PROTECT Tip Sheet for
Research Teams:
"Tips & Tricks: Preparing Reportable New Information Forms"

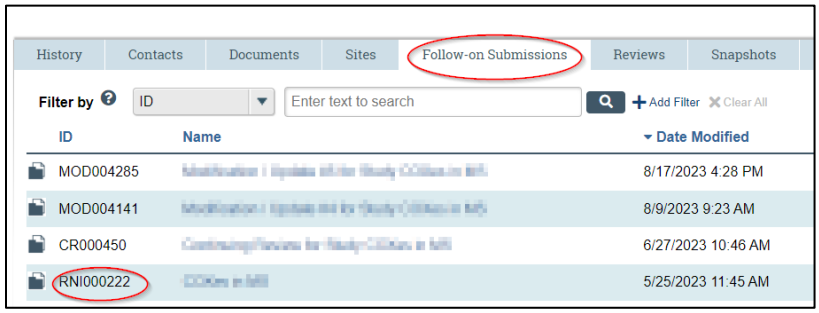
Who has access to read/write/submit RNIs:

- **R**eportable **N**ew **I**nformation (RNI) forms can be submitted by anyone who has an active user account in the PROTECT system. The RNI form does not need to be linked to a specific study unless applicable. This is because RNIs are time-sensitive and need to be reported right away per the policy, so we don't want to hold up the submission of them.
- If the RNI is linked to a specific study, only those with access to that study can view the RNI and **ONLY** those on the study teams of the related studies or submissions will be able to access the RNI. **ONLY** the submitter can edit the RNI submission, everyone else will have "View Only" access.
- If the RNI form is returned for clarifications during the review process, only the initial submitter of the RNI can respond to those clarifications.

Where to find Your RNIs:

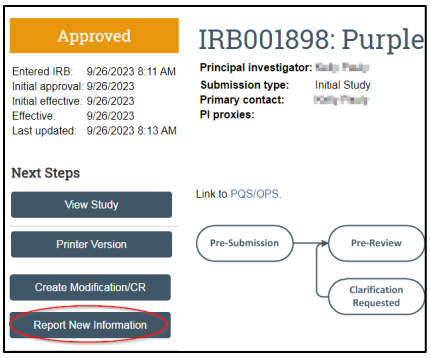
- You can find <u>all</u> the RNIs you have access to and view the related studies by going to the **IRB** tab and choosing the **New Information Reports** tab:

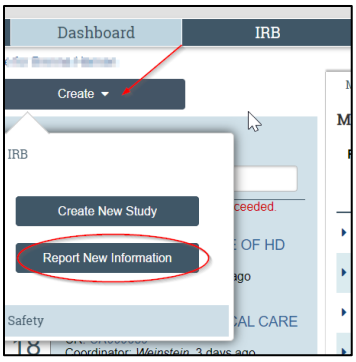
- To find RNIs that are related to your IRB study, navigate to the parent study workspace, and click on the **Follow-on Submissions** tab:



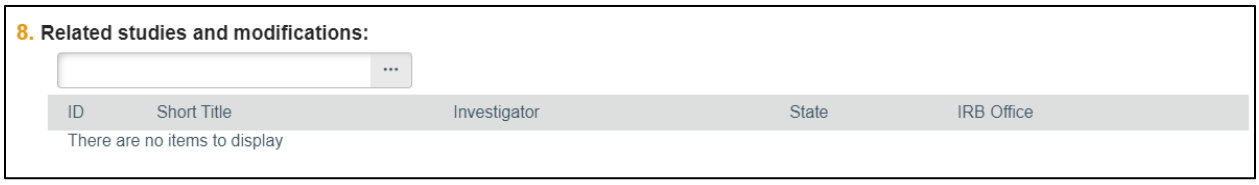
Creating RNIs:

- RNIs can be created within the workspace of a specific study or directly from your dashboard.





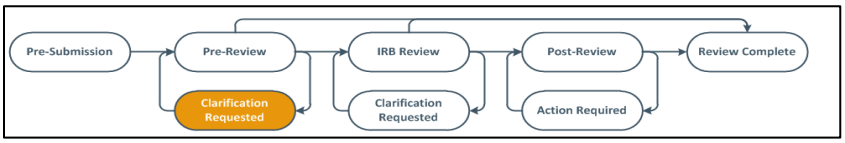
- **Important:** When filling out the RNI smart form, section 8 allows you to add any "Related studies and modifications" that are associated with the RNI. Be sure to choose any **study** that the RNI applies to **HERE** since this section only populates automatically when the RNI is created in a study workspace. RNIs can also be associated with more than one study in PROTECT, so all involved studies should be listed.
- Note that you will only be able to select from studies that you have access to in PROTECT. If the RNI is related to a study you do not have access to, you can include that information in the smart form so the coordinator can add the related studies after you submit the RNI.



- Related **Modifications** can also be linked to an RNI in the PROTECT system.
- **External IRB studies and NIH IRB studies** cannot be linked to the same RNI in PROTECT. External IRB studies require a separate pathway for RNI submissions which is explained at the end of this tipsheet.
- **NOTE**: Those who have access to the RNI can also add a related submission to the RNI at any point by using the "**Add Related Submission**" button in the RNI workspace. This will also update section 8 of the RNI smart form.

Requests for Clarifications:

- The RNI workflow has the same options for the coordinator/reviewer to request clarifications from the person who submitted the RNI during the 'Pre-Review' and 'IRB review' states as those used for Modifications, Continuing Reviews, and Initial Reviews:

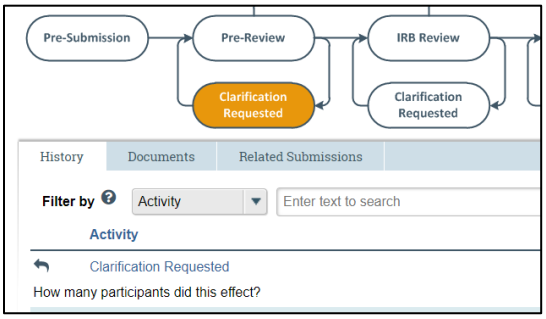


- During the Pre-Review of an RNI, the Office of Human Subjects Research Protections (OHSRP) Division of Compliance and Training may ask for additional information or corrections to the RNI smart form before processing the RNI. Questions regarding RNIs can be emailed to ohsrpcompliance@od.nih.gov

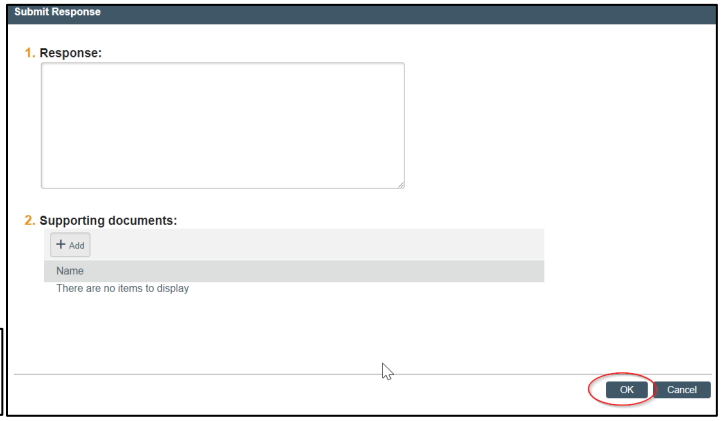
- After the Pre-Review process is complete, the RNI will either be processed administratively by OHSRP or the RNI may be referred for full board review by either the NIH IRB or the NIH Research Compliance Review Committee (RCRC). This process is described below.

Clarification Requests during Pre-Review and Administrative Review:

- When OHSRP sends a clarification request, the information can be viewed in the history tab of the RNI:



- **ONLY** the initial submitter of the RNI can respond to the clarification. To respond, use the **Submit Response** button on the left side of the RNI workspace. Type your response in the "**Response" text box** and attach any supporting documents (Remember not to include PII). **You MUST click "OK" to complete the submission.** If done correctly, you will be able to view your response in the History tab.



- **Administrative Review:** During the Pre-Review process, if OHSRP determines that no additional elevated review needs to take place, then their determination with be recorded and the submission will move to the "Review Complete" state. The study team will receive an acknowledgement letter with the final determination and the submission state will appear as "Acknowledged."

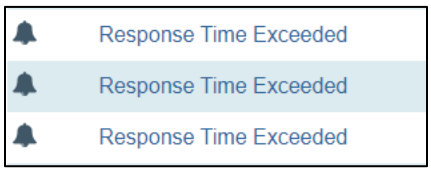
Clarification Requests during Full Board Review:

- OHSRP may also determine during the Pre-Review process that additional review by a full board IRB is required. Depending on the type of RNI, it will either be assigned to the NIH IRB or the RCRC. If the event is a possible "unanticipated problem" or "possible new information that may impact a subject's decision to remain or enroll on the study," the event will be reviewed by the NIH IRB. If the event is potential serious and/or continuing noncompliance, then the event will be reviewed by the RCRC.
- The assigned full board reviewer can also send a **clarification request asking for additional information** before the full board meeting. This request is sent to the initial submitter, and **ONLY** the submitter of the RNI can respond (Not even the PI can respond). **The RNI form cannot be edited at this time.**

Required Action Responses after Full Board Review:

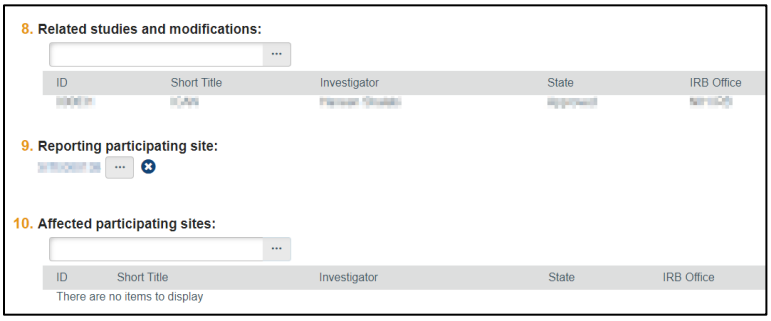
- At the full board meeting, if the board determines that further action requiring a response by the research team is required, a letter will be sent describing the actions needed. A "responsible party" to complete these actions will also be chosen and will be indicated in the letter.
- The **responsible party** is now the person that must respond in PROTECT and not the initial submitter. The responsible party will need to respond using the "Submit Action Response" button on the left-hand side of the screen. This button will only be visible to the responsible party.

- Once the response is submitted back to the board, the board will review the response to see if the required actions have been completed. If they have not, further actions may be requested. Otherwise, a final letter will be sent out and the RNI submission will be completed in the system.
- If an action response has not been submitted in a month's time from the responsible party, you will see "Response Time Exceeded" appear on the History tab of your RNI submission and the responsible party will receive an e-mail notification. This is **ONLY** a reminder. These notifications will automatically be sent monthly until a response has been submitted.

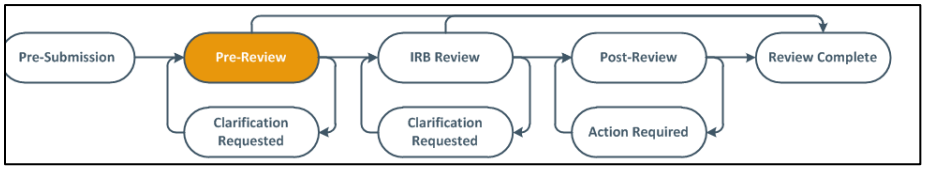


Participating sites:

- Participating sites relying on the NIH IRB can also submit RNIs in PROTECT within their pSite workspace.
- When completing the RNI form from the pSite, the form will have both the option to add related studies and modifications as well as adding affected participating sites.



- After submitting an RNI, the submission advances to the Pre-Review state. The submission will follow the same workflow that was previously mentioned.



External IRB Studies:

- It is expected that NIH PI/study teams will follow the external IRB's requirements for reporting RNIs to the external IRB. Any events occurring locally at NIH should also be reported to the NIH IRB at the same time as being reported to the external IRB according to the requirements of NIH HRPP Policy 801.
- After submitting an RNI for an external IRB study in PROTECT, the RNI advances to the "Pending sIRB review" state. Once the external IRB has made a determination, the submitter will need to upload the final determination documentation in PROTECT via **Add Comment.** The event will be reviewed by OHSRP and the sIRB decision's will then be recorded in PROTECT. An acknowledgement letter will be sent once review is complete.