HEALTH SCIENCES
OFFICE OF RESEARCH

HUMAN RESEARCH PROTECTIONS PROGRAM

Huron IRB Investigator Submission Guide

This document, Huron IRB Investigator Submission Guide, is designed to guide you through the human subjects research submission process specific to the UNM Health Sciences.

Last updated: June 7, 2023 Huron IRB version: 10.5

Navigation and Basic Tasks

After logging into the Huron IRB system, navigate to the **Dashboard** tab, which is the starting point for finding items and performing many basic tasks.

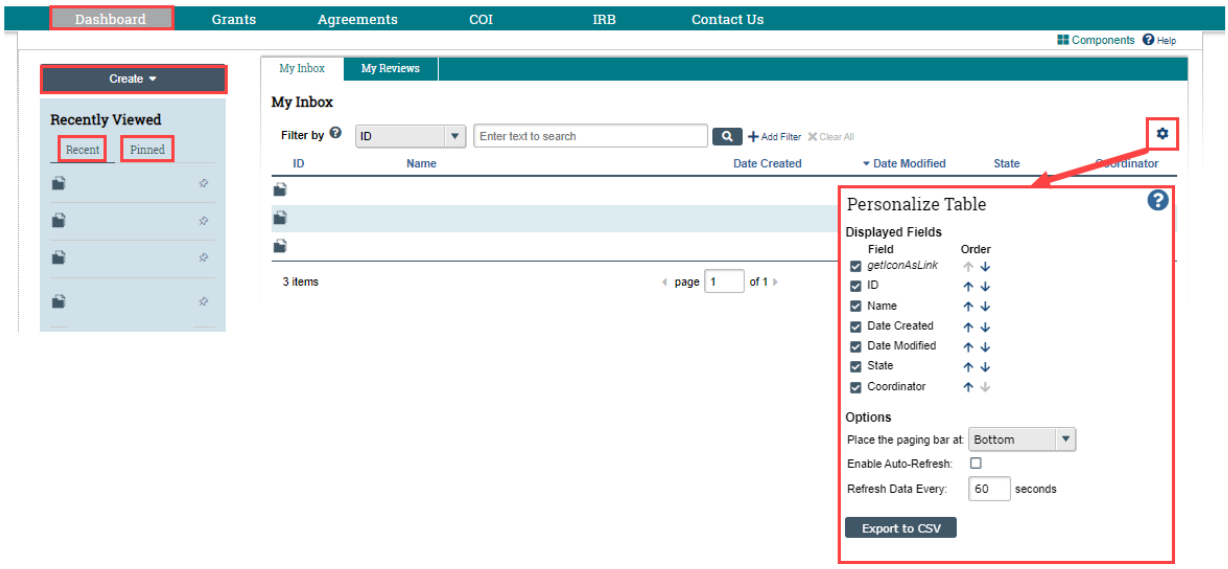
To find key items

From the **Dashboard**, you will see:

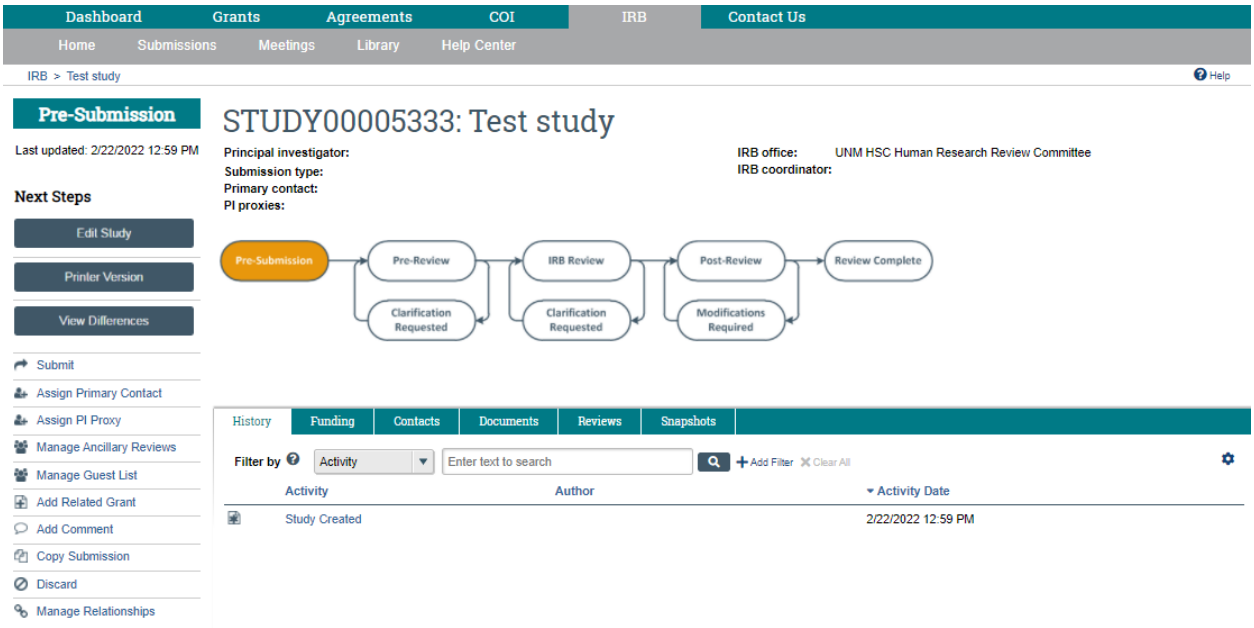
- **My Inbox:** Items that require action
- **My Reviews:** Items assigned for review.

Subset Items

- **Create Menu and Buttons:** Actions that can be performed. The menu will not show if you do not have authorization to view.
- **Recently Viewed:**
  - **Recent:** The last items viewed. Scroll through this list to find an item recently worked on.
  - **Pinned:** You can pin the items in Recently Viewed section for quick access.
- **Personalize Table:** You can alter the tables displayed on the dashboard by using the Personalize Table gear icon.



Create, edit, and submit a new submission



Step 1: Create and edit submission

A study team member or principal investigator may create a new submission. While a submission is in the “Pre-Submission” state, the study team may return to the submission at any time to continue editing the details. Follow the instructions for the appropriate submission type in “Step 1” to enter your submission into the system (New Study, pg. 4-16; Study Modification, pg. 17-18; Site Modification, pg. 19; Continuing Review / Study Closure, pg. 20-21).

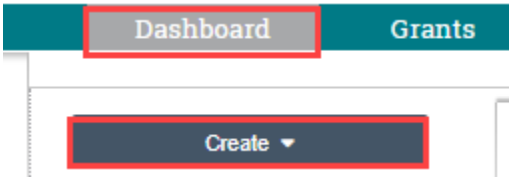
Step 2: Submit

The principal investigator may submit any submission. The PI Proxy may submit follow-on submissions (e.g., modification or continuing review) for an approved study. For all new submissions, follow the instructions in “Step 2” to submit a submission (pg. 21).

Before you begin:

- Use the appropriate **submission checklist** (pg. 42-58) to gather files and information about your submission.
  - Acceptable document file types include: .doc; .docx; .pdf; .mp3; .mp4
  - Final documents should not contain tracked changes or comments.
  - Revised documents must contain tracked changes.

Step 1. Create and edit a New Study submission



- From the **Dashboard** tab or **IRB** tab, click the **Create New Study** button to create a new study submission.
- Complete the pages and click the **Continue** button to advance to the next page.

Pages of a study record may include:

Basic Study Information	
Required for a new study submission. Your responses will determine whether the study will be locally or externally reviewed, and whether it is a single- or multi-site study. Your responses will also determine which additional questions or pages need to be completed.	
*** Title of study:**	Provide the full name of the study.
*** Short title:**	Provide the abbreviated name of the study.
*** Brief description:**	Provide the abstract or brief description of the study.
*** What kind of study is this?**	Select the appropriate response to indicate the type of study: ○ **Single-site study** ○ **Multi-site or collaborative study**
*** Will an external IRB act as the IRB of record for this study?**	Select the appropriate response to indicate whether the study will be locally or externally reviewed: ○ **Yes** – *if selected for single-site study, the submission will convert to an external submission, the External IRB page and the question, Lead principal investigator, will appear. If selected for a multi-site study, the Basic Site Information page will appear in addition to the above.* ○ **No** – *if selected for a multi-site study, the question, Will your IRB act as the single IRB of record for other participating sites, will appear.*
*** Will your IRB act as the single IRB of record for this study?** *Multi-site study; no external IRB*	Select the appropriate response to indicate if UNM HSC is the lead site or a participating site of a multi-site study: ○ **Yes** – *if selected, the submission will remain a new multi-site study submission and you will be able to add participating sites from the submission workspace.* ○ **No** – *if selected, the submission will convert to a participating site submission.*
Lead principal investigator: *Multi-site external study*	Leave blank.
*** Local principal investigator:** *Person must have an active IRB account.* • *Check spelling and spacing*	The person who created the submission will be listed as the principal investigator. If this is correct, do not change the person. If you need to change the person: □ Click the **[…]** button to open a “Select Person” window. □ Use the filter to find the person by last name or first name and click the **Go** button to populate results.

• *Add a percent, %, to the beginning of the word to populate all names with those characters.*	□ Find the person and click the **radio** button next to the name. □ Click the **OK** button to close the "Select Person" window and return to the study page.

*** Attach the protocol:**	Add the protocol: □ Click the **+Add** button to open the "Add Attachment" window. □ *** File to attach:** Click the **Choose File** button to open a "Folder browser" window to allow you to find and open the document. Ensure the title of your document includes the type of document and the version date. The version date must be the same version date within the body or footer of the document. Example: Protocol_ver 5-26-2020 □ **Name:** You may leave this blank or enter a name to override the filename of the document. □ **Version number:** You may leave this blank or enter a number to override the system version of the document. □ Click the **OK and Add Another** button to attach another document *OR* click the **OK** button to close the "Add Attachment" window and return to the study page.

Basic Local Site Information	
Required for a multi-site external new study submission.	
*** Brief description of activities this site will perform:**	Provide a brief summary of the activities to be performed at this site.

External IRB	
Required for an external new study submission.	
*** External IRB:** *Organization must exist in the system.* • *Check spelling and spacing* • *Add a percent, %, to the beginning of the word to populate all organizations with those characters.* If you cannot find an institution, contact the IRB account manager or administrator to add the institution.	Indicate the institution that will serve as the IRB of record: □ Click the **[…]** button to open a "Select IRB Institutional Profile" window. □ Use the filter to find the institution and click the **Go** button to populate results. □ Find the institution and click the **radio** button next to the name. □ Click the **OK** button to close the "Select IRB Institutional Profile" window and return to the study page.
External study ID:	May leave blank or provide the identification number assigned by the external IRB.

Specify the reason the study should be reviewed by an external IRB:	May leave blank or provide the justification for using an external IRB to manage the study.

Study Funding Sources	
Required for a new study submission.	
*** Has this project been submitted to the UNM Health Sciences Sponsored Projects Office (SPO)?**	Select the appropriate response to indicate if this study is a sponsored project. Select "yes" if the funding proposal was submitted to the UNM Health Sciences Sponsored Projects Office (SPO). ○ **Yes** ○ **No**
*** Is this project a clinical trial:**	Select the appropriate response to indicate if this study is a clinical trial – refer to the *Investigator Manual* for the definition: ○ **Yes** – *if selected, the question, Verification and/or authorization of payment for HRRC review fees for clinical trial, will appear.* ○ **No**
*** Identify each organization supplying funding for this study:** *Organization must exist in the system.* • *Check spelling and spacing* • *Add a percent, %, to the beginning of the word to populate all organizations with those characters.* If you cannot find an organization, contact the IRB account manager or administrator to add the organization.	Add an organization: □ Click the **+ Add** button to open an "Add Funding Source" window. □ **Funding organization:** □ *If the study is not funded:* type *No Aff* into the text box to populate a list and select **No Affiliated Company**. □ *If the study is funded:* add a funding source, click the **[…]** button to open the "Select Organization" window. □ Use the filter to find the organization and click the **Go** button to populate results. □ Find the organization and click the **radio** button next to the name. □ Click the **OK** button to close the "Select Organization" window and return to the "Add Funding Source" window. □ **Sponsor's funding ID:** May leave blank or provide the identification number assigned by the sponsor. □ **Grants office ID:** If applicable, provide the funding proposal number issued by the UNM Health Sciences Sponsored Projects Office (SPO). □ **Attach files:** If applicable, attach documents, such as a grant application, relevant to this funding source: □ Click the **+Add** button to open the "Add Attachment" window. □ *** File to attach:** Click the **Choose File** button to open a "Folder browser" window to allow you to find and open the document. □ **Name:** You may leave this blank or enter a name to override the filename of the document. □ **Version number:** You may leave this blank or enter a number to override the system version of the document. □ Click the **OK and Add Another** button to attach another document *OR* click the **OK** button to close the "Add Attachment" window and return to the "Add Funding Source" window. □ Click the **OK and Add Another** button to attach another funding source *OR* click the **OK** button to close the "Add Funding Source" window and return to the study page

*** Verification and/or authorization of payment for HRRC review fees for clinical trial.** *Clinical trial study*	Click the **checkbox** to agree to the terms.
Additional Local Funding Sources	
Appears on an external new study submission and a participating site submission. Complete if applicable (e.g., local site has additional funding sources that are different from the main study).	
Has this project been submitted to the UNM Health Sciences Sponsored Projects Office (SPO)?	Select the appropriate response to indicate if this study is a sponsored project. Select "yes" if the funding proposal was submitted to the UNM Health Sciences Sponsored Projects Office (SPO). ○ **Yes** ○ **No**
Is this project a clinical trial:	Select the appropriate response to indicate if this study is a clinical trial – refer to the *Investigator Manual* for the definition: ○ **Yes** – *if selected, the question, Verification and/or authorization of payment for HRRC review fees for clinical trial, will appear.* ○ **No**
Identify each organization supplying funding for this study: *Organization must exist in the system.* • *Check spelling and spacing* • *Add a percent, %, to the beginning of the word to populate all organizations with those characters.* If you cannot find an organization, contact the IRB account manager or administrator to add the organization.	Add an organization: □ Click the **+ Add** button to open an "Add Funding Source" window. □ **Funding organization:** □ *If NO additional local funding:* type *No Aff* into the text box to populate a list and select **No Affiliated Company**. □ *If additional local funding:* add a funding source, click the **[…]** button to open the "Select Organization" window. □ Use the filter to find the organization and click the **Go** button to populate results. □ Find the organization and click the **radio** button next to the name. □ Click the **OK** button to close the "Select Organization" window and return to the "Add Funding Source" window. □ **Sponsor's funding ID:** May leave blank or provide the identification number assigned by the sponsor. □ **Grants office ID:** If applicable, provide the funding proposal number issued by the UNM Health Sciences Sponsored Projects Office (SPO). □ **Attach files:** If applicable, attach documents, such as a grant application, relevant to this funding source: □ Click the **+Add** button to open the "Add Attachment" window. □ *** File to attach:** Click the **Choose File** button to open a "Folder browser" window to allow you to find and open the document. □ **Name:** You may leave this blank or enter a name to override the filename of the document. □ **Version number:** You may leave this blank or enter a number to override the system version the document. □ Click the **OK and Add Another** button to attach another document *OR* click the **OK** button to close the "Add Attachment" window and return to the "Add Funding Source" window.

	◻ Click the **OK and Add Another** button to attach another funding source *OR* click the **OK** button to close the "Add Funding Source" window and return to the study page
*** Verification and/or authorization of payment for HRRC review fees for clinical trial.** *Clinical trial study*	Click the **checkbox** to agree to the terms.

Local Study Team Members	
Required for a new study submission that includes a study team in addition to the local principal investigator. If the study does not include a study team, do not complete this page.	
Identify each additional person involved in the design, conduct, or reporting of the research AND authorized to access the study record: *Person must have an active IRB account.* • *Check spelling and spacing* • *Add a percent, %, to the beginning of the word to populate all names with those characters.*	Add a study team member: ◻ Click the **+Add** button to open the "Add Study Team Member" window. ◻ **Study team member:** Click the **[…]** button to open a "Select Person" window. ◻ Use the filter to find the person by last name or first name and click the **Go** button to populate results. ◻ Find the person and click the **radio** button next to the name. ◻ Click the **OK** button to close the "Select Person" window and return to the "Add Study Team Member" window. ◻ **Role in research:** Check the appropriate box(es) to indicate the person's role(s) in this study: ◻ **Co-Investigator** ◻ **Data Analyst** ◻ **Research Assistant** ◻ **Statistician** ◻ **Pharmacist** ◻ **Is the team member involved in the consent process?** Select the appropriate response to indicate if the person will or will not be involved in the consent process: ○ **Yes** ○ **No** ◻ Click the **OK and Add Another** button to add another study team member *OR* click the **OK** button to close the "Add Study Team Member" window and return to the study page.
List external team members: *E-mail address should reflect the team member's organization email.* *Organization must exist in the system.* • *Check spelling and spacing* • *Add a percent, %, to the beginning of the word to*	Add an external team member: ◻ Click the **+Add** button to open the "Add External Team Member" window. ◻ *** First Name:** Provide the first name of the person. ◻ *** Last Name:** Provide the last name of the person. ◻ *** E-Mail Address:** Provide the preferred e-mail address of the person. ◻ *** Organization:** Click the **[…]** button to open a "Select Organization" window. ◻ Use the filter to find the organization and click the **Go** button to populate results. ◻ Find the organization and click the **radio** button next to the name.

populate all organizations with those characters. If you cannot find an organization, contact the IRB account manager or administrator to add the organization.	▫ Click the **OK** button to close the "Select Organization" window and return to the "Add External Team Member" window. □ **Role in research:** Check the appropriate box(es) to indicate the person's role(s) in this study: ▫ **Co-Investigator** ▫ **Data Analyst** ▫ **Research Assistant** ▫ **Statistician** ▫ **Pharmacist** □ **Is the team member involved in the consent process?** Select the appropriate response to indicate if the person will or will not be involved in the consent process: ○ **Yes** ○ **No** □ Click the **OK and Add Another** button to add another study team member *OR* click the **OK** button to close the "Add External Team Member" window and return to the study page.

Study Scope	
Required for a new study submission. Your responses to this page will determine which questions or additional pages need to be completed	
*** Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition?**	Select the appropriate response to indicate if this study will use devices: ○ **Yes** – *if selected, the Drugs page will appear.* ○ **No**
*** Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?**	Select the appropriate response to indicate if this study will use drugs, biologics, or supplements: ○ **Yes** – *if selected, the Devices page will appear.* ○ **No**
*** Does the study involve exposure to ionizing radiation (e.g., X-rays, CT or CAT (computed tomography) scans, DXA scans, nuclear medicine scans, radionuclide scans)?**	Select the appropriate response to indicate if this study will use radiation: ○ **Yes** – *if selected, Attach the completed HRP Form(s) question will appear the system will flag your submission for the required HRP Form, HRP-223 Attachment for Human Research Protocol that utilizes ionizing radiation.* ○ **No**
*** Does the study specify the use of biological specimens, or specimen samples originally collected for research or non-research purposes, or**	Select the appropriate response to indicate if this study will use biological specimens: ○ **Yes** – *if selected, Attach the completed HRP Form(s) question will appear and the system will flag your submission for the required HRP Form, HRP-224 Biological Specimens Attachment.* ○ **No**

the use of archived specimens?	
*** Attach the completed HRP Form(s):** *Study involves exposure to ionizing radiation and/or use of biological specimens*	Add the HRP form: □ Click the **+Add** button to open the “Add Attachment” window. □ *** File to attach:** Click the **Choose File** button to open a “Folder browser” window to allow you to find and open the document. □ **Name:** You may leave this blank or enter a name to override the filename of the document. □ **Category:** Click the **down arrow** to reveal a list of attachment categories. Select the appropriate category to the document: ○ **HRP Form: Radiation Safety** – *HRP-223 Attachment for Human Research Protocol that utilizes ionizing radiation must be attached if the study involves exposure to ionizing radiation (e.g., X-rays, CT or CAT (computed tomography) scans, DXA scans, nuclear medicine scans, radionuclide scans).* ○ **HRP Form: Biological Specimens** – *HRP-224 Biological Specimens Attachment must be attached if the study specifies the use of biological specimens, or specimen samples originally collected for research or non-research purposes, or the use of archived specimens.* □ **Version number:** You may leave this blank or enter a number to override the system version the document. □ Click the **OK and Add Another** button to attach another document *OR* click the **OK** button to close the “Add Attachment” window and return to the study page.

Local UNM Research Locations	
Required for a new study submission that includes research locations where research activities will be conducted or overseen by the local investigator. Local research locations must include UNMHSC locations such as the department the PI is associated with.	
Identify local UNM locations where research activities will be conducted or overseen by the local investigator:	Add local UNM research locations: □ Click the **+ Add** button to open an "Add Research Location" window**.** □ **Select the UNM research location:** Click the **[…]** button to open the “Select Research Location” window. □ Use the filter to find the research location and click the **Go** button to populate results. If the location does not populate, try using the wildcard “%” when searching to pull all possible results e.g., %tricore. □ Find the research location and click the **radio** button next to the name. □ Click the **OK** button to close the “Select Research Location” window and return to the “Add Research Location” window. *Complete the following fields only if the research location does not populate from the above method:* If local UNM location cannot be found, please choose "Other" □ **Select the research location:** Select “Other” □ **Location name:** Provide the name of the UNM research location.

	◻ **Location adress:** Provide the adress for the UNM research location (optional). ◻ **Contact phone:** Provide the phone number of the contact. ◻ **Contact name:** Provide the contact name of the UNM research location (optional). ◻ **Contact phone:** Provide the phone number of the UNM research location (optional). ◻ **Contact email:** Provide the email of the UNM research location (optional). ◻ Click the **OK and Add Another** button to add another research location *OR* click the **OK** button to close the "Add Research Location" window and return to the study page.

Drugs	
Required for a new study submission that study that specifies the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition.	
*** List all drugs, biologics, foods, and dietary supplements to be used in the study:**	Add drugs, biologics, foods, and/or dietary supplements to be used in the study: ◻ Click the **+Add** button to open the "Add Drug" window. ◻ **Select the drug:** Click the **[…]** button to open the "Select Drug Selection" window. ◻ Use the filter to find the drug and click the **Go** button to populate results. ◻ Find the drug and click the **radio** button next to the name. ◻ Click the **OK** button to close the "Select Drug Selection" window and return to the "Add Drug" window. *Complete the following fields if the item does not populate from the above method:* ◻ **Generic name:** Provide the generic name. ◻ **Brand name:** Provide the brand name. ◻ ***Specify the type:** Select the drug type. ◻ **Attach files related to this drug:** Attach documents relevant to this drug: ◻ Click the **+Add** button to open the "Add Attachment" window. ◻ *** File to attach:** Click the **Choose File** button to open a "Folder browser" window to allow you to find and open the document. ◻ **Name:** You may leave this blank or enter a name to override the filename of the document. ◻ **Version number:** You may leave this blank or enter a number to override the system version of the document. ◻ Click the **OK and Add Another** button to attach another document *OR* click the **OK** button to close the "Add Attachment" window and return to the "Add Device" window. ◻ Click the **OK and Add Another** button to add another drug *OR* click the **OK** button to close the "Add Drug" window and return to the study page.

*** Will the study be conducted under any IND numbers?**	Select the appropriate response to indicate if the study will be conducted under any IND numbers. ○ **Yes** – *if selected, the question, Identify each IND, will appear.* ○ **No**
*** Identify each IND:**	Provide the IND information for a study to be conducted under any IND number: □ Click the **+Add** button to open the "Add IND Information" window. □ ***IND number:** Provide the IND number. □ ***Who holds the IND:** Select the appropriate response to indicate the entity that holds the IND: ○ **Sponsor** ○ **Investigator** ○ **Other** □ **If "Other," identify the IND holder:** Provide the entity that holds the IND. □ Click the **OK and Add Another** button to add another IND *OR* click the **OK** button to close the "Add IND Information" window and return to the study page.
Attach files:	Attach documents such as IND or other information not attached for a specific drug: □ Click the **+Add** button to open the "Add Attachment" window. □ *** File to attach:** Click the **Choose File** button to open a "Folder browser" window to allow you to find and open the document. □ **Name:** You may leave this blank or enter a name to override the filename of the document. □ **Version number:** You may leave this blank or enter a number to override the system version of the document. □ Click the **OK and Add Another** button to attach another document *OR* click the **OK** button to close the "Add Attachment" window and return to the study page

Devices	
Required for a new study submission that evaluates the safety or effectiveness of a device or use a humanitarian use device (HUD).	
*** Select each device the study will use as an HUD or evaluate for safety or effectiveness:**	Add devices to be used in the study: □ Click the **+Add** button to open the "Add Device" window. □ **Select the device:** Click the **[…]** button to open the "Select Device Selection" window. □ Use the filter to find the device and click the **Go** button to populate results. □ Find the device and click the **radio** button next to the name. □ Click the **OK** button to close the "Select Device Selection" window and return to the "Add Device" window. *Complete the following fields if the item does not populate from the above method:* □ **Device name:** Provide the name. □ **Is this a humanitarian use device (HUD):** Select the appropriate response for the device. ○ **Yes**

	○ **No** □ **Attach files related to this device:** Attach documents relevant to this device: □ Click the **+Add** button to open the "Add Attachment" window. □ *** File to attach:** Click the **Choose File** button to open a "Folder browser" window to allow you to find and open the document. □ **Name:** You may leave this blank or enter a name to override the filename of the document. □ **Version number:** You may leave this blank or enter a number to override the system version of the document. □ Click the **OK and Add Another** button to attach another document *OR* click the **OK** button to close the "Add Attachment" window and return to the "Add Device" window. □ Click the **OK and Add Another** button to add another device *OR* click the **OK** button to close the "Add Device" window and return to the study page.
*** Device exemptions applicable to this study:**	Select the appropriate response to indicate device exemptions applicable to this study: ○ **IDE number** – *if selected, the question, Identify each IND, will appear.* ○ **HDE number**– *if selected, the question, Identify each IND, will appear.* ○ **Claim of abbreviated IDE (nonsignificant risk device)** ○ **Exempt from IDE requirements**
*** Identify each IDE or HDE number:**	Provide the IDE or HDE information for a study to be conducted under any IDE or HDE number: □ Click the **+Add** button to open the "Add IDE and HDE Information" window. □ ***IDE or HDE number:** Provide the IDE or HDE number. □ ***Who holds the IND:** Select the appropriate response to indicate the entity that holds the IDE or HDE: ○ **Sponsor** ○ **Investigator** ○ **Other** □ **If "Other," identify the IDE or HDE holder:** Provide the entity that holds the IDE or HDE. □ Click the **OK and Add Another** button to add another IDE or HDE *OR* click the **OK** button to close the "Add IDE or HDE Information" window and return to the study page.
Attach files:	Attach documents such as IDE, HDE, or other information not attached for a specific device: □ Click the **+Add** button to open the "Add Attachment" window. □ *** File to attach:** Click the **Choose File** button to open a "Folder browser" window to allow you to find and open the document. □ **Name:** You may leave this blank or enter a name to override the filename of the document. □ **Version number:** You may leave this blank or enter a number to override the system version of the document.

	◻ Click the **OK and Add Another** button to attach another document *OR* click the **OK** button to close the "Add Attachment" window and return to the study page

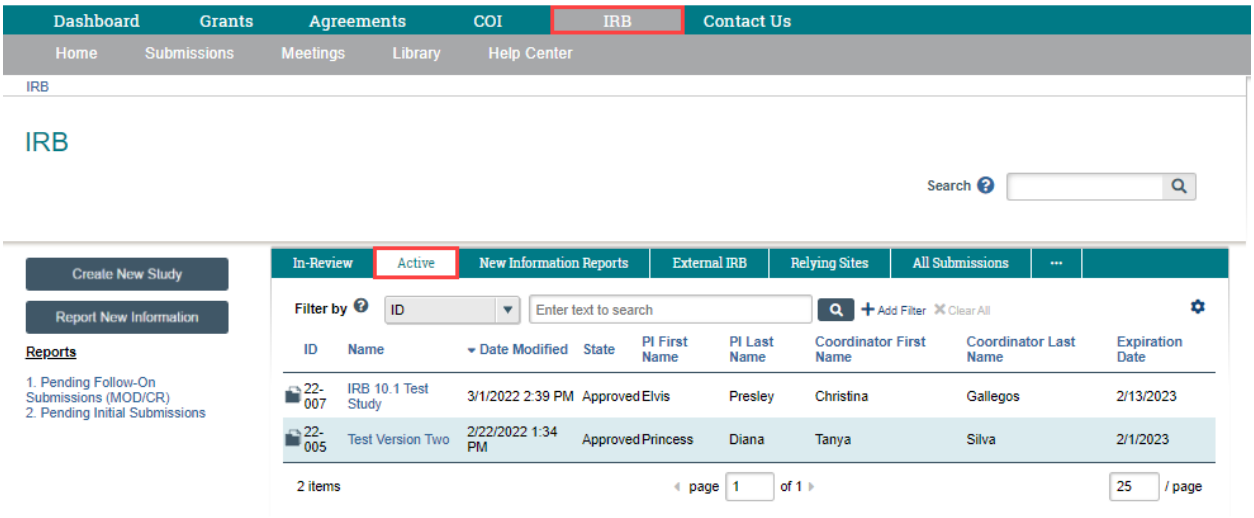
Study-Related Documents	
Required for a new multi-site study submission. Attach templates and other documents that are required study-wide and that participating sites will need to access.	
Consent forms:	Add consent form(s): ◻ Click the **+Add** button to open the "Add Attachment" window. ◻ *** File to attach:** Click the **Choose File** button to open a "Folder browser" window to allow you to find and open the document. ◻ **Name:** You may leave this blank or enter a name to override the filename of the document. ◻ **Version number:** You may leave this blank or enter a number to override the system version of the document. ◻ Click the **OK and Add Another** button to attach another document *OR* click the **OK** button to close the "Add Attachment" window and return to the study page.
Recruitment materials:	Add recruitment materials: ◻ Click the **+Add** button to open the "Add Attachment" window. ◻ *** File to attach:** Click the **Choose File** button to open a "Folder browser" window to allow you to find and open the document. ◻ **Name:** You may leave this blank or enter a name to override the filename of the document. ◻ **Version number:** You may leave this blank or enter a number to override the system version of the document. ◻ Click the **OK and Add Another** button to attach another document *OR* click the **OK** button to close the "Add Attachment" window and return to the study page.
Other attachments:	Add document(s): ◻ Click the **+Add** button to open the "Add Attachment" window. ◻ *** File to attach:** Click the **Choose File** button to open a "Folder browser" window to allow you to find and open the document. ◻ **Name:** You may leave this blank or enter a name to override the filename of the document. ◻ **Category:** Click the **down arrow** to reveal a list of attachment categories. Select the appropriate category to the document: ○ **HRP Form** ○ **Non-Publically Displayed Recruitment Materials** ○ **Training / Education Certificate** ○ **Other** ◻ **Version number:** You may leave this blank or enter a number to override the system version of the document. ◻ Click the **OK and Add Another** button to attach another document *OR* click the **OK** button to close the "Add Attachment" window and return to the study page.

Local Site Documents	
Required for a new study submission to attach documents to be used at the local site.	
Consent forms:	Add consent form(s): □ Click the **+Add** button to open the "Add Attachment" window. □ *** File to attach:** Click the **Choose File** button to open a "Folder browser" window to allow you to find and open the document. Ensure the title of your document includes the type of document and the version date. The version date must be the same version date within the body or footer of the document. Example: Consent_ver 5-26-2020 □ **Name:** You may leave this blank or enter a name to override the filename of the document. □ **Version number:** You may leave this blank or enter a number to override the system version of the document. □ Click the **OK and Add Another** button to attach another document *OR* click the **OK** button to close the "Add Attachment" window and return to the study page.
Recruitment materials:	Add recruitment materials: □ Click the **+Add** button to open the "Add Attachment" window. □ *** File to attach:** Click the **Choose File** button to open a "Folder browser" window to allow you to find and open the document. Ensure the title of your document includes the type of document and the version date. The version date must be the same version date within the body or footer of the document. Example: Poster_ver 5-26-2020 □ **Name:** You may leave this blank or enter a name to override the filename of the document. □ **Version number:** You may leave this blank or enter a number to override the system version of the document. □ Click the **OK and Add Another** button to attach another document *OR* click the **OK** button to close the "Add Attachment" window and return to the study page.
Other attachments:	Add document(s): □ Click the **+Add** button to open the "Add Attachment" window. □ *** File to attach:** Click the **Choose File** button to open a "Folder browser" window to allow you to find and open the document. □ **Name:** You may leave this blank or enter a name to override the filename of the document. □ **Category:** Click the **down arrow** to reveal a list of attachment categories. Select the appropriate category to the document: ○ **HRP Form** ○ **Non-Publically Displayed Recruitment Materials** ○ **Training / Education Certificate** ○ **Other** □ **Version number:** You may leave this blank or enter a number to override the system version of the document. □ Click the **OK and Add Another** button to attach another document *OR* click the **OK** button to close the "Add Attachment" window and return to the study page.

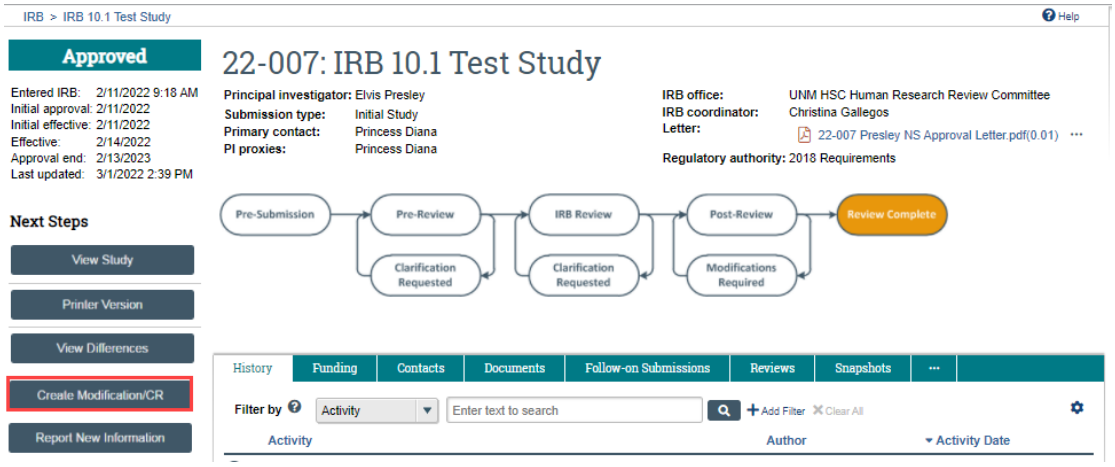
CTSC Submission	
Required for a new study submission.	
* **Is this a Clinical & Translational Science Center (CTSC) pilot project?**	Select the appropriate response to indicate if this study is a CTSC pilot project: ○ **Yes** – *if selected, the questions, When is the IRB submission deadline? and When is the IRB approval deadline for NIH review?, will appear.* ○ **No**
* **When is the IRB submission deadline?**	Click the **calendar** icon to select the date.
* **When is the IRB approval deadline for NIH review?**	Click the **calendar** icon to select the date.

□ On the final page, click the **Finish** button. This will save the new study submission and return you to the submission workspace. The submission is in the project state, **Pre-Submission**. **Go to Step 2. Submit** (pg. 21).

Step 1. Create and edit a Modification submission for a study



- From the **IRB** tab, click the **Active** tab to find your approved study. Click the **Name** of your approved study to open the **Study workspace**.
- From the **Study workspace**, click the **Create Modification/CR** button to create a new modification submission.



- Complete the pages and click the **Continue** button to advance to the next page.

Edits to information and documents in a study record may include: Refer to pg.4-16.

Pages of a modification submission to a study record include:

Modification / Continuing Review / Study Closure	
Required for a new modification submission to a study. Your response to the modification scope will determine which study pages will be available to edit.	
*** What is the purpose of this submission?**	Select **Modification / Update.**
Modification scope:	Check the appropriate box(es) to indicate the scope of the modification: □ **Study team member information** – *if checked, the "Local Study Team Members" page will be available to edit.* □ **Other parts of the study** – *if checked, all other study pages will be available to edit.*

Modification Information	
Required for a new modification submission to a study or site.	
Study enrollment status:	Check the appropriate box(es) to indicate study enrollment status: □ **No subjects have been enrolled to date** □ **Subjects are currently enrolled** □ **Study is permanently closed to enrollment** □ **All subjects have completed all study-related interventions** □ **Collection of private identifiable information is complete**
Notification of subjects:	Check the appropriate box(es) to indicate which subjects will be notified of these changes. □ **Current subjects will be notified of these changes** □ **Former subjects will be notified of these changes**
Summarize the modifications:	Provide a detailed summary of the modification.

Study Pages	
Local Study Team Members	□ Add, update, and/or remove information.
Basic Information – CTSC Submission	□ Change the principal investigator; Add, update, and/or remove information. • New document(s) – Click the **+Add** button. • Revised version of previously approved document(s) – Click the **Update** button. • Revised documents must include track changes reflecting the current revision only. • Remove document – Click the **X (delete)** button.

□ On the final page, click the **Finish** button. This will save the modification submission and return you to the submission workspace. The submission is in the project state, **Pre-Submission**. **Go to Step 2. Submit** (pg. 21).

Step 1. Create and edit a Modification submission for a site

- □ From the **IRB** tab, click the **Relying Sites** tab to find your active site. Click the **Name** of your active site to open the **Site workspace**.
- □ From the **Site workspace**, click the **Create Modification/Update** button to create a new modification submission.
- □ Complete the pages and click the **Continue** button to advance to the next page.

Edits to information and documents in a study record may include: Refer to pg. 23-25.

Pages of a modification submission to a site record include:

Modification Information	
Required for a new modification submission to a site.	
Study enrollment status:	Check the appropriate box(es) to indicate study enrollment status: □ **No subjects have been enrolled to date** □ **Subjects are currently enrolled** □ **Study is permanently closed to enrollment** □ **All subjects have completed all study-related interventions** □ **Collection of private identifiable information is complete**
Notification of subjects:	Check the appropriate box(es) to indicate which subjects will be notified of these changes. □ **Current subjects will be notified of these changes** □ **Former subjects will be notified of these changes**
Summarize the modifications:	Provide a detailed summary of the modification.

Site Pages	
Basic Site Information – Local Site Documents	□ Change the principal investigator; Add, update, and/or remove information. • New document(s) – Click the **+Add** button. • Revised version of previously approved document(s) – Click the **Update** button. • Revised documents must include track changes reflecting the current revision only. • Remove document – Click the **X (delete)** button.

- □ On the final page, click the **Finish** button. This will save the modification submission and return you to the submission workspace. The submission is in the project state, **Pre-Submission**. **Go to Step 2. Submit** (pg. 21).

Step 1. Create and edit a Continuing Review / Study Closure submission

- □ From the **IRB** tab, click the **Active** tab to find your approved study. Click the **Name** of your approved study to open the **Study workspace**.
- □ From the **Study workspace**, click the **Create Modification/CR** button to create a new modification submission.
- □ Complete the pages and click the **Continue** button to advance to the next page.

Pages of a continuing review / study closure include:

Modification / Continuing Review / Study Closure	
Required for a new continuing review / study closure submission.	
*** What is the purpose of this submission?**	Select **Continuing Review**.

Continuing Review / Study Closure Information	
Required for a new continuing review / study closure submission.	
*** Specify the enrollment totals:**	Provide values of subjects enrolled in the study. □ **Total subjects enrolled at this investigator's sites:** Provide the value. □ **Subjects enrolled at this investigator's sites since last continuing approval:** Provide the value. □ **Total subjects enrolled study-wide:** Provide the value.
Research milestones:	Check the appropriate box(es) to indicate progress: □ **Study is permanently closed to enrollment OR was never open for enrollment** □ **All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)** □ **Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)** □ **Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)** *If the top four boxes are checked, the submission will convert to a closure submission and the question, I acknowledge that this study will be closed, will appear.* □ **Remaining study activities are limited to data analysis** □ **Study remains active only for long-term follow-up of subjects**
* **I acknowledge that this study will be closed:** *Study closure submission*	Check the box to verify the study will be closed.
Check the items that are true since the last IRB approval for all sites involved in the study:	Check the appropriate box(es) to indicate reports/findings: □ **NO subjects experienced unexpected harm** □ **Anticipated adverse events have NOT taken place with greater frequency or severity than expected** □ **NO subjects withdrew from the study** □ **NO unanticipated problems involving risks to subjects or others**

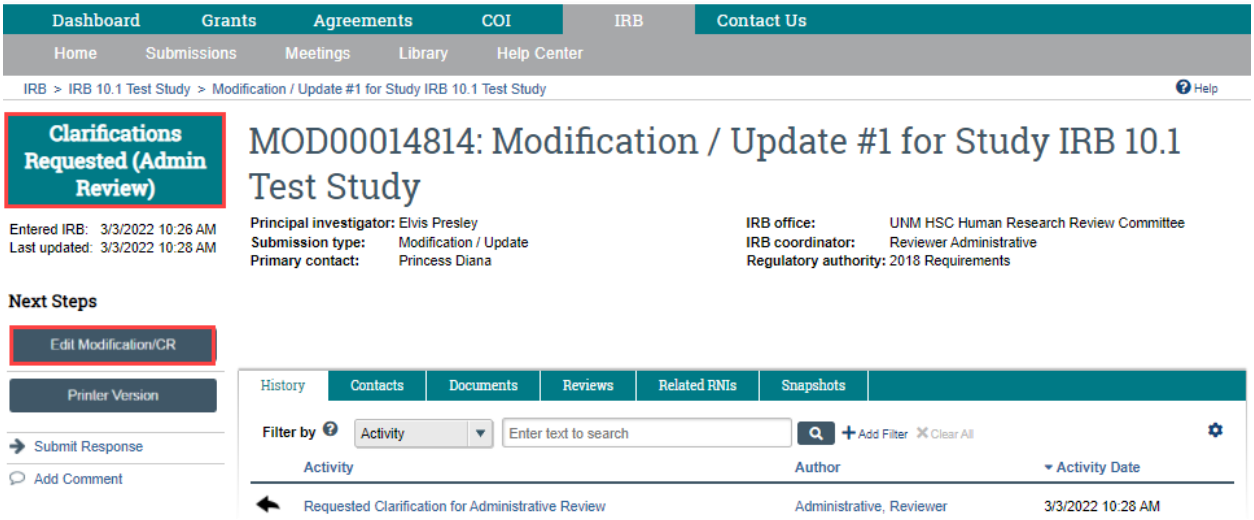
	□ **NO complaints about the study** □ **NO publications in the literature relevant to risks or potential benefits** □ **NO interim findings** □ **NO multi-center trial reports** □ **NO data safety monitoring reports** □ **NO regulatory actions that could affect safety and risk assessments** □ **NO other relevant information regarding this study, especially information about risks** □ **In the opinion of the PI, the risks and potential benefits are unchanged** □ **All modifications to the protocol have been submitted to the IRB** □ **All problems that require prompt reporting to the IRB have been submitted**
Attach supporting documents:	If applicable, add the completed HRP-508 Continuing Review Supporting Information document that includes an explanation of each item left unchecked: □ Click the **+Add** button to open the "Add Attachment" window. □ *** File to attach:** Click the **Choose File** button to open a "Folder browser" window to allow you to find and open the document. □ **Name:** You may leave this blank or enter a name to override the filename of the document. □ **Version number:** You may leave this blank or enter a number to override the system version of the document. □ Click the **OK and Add Another** button to attach another document *OR* click the **OK** button to close the "Add Attachment" window and return to the study page.

□ On the final page, click the **Finish** button. This will save the continuing review submission and return you to the submission workspace. The submission is in the project state, **Pre-Submission**. **Go to Step 2. Submit.**

Step 2. Submit

□ From the **Submission workspace**, click the **Submit** link. The system will check the submission for errors and allow you to complete missing information.
  □ To resolve the errors:
    ○ Click the **name** of the page to go directly to the page.
    ○ Provide a response to the required question(s).
    ○ Click the **Refresh** button to refresh the "Error/Warning Messages" window.
    ○ Click the **Save** button and then the **Exit** button in the submission to return to the submission workspace so that you may click the **Submit** link again.
□ Click the **OK** button to agree to the terms. The system will advance the submission to the next project state, **Administrative Review**.

Respond to clarification requests or required modifications



Step 1: Review the request

The principal investigator and primary contact will receive an email notification indicating action is required. The study team and primary contact may review the request. Follow the instructions in “Step 1” to review the request (pg. 23).

Step 2: Edit the submission

The principal investigator may submit any submission. The PI Proxy may submit follow-on submissions (e.g., modification or continuing review) for an approved study. Follow the instructions in “Step 2” to edit a submission (pg. 23-25).

Step 3: Submit Response

The principal investigator may submit the response on any submission. The PI Proxy may submit the response on follow-on submissions (e.g., modification or continuing review) for an approved study. Follow the instructions in “Step 3” to submit the response (pg. 25).

Step 1. Review the request

- From the **Dashboard** tab, click on **My Inbox,** and the **Name** of your submission to open the **Submission workspace**.
- For submissions in **Clarifications Requested (Admin Review**, **Pre-Review**, or **Designated Review)**:
  - In the **History** tab, review the details of the request under the **"Clarification Requested"** entry.
- For submissions in **Modifications Required:**
  - In the **History** tab, click the **Name** of the correspondence letter under "**Letter Sent"** entry to review the details of the IRB determination.
- After you have gathered the required information, **Go to Step 2. Edit the submission** (pg. 23).

Step 2. Edit the submission

- From the **Submission workspace**, click the **Edit Study**, **Edit Site**, or **Edit Modification/CR** to open the pages of the submission.
- Edit the submission per the request or requirement and click the **Continue** button to advance to the next page.

Edits to information and documents in a study record may include:

Change the principal investigator	
On the **Basic Study Information page:**	
Listed principal investigator:	□ Click the **[…]** button next to the listed name to open a "Select Person" window. □ Use the filter to find the person by last name or first name and click the **Go** button to populate results. □ Find the person and click the **radio** button next to the name. □ Click the **OK** button to close the "Select Person" window and return to the study page.

Update a document on a study page	
On the **study page** that has the document listed:	
Listed document:	□ Click the **Update** button next to the listed document to open the "Edit Attachment" window. □ * **File to attach:** Click the **Choose File** button to open a "Folder browser" window to allow you to find/open the revised document. □ **Name:** You may leave this blank or enter a name to override the filename of the document. □ **Version number:** You may leave this blank or enter a number to override the system version of the document. □ Click the **OK** button to close the "Edit Attachment" window and return to the study page.
Check Documents tab	Verify that the revised document is listed in the **Documents** tab in the submission workspace: □ From the submission workspace, click the **Documents** tab.

	☐ Scan the listed documents for the revised document to ensure that it listed.

Update drug or device	
On the **study page** that has the item listed:	
Listed drug/device:	☐ Click the **Update** button next to the listed drug/device to open the "Edit Drug/Device" window. ☐ Update information as needed. ☐ Click the **OK** button to close the "Drug/Device" window and return to the study page.

Update funding source IDs or files	
On the **study page** that has the funding source listed**:**	
Listed funding source: *Do not change the organization name.*	☐ Click the **Name** of the listed funding source to open the "Edit Funding Source" window. ☐ **Sponsor's funding ID:** Provide the updated identification number assigned by the sponsor. ☐ **Grants office ID:** Provide the updated funding proposal number issued by the UNM Health Sciences Sponsored Projects Office (SPO). ☐ **Attach files:** Add new documents or update/remove listed documents. ☐ Click the **OK** button to close the "Edit Funding Source" window and return to the study page.

Update study team member and/or external team member	
On the **Study Team Members page:**	
Listed study team member:	☐ Click the **Update** button next to the listed person to open the "Edit Study Team Member" window. ☐ *** Study team member:** *Only change this person if the incorrect account is listed (i.e., a duplicate account has (DO NOT USE) and you are replacing it with their correct account).* ☐ **Role in research:** Check or uncheck the appropriate box(es) to indicate the person's updated role(s) in this study. ☐ **Is the team member involved in the consent process?** Change the response to indicate if the person will or will not be involved in the consent process. ☐ Click the **OK** button to close the "Edit Study Team Member" window and return to the study page.
Listed external team member	☐ Click the **Update** button next to the listed person to open the "Edit Study Team Member" window. ☐ **Role in research:** Check or uncheck the appropriate box(es) to indicate the person's updated role(s) in this study. ☐ **Is the team member involved in the consent process?** Change the response to indicate if the person will or will not be involved in the consent process.

	□ Click the **OK** button to close the “Edit Study Team Member” window and return to the study page.

Delete an item from the study page.	
On the **study page** that has the item listed:	
Listed item:	□ Click the **X (Delete)** button next to the name. □ Click the **OK** button to verify the item will be deleted from the study. The item will be removed from the list.

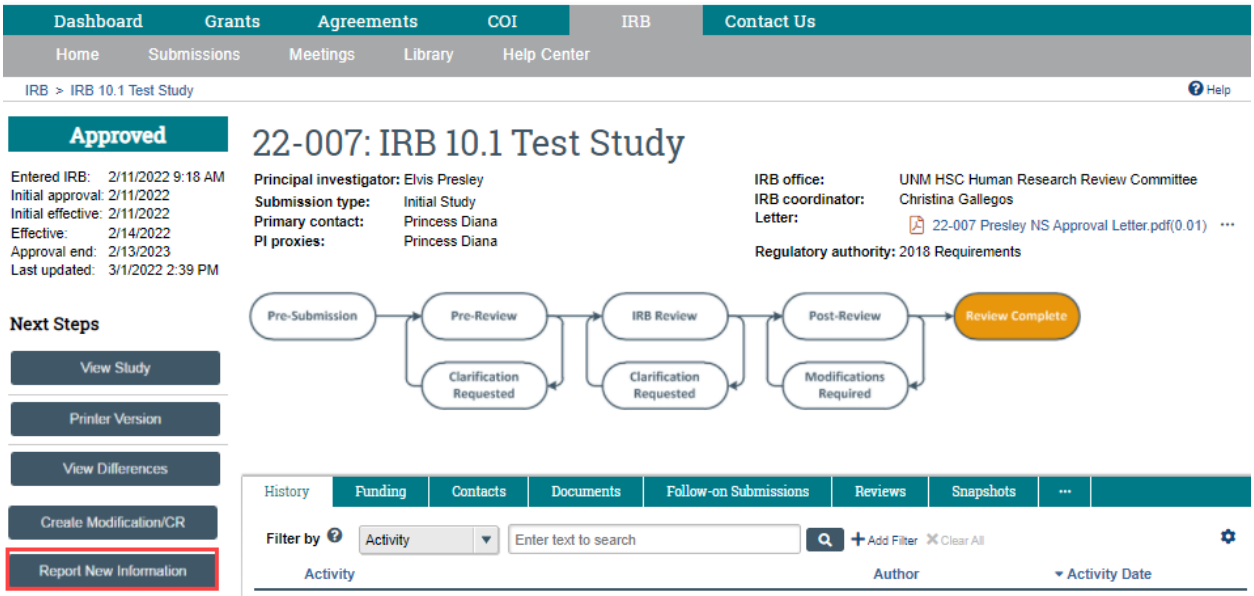
□ On the final page, click the **Finish** button. This will save the edits to the submission and return you to the submission workspace. The submission is in the project state, **Clarifications Requested** or **Modifications Required**. **Go to Step 3. Submit response** (pg. 25).

Step 3. Submit response

□ From the **Submission workspace**, click the **Submit Response** link. The system will check the submission for errors and allow you to complete missing information.
  □ To resolve the errors:
    - Click the **name** of the page to go directly to the page.
    - Provide a response to the required question(s).
    - Click the **Refresh** button to refresh the “Error/Warning Messages” window.
    - Click the **Save** button and then the **Exit** button in the submission to return to the submission workspace so that you may click the **Submit** link again.

□ Click the **OK** button to agree to the terms. The system will advance the submission to the next project state, **Administrative Review** or **Pre-Review** or **Modifications Submitted**.

Report new information



Step 1: Create and edit submission

Any user may report new information. The person who created the RNI may return to the submission at any time to continue editing the submission until it is ready to be submitted. Follow the instructions in “Step 1” to enter your submission into the system (pg. 27-28).

Step 2: Submit

The person who created the RNI may submit the RNI. Follow the instructions in “Step 2” to submit the RNI (pg. 29).

Before you begin:

- Gather files and information about your submission.
  - Acceptable document file types include: .doc; .docx; .pdf; .mp3; .mp4
  - New documents should not contain tracked changes or comments.

Step 1. Report RNI

- □ From the **My Inbox, IRB, or Study workspace**, click the **Report New Information** button.
- □ Complete the pages and click the **Continue** button to advance to the next page.

Page of a RNI submission:

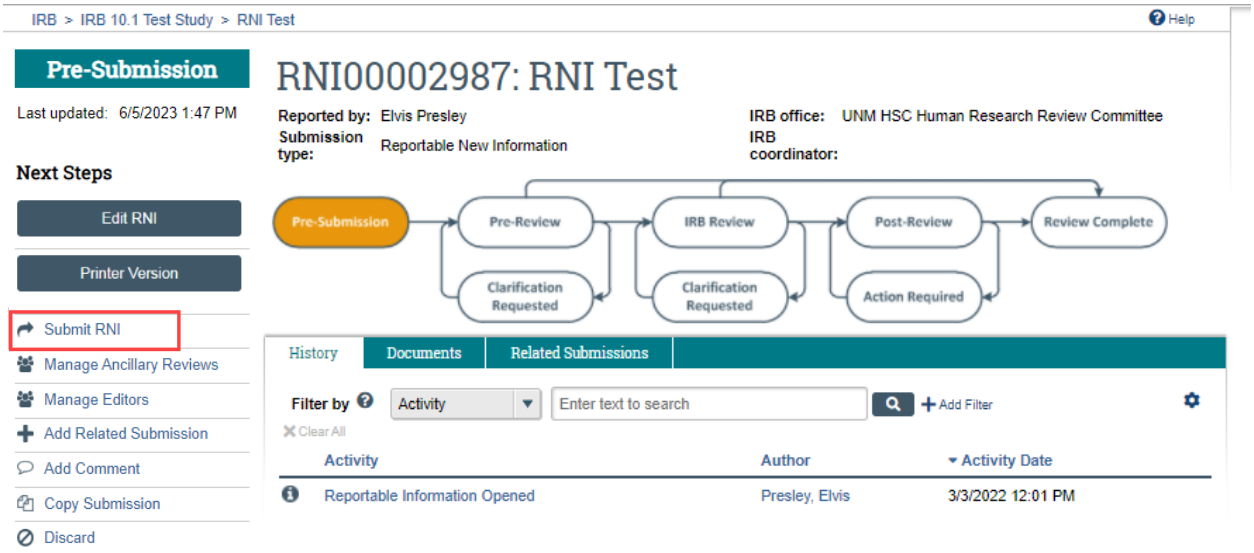
Reportable New Information	
Required for a new reportable new information submission.	
RNI short title:	Provide an abbreviated name for the information.
*** Date you became aware of the information:**	Click the **calendar** icon to select the date.
Identify the categories that represent the new information:	Check the appropriate box(es) to indicate the categories that represent the new information: □ **Risk:** Information that indicates a new or increased risk, or a safety issue. For example: **a.** New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk. **b.** An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or to describe a new risk. **c.** Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol. **d.** Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm. **e.** Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm. **f.** Any changes significantly affecting the conduct of the research. □ **Harm:** Any harm experienced by a subject or other individual that, in the opinion of the investigator, is unexpected and at least probably related to the research procedures. **a.** A harm is "**unexpected**" when its specificity or severity is inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, and characteristics of the study population. **b.** A harm is "**probably related**" to the research procedures if, in the opinion of the investigator, the research procedures more likely than not caused the harm. □ **Non-compliance**: Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance. □ **Audit:** Audit, inspection, or inquiry by a federal agency. □ **Report:** Written reports of study monitors. □ **Researcher error:** Failure to follow the protocol due to the action or inaction of the investigator or research staff. □ **Confidentiality:** Breach of confidentiality.

	□ **Unreviewed change:** Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject. □ **Incarceration:** Incarceration of a subject in a study not approved by the IRB to involve prisoners. □ **Complaint:** Complaint of a subject that cannot be resolved by the research team. □ **Suspension**: Premature suspension or termination of the research by the sponsor, investigator, or institution □ **Unanticipated adverse device effect:** Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects. □ **VA-SAE:** For Department of Veterans Affairs (VA) research, all local or internal serious adverse events (SAEs).
*** Briefly describe the new information:**	Provide a detailed description.
In the submitter's opinion:	Select the appropriate response: **a. * Does this information indicate a new or increased risk, or a safety issue?** ○ **Yes** ○ **No** **b. * Does the study need revision?** ○ **Yes** ○ **No** **c. * Does the consent document need revision?** ○ **Yes** ○ **No**
Related studies and modifications:	Add a related submission: □ Click the **[…]** button to open a "Select One or More IRB Submission Projects" window. □ Check the appropriate box(es) next to each submission that is related to this information. □ Click the **OK** button to close the "Select One or More IRB Submission Projects" window and return to the page.
Attach files containing supporting information:	□ If applicable, attach documents relevant to this information: □ Click the **+Add** button to open the "Add Attachment" window. □ *** File to attach:** Click the **Choose File** button to open a "Folder browser" window to allow you to find and open the document. □ **Name:** You may leave this blank or enter a name to override the filename of the document. □ **Version number:** You may leave this blank or enter a number to override the system version of the document. □ Click the **OK and Add Another** button to attach another document *OR* click the **OK** button to close the "Add Attachment" window and return to the page.

Final Page:	□ Ensure all steps have been completed successfully. Click “Finish” to exit the form.

Step 2. Submit RNI

- □ From the **RNI Submission workspace**, click the **Submit RNI** link. The system will check the submission for errors and allow you to complete missing information.
  - □ To resolve the errors:
    - Click the **name** of the page to go directly to the page.
    - Provide a response to the required question(s).
    - Click the **Refresh** button to refresh the “Error/Warning Messages” window.
    - Click the **Save** button and then the **Exit** button in the submission to return to the submission workspace so that you may click the **Submit** link again.
- □ Click the **OK** button to agree to the terms. The system will advance the submission to the next project state, **Pre-Review** (UNM is the lead) or **Pending sIRB Review** (UNM is a participating site on a multi-site study OR External IRB study).
- □ New Next steps option: **Manage Editors**
  - □ The activity is available to the IRB Coordinator, IRB Director and RNI Creator in all states and allows them to select contacts/users from the system as RNI additional editors. The RNI additional editors will be able to respond to RNI clarifications and submit on behalf of the PI.



Update study details for an external IRB study

Step 1: Update study details

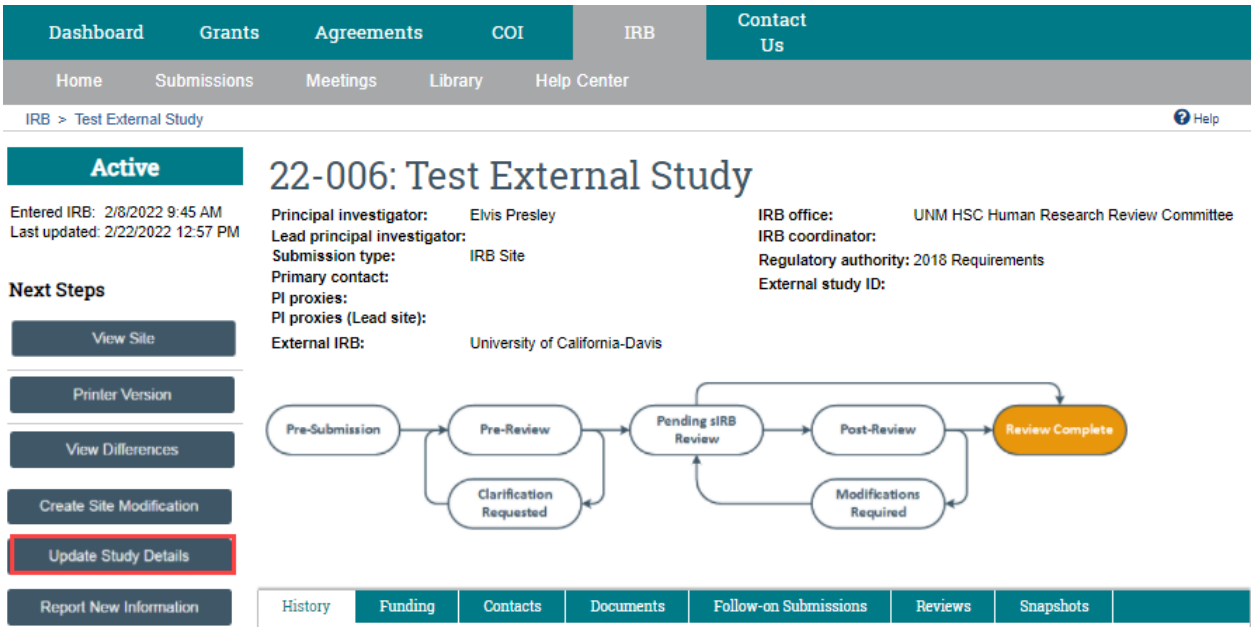
The principal investigator or PI proxy may update the external IRB study record only to reflect what the external IRB has approved. Follow the instructions in “Step 1” to enter your submission into the system (pg. 30-31).

Step 2: Wait for the HRPO to finalize updates

The principal investigator must receive confirmation from the HRPO before the updates may be finalized. The assigned IRB coordinator will work with the PI and study team to ensure all new external IRB approved study information has been properly entered into the system and local reviews, if required, are complete. The HRPO staff will finalize the updates.

Before you begin:

- Use the appropriate **submission checklist** (pg. 42) to gather files and information about your submission.
  - Acceptable document file types include: .doc; .docx; .pdf; .mp3; .mp4
  - Final documents should not contain tracked changes or comments.
- Work with the HRPO staff to ensure all new external IRB approved study information has been properly entered into the system.



Step 1. Update study details

- □ From the **IRB tab**, click the **External IRB** tab and click the **Name** of the study to open the **Study workspace**.
- □ From the **Study workspace**, click the **Update Study Details** button.
- □ Complete the pages and click the **Continue** button to advance to the next page.

Pages of an update study details submission:

Study Update Information	
Required for study updates to an External IRB submission.	
* **Summarize the updates:**	Provide a detailed summary of the updates.

Study Pages	
Basic Study Information	□ Add, update, and/or remove information
External IRB	□ Add, update, and/or remove information
Study Funding Sources	□ Add, update, and/or remove information
Study Scope	□ Add, update, and/or remove information
Study-Related Documents	□ Add, update, and/or remove information

☐ On the final page, click the **Finish** button. This will save the submission and return you to the submission workspace. The submission is in the project state, **Updating Study**. **Go to Step 2. Wait for the HRPO to finalize updates** (pg. 30).

Step 2. Wait for the HRPO to finalize updates

HRPO IRB coordinator will perform this activity. If you need to continue editing the study, contact the HRPO IRB coordinator that is assigned to your submission.

For reference purposes only:

- From the **Submission workspace**, click the **Finalize Updates** link. The system will check the submission for errors and allow you to complete missing information.
  - To resolve the errors:
    - Click the **name** of the page to go directly to the page.
    - Provide a response to the required question(s).
    - Click the **Refresh** button to refresh the “Error/Warning Messages” window.
    - Click the **Save** button and then the **Exit** button in the submission to return to the submission workspace so that you may click the **Submit** link again.
- Click the **OK** button to agree to the terms. The system will advance the submission to the next project state, **Updates Complete**.

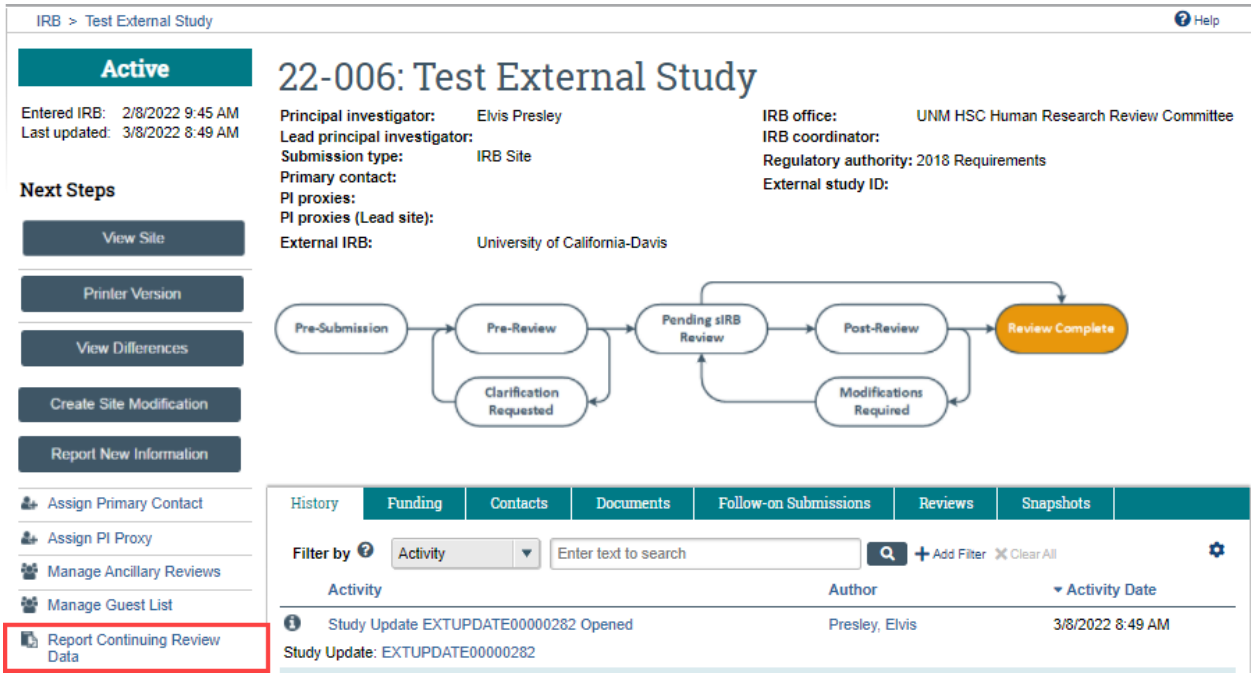
Report CR data for a multi-site external IRB study or site

Step 1: Report continuing review data

The principal investigator may report continuing review data for an external IRB study or a participating site. Follow the instructions in “Step 1” to enter your submission into the system (pg. 30-31).

Before you begin:

- Use the appropriate **submission checklist** (pg. 42) to gather files and information about your submission.
  - Acceptable document file types include: .doc; .docx; .pdf; .mp3; .mp4
  - Documents should not contain tracked changes or comments.
- If this is the final report for an external IRB study or participating site (i.e. study/site will be closed), notify the HRPO staff that you will report CR data with intention to close.



Step 1. Report continuing review data

- □ From the **IRB** tab, click the **External IRB** tab and click the **Name** of the study to open the **Study workspace** OR click the **Relying Sites** tab and click the **Name** of the site to open the **Site Workspace**.
- □ From the **Study workspace** or **Site workspace**, click the **Report Continuing Review Data** link.
- □ Complete the page and click the **OK** button to submit report and return to the **Study workspace**.

Page of a report continuing review data submission:

Report Continuing Review Data	
Required for continuing review/closure for an External IRB study or participating site.	
*** Specify enrollment totals:**	Provide values of subjects enrolled in the study. □ **Total subjects enrolled at this investigator's sites:** Provide the value. □ **Subjects enrolled at this investigator's sites since last continuing approval:** Provide the value.
Check the items that are true for this site since the last IRB approval:	Check the appropriate box(es) to indicate reports/findings: □ **NO subjects experienced unexpected harm** □ **Anticipated adverse events have NOT taken place with greater frequency or severity than expected** □ **NO subjects withdrew from the study** □ **NO unanticipated problems involving risks to subjects or others** □ **NO complaints about the study** □ **NO publications in the literature relevant to risks or potential benefits** □ **NO interim findings** □ **NO multi-center trial reports** □ **NO data safety monitoring reports** □ **NO regulatory actions that could affect safety and risk assessments** □ **NO other relevant information regarding this study, especially information about risks** □ **In the opinion of the PI, the risks and potential benefits are unchanged** □ **All modifications to the protocol have been submitted to the IRB** □ **All problems that require prompt reporting to the IRB have been submitted**
Supporting documents:	If applicable, add the completed HRP-508 Continuing Review Supporting Information document that includes an explanation of each item left unchecked: □ Click the **+Add** button to open the "Add Attachment" window. □ *** File to attach:** Click the **Choose File** button to open a "Folder browser" window to allow you to find and open the document. □ **Name:** You may leave this blank or enter a name to override the filename of the document. □ **Version number:** You may leave this blank or enter a number to override the system version of the document. □ Click the **OK and Add Another** button to attach another document *OR* click the **OK** button to close the "Add Attachment" window and return to the study page.
Comments:	Provide comments about the progress of the study.

Workspace buttons

Navigate through a submission	
Save	Save progress.
Exit	Return to the submission workspace
Print	Open a printer-friendly version of the page.
Continue	Save progress and advance to the next page.
Validate	Reveal complete or incomplete pages in the submission
Compare	Reveal changes that occurred in the submission.
Left Navigation	Navigate through pages

Submit

- 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.

Assign Primary Contact

- From the **Study workspace**, click the **Assign Primary Contact** link to open an "Assign Primary Contact" window.
  - **Select a new primary contact to receive all communications from the IRB:** Click the **[…]** button to open a "Select Person" window.
    - Use the filter to find the person by last name or first name and click the **Go** button to populate results.
    - Find the person and click the **radio** button next to the name.

- Click the **OK** button to close the “Add Comment” window and return to the **Study workspace**.
- Review the **History** tab to see the posted comment.

Assign PI proxy

- From the **Study workspace**, click the **Assign PI Proxy** link to open an “Assign PI Proxy” window.
  - **Select study team members to act as proxy:** Click the **[…]** button to open a “Select One or More Persons” window.
    - Check the **box** next to the name of the study team member(s) you want to assign proxy.
    - Click the **OK** button to close the “Select One or More Persons” window and return to the “Assign PI Proxy” window.
  - Click the **OK** button to open the “Confirm Credentials” window.
  - Enter your credentials and click the **OK** button to close the “Assign PI Proxy” window and return to the **Study workspace.** The PI proxies are listed in the **Study workspace**.

For a site, the site investigator may assign any user as the PI Proxy.

Add Comment

- From the **Study workspace**, click the **Add Comment** link to open an “Add Comment” window.
  - **Comment:** Enter your comment.
  - **Supporting documents:** Click the **+Add** button to add an attachment.
  - **Who should receive an e-mail notification?** Check the box(es) next to each recipient:
    - **PI/Primary Contact**
    - **Study Team**
    - **IRB Coordinator**
  - Click the **OK** button to close the “Add Comment” window and return to the **Study workspace.**

Manage Guest List

- From the **Study workspace**, click the **Manage Guest List** link to open a “Manage Guest List” window.
- **Guest list for allowing additional people to view the submission:** Click the **[…]** button to open a “Select One or More Persons” window.
  - Use the filter to find the person by last name or first name and click the **Go** button to populate results.
  - Check the **box** next to the name of the person you want to add as a guest.
  - Click the **OK** button to close the “Select One or More Persons” window and return to the “Manage Guest List” window.
  - Click the **OK** button to close the “Manage Guest List” window and return to the **Study workspace**.

Copy Submission

- From the **Study workspace**, click the **Copy Submission** link to open a “Copy Submission” window.
  - **New submission name:** Provide a name for the submission.
  - Check the **box** next to the name of the person you want to add as a guest.

- Click the **OK** button to close the "Copy Submission" window and return to the **Study workspace**.

Discard

- From the **Submission workspace**, click the **Discard** link to open a "Discard" window.
  - Click the **OK** button to verify the submission will be permanently removed, close the "Discard" window, and return to the **Submission workspace**. The state of the submission will move to "**Discarded."**

Withdraw (Will appear once submission is submitted)

- From the **Submission workspace**, click the **Withdraw** link to open a "Withdraw" window.
  - **Comment:** You may provide a justification for withdrawing the submission.
  - **Supporting documents:** You may attach documents.
  - Click the **OK** button to verify that IRB review will be discontinued, close the "Withdraw" window, and return to the **Submission workspace**. The state of the submission will move to "**Pre-Submission**."

Manage Relationships

- From the **Study workspace**, click the **Manage Relationships** activity to open a "Manage Relationships" window.
  ADD related project: Executing this activity creates a bi-directional relationship between two projects.
    - **Related projects:** Click the **[…]** button to open an "Select One or More Integration Projects" window.
    - Use the filter to find the project and click the **Go** button to populate the results.
    - Check the box next to the project(s) you want to add as a related project.
    - Click the **OK** button to close the "Select One or More Integration Projects" window and return to the "Manage Related Projects" window.

  REMOVE related project: Executing this activity breaks the bi-directional relationship between two projects. This removal will be documented in the system where the activity was executed.
    - **Click the X** next to the project you want to remove.
  - Click the **OK** button to close the "Manage Related Projects" window and return to the **Study workspace**. The history will be updated to reflect "Relationships Managed."
  - Review the **Related Projects** tab in the submission workspace to view list of related projects. Click the name of the related project to *access the related project workspace.

*Requires user to be granted view/edit permissions on related project (e.g., principal investigator/study team member on IRB project and on funding proposal project).

For reference purposes only

Add or Manage Participating Sites

HRPO sIRB reliance coordinator will perform this activity. If you need to add or manage participating sites, contact the HRPO sIRB reliance coordinator.

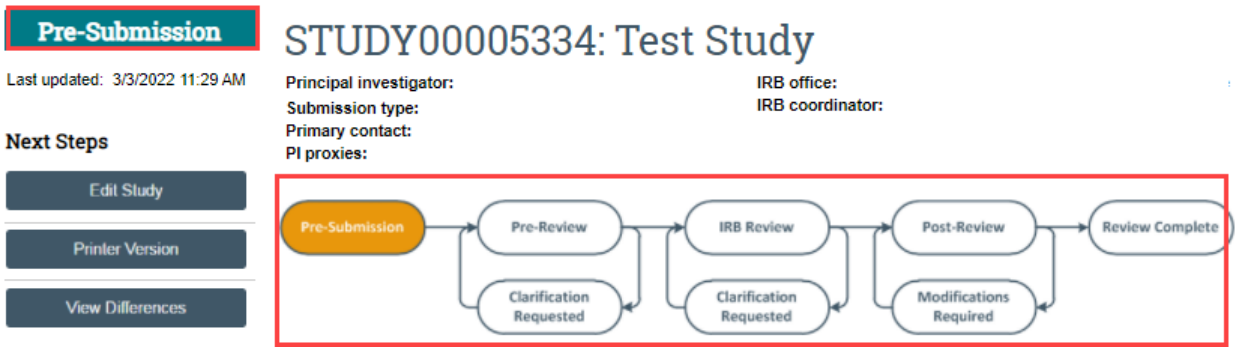
- ☐ From the **Study workspace** of a multi-site study, click the **Add or Manage Participating Site** link to open an "Add or Manage Participating Site" window.
  - ☐ **Add or manage participating sites:** Click the **+ Add** button to reveal the Institutional Profile and Principal Investigator fields:
    - ☐ *** Institutional Profile:** Click the **[…]** button to open a "Select IRB Institutional Profile" window.
      - ☐ Use the filter to find the institution by name and click the **Go** button to populate results.
      - ☐ Find the institution and click the **radio** button next to the name.
      - ☐ Click the **OK** button to close the "Select IRB Institutional Profile" window and return to the "Manage Participating Sites" window.
    - ☐ *** Principal Investigator:** Click the **[…]** button to open a "Select Person" window.
      - ☐ Use the filter to find the person by last name or first name and click the **Go** button to populate results.
      - ☐ Find the person and click the **radio** button next to the name.
      - ☐ Click the **OK** button to close the "Select Person" window and return to the "Manage Participating Sites" window.
  - ☐ Click the **+Add** button to add more sites.
  - ☐ Click the **OK** button close the "Withdraw" window, and return to the **Submission workspace**. The site(s) will be listed in the **Sites** tab in an "Invitation Pending" state.

Manage Ancillary Reviews

HRPO IRB coordinator will perform this activity. If you need to manage ancillary reviews, contact the HRPO IRB coordinator that is assigned to your submission.

- ☐ From the **Study workspace**, click the **Manage Ancillary Reviews** link to open a "Manage Ancillary Reviews" window.
  - ☐ **Identify each organization or person that should provide additional review:** Click the **+Add** button to open an "Add Ancillary Review" window.
    - ☐ *** Select either an organization or a person as reviewer:** Click the **[…]** button next to the organization or person field to open a "Select Organization or Select Person" window.
      - ☐ Use the filter to find the organization or person by name and click the **Go** button to populate results.
      - ☐ Check the **box** next to the name of the organization or person you want to add as an ancillary reviewer.
    - ☐ **Review Type**: Click the **down arrow** to reveal a menu of ancillary review types:
      - ☐ CTSC
      - ☐ Department
      - ☐ DUA
      - ☐ ESCRO
      - ☐ HTOC
      - ☐ Faculty
      - ☐ IBC
      - ☐ NMCC
      - ☐ MTA
      - ☐ Other
      - ☐ Radiation Safety
      - ☐ Scientific
      - ☐ UNM HSC COI
      - ☐ VA
    - ☐ * **Is a response required?** Select the appropriate response.
      - ○ Yes
      - ○ No
    - ☐ Click the **OK and Add Another** button to add another ancillary review OR click the **OK** button to close the "Add Ancillary Review" window and return to the "Manage Ancillary Reviews" window.
  - ☐ Click the **OK** button to close the "Manage Ancillary Reviews" window and return to the **Study workspace**.
- ☐ Review the **Reviews** tab to view the ancillary review.

Track the progress of a submission



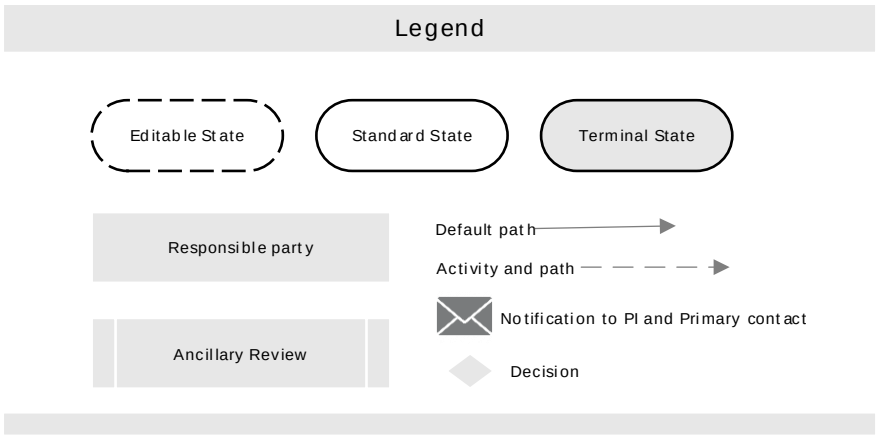
Huron IRB allows the study team to track the progress of a submission as it flows through the review process. The system uses “project states” to identify the status of a submission. The project state of a submission appears in two places in the top section of the submission workspace.

Project states may include:

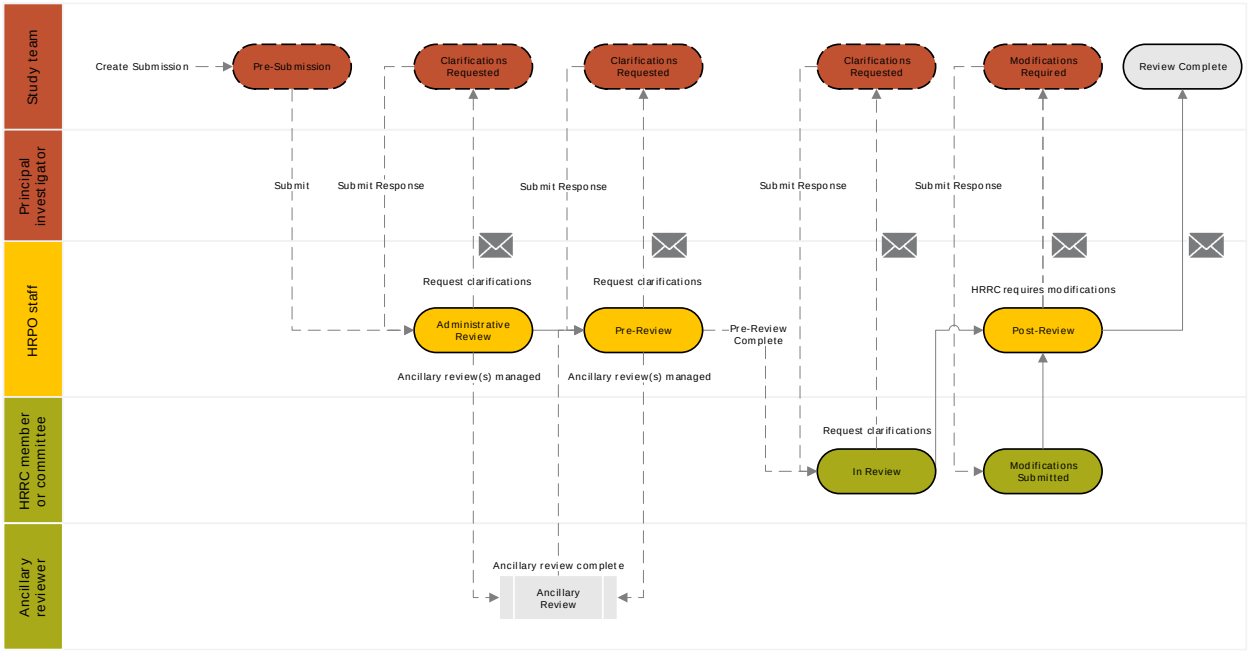
Review of the submission is pending:	
Pre-Submission	Study team is editing a submission (not yet submitted).
Invitation Pending	sIRB Reliance Coordinator is reviewing the site submission.
Awaiting Site Materials	Principal investigator is working with the sIRB Reliance Coordinator to attach site materials.
Administrative Review	HRPO staff is reviewing the submission.
Pre-Review	HRPO staff is reviewing the submission.
Clarifications Requested	Study team is responding to requested clarifications from HRPO staff.
Pre-Review Completed	HRPO staff is routing the submission for review.
pSite Review	HRPO staff is routing the submission for sIRB review.
In-Review	HRRC is reviewing the submission.
Pending sIRB Review	External IRB or sIRB is reviewing the submission.
RNI Review	HRRC is reviewing the RNI.
Post-Review	HRPO staff is conducting post-review activities on the submission.
Action Required	RNI submitter is responding to the request.
Modifications Required	Study team is responding to required modifications to secure approval.
Action Submitted	HRPO staff is reviewing the action response.
Modifications Submitted	HRPO staff or HRRC member is reviewing the modification response.
Review of the submission is complete:	
Approved	HRRC approved the submission.

Active	HRRC, sIRB, or External IRB approved the site.
Acknowledged	HRRC acknowledged the submission.
Not Human Research	HRRC determined the study is not human research.
Human Research, Not Engaged	HRRC determined the study is human research, but, the institution is not engaged.
Disapproved	HRRC disapproved the submission.
Deferred	HRRC deferred review of the submission.
External IRB	External IRB approved the single-site study.
Closed	HRRC, sIRB, or External IRB closed the study or site.
Inactive	Site is no longer active.
Complete	Review of the submission is complete.
RNI Review Completed	Review of the RNI is complete
Other states:	
Lapsed	Study approval is lapsed.
Suspended	Study is suspended.
Terminated	Study is terminated.
Discarded	Submission is removed from the IRB.
Updating Study	Study team is updating the External IRB study.
Updates Complete	The study updates have been applied to the External IRB study submission.

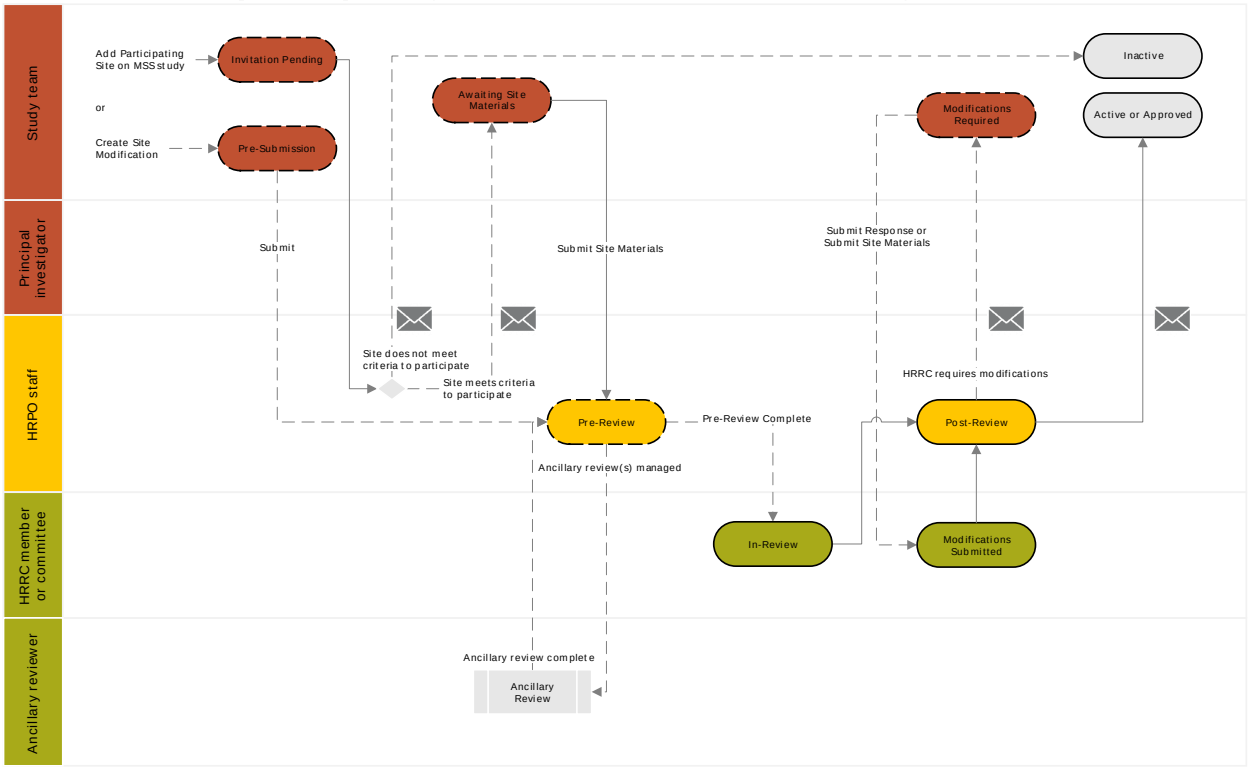
The following pages contain the workflows of different submission types and reviews.



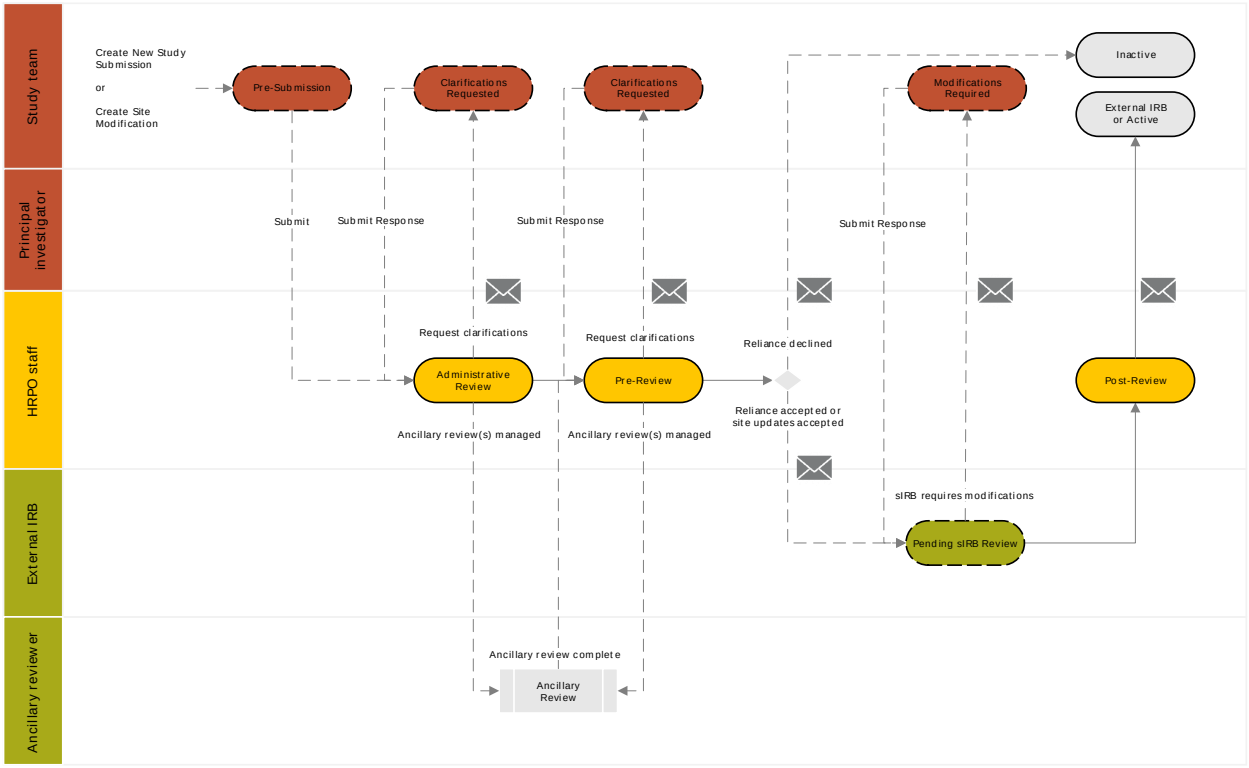
Workflow of a submission that undergoes HRRC review:



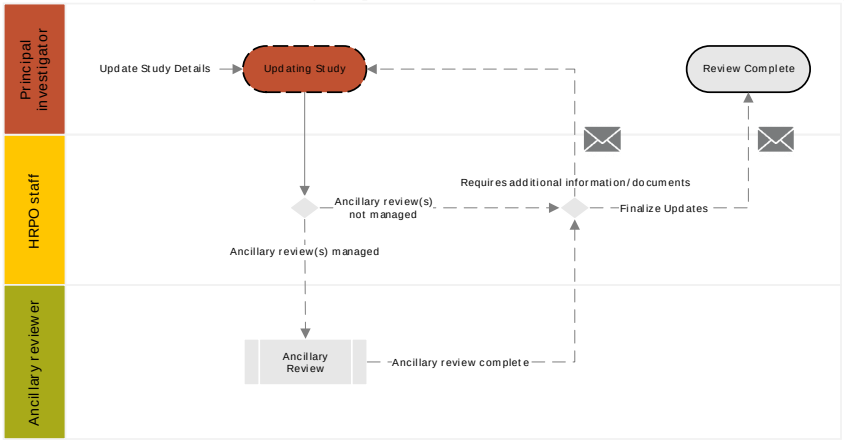
Workflow of a participating site submission that undergoes HRRC review:



Workflow of a study or participating site submission that uses an external IRB to manage the review



Workflow of a study update to an external IRB study



Submission checklists and support

Submission checklists:

Notes:

- Acceptable document file types include: .doc; .docx; .pdf; .mp3; .mp4
- Final documents should not contain tracked changes or comments.
- Revised documents must contain tracked changes.

HRPO staff support:

- **IRB-on-the-go specialist** will provide consultations on any new submission to ensure you are completing the appropriate templates and forms.
- **sIRB reliance coordinator** will assist the principal investigator and site investigators to ensure all study and site information have been properly entered into the system; will also set up new institutional profiles.
- **Assigned IRB coordinator** on an active external IRB study will assist the principal investigator to ensure all external IRB approved study information has been properly entered into the system.
- **Assigned IRB coordinator** on a submission will facilitate the review of the submission and work with the principal investigator, primary contact, and study team to ensure study information has been properly entered into the system.
- **System administrator** will assist IRB users who experience technical issues with the IRB system and will set up new organization profiles.
- **IRB account manager** will assist IRB users who need to update their profiles (e.g., email address, department, name change) or set up new accounts for new IRB users; will also set up new organization profiles.

Single-Site HRRC study submission checklist

Document or information	***Where to attach document or provide information***
Required for a single-site HRRC study:	
□ Single-Site HRRC study information	*Basic Study Information,* □ *"What kind of study is this?" Select **Single-Site study**;* □ *"Will an external IRB act as the IRB of record for this study?" Select **No**.*
□ Protocol	*Basic Study Information, "Attach the protocol."*
□ Signed HRP-226 Department Scientific Review Form *Not required for Exempt protocol*	*Local Site Documents, "Other attachments."* *Category = **HRP Form**.*
□ Curriculum Vitae (CV) of local principal investigator	*Local Site Documents, "Other attachments."* *Category = **Other**.*
□ CITI Group 1 Biomedical Research Investigator or CITI Group 2 Social & Behavioral Research Investigator	*Each study team member must complete the training at **CITIprogram.org** every 3 years. You may review the "List of people who have completed CITI Training" at **hsc.unm.edu/research/hrpo/investigators/getting-started/training**.*
For UNM/HSC investigators: □ Completed COI trainings – 1. Electronic Research Administration: COI Disclosures and 2. HSC Financial Conflict of Interest training and □ Completed HSC-COI certification For non-UNM investigators: □ Completed HRP-229 COI Form for Non-UNM investigators affiliated with another university	*Each investigator will receive an e-mail notification indicating that the HSC-initiated certification for this project must be completed at **era.health.unm.edu**. For investigators that do not have an active COI account, COI trainings and COI account activation information and instructions will be included in the e-mail notification.* *Local Site Documents, "Other attachments."* *Category = **HRP Form**.*
Required for a protocol that requires ancillary review(s):	
□ Completed ancillary review – see full list on pg. 35.	*HRPO IRB coordinator will indicate that an ancillary review has been triggered for the study. Review the details and status of the ancillary review in the history of the submission.*
Required if study involves recruitment and/or consent:	
□ Recruitment material(s)	*Local Site Documents, "Recruitment Materials."*
□ Participant material(s)	*Local Site Documents, "Other attachments."* *Category = **Other**.*
□ Consent form(s)	*Local Site Documents, "Consent forms."*
□ HIPAA consent form(s)	*Local Site Documents, "Consent forms."*

Required if study involves the following:	
□ Survey(s), questionnaire(s), interview script(s)	*Local Site Documents, "Other attachments."* *Category =* ***Other****.*
□ Data collection tools	*Local Site Documents, "Other attachments."* *Category =* ***Other****.*
Required if study involves children:	
□ Assent form(s)	*Local Site Documents, "Consent forms."*
□ Parental permission form	*Local Site Documents, "Other attachments."* *Category =* ***Other****.*
Required if study involves other IRBs or agencies:	
□ Other IRB approvals	*Local Site Documents, "Other attachments."* *Category =* ***Other****.*
□ Letter(s) of support from external sites/agencies	*Local Site Documents, "Other attachments."* *Category =* ***Other****.*
□ Completed HRP-231 Institutional Review Board (IRB) Authorization agreement – HRRC is being relied upon	*Local Site Documents, "Other attachments."* *Category =* ***HRP Form****.*
Required if study involves drugs, biologics, foods, and/or dietary supplements:	
□ Drug information	□ *Study Scope, "Does the study specify the use of an approved drug …" Select* ***Yes****;* □ *Drugs, "List all drugs, biologics, foods, and dietary supplements to be used in the study:"*
□ Completed HRP-222 Drug Attachment	*Drugs, "Attach files."*
□ IND information, approvals	*Drugs,* □ *"Will the study be conducted under any IND numbers?" Select* ***Yes****;* □ *"Identify each IND:"*
□ Investigator brochure	*Drugs, "Attach files."*
Required if study involves devices:	
□ Device information	□ *Study Scope, "Does the study evaluate the safety or effectiveness of a device …" Select* ***Yes****;* □ *Devices, "Select each device the study will use as an HUD or evaluate for safety or effectiveness:"*
□ IDE or HDE information, approvals	*Devices,* □ *"Device exemptions applicable to this study:" Select* ***IDE number*** *or* ***HDE number****;* □ *"Identify each IDE or HDE number:"*
□ Investigator brochure	*Devices, "Attach files."*

Required if study involves ionizing radiation:	
□ Completed HRP-223 Attachment for Human Research Protocol that utilizes ionizing radiation	*Study Scope,* □ *"Does the study involve exposure to ionizing radiation (e.g., X-rays…" Select **Yes**;* □ *"Attach the completed HRP form(s)." Category = **HRP Form: Radiation Safety**.*
Required if study involves biological specimens:	
□ Completed HRP-224 Biological Specimens Attachment	*Study Scope,* □ *"Does the study specify the use of biological specimens, or specimen …" Select **Yes**;* □ *"Attach the completed HRP form(s)." Category = **HRP Form: Biological Specimens**.*

Multi-Site sIRB study (UNM HSC lead) submission checklist

The HRRC must approve the MS study before participating sites may be added. After the HRRC has approved the study, the PI/ study team must distribute HRRC approved documents and templates to each site. Each site must revise the templates to incorporate information per their local IRB.

Document or information	***Where to attach document or provide information***
Required for a multi-site sIRB study (UNM HSC lead):	
□ Multi-site sIRB study (UNM HSC is the lead site) information	*Basic Study Information,* □ *"What kind of study is this?" Select **Multi-Site study**;* □ *"Will an external IRB act as the IRB of record for this study?" Select **No**;* □ *"Will your IRB act as the single IRB of record for this study?" Select **Yes**.*
□ Protocol	*Basic Study Information, "Attach the protocol."*
□ Local protocol addendum	*Basic Study Information, "Attach the protocol."*
□ Signed HRP-226 Department Scientific Review Form	*Local Site Documents, "Other attachments."* *Category = **HRP Form**.*
□ Curriculum Vitae (CV) of local principal investigator	*Local Site Documents, "Other attachments."* *Category = **Other**.*
□ CITI Group 1 Biomedical Research Investigator or CITI Group 2 Social & Behavioral Research Investigator	*Each study team member must complete the training at **CITIprogram.org** every 3 years. You may review the "List of people who have completed CITI Training" at **hsc.unm.edu/research/hrpo/investigators/getting-started/training**.*
For UNM/HSC investigators: □ Completed COI trainings – 1. Electronic Research Administration: COI Disclosures and 2. HSC Financial Conflict of Interest training and □ Completed HSC-COI certification For non-UNM investigators: □ Completed HRP-229 COI Form for Non-UNM investigators affiliated with another university	*Each investigator will receive an e-mail notification indicating that the HSC-initiated certification for this project must be completed at **era.health.unm.edu**. For investigators that do not have an active COI account, COI trainings and COI account activation information and instructions will be included in the e-mail notification.* *Local Site Documents, "Other attachments."* *Category = **HRP Form**.*
□ Complete list of participating sites and site documents – see "**Participating site (external institution) submission checklist**"	*Must e-mail information directly to the UNM sIRB reliance coordinator, Tanya Silva, at **TLSilva@salud.unm.edu***
Required for a protocol that requires ancillary review(s):	
□ Completed ancillary review – see full list on pg. 35.	*HRPO IRB coordinator will indicate that an ancillary review has been triggered for the study. Review the details and status of the ancillary review in the history of the submission.*

Required if study involves drugs, biologics, foods, and/or dietary supplements:	
□ Drug information	□ *Study Scope, "Does the study specify the use of an approved drug …" Select **Yes**;* □ *Drugs, "List all drugs, biologics, foods, and dietary supplements to be used in the study:"*
□ Completed HRP-222 Drug Attachment	*Drugs, "Attach files."*
□ IND information, approvals	*Drugs,* □ *"Will the study be conducted under any IND numbers?" Select **Yes**;* □ *"Identify each IND:"*
□ Investigator brochure	*Drugs, "Attach files."*
Required if study involves devices:	
□ Device information	□ *Study Scope, "Does the study evaluate the safety or effectiveness of a device …" Select **Yes**;* □ *Devices, "Select each device the study will use as an HUD or evaluate for safety or effectiveness:"*
□ IDE or HDE information, approvals	*Devices,* □ *"Device exemptions applicable to this study:" Select **IDE number** or **HDE number*** □ *"Identify each IDE or HDE number:"*
□ Investigator brochure	*Devices, "Attach files."*
Required if study involves ionizing radiation:	
□ Completed HRP-223 Attachment for Human Research Protocol that utilizes ionizing radiation	*Study Scope,* □ *"Does the study involve exposure to ionizing radiation (e.g., X-rays…" Select **Yes**;* □ *"Attach the completed HRP form(s)." Category = **HRP Form: Radiation Safety**.*
Required if study involves biological specimens:	
□ Completed HRP-224 Biological Specimens Attachment	*Study Scope,* □ *"Does the study specify the use of biological specimens, or specimen …" Select **Yes**;* □ *"Attach the completed HRP form(s)." Category = **HRP Form: Biological Specimens**.*
Required if participating sites involves recruitment and/or consent:	
□ Template recruitment material(s)	*Study-Related Documents, "Recruitment Materials."*
□ Template participant material(s)	*Study-Related Documents, "Other attachments." Category = **Other**.*
□ Template consent form(s)	*Study-Related Documents, "Consent forms."*
□ Template HIPAA consent form(s)	*Study-Related Documents, "Consent forms."*

Required if study involves the following:	
□ Survey(s), questionnaire(s), interview script(s)	*Study-Related Documents, "Other attachments."* *Category = **Other**.*
□ Data collection tools	*Study-Related Documents, "Other attachments."* *Category = **Other**.*
Required if participating sites involves children:	
□ Template assent form(s)	*Study-Related Documents, "Consent forms."*
□ Template parental permission form	*Study-Related Documents, "Other attachments."* *Category = **Other**.*
Required if UNM HSC site involves recruitment and/or consent:	
□ UNM HSC recruitment material(s)	*Local Site Documents, "Recruitment Materials."*
□ UNM HSC participant material(s)	*Local Site Documents, "Other attachments."* *Category = **Other**.*
□ UNM HSC consent form(s)	*Local Site Documents, "Consent forms."*
□ UNM HSC HIPAA consent form(s)	*Local Site Documents, "Consent forms."*
Required if UNM HSC site involves children:	
□ UNM HSC assent form(s)	*Local Site Documents, "Consent forms."*
□ UNM HSC parental permission form	*Local Site Documents, "Other attachments."* *Category = **Other**.*

Participating site (external institution) submission checklist

The PI/ study team must collect final site documents that have been reviewed and acknowledged by the local IRB. The following must be provided to the sIRB reliance coordinator. The sIRB reliance coordinator will add each participating site to the approved MS study and then attach documents to each site submission for HRRC review and site activation.

Document	***Where document will be attached***
Required for each participating site on a multi-site HRRC study	
□ Completed HRP-509 Local protocol addendum	*Local Site Documents, "Other attachments."* *Category = **Other**.*
□ For institution using smart IRB: Cede confirmation letter or	*Local Site Documents, "Other attachments."* *Category = **Other**.*
□ For institution not using smart IRB: Completed HRP-231 Institutional Review Board (IRB) Authorization agreement – HRRC is being relied upon	*Local Site Documents, "Other attachments."* *Category = **HRP Form**.*
Required if participating site involves recruitment and/or consent:	
□ Site recruitment material(s) acknowledged by local IRB	*Local Site Documents, "Recruitment Materials."*
□ Site participant material(s) acknowledged by local IRB	*Local Site Documents, "Other attachments."* *Category = **Other**.*
□ Site consent form(s) acknowledged by local IRB	*Local Site Documents, "Consent forms."*
□ Site HIPAA consent form(s) acknowledged by local IRB	*Local Site Documents, "Consent forms."*
Required if participating site involves children:	
□ Site assent form(s) acknowledged by local IRB	*Local Site Documents, "Consent forms."*
□ Site parental permission form acknowledged by local IRB	*Local Site Documents, "Other attachments."* *Category = **Other**.*

Participating site (UNM HSC) submission checklist

Document or information	*Where to attach document or provide information*
Required for an External IRB study or UNM HSC participating site on a multi-site study:	
□ Multi-site study (UNM HSC is a participating site) information	*Basic Study Information,* □ *"What kind of study is this?" Select **Multi-Site study**;* □ *"Will an external IRB act as the IRB of record for this study?" Select **Yes**.*
□ Study approval letter	*Study-Related Documents, "Other attachments." Category = **Other**.*
□ Study-wide Approved protocol	*Basic Study Information, "Attach the protocol."*
□ Completed HRP-509 Local protocol addendum	*Local Site Documents, "Other attachments." Category = **Other**.*
□ Cede confirmation letter from SMART IRB or □ If not using SMART IRB: Completed HRP-232 Institutional Review Board (IRB) Authorization agreement – HRRC is relying	*Local Site Documents, "Other attachments." Category = **Other**.* *Local Site Documents, "Other attachments." Category = **HRP Form**.*
□ Curriculum Vitae (CV) of local principal investigator	*Local Site Documents, "Other attachments." Category = **Other**.*
□ CITI Group 1 Biomedical Research Investigator or CITI Group 2 Social & Behavioral Research Investigator	*Each study team member must complete the training at **CITIprogram.org** every 3 years. You may review the "List of people who have completed CITI Training" at **hsc.unm.edu/research/hrpo/investigators/getting-started/training**.*
For UNM/HSC investigators: □ Completed COI trainings – 1. Electronic Research Administration: COI Disclosures and 2. HSC Financial Conflict of Interest training and □ Completed HSC-COI certification For non-UNM investigators: □ Completed HRP-229 COI Form for Non-UNM investigators affiliated with another university	*Each investigator will receive an e-mail notification indicating that the HSC-initiated certification for this project must be completed at **era.health.unm.edu**. For investigators that do not have an active COI account, COI trainings and COI account activation information and instructions will be included in the e-mail notification.* *Local Site Documents, "Other attachments." Category = **HRP Form**.*
Required for a protocol that requires ancillary review(s):	
□ Completed ancillary review – see full list on pg. 35.	*HRPO IRB coordinator will indicate that an ancillary review has been triggered for the study. Review the details and status of the ancillary review in the history of the submission.*

Required if study involves ionizing radiation:	
□ Completed HRP-223 Attachment for Human Research Protocol that utilizes ionizing radiation	*Study Scope,* □ *"Does the study involve exposure to ionizing radiation (e.g., X-rays…" Select **Yes**;* □ *"Attach the completed HRP form(s)." Category = **HRP Form: Radiation Safety**.*
Required if study involves the following:	
□ Survey(s), questionnaire(s), interview script(s)	*Study-Related Documents, "Other attachments." Category = **Other**.*
□ Data collection tools	*Study-Related Documents, "Other attachments." Category = **Other**.*
Required if study involves biological specimens:	
□ Completed HRP-224 Biological Specimens Attachment	*Study Scope,* □ *"Does the study specify the use of biological specimens, or specimen …" Select **Yes**;* □ *"Attach the completed HRP form(s)." Category = **HRP Form: Biological Specimens**.*
Required if UNM HSC site involves recruitment and/or consent:	
□ UNM HSC recruitment material(s)	*Local Site Documents, "Recruitment Materials."*
□ UNM HSC participant material(s)	*Local Site Documents, "Other attachments." Category = **Other**.*
□ UNM HSC consent form(s)	*Local Site Documents, "Consent forms."*
□ UNM HSC HIPAA consent form(s)	*Local Site Documents, "Consent forms."*
Required if UNM HSC site involves children:	
□ UNM HSC assent form(s)	*Local Site Documents, "Consent forms."*
□ UNM HSC parental permission form	*Local Site Documents, "Other attachments." Category = **Other**.*

External IRB study submission checklist

Document or information	*Where to attach document or provide information*
Required for an External IRB study or UNM HSC participating site on a multi-site study:	
□ External IRB study information	*Basic Study Information,* □ *"What kind of study is this?" Select **Single-Site** or **Multi-Site study**;* □ *"Will an external IRB act as the IRB of record for this study?" Select **Yes**.*
□ External IRB Study approval letter	*Study-Related Documents, "Other attachments." Category = **Other**.*
□ External IRB Approved protocol	*Basic Study Information, "Attach the protocol."*
□ CITI Group 1 Biomedical Research Investigator or CITI Group 2 Social & Behavioral Research Investigator	*Each study team member must complete the training at **CITIprogram.org** every 3 years. You may review the "List of people who have completed CITI Training" at **hsc.unm.edu/research/hrpo/investigators/getting-started/training**.*
For UNM/HSC investigators: □ Completed COI trainings – 1. Electronic Research Administration: COI Disclosures and 2. HSC Financial Conflict of Interest training and □ Completed HSC-COI certification	*Each investigator will receive an e-mail notification indicating that the HSC-initiated certification for this project must be completed at **era.health.unm.edu**. For investigators that do not have an active COI account, COI trainings and COI account activation information and instructions will be included in the e-mail notification.*
For non-UNM investigators: □ Completed HRP-229 COI Form for Non-UNM investigators affiliated with another university	*Local Site Documents, "Other attachments." Category = **HRP Form**.*
Required for a protocol that requires ancillary review(s):	
□ Completed ancillary review – see full list on pg. 35.	*HRPO IRB coordinator will indicate that an ancillary review has been triggered for the study. Review the details and status of the ancillary review in the history of the submission.*
Required if study involves ionizing radiation:	
□ Completed HRP-223 Attachment for Human Research Protocol that utilizes ionizing radiation	*Study Scope,* □ *"Does the study involve exposure to ionizing radiation (e.g., X-rays…" Select **Yes**;* □ *"Attach the completed HRP form(s)." Category = **HRP Form: Radiation Safety**.*
Required if study involves the following:	
□ Survey(s), questionnaire(s), interview script(s)	*Study-Related Documents, "Other attachments." Category = **Other**.*
□ Data collection tools	*Study-Related Documents, "Other attachments." Category = **Other**.*

Required if UNM HSC site involves recruitment and/or consent:	
□ UNM HSC recruitment material(s)	*Local Site Documents, "Recruitment Materials."*
□ UNM HSC participant material(s)	*Local Site Documents, "Other attachments."* *Category =* ***Other****.*
□ UNM HSC consent form(s)	*Local Site Documents, "Consent forms."*
□ UNM HSC HIPAA consent form(s)	*Local Site Documents, "Consent forms."*
Required if UNM HSC site involves children:	
□ UNM HSC assent form(s)	*Local Site Documents, "Consent forms."*
□ UNM HSC parental permission form	*Local Site Documents, "Other attachments."* *Category =* ***Other****.*

Study or site continuing review or closure submission checklist

Document or information	*Where to attach document or provide information*
Required for any continuing review:	
□ Enrollment numbers are correctly calculated.	
□ Milestones are correctly checked to reflect study progress: • Study is on-going – either no boxes are checked OR some of the boxes are checked. • Study is closing – top 4 or 5 boxes are all checked.	
Required if item in reportable information/events is unchecked:	
□ Completed HRP-508 Continuing Review Supporting Information	*Continuing Review/ Study Closure Information, "Supporting Documents" OR Report Continuing Review Data, "Supporting documents"*
Required if multi-site study:	
□ Report Continuing Review data for each site. □ Ensure CR data report is accurate for each.	

HRRC study or UNM HSC site modification submission checklist

The HRRC must approve the MSS modification. After the HRRC has approved the modification, the PI/ study team must distribute HRRC approved documents and templates to each site. Each site must revise the templates to incorporate information per their local IRB.

Document or information	***Where to attach document or provide information***
Required for modification to study team:	
□ Study team member information	*Modification/Continuing Review/ Study Closure,* □ *"Modification scope:" Select* ***Study team member information****.*
□ Modification summary lists the full name of each study team member and the details of the change (e.g., add, remove, update role).	*Modification Information, "Summarize the Modification:"*
Required for modification to other parts of the study:	
□ Change local principal investigator and/or □ Changes to approved study documents and/or information (e.g., update contact information, revise listed personnel in protocol document, update funding information, update consent form, add new recruitment document, etc.)	*Modification/Continuing Review/ Study Closure,* □ ***Other parts of the study****.*
□ Modification summary outlines the details of the modification (e.g., full name of new PI; list of documents/information and details of the change (adding, removing, updating)).	*Modification Information, "Summarize the Modification:"*
Required if adding new study team member(s) or changing local principal investigator:	
□ CITI Group 1 Biomedical Research Investigator or CITI Group 2 Social & Behavioral Research Investigator	*Each study team member must complete the training at* ***CITIprogram.org*** *every 3 years. You may review the "List of people who have completed CITI Training" at* ***hsc.unm.edu/research/hrpo/investigators/getting-started/training****.*
For UNM/HSC investigators: □ Completed COI trainings – 1. Electronic Research Administration: COI Disclosures and 2. HSC Financial Conflict of Interest training and □ Completed HSC-COI certification	*Each investigator will receive an e-mail notification indicating that the HSC-initiated certification for this project must be completed at* ***era.health.unm.edu****. For investigators that do not have an active COI account, COI trainings and COI account activation information and instructions will be included in the e-mail notification.*
For non-UNM investigators: □ Completed HRP-229 COI Form for Non-UNM investigators affiliated with another university	*Local Site Documents, "Other attachments."* *Category =* ***HRP Form****.*

Required if changing local principal investigator:	
□ Principal Investigator	*Basic Study Information, "Local principal investigator:". Click* ***+Add***
□ Curriculum Vitae (CV) of local principal investigator	*Local Site Documents, "Other attachments." Category =* ***Other****.*
Required if changes impact approved study documents/information:	
□ New document/information	*Applicable study page. Click* ***+Add***
□ Revised document/information	*Applicable study page. Click* ***Update***
Required if notifying subjects:	
□ Communication plan – Notice of changes	*Local Site Documents, "Other attachments." Category =* ***Other****.*
Required for changes that requires ancillary review(s):	
□ Completed ancillary review – see full list on pg. 35.	*HRPO IRB coordinator will indicate that an ancillary review has been triggered for the submission. Review the details and status of the ancillary review in the history of the submission.*

Site (external institution) modification submission checklist

Document or information	***Where to attach document or provide information***
□ Modification summary outlines the details of the modification (e.g., full name of new PI; list of documents/information and details of the change (adding, removing, updating)).	*Modification Information, "Summarize the Modification:"*
Required if changing site investigator:	
□ Curriculum Vitae (CV) of the site investigator	*Local Site Documents, "Other attachments."* *Category = **Other**.*
□ CITI Group 1 Biomedical Research Investigator or CITI Group 2 Social & Behavioral Research Investigator	*Each study team member must complete the training at **CITIprogram.org** every 3 years. You may review the "List of people who have completed CITI Training" at **hsc.unm.edu/research/hrpo/investigators/getting-started/training**.*
For UNM/HSC investigator: □ Completed COI trainings – 1. Electronic Research Administration: COI Disclosures and 2. HSC Financial Conflict of Interest training and □ Completed HSC-COI certification	*Each investigator will receive an e-mail notification indicating that the HSC-initiated certification for this project must be completed at **era.health.unm.edu**. For investigators that do not have an active COI account, COI trainings and COI account activation information and instructions will be included in the e-mail notification.*
For non-UNM investigators: □ Completed HRP-229 COI Form for Non-UNM investigators affiliated with another university	*Local Site Documents, "Other attachments."* *Category = **HRP Form**.*
Required if changes impact approved site documents/information:	
□ New document/information	*Applicable site page. Click **+Add***
□ Revised document/information	*Applicable site page. Click **Update***
Required if notifying subjects:	
□ Communication plan – Notice of changes	*Local Site Documents, "Other attachments."* *Category = **Other**.*
Required for changes that requires ancillary review(s):	
□ Completed ancillary review – see full list on pg. 34.	*HRPO IRB coordinator will indicate that an ancillary review has been triggered for the submission. Review the details and status of the ancillary review in the history of the submission.*

External IRB study update checklist

The PI/ study team must collect final documents that have been reviewed and approved by the external IRB. The assigned IRB coordinator will work with the study team before finalizing the updates.

Document or information	***Where to attach document or provide information***
Required if external IRB approved new and/or revised documents/information:	
□ External IRB Modification approval letter	*Study-Related Documents, "Other attachments." Category = **Other**.*
□ New document/information	*Applicable study or site page. Click **+Add***
□ Revised document/information	*Applicable study or site page. Click **Update***
□ Modification summary outlines the details of the modification (e.g., full name of new PI; list of documents/information and details of the change (adding, removing, updating)).	*Study Update Information, "Summarize the updates:"*
Required if changing local principal investigator:	
□ CITI Group 1 Biomedical Research Investigator or CITI Group 2 Social & Behavioral Research Investigator	*Each study team member must complete the training at **CITIprogram.org** every 3 years. You may review the "List of people who have completed CITI Training" at **hsc.unm.edu/research/hrpo/investigators/getting-started/training**.*
For UNM/HSC investigator: □ Completed COI trainings – 1. Electronic Research Administration: COI Disclosures and 2. HSC Financial Conflict of Interest training and □ Completed HSC-COI certification For non-UNM investigators: □ Completed HRP-229 COI Form for Non-UNM investigators affiliated with another university	*Each investigator will receive an e-mail notification indicating that the HSC-initiated certification for this project must be completed at **era.health.unm.edu**. For investigators that do not have an active COI account, COI trainings and COI account activation information and instructions will be included in the e-mail notification.* *Local Site Documents, "Other attachments." Category = **HRP Form**.*
Required for changes that requires ancillary review(s):	
□ Completed ancillary review – see full list on pg. 35.	*HRPO IRB coordinator will indicate that an ancillary review has been triggered for the submission. Review the details and status of the ancillary review in the history of the submission.*