

# Huron IRB 8.2 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

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# 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 >> breadcrumb, **My Inbox** and secondary navigation menu will change based on the system you are viewing.
  - In IRB, the >> breadcrumb allows you to toggle between IRB submission-specific workspaces: **Study, Submission,** and **Site.**

## 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:

- >> - bread crumb to toggle between workspaces
- **My Inbox** - submissions that require you to take action. Changes based on system you are viewing (refer to URL address)
- **COI** - COI submission system
- **Grants** - Grants submission system
- **Agreements** - Agreements 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.

Home workspace screenshot showing navigation menus and an announcement.

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
- **Support** - contact information for assistance
- **Submissions** - all submissions
- **Newsletters** - quarterly communications from the HRPO

Pictured: Sample rendering of the Home workspace

Next: My Inbox Workspace



# My Inbox

The **My Inbox workspace** lists IRB submissions that require you to take action. The options will change based on the system you are viewing.

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 secondary top navigation:

- **Submissions** – all IRB submissions
- **Meetings** – content visible to HRPO staff and HRRC members only
- **Reports** – standard reports to query submissions you have permission to view
- **Library** – all standard operating procedures, worksheets, checklists, templates, forms, training materials, and general information items
- **Help Center** – guides and videos

**My Inbox**

Filter by ? ID

ID	Name	Date Created	Date Modified	State	Coordinator
STUDY00004137	MSS Bacon	1/16/2020 12:14 PM	1/16/2020 3:10 PM	Pre-Submission	

1 items  page  of 1   / page

Pictured: Sample rendering of the My Inbox workspace in the IRB system

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.

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



# IRB

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

Activities you may perform:

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

Reports you may run:

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

The screenshot shows the IRB workspace interface. On the left, there are two sections: 'Activities you may perform:' with buttons for 'Create New Study' and 'Report New Information', and 'Reports you may run:' with a list of reports: '1. Pending Follow-On Submissions (MOD/CR)' and '2. Pending Initial Submissions'. The main area displays a list of submissions under the 'In-Review' tab. The list has columns for ID, Name, Date Modified, State, PI First Name, PI Last Name, Coordinator First Name, Coordinator Last Name, and Submission Type. A single submission is listed: ID 'STUDY00004137', Name 'MSS Bacon', Date Modified '1/16/2020 3:10 PM', State 'Pre-Submission', PI 'Principal Investigator', and Submission Type 'Initial Study'. The interface also includes a search bar, filter options, and pagination controls.

Pictured: Sample rendering of the IRB workspace

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).





# 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

**Pre-Submission**  
Last updated: 1/16/2020 12:14 PM

**STUDY00004137: Bacon**

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

**IRB office:** UNM HSC Human Research Review Committee  
**IRB coordinator:**

**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

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

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

Activity	Author	Activity Date
Study Created	Investigator, Principal	1/16/2020 12:14 PM

The flowchart shows the submission process: Pre-Submission (highlighted) leads to Pre-Review, which can lead to IRB Review or Clarification Requested. IRB Review can lead to Post-Review or Clarification Requested. Post-Review can lead to Review Complete or Modifications Required. Clarification Requested can lead back to Pre-Review or IRB Review. Modifications Required can lead back to Post-Review.

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

The screenshot shows a submission workspace for 'STUDY00004137: MSS Bacon'. At the top, it indicates 'Pre-Submission' status, last updated on 1/16/2020 at 3:10 PM. Key details include: Principal investigator: Principal Investigator; Submission type: Initial Study; IRB office: UNM HSC Human Research Review Committee; IRB coordinator: [blank]; Primary contact: [blank]; PI proxies: [blank].

On the left, there are 'Next Steps' buttons: 'Edit Study', 'Printer Version', and 'View Differences'. Below these is a 'Submit' button with a right-pointing arrow.

In the center, a process flow diagram shows the submission lifecycle: Pre-Submission (highlighted in orange) leads to Pre-Review, which can lead to IRB Review or Clarification Requested. IRB Review can lead to Post-Review or Clarification Requested. Post-Review can lead to Review Complete or Modifications Required. Clarification Requested can lead back to Pre-Review or IRB Review. Modifications Required can lead back to Post-Review.

At the bottom, there are tabs for 'History', 'Funding', 'Contacts', 'Documents', 'Sites', 'Reviews', and 'Snapshots'. The 'History' tab is active, showing a table with columns for Activity, Author, and Activity Date. A search bar and filter options are also present.

Activity	Author	Activity Date
Study Created	Investigator, Principal	1/16/2020 12:14 PM

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



# 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**

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

**SITE00000868: Dartmouth College Participating Site for MSS Bacon**

Principal investigator: Vanessa Tan  
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

**Workflow:** Invitation Pending → Awaiting Site Materials → Pre-Review → IRB Review → Post-Review → Review Complete. (Modifications Required branches from IRB Review to Post-Review)

**History** | Funding | Documents | Snapshots

Filter by: Activity [v] Enter text to search for [ ] [ ] + Add Filter ✕ Clear All

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 IRB).

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

**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 Committee  
**IRB coordinator:**  
**Letter:** Correspondence\_for\_20-004.pdf(0.02)  
**Regulatory authority:** 2016 Requirements

**Next Steps**

- View Study
- Printer Version
- View Differences
- Create Modification/CR
- Report New Information

**History** | Funding | Contacts | Documents | Follow-on Submissions | Reviews | Snapshots

Filter by Activity [dropdown] Enter text to search for [input] [search icon] + Add Filter x Clear All

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

Pictured: Sample rendering of a principal investigators Study workspace for a HRC 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

**Next Steps**

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

**Assign Primary Contact**  
**Assign PI Proxy**  
**Manage Guest List**

## 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:** 2018 Requirements  
**Study:** 20-005

```

  graph LR
    A[Invitation Pending] --> B[Awaiting Site Materials]
    B --> C[Pre-Review]
    C --> D[IRB Review]
    D --> E[Post-Review]
    E --> F[Review Complete]
    E --> G[Modifications Required]
    G --> E
  
```

**History** | Funding | Documents | Follow-on Submissions | Snapshots

Filter by: Activity [v] Enter text to search for [ ] [Q] + Add Filter x Clear All

Activity	Author	Activity Date
Letter Sent	Tan, Vanessa	2/6/2020 1:55 PM
Correspondence_for_SITE00000868.pdf		
Finalized Documents	Tan, Vanessa	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).



# 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

**20-007: MSS Bacon - UNM pSite**

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

Principal investigator: Principal Investigator  
Submission type: IRB Site  
IRB office: UNM HSC Human Research Review Committee  
IRB coordinator:  
Primary contact:  
Regulatory authority: 2018 Requirements  
External study ID:  
PI proxies:  
Institution: Michigan Medicine

**Next Steps**

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

Assign Primary Contact  
Assign PI Proxy  
Manage Ancillary Reviews  
Manage Guest List

**History** | Funding | Contacts | Documents | Follow-on Submissions | Reviews | ...

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

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

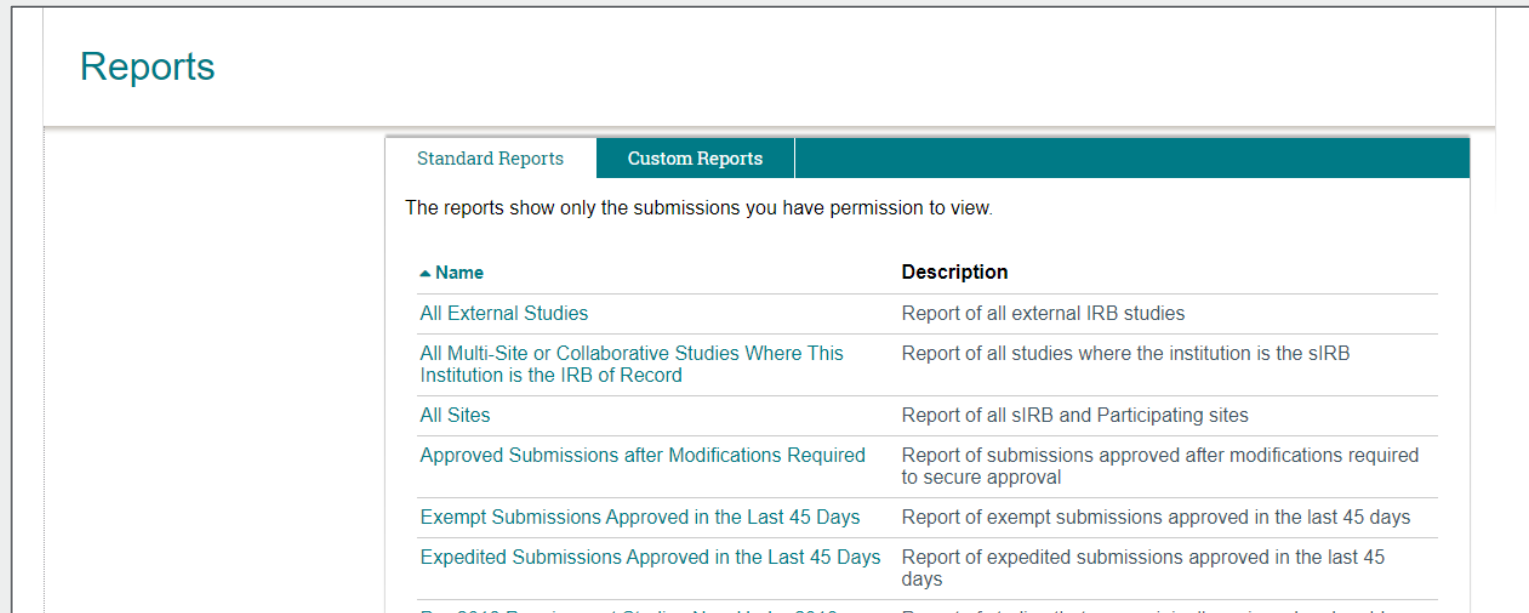
Pictured: Sample rendering of a principal investigators IRB Site workspace for an internal participating site (i.e., UNM HSC is the pSite) for an external approved multi-site new study.

Next: IRB Reports



# IRB Reports |

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



The screenshot displays the 'Reports' section of the IRB Reports workspace. It features two tabs: 'Standard Reports' and 'Custom Reports', with 'Custom Reports' currently selected. Below the tabs, a message states: 'The reports show only the submissions you have permission to view.' A table lists various report categories with their descriptions.

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



# IRB Library |

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

The screenshot shows the IRB Library workspace. On the left is a sidebar with navigation options: Submissions, Meetings, Library, Reports, Help Center, Shortcuts, My Inbox, Meetings, Reports, and Help. The main content area has a header 'Library' and a set of tabs: Standard Operating Procedures, General, Worksheets, Checklists, Templates, and an ellipsis menu. The 'Standard Operating Procedures' tab is active, displaying a table of SOPs. An 'Export' button is located in the top right of the table area.

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





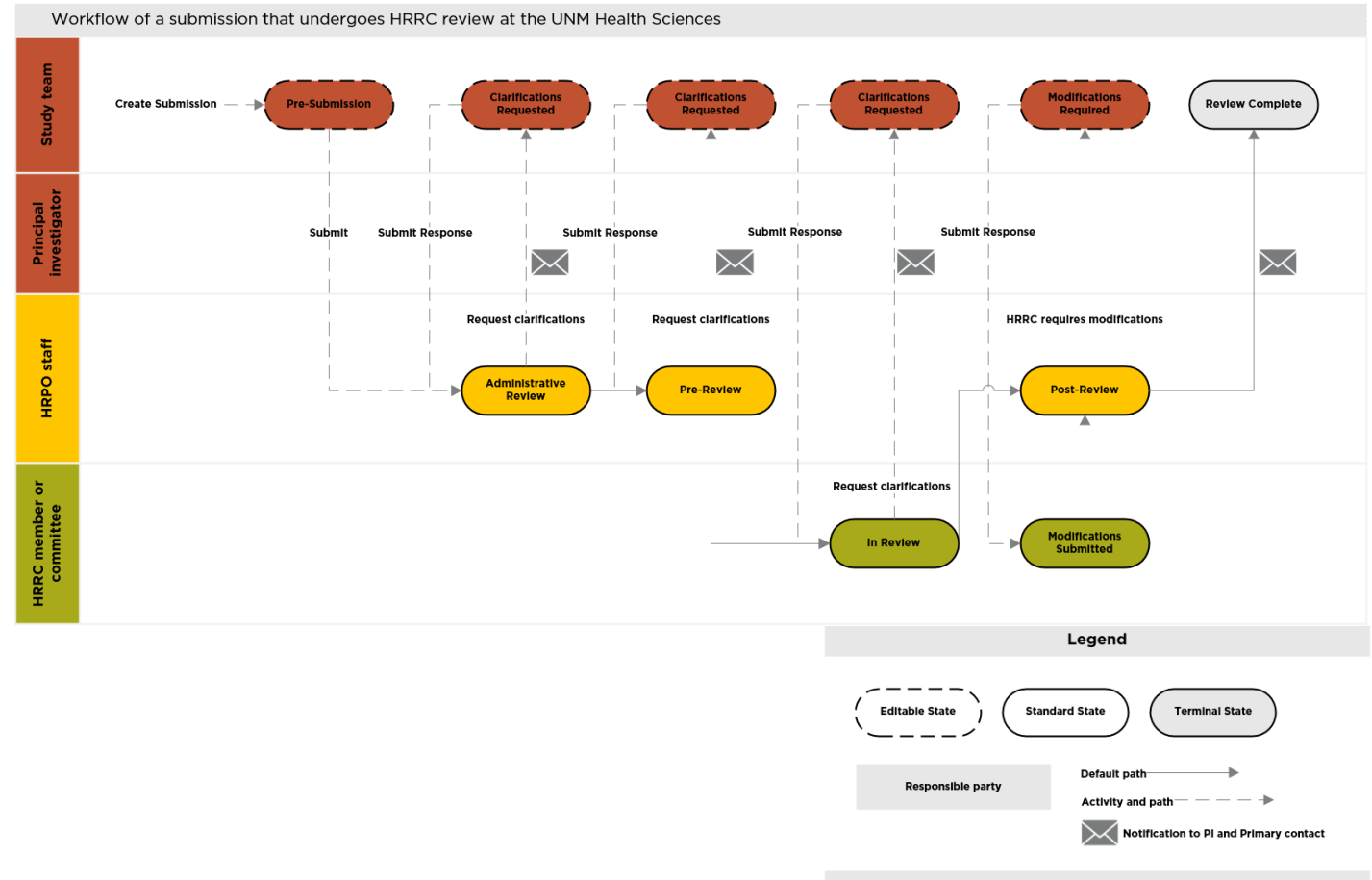
# Walk-through a new single-site study submission

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](mailto: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 browser window titled "You Are Here: IRB Submission". The page is titled "Basic Study Information" and contains the following fields:

- 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 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 alcafra 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" (unselected) and "Single-site study" (selected). A "Clear" link is below.
- 5. \* Will an external IRB act as the IRB of record for this study?** Radio buttons for "Yes" (unselected) and "No" (selected). A "Clear" link is below.
- 6. \* Local principal investigator:** A dropdown menu with "Principal Investigator" selected.

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.

- From the **submission workspace**, click the **Submit** link.
  - The system will check the submission for errors and allow you to complete missing information.
- 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 proxy:  
IRB office: IRB coordin

**Next Steps**

- Edit Study
- Enter Version
- View Differences

Submit

Assign Primary Contact

Assign PI Proxy

Manage Ancillary Reviews

Manage Guest List

Add Comment

Copy Submission

Discard

(UNM 8.2 IRB - STUDY - In-Review)

History | Funding | Contacts | Documents | Reviews

Filter by <sup>?</sup> 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**.

The screenshot shows a workspace for 'STUDY00004138: SS Bacon' in the 'Administrative Review' state. It includes a sidebar with 'Next Steps' (View Study, Enter Version, View Differences, Add Comment, Withdraw, Discard) and a main area with tabs for History, Funding, Contacts, Documents, and Reviews. A table shows activity logs for 'Submitted' and 'Study Created'.

Activity	Author	Time
Submitted	Investigator, Principal	1/30/2020 1:23 PM
Study Created	Investigator, Principal	1/30/2020 1:23 PM

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

**Next: Respond to requested clarifications**





## 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**.

The screenshot shows the submission workspace for STUDY00004138: SS Bacon. The page is titled "Clarifications Requested (Admin Review)". Key information includes:
 

- Principal Investigator:** Principal Investigator
- Submission type:** Initial Study
- Primary contact:** (blank)
- PI proxy:** (blank)
- IRB office:** UNM HS
- IRB coordinator:** (blank)
- Entered IRB:** 1/30/2020 1:23 PM
- Last updated:** 1/31/2020 10:24 AM

 The "Next Steps" section includes buttons for "Edit Study", "Printer Version", and "View Differences", along with links for "Submit Response", "Add Comment", "Withdraw", and "Discard". The "History" tab is active, showing a list of activities:
 

- Requested Clarification for Administrative Review (Author: Tan, Vanessa)
- Submitted (Author: Investigator, F)
- Study Created (Author: Investigator, F)

 A detailed description of the requested clarification is visible: "Pancetta pork loin shoulder spare ribs picanha pork chop chislic. Strip steak r chicken tenderloin, jowl tri-tip andouille spare ribs pastrami chislic tongue. And prosciutto meatball swine kevin tenderloin ball tip turducken bresaola hambur".

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

**Pre-Review**

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

**20-004: SS Bacon**

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

IRB office:  
IRB coordin

**Next Steps**

- View Study
- Print Version
- View Differences
- Assign Primary Contact
- Assign PI Proxy
- Manage Ancillary Reviews
- Manage Guest List
- Add Comment
- Copy Submission
- Withdraw
- Discard

History | Funding | Contacts | Documents | Reviews

Filter by <sup>?</sup> Activity

Activity	Auth
Submitted Administrative Review	Tan, V
Response Submitted	Invest
Requested Clarification for Administrative Review	Tan, V
Submitted	Invest

Pancetta pork loin shoulder spare ribs picanha pork chop chislic. Strip steak tenderloin, jowl tri-tip andouille spare ribs pastrami chislic tongue. Andouille b kevin tenderloin ball tip turducken bresaola hamburger burdoggen.

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)**

20-004: SS Bacon

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

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

IRB office:  
IRB coordin

**Next Steps**

- Edit Study
- Print Version
- View Differences

Submit Response

Assign Primary Contact

Assign PI Proxy

Manage Ancillary Reviews

Manage Guest List

Add Comment

Copy Submission

Withdraw

Discard

Pre-Submission → Pre-Review → IRB Review

Clarification Requested (highlighted) → Clarification Requested

History | Funding | Contacts | Documents | Reviews

Filter by: Activity

Activity	Auth
← 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 leberka strip steak bacon capicola ground round. Falback ham hock alcatra meatbal	
→ Submitted Administrative Review	Tan,
→ Response Submitted	Inves
← 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.

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

**Next: Respond to requested clarifications**







## 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**.

The screenshot shows a submission workspace for a study titled "20-004: SS Bacon". The status 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 proxies:  
 IRB office: IRB coordinator  
 Regulatory auth:

**Next Steps:**  
 Edit Study  
 Enter Version  
 View Differences

**Workflow Diagram:**  
 Pre-Submission → Pre-Review → IRB Review → Clarification Requested → Clarification Requested → IRB Review

**History Table:**

Activity	Auth
Clarification Requested by Designated Reviewer	Tan,
Response Submitted	Inves
Clarification Requested	Tan,
Submitted Administrative Review	Tan,

**Activity Log:**  
 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 leberka strip steak bacon capicola ground round. Fatback ham hock alcatra meatball

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

Submit Response

Assign Primary Contact

Assign PI Proxy

Manage Ancillary Reviews

Manage Guest List

Add Comment

Copy Submission

Discard

(UNM 8.2 IRB - STUDY - In-Review)

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

Filter by <sup>?</sup> Activity

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 of filet mignon tongue turducken. Kevin pastrami t-bone ribeye jerky tail ground corned beef ham pastrami. Pork cuoim shoulder ham hock sausage leberkas.

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

Next: Modifications Submitted and 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.

**Modifications Submitted**

20-004: SS Bacon

Entered IRB: 1/31/2020 10:39 AM  
Last updated: 1/31/2020 1:56 PM

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

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

History: Funding, Contacts, Documents, Reviews

Filter by: Activity [dropdown] Enter text to search for

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**

20-004: SS Bacon

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:  
PI proxies:

IRB office:  
IRB coordinator:  
Regulatory autho

**Next Steps**

- View Study
- Enter Version
- View Differences

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

History: Funding, Contacts, Documents, Reviews

Filter by: Activity [dropdown] Enter text to search for

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

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



**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 Re  
**IRB coordinator:**  
**Letter:** Correspondence\_for\_20-004.pdf  
**Regulatory authority:** 2018 Requirements

**Next Steps**

- View Study
- Print 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

(UNM 6.2 IRB - STUDY - Review Complete)

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

Filter by Activity

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 prosciutto filet 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 investigator's Study workspace in “Approved”



# 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](mailto: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](mailto: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](mailto:FConant@salud.unm.edu)**

