

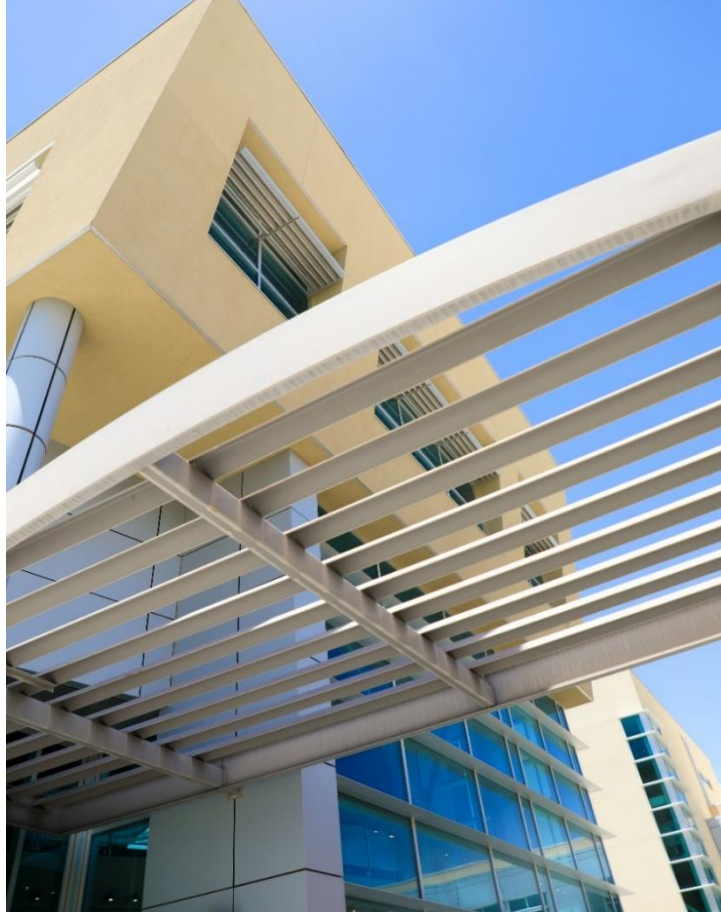
Huron IRB 10.5 Self-Guided Training for Investigators

- 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 26, 2025



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.

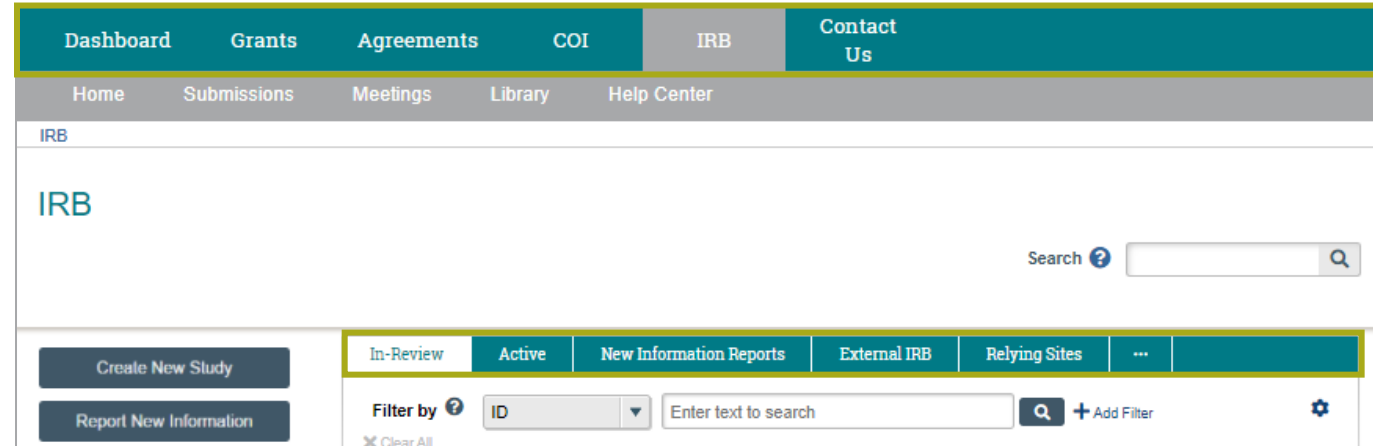
- As a guest on a study, you may view the study.
- As a primary contact on a study, you may view the study and receive notifications related to the study and follow-on submissions.
- As a study team member, you may create a new study submission, edit the submission, and attach documents. You may also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

Dashboard Grants Agreements COI IRB Contact Us

Home Submissions Meetings Library Help Center

IRB > Home

Subscribe

Home

Announcements

1/31/2021 - Protocol templates updated

Hello UNM HSC Researchers:

We are pleased to announce the release of revised protocol templates. They have been revised to enhance clarity, add missing elements and provide much improved, more robust guidance verbiage including examples.

- ▶ Home
 - ▶ How-Tos
 - ▶ FAQs
- ▶ Submissions
- ▶ Meetings
- ▶ Library
- ▶ Help Center

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

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

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



IRB |

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

The screenshot shows the IRB workspace interface. At the top left, there is a search bar with a magnifying glass icon and a question mark. Below the search bar, there are several tabs: "In-Review", "Active", "New Information Reports", "External IRB", "Relying Sites", and an ellipsis menu. Below the tabs, there is a "Filter by" dropdown menu set to "ID", a search input field with the placeholder text "Enter text to search", and a gear icon. Below the search input, there are buttons for "+ Add Filter" and "X Clear All". Below the filter section, there is a table with the following columns: "ID", "Name", "Date Modified", "State", "PI First Name", "PI Last Name", "Coordinator First Name", "Coordinator Last Name", and "Submission Type". The table contains one row of data: "STUDY00005334", "Test Study", "3/8/2022 11:14 AM", "Pre-Submission", "Elvis", "Presley", "", "", "Initial Study".

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

Activities you may perform:

- Create New Study
- Report New Information

Reports you may run:

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

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
- Conv. 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

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

Pre-Submission

Last updated: 1/16/2020 3:10 PM

STUDY00004137: MSS Bacon

Principal investigator: Principal Investigator **IRB office:** UNM HSC Human Research Review Committee
Submission type: Initial Study **IRB coordinator:**
Primary contact:
PI proxies:

Next Steps

Edit Study
 Printer Version
 View Differences

Submit
 Manage Participating Sites
 Assign Primary Contact
 Assign PI Proxy
 Manage Ancillary Reviews
 Manage Guest List
 Add Comment

Flowchart: Pre-Submission → Pre-Review → IRB Review → Post-Review → Review Complete. Clarification Requested branches off from Pre-Review, IRB Review, and Post-Review. Modifications Required branches off from Post-Review.

Navigation Tabs: History | Funding | Contacts | Documents | Sites | Reviews | Snapshots

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

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

- 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

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

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

Site tabs: History, Funding, Documents, Snapshots

Activity Log:

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

Approved

20-004: SS Bacon

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

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: 2018 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 | Enter text to search for | + Add Filter | x Clear All

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

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: 20-005
 Study: 20-005

Next Steps

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

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

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

• Study ID: Name – HRRC site number, followed by the site name for the study

• Letter - View/download the HRRC determination letter.

• Study – Access the HRRC study workspace.

Site tabs:

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

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



IRB Site

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

At a glance, you can see:

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

Activities you may perform:

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

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

Active

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

20-007: MSS Bacon - UNM pSite

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

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**

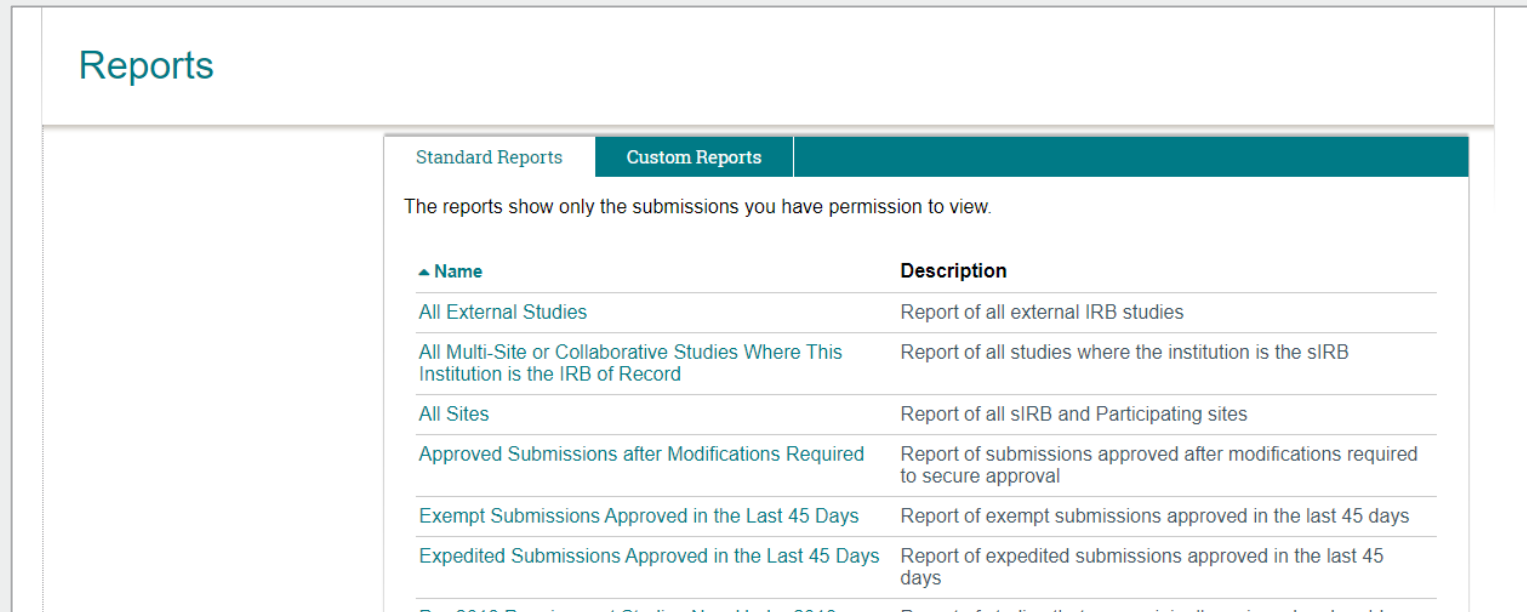
Activity	Author	Activity Date
<input checked="" type="checkbox"/> Reliance Confirmed		2/6/2020 3:44 PM
<input type="checkbox"/> Submitted Administrative Review		2/6/2020 3:41 PM
<input type="checkbox"/> Response Submitted		2/6/2020 3:41 PM
<input type="checkbox"/> Requested Clarification for Administrative Review		2/6/2020 3:41 PM

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.



IRB Reports |

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



The screenshot shows a web interface titled "Reports". It features two tabs: "Standard Reports" and "Custom Reports", with "Custom Reports" being the active tab. Below the tabs, a message states: "The reports show only the submissions you have permission to view." A table follows, listing various report categories and 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
Pre-2010 Requirement 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.

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 is titled 'Library' and has a tabbed interface with 'Standard Operating Procedures' selected. Below the tabs is a table of SOPs with columns for 'Name' and 'Document'. 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



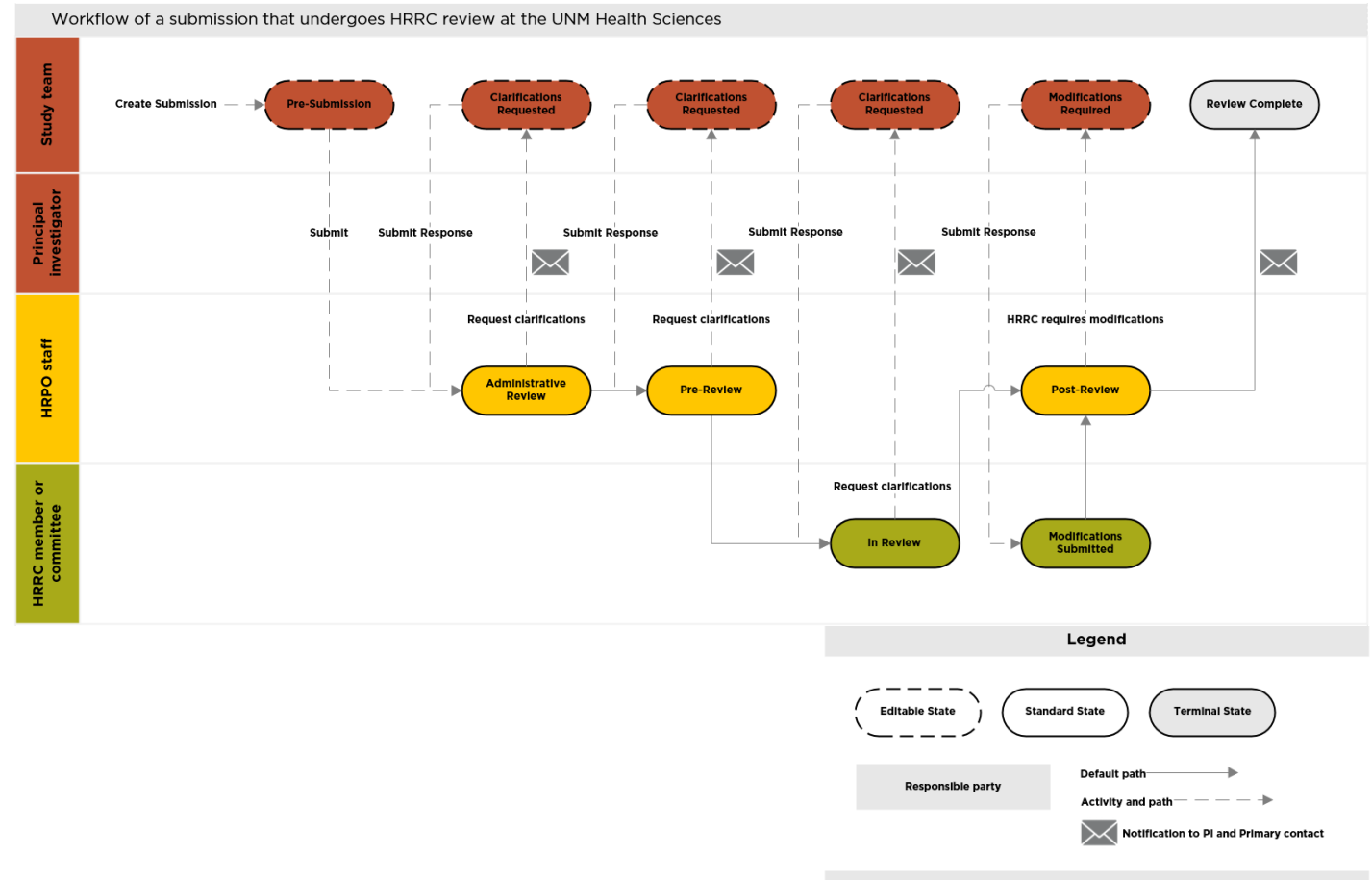
Walk-through a new single-site study submission

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 browser window titled "You Are Here: IRB Submission". The browser's address bar shows "IRB Submission" and navigation buttons for "Back", "Save", "Print", and "Continue". The main content area is titled "Basic Study Information" and contains six numbered 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 alcatra 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 and a search icon.

Pictured: Sample rendering of the Basic Study Information form



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 8.2 IRB - STUDY - In-Review)

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”



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

STUDY00004138: SS Bacon

Principal Investigator: Principal Investigator IRB office: UNM H
Submission type: Initial Study IRB coordinator:
Primary contact:
PI proxies:

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

Next Steps

View Study
Printer Version
View Differences

Add Comment
Withdraw
Discard

(UNM 8.2 IRB - STUDY - In-Review)

History Funding Contacts Documents Reviews

Filter by Activity Enter text to search for

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





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.

Clarifications Requested (Admin Review)

STUDY00004138: SS Bacon

Principal Investigator: Principal Investigator IRB office: UNM HS
 Submission type: Initial Study IRB coordinator:
 Primary contact:
 PI proxies:

Entered IRB: 1/30/2020 1:23 PM
Last updated: 1/31/2020 10:24 AM

Next Steps

Edit Study

Printer Version

View Differences

→ [Submit Response](#)

☞ [Add Comment](#)

← [Withdraw](#)

⊗ [Discard](#)

(UNM 5.2 IRB - STUDY - In-Review)

History
Funding
Contacts
Documents
Reviews

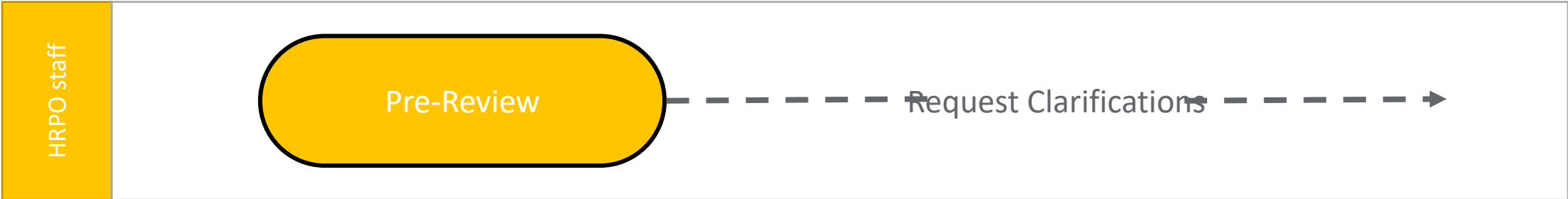
Filter by ? Activity ▼

Activity	Author
← Requested Clarification for Administrative Review	
Pancetta pork loin shoulder spare ribs picanha pork chop chislic. Strip steak n chicken tenderloin, jowl tri-tip andouille spare ribs pastrami chislic tongue. And prosciutto meatball swine kevin tenderloin ball tip turducken bresaola hamburger	
↶ Submitted	Investigator, F
📄 Study Created	Investigator, F

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

Next: Pre-Review





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

(UNM 6.2 IRB - STUDY - In-Review)

History | Funding | Contacts | Documents | Reviews

Filter by [?] Activity

Activity	Auth
Submitted Administrative Review	Tan,
Response Submitted	Inves
Requested Clarification for Administrative Review	Tan,
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.	
Submitted	Inves

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

Next: Respond to requested clarifications



Principal investigator



Clarification Requested
(Pre- Review)

Submit Response

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

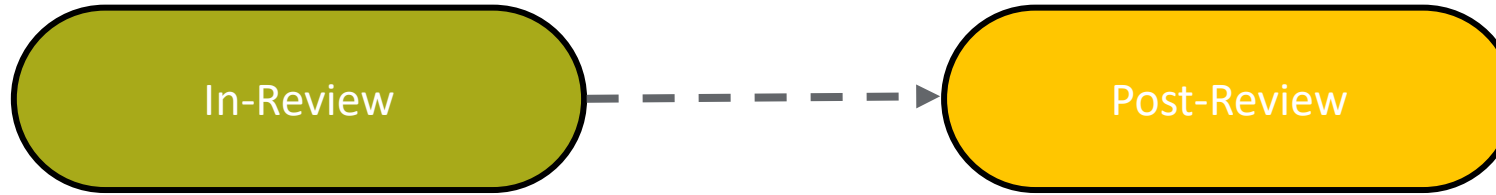
1. Refer to the History tab to review the details of the request.
2. Click the Edit Study button to open the study record and make requested changes.
3. After you have addressed all issues, click the Submit Response link.
4. Click the OK button to submit your response.
 - The system will advance the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

The screenshot shows a submission workspace for '20-004: SS Bacon'. The status is 'Clarification Requested (Pre-Review)'. Key details include: Principal Investigator: Principal Investigator, Submission type: Initial Study, Primary contact, and PI proxies. The workspace includes a 'Next Steps' section with buttons for 'Edit Study', 'Printer Version', and 'View Differences'. A 'Submit Response' button is also present. A flowchart shows the process: Pre-Submission -> Pre-Review -> IRB Review -> Clarification Requested -> Pre-Review. The 'History' tab is active, showing a list of activities: Clarification Requested, Submitted Administrative Review, Response Submitted, and Requested Clarification for Administrative Review.

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.

Clarification Requested (Designated Review)

20-004: SS Bacon

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

IRB office:
IRB coordinator:
Regulatory authority:

Entered IRB: 1/31/2020 10:39 AM
Last updated: 1/31/2020 1:28 PM

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

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

Filter by ? Activity ▼

Activity	Auth
← Clarification Requested by Designated Reviewer	Tan,
→ Response Submitted	Inve
← 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. Fatback ham hock alcatra meatba	
➔ Submitted Administrative Review	Tan,

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

Next: Respond to required modifications



Principal investigator



Modifications Required

Submit Response

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

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

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

Submit Response

History Funding Contacts Documents Reviews

Filter by Activity

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

Chuck meatloaf sausage picanha frankfurter, salami jowl meatball beef ham ch filet mignon tongue turducken. Kevin pastrami t-bone ribeye jerky tail ground round corned beef ham pastrami. Pork cupim 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'. The left screenshot is titled 'Modifications Submitted' and the right is 'Post-Review'. Both show a flowchart with stages: Pre-Submission, Pre-Review, IRB Review, and Clarification Requested. The 'Modifications Submitted' view includes a 'Next Steps' section with buttons for 'View Study', 'Enter Version', and 'View Differences', and a list of actions like 'Assign Primary Contact' and 'Manage Ancillary Reviews'. The 'Post-Review' view includes buttons for 'View Study', 'Enter Version', and 'View Differences', and a list of actions like 'Assign Primary Contact' and 'Manage Guest List'. Both views show a 'History' table with columns for Activity, Author, and Date.

Activity	Author	Date
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	

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 proxy:

IRB office: UNM HSC Human Research Rev
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 8.2 IRB - STUDY - Review Complete)

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

Filter by **Activity** **Q** **+ 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 10:43
Clarification Requested	Tan, Vanessa	1/31/2020 10:4
Chuck meatloaf sausage picanha frankfurter, salami jowl meatball beef ham chistic doner. Drumstick andouille prosci 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 10:39

Pictured: Sample rendering of a principal investigators 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:

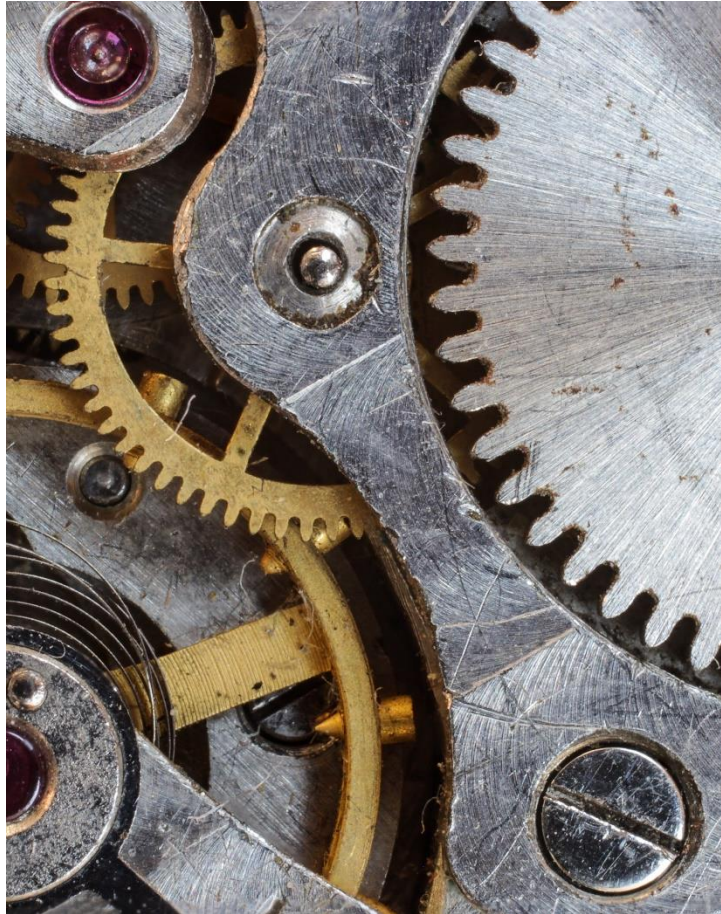
UNM Health Sciences Human Research Protections Office (HRPO)

HSC-HRPO@salud.unm.edu

(505) 272-1129



Huron IRB Support



If you experience technical issues or cannot find an organization in the system, contact UNM HSC OOR IT Services

OOR-ITServices@salud.unm.edu