



RAP IRB REPORTABLE NEW INFORMATION (RNI)

Report unanticipated problems and adverse events involving risks to participants or others. Unanticipated problems and events should be reported no later than 7 days of the investigator becoming aware of the occurrence. *However, investigators should contact Research Compliance Services (RCS) immediately upon discovery of an unanticipated problem or event involving risks to subjects or others.*

For additional information on unanticipated problems, please see the Federal guidance which can be found at the [Office for Human Research Protections \(OHRP\) website](#).

If you have questions, please contact [Research Compliance Services](#).

Table of Contents

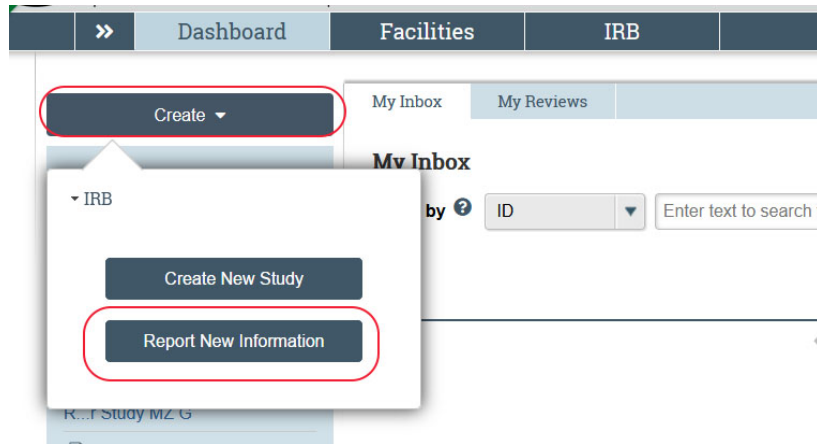
RAP Tips	1
Login and Create Submission	1
Reportable New Information	2
Submit RNI.	3
Post submission options.	4

RAP Tips

- When selecting from drop-down lists, use the percentage sign (%) as a wildcard to maximize your search results. For example, "%geography" will bring up sources with "geography" anywhere in the name.
- You can save your work by clicking "Save" in the lower right corner of the page. Choosing "Continue" saves your work and takes you to the next smart form.
- To withdraw your submission and return it to its pre-submission state, choose "Withdraw" from the options listed on the left side of the screen after you have accessed your study.
- To permanently remove the submission, choose "Discard" from the options listed to the left side of the screen after you have accessed your study.
- Once you have completed all forms and have clicked "Finish", you must click "Submit RNI" to submit the information to RCS. Your submission will not enter the queue for review until it is submitted.

Login and Create Submission

1. Go to irb.rap.uoregon.edu and login using your Duck ID. If you are having issues logging in, email [RCS](#).
2. Once logged in, the system will take you to your dashboard. Click "Create" and choose "Report New Information" from the options.



Reportable New Information

- Complete the information on the **Reportable New Information** smart form.
- All fields with an asterisk are required.



1. *RN Short title.* Enter a unique name to identify this new information.
2. *Date you became aware of the information.* Enter date.
3. *Identify the categories that represent the new information (check all that apply).* Chose which category(ies) that best correspond to the information.
4. *Provide a brief summary of the Reportable New Information.* Describe the event. If revisions to a currently approved study are required, describe them here and submit a modification for review.
5. *In the submitters opinion?* Answer the questions that follow.
6. *Related studies and modifications.* If this information is related to a currently approved or recently submitted study, associate that study here.
7. *Reporting participating site.* If this event was reported by a participating site, associate that site here.
8. *Affected participating site.* If this event effects a participating site, associate that site here.
9. *Attach the [Reportable New Information supplemental](#) form and any other supporting documentation.*

Select "Continue" at the lower right side of the screen to save the form and be returned to the RNI workspace. You may also select "Save" to return at a later time by selecting the study and choosing "Edit Study".





Submit RNI.

1. The RNI workspace will be in the pre-submission state. Select "Submit" from the choices at the left side of the screen.

Pre-Submission

Last updated: 12/30/2020 11:12 AM

Reported by: Phil Bivens (pi2)
Submission type: Reportable New Information

Next Steps

- Edit RNI
- Printer Version
- Submit RNI**
- Add Related Submission
- Add Comment
- Copy Submission
- Discard

RNI00000018: Step 1

```

graph LR
    A[Pre-Submission] --> B[Pre-Review]
    B --> C[Clarification Requested]
    C --> B
    C --> A
  
```

History	Documents	Related Submiss
Filter by ? Activity <input type="text" value="Enter text"/>		
Activity		
<i>i</i> Reportable Information Opened		

2. If you have not entered required information on any smart form, you will be prompted to edit the information. Once all the required information is entered, you will see the submit screen. Once you have verified the information presented, click "OK" at the lower right corner of the screen.

Submit RNI

By signing below you are verifying that:

- The information you have submitted is complete and correct to the best of your knowledge.
- The information you have submitted has been done so in accordance with requirements in the [HRP-103 - Investigator Manual](#)

OK Cancel

3. The RNI has been submitted for review. You can see that your study is now in the pre-review state. At this stage, you are no longer able to edit your study, but you do have some options listed below.



Post submission options.

- Once your RNI is in pre-review status, there are several options.
 1. *Add Related Submission.* Here you can add studies, reporting participating sites, and affected participating sites to this submission.
 2. *Add Comment.* You may add additional information and supporting documentation to the submission by choosing "Add Comment". The comment will be visible to anyone with access to the submission.
 3. *Copy Submission.* You may create a copy of the submission. You will remain the PI for the new submission.
 4. *Withdraw.* If you would like to withdraw the submission for any reason, choose "withdraw". The submission will be reverted back to Pre-Submission status and you will be able to make edits. You may submit again when you are ready.
 5. *Discard.* Choosing this action will permanently remove the submission.