HRRC Study Submission Guide
January 2018
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Obtaining Access to Click IRB

Current and prospective research teams and support staff intending to submit a study for HRRC review will need access to the Click IRB system. In order to be granted access to Click you will need to complete the Click IRB Online Training and take the survey. The Online Training is currently offered through the UNM HRPO website and Learning Central.

▶ To find the Click IRB training on the HRPO Website:
  1. Go to the UNM HRPO website
  2. Click on the Investigators tab
  3. Click on Getting Started, then Training Requirements

You can request a group Click IRB Training to be presented at your next faculty/department meeting or class. Email the HRPO IRB On-The-Go Specialist Sarah Targownik (stargownik@salud.unm.edu) to request a group training.

After you have successfully completed the training and survey, you will receive an email that will contain your user access information. Please allow a few days for processing between when you complete the survey and receive your user access information.

Logging In

The Click IRB system is secure, which means only authorized individuals have access to it. When you log in to the system, you get a personalized view of the information and possible actions pertinent to you.

▶ UNM HSC Login:
  1. If you do not see the form shown to the right, click the Login link located at the top right corner of your screen.
  2. Type your UNM HSC NetID user name and password into the boxes.
  3. Click Login (or press Enter).

▶ Non HSC Login:
  1. Type the user name and password you received into the boxes.
  2. Click Login (Or press Enter).

Tip: If you do not know your username or password, contact the Click Administrators or HRPO for assistance.
Creating a New Study

You can prepare a new study for HRRC review by entering information into a series of online SmartForms. The number of SmartForms included may change based on the answers you provide. The SmartForms tell you where to attach files to provide supporting information.

The simplest approach is to follow the SmartForms in order, answering the questions and clicking **Continue** to save your information and move to the next SmartForm. When you reach the end of the series of SmartForms, click the **Finish** button. (For a list of all the SmartForm pages and the attachments see, SmartForm Attachments and Supplements on page 23).

**Note:** A Continuing Review, Modification/Update, or RNI (Reportable New Information) submission can be handled similarly to a New Study.

**Before you begin:**

- Gather supporting information files (for a list, see New Study Submission Checklist on page 6).
- Ensure that all study team members have completed the appropriate CITI Human Research training (CITI training is valid for three years from the date of completion) and FCOI training (found in learning Central through MyUNM). All required training is listed on the HRPO Website.
- Confirm/ensure Principal Investigator eligibility as defined in the Investigator Manual and on the HRPO Website.
- Gather all contact information and HRRC oversight information for external sites involved in the study.

**Tip:** If you regularly create studies with a similar set of team members, you can save time by defining the default team members to be added to each study you create. You can add this default study team in your Research Profile in your Personal Profile.

**Navigation notes**

You will find the navigation bar at the top and bottom of each SmartForm page.

- Click **Back** to go to the previous page and automatically delete your progress
- Click **Save** to manually save your progress
- Click **Exit** to go to the Submission Workspace
- Click **Print** to print a copy of the project
- Click the **drop-down** menu to select an item to “jump to” another SmartForm page

- Click **Hide/Show Errors** to find and correct errors
- Click **Continue** to go to the next page and automatically save your progress
- Click **Finish** to complete the SmartForm pages and be directed back to the submission workspace.
To Create a New Study Submission

1. From My Inbox, click Create New Study. This will begin the process of creating your new study submission. The Click system will take you through several SmartForms and provide you with the opportunity to upload associated attachments that will clarify and document your study details.

Note: If you do not see the Create New Study button, click the My Inbox link (upper right hand corner).

3. Fill in the applicable boxes and answer the questions. Updated questions on the basic information page:

5. *Will an external IRB act as the IRB of record for this study?*
   - ☐ Yes  ☐ No  Clear

6. *What kind of study is this?*
   - ☐ Multi-site study (More than one site will conduct the entire study)
   - ☐ Collaborative study (each site will conduct a portion of the study)
   - ☐ Single-site study
   - Clear

External IRB of Record (if you have ANY Questions, call the HRPO)

For a multi-site study (MSS):

Select Yes if an IRB outside your institution will review this study and decide whether to approve it—with permission from the local (your institution’s) IRB. For example, if you are a participating site in an MSS, select Yes.

If you are the sIRB of record for a multi-site or collaborative study, select No.

Related Topics

"Manually Create a Site" in the Multi-Site Study Quick Reference

For a single-site study (that takes place at one location only):

For an external IRB study, you must also submit the study to the local IRB so they are aware of the research. Talking to the local IRB before submitting the study locally helps prepare your submission for success.

External IRB study forms require less study information than normal, but do require information about the external IRB.
Because an external IRB is reviewing the study, the local IRB workflow does not have an IRB Review state. When the local IRB is satisfied with the information provided and has an agreement with the external IRB in place, the study can be moved from the Pre-Review state directly to the External IRB state.

Using the Update Study activity, you can create a follow-on study in which you can update the study's approval information later to reflect actions taken by the external IRB, such as extended approval and study closure.

**Kind of Study**

A multi-site study is one where study activities outlined in a single protocol are carried out at multiple institutions.

A collaborative study is one where two or more institutions coordinate to complete a portion of the research outlined in a specific protocol.

A single-site study is one where all research activities occur at one institution.

Once you have completed the enhanced questions upload your protocol as instructed on the last question of the Basic Information Smart Form.

3. Click **Continue** to move to the next SmartForm.

   **Note:** A red asterisk (*) precedes each question that requires an answer. If you cannot answer a required question at this time, or if you need to stop and continue at a later time, click on **save** and **exit** at the top of the SmartForm page. If you do not answer a required question, you must return and answer it before you can submit the study for review.

4. When you reach the final page, click **Finish** to exit the study.
   You can continue to edit the study until you submit it for review. See **Editing a Study on page 7**.

**Important!** The study has not been submitted for review yet. For instructions see **Submitting the Study for Review on page 11**.

**Important!** Please do not infer approval, initiate study activities, or implement modifications to study activities until you receive an HRRC approval letter in Click.

**It is important that documents get attached to the correct SmartForm page. Please see page 23 SmartForm Attachments and Supplements.**
HRPO Checklist for New Study Submissions in Click IRB

The information below will help you prepare a more complete new study submission, thus avoiding timely delays in the processing of your new study. 1

All documents with signature lines require a physical signature in the spaces provided. Please ensure that documents are not password-protected and are named appropriately.

**Required Training for ALL Study Team Members**

☒ Click IRB Training **required for the PI and those study team members that will access study in Click IRB
☒ Click COI Training **required of all study team members
☒ Financial Conflicts of Interest Training **conducted in learning central
☒ CITI Training **conducted in the CITI website citiprogram.org

**Required for ALL New Study Applications**2

☒ New Study submission in Click IRB - To begin a new study submission, select “Create New Study” from “My Inbox” in Click IRB.
☒ Protocol(s).doc/.pdf (required; no password protection, include investigator and sponsor protocol as applicable)
☒ Departmental Scientific Review (required)
☒ IRB Fees Determination Form
☒ Curriculum Vitae (CV) **only Required for PI
☒ Conflict of Interest Disclosures (COI) **you will be instructed to complete in the Click Electronic Research Administration System era.health.unm.edu AFTER study is submitted in Click IRB

If Applicable to the study submission (including but is not limited to):

☐ CTSC Attachment: HRP-225
☐ Assent Form(s).doc
☐ HIPAA Addendum.doc (if not combined w/the consent form)

☐ Recruitment Material(s): Publically and Non-publically displayed

☐ Drug/Device Information: (i.e. information sheets or drug brochure).

☐ Scientific Review Committee (SRC)

☐ Drug Attachment: HRP-222
☐ Radiation Safety Attachment: HRP-223
☐ Biological Specimens Attachment HRP-224

☐ Investigator Brochure

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1 After you submit your application with all the required documents, the HRPO will assess completeness of the submission via Administrative Review. Incomplete submissions cannot be considered for review and will be returned to address deficiencies.

2 All files/attachments to the submission must be named accordingly and be uploaded to the correct smart form pages within Click IRB. For instructions on how to get access to Click IRB please visit our website [http://hsc.unm.edu/research/hrpo/index.html](http://hsc.unm.edu/research/hrpo/index.html)
IND/HDE Information, Approvals

- Human Tissue Oversight Committee (HTOC)
- Consent Form(s).doc (See consent builder)
- Other IRB Approvals (NNIRB, Other IRB)
- Letters of Support (External Sites/Agencies)

- Executed DUA/MTA Agreement(s): For data/materials to and from the institution.
- Grant or grant application

Other Study Documents (including but not limited to):
- Participant Materials
- Data Collection
- Case Report Forms
- Surveys
- Interview Script/Questions
- Questionnaires
Editing a Study

You can continue to make changes to a study until you submit for HRRC review. You can also make changes if the HRRC requests clarifications (except during committee review) or modifications.

To Edit a Study:

1. From My Inbox, click the name of the study to open it.
   Note: If the study does not appear in your inbox, see Accessing a Study on page 26.
2. Click Edit Study on the left.

3. Make changes as appropriate. When updating a study document previously submitted to the HRRC, revise it in Tracked Changes format (Microsoft Word) and replace the original document with the Tracked Changes version using the update feature. When the HRRC approves the document, all tracked changes will be accepted in the final version. If you’re unfamiliar with Tracked Changes in Word you can read about it here. Remove all comments prior to submitting.
4. Exit the study.

   Tip: Choose one of these ways to exit:
   - Click the Exit link. If prompted to save the study, click Yes
   - Click Continue on each form, and then click the Finish button on the final SmartForm.

Checking the Study for Errors

Checking the study for errors and omissions helps you include all the relevant information, which is critical for receiving a timely review of your study.

Using these types of error checking tools helps you supply all the information the HRRC needs:

- **Automatic System Error Checking** identifies any omitted answers to required questions on the SmartForm when you click Continue. A red asterisk (*) precedes each blank or question that requires an answer. Keep in mind that the system cannot catch every omission while you edit the study if you skip questions that cause more SmartForms to be added to your study.

- **Visually inspecting** the forms to see what you may have missed, especially:
  - Questions that are relevant to your study but are not required for all studies
  - Documents that should be attached (see New Study Submission Checklist on page 6)

To perform a visual inspection, open the study and look through the SmartForms in order. To open the study, see Editing a Study on page 7.

   Tip: Have someone else in the study team review and proofread the documents for errors prior to submitting them. Reviewers may require grammatical and spelling errors be corrected prior to approval.
- Use the **Hide/Show Errors** option to find and correct all errors before submitting the study. The system automatically checks for errors when the PI attempts to submit the study. However, if you are filling out the SmartForms on behalf of the PI, it is best to check the study for errors before the PI attempts to submit it, using the steps below.

**To use Hide/Show Errors to find and correct errors**

1. Open the study, as explained in *Editing a Study* on page 6.
2. From the top navigation area, click **Hide/Show Errors**.

   ![Hide/Show Errors button](image)

   The **Error/Warning Messages** pane appears at the bottom of the window, listing all the current errors and where to find them.

3. For one of the errors listed, click the link in the **Jump To** column to go to the SmartForm containing the error.
4. Click **Continue** to identify the specific questions on the form with errors.
5. Fill in the missing information.
6. Click **Refresh** in the **Error/Warning Messages** pane to update the list of errors.
7. Continue correcting errors until no errors are listed.
Submitting the Study for Review

After entering all required information into the SmartForms and attaching files, the Principal Investigator must submit the study for HRRC review.

To submit the study for HRRC review:

1. Log in to the system.

   Important! Only the Principal Investigator can complete the following steps. Once the new study has been submitted by the Principal Investigator, a proxy can be assigned (See Assigning a PI Proxy on page 26.

2. Make sure you are in My Inbox.

   Note: If you do not see My Inbox, click the My Inbox link (top right corner of the page).

3. Click the name of the study to open it.

4. Click Submit from the My Current Actions list on the left.

   Tip: If any errors or warnings are shown, click the link in the Jump To column to go to the SmartForm containing the problem. For more information, see Checking the Study for Errors on page 7. When all errors are corrected, try submitting the study by clicking Submit again.

5. Click OK to agree to the statement presented on the screen.

6. When prompted, log in again to verify your identity as the study PI.

7. Click Submit.
What to Expect After Submitting

Submitting information to the HRRC initiates a series of review activities that include:

- Administrative review by the HRPO
- Pre-Review by the HRPO
- Review by the HRRC committee or designated reviewer
- Communication of the HRRC determination to the investigator by the HRPO via Post-Review

Any of these may lead to a request for the study team to take further action, such as providing clarifications or modifying the study. **Whenever the study team needs to act, the PI, PI Proxy, and Primary Contact receive an e-mail notification, and the study appears in My Inbox when they log in to Click IRB.**

**Important!** Failure to respond promptly slows the review and approval process for your submission. If you delay your submission may be discarded.

**Important!** Make sure the appropriate person is listed as the Primary Contact to receive e-mails and see the study in **My Inbox** (along with the PI and any PI Proxies). By default, the person who created the study is the Primary Contact. See **Changing the Primary Contact on page 25.**

Checking the Status of Your Study

You can see a diagram showing the state of your study within the HRRC review process by opening the study. For example:

![Diagram showing the status of a study](image)

You can easily open your study from one of the following lists (depending on its status):

- My Inbox
- IRB In-Review Studies
- IRB Active Studies

For instructions about opening your study, see **Accessing a Study on page 26.**
Responding to a Request for Clarifications or Modifications

At any stage during the review process, the HRRC may request clarifications to the study content. Similarly, the official HRRC determination may be that the study requires changes before research approval is granted. Both situations require the study staff to take similar actions. In either case, the PI, PI Proxy, and the Primary Contact receive an e-mail. The study also appears in My Inbox for all three designated individuals.

Important! Failure to respond promptly slows the review and approval process for your submission. In some cases, your submission may be rescheduled for review at a later HRRC meeting because the committee requires your response before making a decision.

To view the details of the request and respond with the changes

- From My Inbox, click the name of the study to open it.
- Locate the details of the request. There are two types of requests:
  1. For clarification requested: In the Activity column under Clarification Requested, read the request details. If applicable, click the read more link to display the remaining text.

    Dear Dr. Levine,

    Please clarify the following points:
    - What is your favorite song?
    - What is the goal of your research/music?
    - Please have Faidi Torres complete her COD training.

    Analgesic remedies for amputees
    Principal Investigator: Martha Mears
    Submission type: Initial Study
    Primary contact: Carmen Alverado
    IRB coordinator: Lisa Jones

    Letter: Correspondence for IRB297.pdf
2. Edit the study to incorporate changes as needed. For instructions, see Editing a Study on page 7.

Notes:
- In most cases, you can update all aspects of the study, including adding, updating, or removing attached documents.
- When updating a study document previously submitted to the HRRC, revise it in Track Changes format and replace the original document with the tracked changes version using the update feature. When the HRRC approves the document, all tracked changes will be accepted in the final version.
- If clarifications were requested from the reviewer during committee review you will see the View Study button instead of the Edit Study button. In that case, respond to the reviewer by commenting in the Submit Response SmartForm, as described in the next step.

3. Click Submit Response to return the study to the reviewers.

Notes:
- The Submit Response SmartForm gives you space to type a response to the requests and to attach your point-by-point response letter. All permanent study information should be incorporated into the study itself.
- If clarifications were requested during committee review, you may be asked to make changes to the study after the review is complete by submitting an additional modification.

4. Click OK. The study returns to the review process.

Important! You must submit a point-by-point response to all requested modifications detailing where and how you have implemented the changes. This requirement is listed in the letter and the submitted modifications will not be accepted without it.
Changing Documents on a Study

You may need to modify a study's documents when:

- The HRPO requires changes prior to being assigned for review.
- Submitting modifications required to secure HRRC approval.

To change documents prior to study approval:

**Note:** These steps apply if the HRRC decision was modifications required, disapproved, or deferred.

1. From My Inbox, click the name of the study to open it.
2. Click the Documents tab.

<table>
<thead>
<tr>
<th>History</th>
<th>Project Contacts</th>
<th>Documents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filter by</td>
<td>ID</td>
<td>ID</td>
</tr>
</tbody>
</table>

3. Click the document in the Draft column and save it to your computer.

4. Open the document in Microsoft Word.
5. Enable the Track Changes feature and update the document.
6. When finished, replace the original study document with the tracked changes version using the update feature. When the HRRC approves the document, all tracked changes will be accepted in the final version. Remove all comments before submitting.

**Tip:** Follow these tips when naming and uploading documents:

- Add version dates to the Protocol, Consent, HIPAA, and recruitment documents. Use the last revised date instead of a version number.
- Remember, the name you give the file is the name that will appear on your approval letters. The HRPO will not revise document names in the letter or resend letters to change document titles.
- We cannot accept password protected documents.
- It is not necessary to add the study number or the PI name to document titles.
- Do not upload clean and tracked changes versions. This creates opportunity for error and a messy study record. You may be asked to remove duplicate documents.
- Remove template language and all comments from documents prior to submitting.
To change documents on an approved study:

1. Click **IRB** in the top left navigation header and select the **Active** tab.

2. Click the name of the approved study.

3. Click the **Documents** tab.

4. Click the document in the **Final** column and save it to your computer.

   **Tip:** In some cases, you may only be able to use the draft document because the final document is a PDF. In this case, the draft document may contain tracked changes and comments. To make its content match the final PDF, use the review features in Word to accept all the changes and remove any comments. Use this clean document as a starting point for your revisions.

5. Open the document and revise it in Track Changes format.

6. When finished, replace the original document with the tracked changes version in the modification using the update feature. When the HRRC approves the document, all tracked changes will be accepted in the final version.

**Important!** When revising a document in Track Changes for HRRC approval do not leave any comments in the document. Comments cannot be accepted and therefore cannot be finalized by Click. When you think you are finished with a document, proof read it and “accept all tracked changes” to see how the document will appear once it’s been finalized. However it looks when you submit, is how it will appear after finalization. Any formatting issues or errors that appear after finalization may require a modification submission at the study's expense.
## Submitting Modifications, Continuing Reviews, and New Information

<table>
<thead>
<tr>
<th>To submit this type of information...</th>
<th>...start here...</th>
<th>...and click this button.</th>
<th>Notes:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuing review updates for an active study</td>
<td>From the Active tab, click the study name (see Accessing a Study on page 26)</td>
<td>Create Modification / CR</td>
<td>You can submit a continuing review and a modification at the same time. The first form prompts you to identify the type of information to submit. To request study closure, submit a CR. Based on the research milestones completed, the study may be closed.</td>
</tr>
<tr>
<td>Modifications to an active study</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Request to close study</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reportable New Information (RNI) or an adverse event report</td>
<td>For new information about a particular study, start from the Active tab and click the study name (see Accessing a Study on page 26)</td>
<td>Report New Information</td>
<td>Report new information as soon as you become aware of it. The form identifies the types of information you must report. See Reportable New Information Submission on page 19.</td>
</tr>
<tr>
<td></td>
<td>For information affecting multiple studies, start in My Inbox</td>
<td></td>
<td></td>
</tr>
<tr>
<td>New study for review</td>
<td>My Inbox</td>
<td>Create New Study</td>
<td>See Creating a New Study on page 4.</td>
</tr>
<tr>
<td>Updates to a new study that hasn't been submitted for HRRC review</td>
<td>Within the study (see Accessing a Study on page 26)</td>
<td>Edit Study</td>
<td>See Editing a Study on page 7.</td>
</tr>
</tbody>
</table>
Modification Submission Checklist

**Required for ALL Modifications to Approved Research:**
- Modification Submission (Click SmartForm): Please include summary of the modifications and an itemized list of documents and changes in your description of the modification
- IRB Fees Determination Form (HRP-227) (Not Required for “Add Study Team Members” Modification)

**Changes to Approved Study Documents:** (Create Modification/CR, choose Modification/Update, choose Other Parts of the Study under modification scope)
- Revised Document(s).doc (in Track Changes; no password protection)
- Sponsor Summary of Changes (if applicable)

**Changing the PI of Record:** (Create Modification/Update, choose Other Parts of the Study and Study Team Member Information under modification scope.)
- Curriculum Vitae (CV).pdf (required)
- The HRPO will confirm that the PI (and all study team members) have completed the required CITI training (Valid 3 years from completion date) and FCOI training (available in Learning Central through MyUNM)(NOTE: Eligible CITI training groups are listed on the HRPO website along with all training requirements.)
- Updated Protocol, Consent(s), and Supporting Documents with the new PI's name and information (if applicable)

**If Changing Study Team Members:** (Create Modification/Update, choose Study Team Member Information under modification scope. Include full names of all investigators being added or removed in the modification summary.)
- The HRPO will confirm that the new study team members have completed the required CITI training (Valid 3 years from completion date) and FCOI training (available in Learning Central through MyUNM).(NOTE: Eligible CITI training groups are listed on the HRPO website along with all training requirements.)

**Tip:** If changing approved study documents and study team members: Create Modification/Update, choose BOTH Study Team Member Information and Other Parts of the Study under modification scope. Use the lists above for all required documents.
Continuing Review Checklist

Required for ALL Continuing Reviews:

- Continuing Review Submission (Click SmartForm)
- HRP 508 if applicable (if any boxes in Section 3 are left unchecked)
- IRB Fees Determination Form (HRP-227) (Not required for study closures)

Tip: If you need to change study team information at the time of Continuing Review, submit a separate Modification/Update submission for the study team. The HRPO doesn’t recommend submitting combined Modification and Continuing Review submission.
Submitting a Closure
To submit a closure in Click IRB: Navigate to the study that you want to close.

1. Click **Create Modification / CR**
2. Click the **Continuing Review** button, click **Continue**.
3. The Continuing Review/Study Closure Information SmartForm page will come up (See image below):

   1. **Specify enrollment totals**: Enter the enrollment totals.
   2. **Research milestones**: In order to close the study (to discontinue IRB oversight), you must be able to check the first four check boxes in this list. You may check more than the first four.
   3. **Since last HRRC continuing review**: Click the boxes as appropriate. If you are able to check each of the boxes, no additional action is required. If, when completing this section, you are unable to check one (or more) of the check boxes, you must provide a summary or supporting document for each unchecked item. Use **HRP-508** as a template.
4. Click **Continue**.
5. Click **Finish**.
6. The PI/PI Proxy will need to “Submit” the closure by clicking **Submit**

### Continuing Review / Study Closure Information

1. **Specify enrollment totals**: Enrollment totals include: Participants enrolled, charts reviewed, specimens analyzed, etc.

<table>
<thead>
<tr>
<th>Subjects Enrolled</th>
<th>Total</th>
<th>Since Last Continuing Review Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>At this investigator’s sites:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study-wide (if local site only, study-wide total equals this investigator’s sites total):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. **Research milestones**: (select all that apply)

   **Important! If the first four research milestones are complete, the study will be closed to discontinue IRB oversight.**

   - 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)
   - Remaining study activities are limited to data analysis
   - Study remains active only for long-term follow-up of subjects

3. **Check the items that are true since the last HRRC continuing review** for all sites involved in the study.

   **Important! If, when completing this section, you are unable to check one of the checkboxes below, you must provide a summary or supporting document for each unchecked item. Use HRP-508 as a template and for guidance on what information is required for each item.**

   - 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
Submitting a Reportable New Information (RNI)

To submit an RNI in Click IRB: Navigate to the study for which you want to submit the RNI. The Reportable New Information (RNI) function in Click should be used to report Adverse Events (AEs), Serious Adverse Events (SAEs), and to submit events that meet reporting criteria (the event is unanticipated AND related AND caused harm or increased the risk of harm to the participant or others). The RNI function can also be used to submit items that require acknowledgment from the sponsor or Data Safety Monitoring Board (DSMB), Data Safety Monitoring Committee (DSMC), or Data Safety Monitoring Person (DSMP). This may include but is not limited to:

- Data Safety Monitoring Reports or minutes that are outside of the Continuing Review cycle
- Temporary closures (not due to safety issues)
- Closures to accrual (not due to safety issues)
- Investigator brochure updates that do not require revisions
- Action letters (not due to safety issues)

Anyone with access to Click may submit an RNI for any purpose. The submitter does not have to be affiliated with the study as research staff and does not need to be on the Click study team. The person that generates the action in Click is the only one that can submit changes, unless action is required by Committee Review and a “responder” is assigned.

1. To generate an RNI associated with an existing study, begin on the study home page.
2. Click Report New Information
3. Complete the SmartForm page by answering the questions. Questions with a red asterisk (*) must be answered before you can finish the page.
   1. RNI Short Title: Create a descriptive title that identifies what the RNI is about.
   2. Date you became aware of the information.

**Tip:** It is a regulatory requirement that AEs and SAEs are reported within five (5) days of the occurrence. This is the date that should be selected in the calendar date option. However, it is not uncommon that events are identified past this five day requirement. Do not delay submission in these cases and be honest in the dates that are outlined in the RNI summary and the date the study staff became aware of the event.

3. Identify the categories that represent the new information (check all that apply). If none apply, you may leave this section blank (i.e. if you only require acknowledgement of receipt, it doesn't meet reporting criteria, etc).
4. Briefly describe the new information.
   a. Provide details of the series of events that led to the new submission information.
   b. Detail how the participant was affected (if applicable).
   c. Provide a detailed corrective action plan to mitigate future occurrences.
5. In the submitter opinion:
   a.  Does this information indicate a new or increased risk, or a safety issue?
      ☐ Yes  ☐ No  Clear
   b.  Does the study need revision?
      ☐ Yes  ☐ No  Clear
   c.  Does the consent document need revision?
      ☐ Yes  ☐ No  Clear

6. Related studies and modifications. Type the study number in the free text area and the study or possible studies will become available for selection. If a Modification was generated to resolve the new information, it is possible to add that submission to this section by entering the MOD# (e.g. MOD00001234).

7. Attach files containing supporting information.

4. Once you've answered each question on the SmartForm page, click Continue or Finish.

5. Click Submit when you're ready to submit the RNI for review and processing by the HRPO.

Submit RNI

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Important! For complaints, concerns, potential HIPAA violations, fraud, theft, or other unethical behavior contact the UNM Compliance hotline at 1-888-899-6092.

Reportable New Information (RNI) Submission Checklist

Required for ALL Event Reporting of Approved Research:

☐ Reportable New Information (Click SmartForm)
Submitting an External IRB (Refer to the **New Guide in Click under Home – Click IRB Submission Help - **)  

In order to help facilitate human research by allowing investigators to avoid duplicative IRB review while at the same time protecting the rights and welfare of human subjects, the UNMHSC is willing to rely on external IRBs in limited circumstances. The UNMHSC has negotiated reliance agreements with the following external IRBs that may be applicable when UNMHSC researchers are involved in certain clinical trials:

- Central Institutional Review Board (CIRB) of the National Cancer Institute (NCI) under particular circumstances.
- Western IRB (WIRB) under particular circumstances.
- All other research must be reviewed by the UNMHSC HRRC unless authorized by the Vice Chancellor for Research through the submission and approval of an Institutional Authorization Agreement (IAA).

For more information about IAA submissions, please contact the HRPO.

5. Click **Continue** to move to the External IRB SmartForm page.

6. Complete sections 1 - 6:
   - Section 1: Enter the name of the External IRB that will act as the IRB of record. If you cannot find the external IRB in the list, contact the HRPO.
   - Section 2: Upload a copy of the Institutional Authorization Agreement (IAA). If an existing agreement covers your WIRB or CIRB, you do not need to upload the agreement.
   - Section 3: Upload a copy of the External IRB Initial Review Approval Letter.
   - Section 4: Enter initial approval date by External IRB.
   - Section 5: Enter the last date of the approval period.
   - Section 6: Describe the reason the study should be reviewed by an external IRB. (e.g. "this is a CIRB sponsored study, this is a multi-center clinical trial overseen by WIRB," etc.)

7. Click **Continue** and complete the remaining SmartForm Pages. (Note: An IRB Fees Determination Form is **NOT** required for External IRB Studies.)
8. Click **Finish** on the final page.

9. The **Submit** button will be highlighted.

Note about External IRB Study Team Members:
- Enter study team members for both WIRB and CIRB studies.
- For WIRB studies, the Click study team list should reflect the Click COIs triggered by your designated site grant personnel at SPO.
- For CIRB studies the HRPO will trigger Click COIs.

After Administrative Review is complete and the submission is in Pre-Review, the site coordinator may upload approval documentation from the PI authorizing PI Proxy as a Click Comment OR you may forward an email from the PI to the HRPO authorizing PI Proxy. The assigned HRPO analyst will then assign PI Proxy, which will allow the authorized study coordinator to complete and submit all future updates.

**Important!** An approval letter will **NOT** be generated by the HRPO in Click IRB for External IRB submissions. If you need proof of submission and approval, please take a screen shot of your submission page.
## SmartForm Attachments & Supplements

Use this table to ensure you are attaching the right forms and supplemental documents to the correct SmartForm page for your submission in Click IRB.

<table>
<thead>
<tr>
<th>SmartForm</th>
<th>Document Description</th>
<th>Click IRB Library Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic Information</td>
<td>Protocol*</td>
<td>HRP-503, HRP-580 to HRP-584; Sponsor Protocol + HRP-509</td>
</tr>
<tr>
<td>Funding Sources</td>
<td>Grant Application(s)</td>
<td>None Associated</td>
</tr>
<tr>
<td></td>
<td>Funding Source Fee Form</td>
<td>HRP-227</td>
</tr>
<tr>
<td>Drugs</td>
<td>Investigator Brochure</td>
<td>None Associated</td>
</tr>
<tr>
<td></td>
<td>IND Attachment</td>
<td>None Associated</td>
</tr>
<tr>
<td></td>
<td>Drugs Attachment</td>
<td>HRP-222</td>
</tr>
<tr>
<td>Consent Forms and</td>
<td>Consent Form(s)</td>
<td>HRP-502 Template</td>
</tr>
<tr>
<td>Recruitment Materials</td>
<td>Consent Cover Letter(s)</td>
<td>HRP-507 Template</td>
</tr>
<tr>
<td></td>
<td>Short Form(s) of Consent Consent Form(s)</td>
<td>HRP-507 Template</td>
</tr>
<tr>
<td></td>
<td>Tissue Bank Consent Form(s)</td>
<td>HRP-507 Template</td>
</tr>
<tr>
<td></td>
<td>Assent Form(s)</td>
<td>None Associated</td>
</tr>
<tr>
<td></td>
<td>Brochure(s)</td>
<td>None Associated</td>
</tr>
<tr>
<td></td>
<td>Postcard(s)</td>
<td>None Associated</td>
</tr>
<tr>
<td></td>
<td>Advertisement(s)</td>
<td>None Associated</td>
</tr>
<tr>
<td>CTSC Submission</td>
<td>CTSC Request for Resources Attachment</td>
<td>HRP-225</td>
</tr>
<tr>
<td>Additional Information</td>
<td>Individual Investigator Agreement</td>
<td>None Associated</td>
</tr>
<tr>
<td></td>
<td>Institutional Authorization Agreement</td>
<td>None Associated</td>
</tr>
<tr>
<td></td>
<td>Drug Attachment</td>
<td>HRP-222</td>
</tr>
<tr>
<td></td>
<td>Radiation Safety Attachment</td>
<td>HRP-223</td>
</tr>
<tr>
<td></td>
<td>Biological Specimens Attachment</td>
<td>HRP-224</td>
</tr>
<tr>
<td>Supporting Documents and</td>
<td>Principal Investigator’s CV</td>
<td>None Associated</td>
</tr>
<tr>
<td>Non-Publicly Displayed</td>
<td>Postcard(s); Survey(s); etc.</td>
<td>None Associated</td>
</tr>
<tr>
<td>Recruitment Materials</td>
<td>Recruitment Letter(s) and Script(s)</td>
<td>None Associated</td>
</tr>
<tr>
<td></td>
<td>HIPAA Form(s)</td>
<td>None Associated</td>
</tr>
<tr>
<td></td>
<td>Data Safety Monitoring Plan (DSMP)</td>
<td>None Associated</td>
</tr>
<tr>
<td></td>
<td>Departmental Scientific Review Form</td>
<td>HRP-226</td>
</tr>
</tbody>
</table>

*There are 3 Protocol templates: HRP-503: Standard Biomedical Clinical Research template, HRP-580: Chart Review template, HRP-581: Social-Behavioral template, HRP-582: Exempt Category 4 template, HRP-583: Exempt Category 2 & 3 template, HRP-584: Exempt Category 1 template. If a Sponsor Protocol is applicable and available you may complete and include the HRP-509: Local Protocol Addendum template along with the Sponsor Protocol.
Assigning a PI Proxy

Once the study has been submitted a PI Proxy can be assigned by the Principal Investigator. The PI Proxy can perform PI responsibilities on behalf of the PI, such as submitting the study to the HRRC (after the initial submission), modifying the study, and submitting Continuing Reviews.

Notes:
- Only the PI can assign a PI Proxy.
- For security purposes, the PI’s username and password will be required for verification during the assignment process.
- The PI Proxy will receive all notifications that the PI receives.
- A Proxy can only be chosen from among the current study team members.

To Assign a PI Proxy:
- Open the study by clicking the study name. (For instructions about finding the study, see Accessing a Study on page 26)
- Click Assign PI Proxy from the My Current Actions list on the left. A new window opens.
- Click the box beside the name of the person you wish to assign as the PI Proxy. A new window opens.
- Confirm your username and password.
- Click OK.
Changing the Primary Contact

The study's Primary Contact for receiving communications from the HRRC can be changed at any time. It may help to provide a contact person in addition to the PI if the PI does not check e-mail frequently. The Primary Contact can also edit the study just as a study team member can.

Notes:
- To change the Primary Contact, you must be a member of the study team.
- By default, the person who created the study in the system is the Primary Contact.
- The PI and any PI Proxies continue to receive notifications regardless of the Primary Contact assignment.
- Modifications or Continuing Reviews have the same Primary Contact as the initial study. To change the Primary Contact on these submissions, do so in the initial study.

To change the Primary Contact:
- Open the study by clicking the study name. (For instructions about finding the study, see Accessing a Study on page 26)
- Click Assign Primary Contact from the My Current Actions list on the left. A new window opens.
- Click Clear to remove the current contact.
- Begin typing the name of the new contact. A list of matching names appears.
- Select the correct name using the mouse or down arrow key.
- Click OK.

Note: If the Primary Contact is also engaged in the research, make sure the list of team members within the study includes the person.
**Accessing a Study**

You may want to open a specific study to view or update its contents, submit it for review, review it, or take other actions on the study.

**Note:** Your access to a study is personalized based on your role in the system and the role you play in relation to the particular study. In addition, the actions you can take on a study are personalized.

To open a study, click its name or submission ID when you find it in a list of studies.

<table>
<thead>
<tr>
<th>Check this list...</th>
<th>For...</th>
<th>Instructions for finding the list:</th>
</tr>
</thead>
<tbody>
<tr>
<td>My Inbox</td>
<td>Studies assigned to you for action. Examples: Preparing to submit, Assigned to review</td>
<td>Click the My Inbox link in the top right navigation header.</td>
</tr>
<tr>
<td>IRB In-Review Tab</td>
<td>Studies the HRRC has not reviewed or for which it has not released a determination letter</td>
<td>Click IRB in the top left navigation header and select the In-Review tab.</td>
</tr>
<tr>
<td>IRB Active Tab</td>
<td>Studies approved by the HRRC and currently in progress</td>
<td>Click IRB in the top left navigation headers and select the Active tab.</td>
</tr>
<tr>
<td>IRB All Submissions Tab</td>
<td>All studies, continuing reviews, modifications, and RNIs entered in the system that you have permission to view</td>
<td>Click IRB in the top left navigation header and select the All Submissions tab.</td>
</tr>
<tr>
<td>IRB New Information Reports Tab</td>
<td>Reportable New Information (RNI) submissions, possibly related to one or more studies</td>
<td>Click IRB in the top left navigation header and select the New Information Reports tab.</td>
</tr>
</tbody>
</table>
Finding More Information

<table>
<thead>
<tr>
<th>To find this...</th>
<th>...look for this...</th>
<th>...and click...</th>
</tr>
</thead>
<tbody>
<tr>
<td>More information about a question or form.</td>
<td>?</td>
<td>Click the question mark icon next to the question or form title.</td>
</tr>
<tr>
<td>The full online help system, with search and table of contents.</td>
<td>Shortcuts</td>
<td>Click the Help link in the Shortcuts area on the left.</td>
</tr>
<tr>
<td>The online help contains additional procedures and information for all users.</td>
<td>Study Submission Guide</td>
<td>Click the Study Submission Guide link in the Shortcuts area on the left.</td>
</tr>
<tr>
<td>Instructions for submitting a study for review.</td>
<td>Shortcuts</td>
<td>Click the Study Submission Guide link in the Shortcuts area on the left.</td>
</tr>
<tr>
<td>Document templates, standard operating procedures, checklists, and HRRC procedures.</td>
<td>IRB</td>
<td>Click IRB and then IRB library in the upper left corner.</td>
</tr>
</tbody>
</table>

Contacting Support

For additional answers to your questions, feel free to use the following resources:

<table>
<thead>
<tr>
<th>Resource</th>
<th>Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>HRPO Website</td>
<td><a href="http://hsc.unm.edu/research/hrpo">http://hsc.unm.edu/research/hrpo</a></td>
</tr>
<tr>
<td>Training materials and requirements on the website</td>
<td><a href="http://hsc.unm.edu/research/hrpo/investigators/getting-started/training.html">http://hsc.unm.edu/research/hrpo/investigators/getting-started/training.html</a></td>
</tr>
<tr>
<td>IRB On-The-Go Specialist: Sarah Targownik</td>
<td>To schedule consults, group trainings, and receive personal submission help: <a href="mailto:stargownik@salud.unm.edu">stargownik@salud.unm.edu</a> 505-272-0949</td>
</tr>
<tr>
<td>HRPO Staff</td>
<td><a href="mailto:HSC-HRPO@salud.unm.edu">HSC-HRPO@salud.unm.edu</a> 505-272-1129</td>
</tr>
</tbody>
</table>