

## Reportable New Information (RNI)



### WORK INSTRUCTIONS

1. Log into PACS Portal and select the **IRB** tab. You can create an RNI from a study workspace by clicking on the **Report New Information** button in the left hand navigation area.

ID	Name	Date Modified	State	PI First Name
RNI00000070	_IRBSubmission - 6/22/2017 4:50:36 PM	6/22/2017 12:50 PM	Pre-Review	Rebecca
STUDY00000899	For Board Members	6/22/2017 11:33 AM	Non-Committee Review	Rebecca
RNI00000074	_IRBSubmission - 6/21/2017 5:36:50 PM	6/21/2017 1:36 PM	Pre-Submission	Michele
STUDY00000700	Stress Test	6/16/2017 12:45 PM	Clarification Requested (Designated Review)	Rebecca
STUDY00000896	Test Study; Expedited	6/15/2017 12:23 PM	Approved	Rebecca

2. Enter the required information marked with asterisks (\*) on the first page of the SmartForm and click **Continue** from either the top right or bottom right of the page.
  - Indicate which study this RNI is for by adding the study in the **Related studies and modifications**.
  - Use this same activity to link multiple studies to one RNI submission, when appropriate.

**Reportable New Information**

1. **PII about title:** (optional) identify the new information clearly.

2. **Date you became aware of the information:**

3. **Identify the categories that represent the new information:** (check all that apply)

- Make:** New information (e.g., an interim analysis, interim monitoring based on deviation in the treatment, protocol errors or investigator findings) indicates an increase in the frequency or magnitude of a previously known risk, or increases a new risk.
- Make:** An investigator protocol, protocol amendment, or device labeling is revised to mitigate an increase in the frequency or magnitude of a previously known risk, or identify a new risk.
- Make:** A new protocol, amendment, or modification of a protocol amendment of a drug, device, or device used in a research protocol that reduces a risk or increases risk or a safety issue.
- Make:** Revised criteria for further studies or other in the ongoing protocol or other might be increased risk of harm.
- Make:** Completion of a subject that indicates subjects or others might be increased risk of harm or a new risk.
- Make:** Any change significantly affecting the conduct of the research that indicates a new or increased risk or a safety issue.
- Make:** Any harm experienced by a subject or other individual that, in the opinion of the investigator, is enhanced and/or has been previously related to the research procedure (i.e., "Unanticipated problems involving risks to subjects or others").
  - a. A harm is "unanticipated" when its severity or nature is inconsistent with risk information previously received and approved by the IRB in terms of nature, severity, frequency, and characteristics of the study population.
  - b. A harm is "previously related" to the research procedure if in the opinion of the investigator, the research procedure was likely to have 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 violation of such requirements.
- Adverse:** Adverse reaction or injury to a federal agency.
- Report:** Written report of study members.
- Non-compliance:** Failure to follow the protocol due to the failure of inclusion of the investigator or research staff.
- Confidentiality:** Breach of confidentiality.
- Unintended change:** Change to the protocol that, without prior IRB review to determine an appropriate immediate action to a subject.
- Investigator:** Impairment of a subject to a study not approved by the IRB or in the process.
- Completion:** Completion of a subject that cannot be applied to the research team.
- Investigator:** Impairment or suspension of operation of the research by the sponsor, investigator, or institution.
- Unanticipated adverse device effect:** Any serious adverse effect or 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 description (including a representative plan or application) or any other unanticipated adverse problem associated with a device that relates to the rights, safety, or welfare of subjects.
- IRB:** For Research on Reportable New Information, Research, or other in related research subject to IRB.

**Disclaimer:** Information that does not fit into one of the categories above does not need to be reported to the IRB as new information.

4. **Describe the new information:**

5. **In the subject's opinion:**

- a.  Does this information indicate a new or increased risk, or a safety issue?  
 Yes  No  N/A
- b.  Does the study need revision?  
 Yes  No  N/A
- c.  Does the consent document need revision?  
 Yes  No  N/A

If revision is required, describe them above and submit a study modification for review.

6. **Related studies and modifications:**

Study Number	Investigator	Date	IRB Office
	Research Center at Binghamton	04/01/2010	IRB Office

7. **Attach files containing supporting information:**

There are no files to attach.

3. You will now be viewing the workspace page and see a notation under **Activity** stating **Reportable Information Opened**. If you need to review or edit the RNI, click on **Edit RNI** under **My Current Actions**.
4. If you are ready to submit the RNI, click on **Submit RNI** in the left hand navigation. A pop up box will appear and if your submission is in order, it will direct you to click the **OK** button.

Home Courses Agreements COI Facilities Grants IACUC IRB Safety

IRB > Test Study: Expedited > \_IRBSubmission - 6/22/2017 4:59:42 PM

**Pre-Submission** **RNI0000079: \_IRBSubmission - 6/22/2017 4:59:42 PM**

Reported by: Rebecca Simms (pi)(020) IRB office: t  
 Submission type: Reportable New Information  
 Entered IRB: IRB coordinator:  
 Modified: 6/22/2017 12:59 PM

Pre-Submission → Pre-Review → IRB Review → Post-Review → Review Complete  
 Clarification Requested → Clarification Requested → Action Required

**My Current Actions**

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

History Documents Related Submissions

Filter by Activity Go Clear Advanced

Activity	Author
Reportable Information Opened	Simms (pi)(020), Rebecca

**Submit RNI**

By clicking the "OK" button on this page 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

4.

5. You will now be directed back to the workspace where you will see a new message under **Activity** stating **RNI Submitted**. You may view the RNI by clicking on **View RNI** under **My Current Actions**.

The screenshot displays the IRB submission workspace for submission RNI0000081. At the top, a navigation bar includes links for Home, Courses, Agreements, COX, Facilities, Grants, IACUC, IRB, and Safety. Below this, a breadcrumb trail shows the path: IRB > IRB Submissions > IRBSubmission - 6/22/2017 6:20:04 PM. The main header area contains the submission title "RNI0000081: \_IRBSubmission - 6/22/2017 6:20:04 PM" and the IRB office name "Binghamton University IRB Office".

Key submission details include:  
Reported by: Rebecca Simms (pi)(020)  
Submission type: Reportable New Information  
Entered IRB: 6/22/2017 2:30 PM  
Modified: 6/22/2017 2:20 PM  
IRB coordinator:

A workflow diagram illustrates the process stages: Pre-Submission, Pre-Review, IRB Review, Post-Review, and Review Complete. Transitions between stages include "Clarification Requested" and "Action Required".

The "My Current Actions" menu on the left lists several options, with "View RNI" circled in red. Below the menu, a "History" tab is active, showing a table of activities. The "Activity" column is filtered, and the entry "RNI Submitted" is circled in red. A box with the number "5." has arrows pointing to the "View RNI" button and the "RNI Submitted" activity entry.

Activity	Author
RNI Submitted	Simms (pi)(020), Rebecca
Reportable Information Opened	Simms (pi)(020), Rebecca