Next Steps" section with buttons for "Edit Study", "Printer Version", and "View Differences". There are also links for "Submit Response", "Add Comment", "Withdraw", and "Discard". On the right, there are tabs for "History", "Funding", "Contacts", "Documents", and "Reviews". The "History" tab is active, showing a list of activities. The first activity is "Requested Clarification for Administrative Review" by the investigator, with a description of food items. The second activity is "Submitted" by the investigator. The third activity is "Study Created" by the investigator. At the bottom, it says "(UNM 5.2 IRB - STUDY - In-Review)".

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



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

The screenshot displays a web interface for a submission workspace. At the top, a teal header bar contains the text 'Pre-Review'. Below this, the submission ID '20-004: SS Bacon' is prominently displayed. To the left, a sidebar lists 'Next Steps' with buttons for 'View Study', 'Printer Version', and 'View Differences'. Below these are several action items with icons: 'Assign Primary Contact', 'Assign PI Proxy', 'Manage Ancillary Reviews', 'Manage Guest List', 'Add Comment', 'Copy Submission', 'Withdraw', and 'Discard'. The main content area on the right shows a flowchart of the submission process: 'Pre-Submission' leads to 'Pre-Review' (highlighted in orange), which can lead to 'IRB Review' or 'Clarification Requested'. Below the flowchart, there are tabs for 'History', 'Funding', 'Contacts', 'Documents', and 'Reviews'. The 'History' tab is active, showing a list of activities with columns for 'Activity' and 'Auth'. The activities listed are 'Submitted Administrative Review', 'Response Submitted', 'Requested Clarification for Administrative Review', and 'Submitted'. At the bottom, there is a text area containing a list of food items: 'Pancetta pork loin shoulder spare ribs picanha pork chop chislic. Strip steak tenderloin, jowl tri-tip andouille spare ribs pastrami chislic tongue. Andouille kevin tenderloin ball tip turducken bresaola hamburger burgdoggen.'

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

Next: Respond to requested clarifications





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**.

Clarification Requested (Pre-Review)

Entered IRB: 1/31/2020 10:39 AM
Last updated: 1/31/2020 10:41 AM

Next Steps

Edit Study

Printer Version

View Differences

Submit Response

Assign Primary Contact

Assign PI Proxy

Manage Ancillary Reviews

Manage Guest List

Add Comment

Copy Submission

Withdraw

Discard

20-004: SS Bacon

Principal Investigator: Principal Investigator
Submission type: Initial Study
Primary contact:
PI proxies:

IRB office:
IRB coord:

```

graph LR
    A[Pre-Submission] --> B[Pre-Review]
    B --> C[IRB Review]
    C --> D[Clarification Requested]
    D --> B
  
```

History | Funding | Contacts | Documents | Reviews

Filter by Activity

Activity	Aut
Clarification Requested	Tan,
Chuck meatloaf sausage picanha frankfurter, salami jowl meatball beef ham filet mignon tongue turducken. Kevin pastrami t-bone ribeye jerky tail ground corned beef ham pastrami. Pork cupim shoulder ham hock sausage leberke strip steak bacon capicola ground round. Fatback ham hock alcatraz meatbe	
Submitted Administrative Review	Tan,
Response Submitted	Inve
Requested Clarification for Administrative Review	Tan,

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

Next: In-Review and Post-Review





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.

The image shows two side-by-side screenshots of the submission workspace for study 20-004: SS Bacon, illustrating the transition from 'Non-Committee Review' to 'Post-Review'.

Non-Committee Review (Left):

- Header:** 20-004: SS Bacon
- Metadata:** Entered IRB: 1/31/2020 10:39 AM, Last updated: 1/31/2020 11:02 AM. Principal Investigator: Principal Investigator, Submission type: Initial Study, Primary contact: [redacted], PI proxies: [redacted]. IRB office: [redacted], IRB coordinator: [redacted], Regulatory [redacted].
- Next Steps:** View Study, Enter Version, View Differences.
- Activity History:**
 - Response Submitted
 - Clarification Requested
 - Submitted Administrative Review
 - Response Submitted

Post-Review (Right):

- Header:** 20-004: SS Bacon
- Metadata:** Entered IRB: 1/31/2020 10:39 AM, Last updated: 1/31/2020 1:45 PM. Principal Investigator: Principal Investigator, Submission type: Initial Study, Primary contact: [redacted], PI proxies: [redacted].
- Next Steps:** View Study, Enter Version, View Differences.
- Activity History:**
 - Response Submitted
 - Clarification Requested by Designated Reviewer
 - Response Submitted
 - Clarification Requested

An arrow points from the 'Non-Committee Review' workspace to the 'Post-Review' workspace, indicating the progression of the submission process.

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

Next: Respond to requested clarifications





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**.

The screenshot shows the Submission workspace for a study titled "20-004: SS Bacon". The state is "Clarification Requested (Designated Review)".

Metadata:

- Entered IRB: 1/31/2020 10:39 AM
- Last updated: 1/31/2020 1:28 PM
- Principal Investigator: Principal Investigator
- Submission type: Initial Study
- Primary contact: PI proxy
- IRB office: IRB coordinator
- Regulatory authority: Regulatory authority

Next Steps:

- Edit Study
- Enter Version
- View Differences

Workflow Diagram:

```
graph LR; A([Pre-Submission]) --> B([Pre-Review]); B --> C([IRB Review]); C --> D([Clarification Requested]); D --> B; D --> E([Clarification Requested]);
```

History Tab:

Activity	Author
Clarification Requested by Designated Reviewer	Tan...
Response Submitted	Inve...
Clarification Requested	Tan...
Submitted Administrative Review	Tan...

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

Next: Respond to required modifications





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**.

Modifications Required

Entered IRB: 1/31/2020 10:39 AM
Last updated: 1/31/2020 1:51 PM

20-004: SS Bacon

Principal Investigator: Principal Investigator
Submission type: Initial Study
Primary contact:
PI proxies:

IRB office:
IRB coordinator:
Letter:
Regulatory author:

Next Steps

Edit Study
Printer Version
View Differences

Pre-Submission → Pre-Review → IRB Review
Clarification Requested → Pre-Review
Clarification Requested → IRB Review

Submit Response
Assign Primary Contact
Assign PI Proxy
Manage Ancillary Reviews
Manage Guest List
Add Comment
Copy Submission
Discard

History Funding Contacts Documents Reviews

Filter by Activity Enter text to search for

Activity	Author
Letter Sent	Tan, V
Correspondence_for_20-004.pdf	
Response Submitted	Investig
Clarification Requested by Designated Reviewer	Tan, V
Response Submitted	Investig
Clarification Requested	Tan, V

Chuck meatloaf sausage picanha frankfurter, salami jowl meatball beef ham cl
filet mignon tongue turducken. Kevin pastrami t-bone ribeye jerky tail ground r
corned beef ham pastrami. Pork cuisin shoulder ham hock sausage leberkas.

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

Next: Modifications Submitted and Post-Review



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.

The image shows two side-by-side screenshots of a submission workspace for '20-004: SS Bacon', illustrating the transition from the 'Modifications Submitted' state to the 'Post-Review' state.

Modifications Submitted State (Left):

- Header:** 'Modifications Submitted' (green bar), '20-004: SS Bacon', 'Entered IRB: 1/31/2020 10:39 AM', 'Last updated: 1/31/2020 1:56 PM'.
- Metadata:** 'Principal Investigator: Principal Investigator', 'Submission type: Initial Study', 'Primary contact: PI proxies:'. 'IRB office: IRB coordinator: Letter: Regulatory autho'.
- Next Steps:** 'View Study', 'Enter Version', 'View Differences'.
- Flowchart:** Pre-Submission → Pre-Review → IRB Review. A feedback loop exists from IRB Review back to Pre-Review via 'Clarification Requested'.
- Left Sidebar:** Assign Primary Contact, Assign PI Proxy, Manage Ancillary Reviews, Manage Guest List, Add Comment, Copy Submission.
- History Table:**

Activity	Author
Response Submitted	Investi
Letter Sent	Tan, V
Correspondence_for_20-004.pdf	
Response Submitted	Investi
Clarification Requested by Designated Reviewer	Tan, V
Response Submitted	Investi
Clarification Requested	Tan, V

Post-Review State (Right):

- Header:** 'Post-Review' (green bar), '20-004: SS Bacon', 'Entered IRB: 1/31/2020 10:39 AM', 'Last updated: 1/31/2020 1:45 PM'.
- Metadata:** Same as the previous state.
- Next Steps:** 'View Study', 'Enter Version', 'View Differences'.
- Flowchart:** Identical to the previous state.
- Left Sidebar:** Assign Primary Contact, Assign PI Proxy, Manage Ancillary Reviews, Manage Guest List, Add Comment, Copy Submission.
- History Table:**

Activity	Author
Response Submitted	Investi
Clarification Requested by Designated Reviewer	Tan, V
Response Submitted	Investi
Clarification Requested	Tan, V
Submitted Administrative Review	Tan, V

An arrow points from the 'Modifications Submitted' state to the 'Post-Review' state, indicating the progression of the submission process.

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

Next: Review complete





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.

Approved

Entered IRB: 1/31/2020 10:39 AM
Initial approval: 1/31/2020
Initial effective: 1/31/2020
Effective: 1/31/2020
Approval end: 1/30/2021
Last updated: 1/31/2020 2:13 PM

20-004: SS Bacon

Principal Investigator: Principal Investigator
Submission type: Initial Study
Primary contact:
PI proxies:

IRB office: UNM HSC Human Research Review
IRB coordinator:
Letter: Correspondence_for_20-004.pdf
Regulatory authority: 2018 Requirements

Next Steps

- View Study
- Enter Version
- View Differences
- Create Modification/CR
- Report New Information
- Assign Primary Contact
- Assign PI Proxy
- Manage Ancillary Reviews
- Manage Guest List
- Add Comment
- Copy Submission

History | Funding | Contacts | Documents | Follow-on Submissions | Reviews | —

Filter by: Activity | Enter text to search for | + Add Filter | X Clear All

Activity	Author	Activity Date
Letter Sent	Tan, Vanessa	1/31/2020 2:13
Correspondence_for_20-004.pdf		
Finalized Documents	Tan, Vanessa	1/31/2020 2:13
Required Modifications Reviewed	Tan, Vanessa	1/31/2020 2:13
Response Submitted	Investigator, Principal	1/31/2020 1:56
Letter Sent	Tan, Vanessa	1/31/2020 1:51
Correspondence_for_20-004.pdf		
Response Submitted	Investigator, Principal	1/31/2020 1:40
Clarification Requested by Designated Reviewer	Tan, Vanessa	1/31/2020 1:28
Response Submitted	Investigator, Principal	1/31/2020 10:4
Clarification Requested	Tan, Vanessa	1/31/2020 10:4
Chuck meatloaf sausage picanha frankfurter, salami jowl meatball beef ham chislic doner. Drumstick andouille pros flet mignon tongue turducken. Kevin pastrami t-bone ribeye jerky tail ground round flank cupim pork bresaola swine corned beef ham pastrami. Pork cupim shoulder ham hock sausage leberkas. Salami short loin tenderloin, turducken strip steak bacon capicola ground round. Fatback ham hock alcatra meatball, leberkas short ribs venison buffalo po		
Submitted Administrative Review	Tan, Vanessa	1/31/2020 10:3

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



Huron IRB Support



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

HSC-ClickSupport@salud.unm.edu

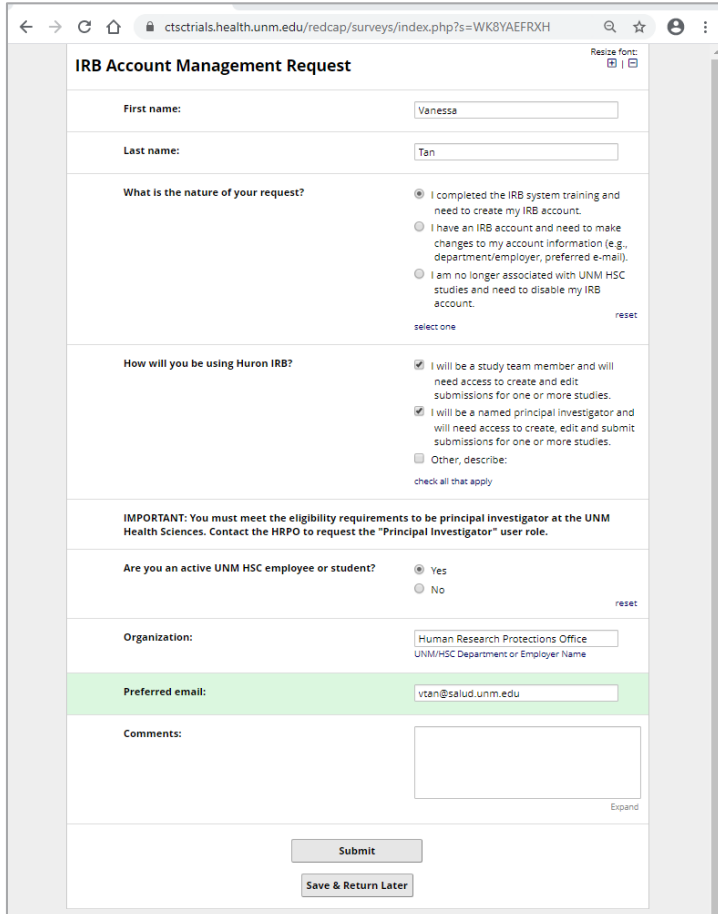
If you need help with an IRB account or cannot find an organization, contact:

Fabian Conant

FConant@salud.unm.edu



Huron IRB Account Management Request



The screenshot shows a web browser window with the URL `ctsctrials.health.unm.edu/redcap/surveys/index.php?s=WK8YAEFRXH`. The form is titled "IRB Account Management Request". It contains the following fields and options:

- First name:** Text input field with "Vanessa" entered.
- Last name:** Text input field with "Tan" entered.
- What is the nature of your request?** Radio button options:
 - ☒ I completed the IRB system training and need to create my IRB account.
 - ☐ I have an IRB account and need to make changes to my account information (e.g., department/employer, preferred e-mail).
 - ☐ I am no longer associated with UNM HSC studies and need to disable my IRB account.A "select one" label and a "reset" link are present.
- How will you be using Huron IRB?** Check box options:
 - ☒ I will be a study team member and will need access to create and edit submissions for one or more studies.
 - ☒ I will be a named principal investigator and will need access to create, edit and submit submissions for one or more studies.
 - ☐ Other, describe: [text input field]A "check all that apply" label is present.
- IMPORTANT:** You must meet the eligibility requirements to be principal investigator at the UNM Health Sciences. Contact the HRPO to request the "Principal Investigator" user role.
- Are you an active UNM HSC employee or student?** Radio button options:
 - ☒ Yes
 - ☐ NoA "reset" link is present.
- Organization:** Text input field with "Human Research Protections Office" entered. Below it is the text "UNM/HSC Department or Employer Name".
- Preferred email:** Text input field with "vtan@salud.unm.edu" entered. This field is highlighted with a green background.
- Comments:** Text area with an "Expand" link below it.
- Buttons:** "Submit" and "Save & Return Later".

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.

