

Click IRB Quick Guide

Reporting New Information (RNI)

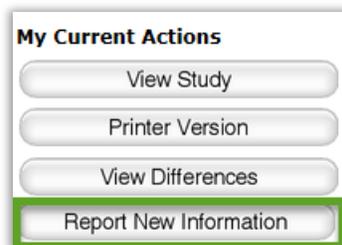


This Quick Guide will help me

- Know how to report new information to the IRB
- When to report to the IRB
- What information to report to the IRB
- Tips for filling out the form

How to Report New Information (RNI):

- On the parent study record, in the left hand navigation menus under “My Current Actions”, click the Report New Information button:



- HRP-214A (RNI attachment) is mandatory when you are reporting certain categories of information. Be sure to follow the form’s instructions to see if you need to attach it.

When do you report?

- You are required to report new information that fits into an RNI category **within 5 business days** of becoming aware of the information .

What you report:

- See a screenshot of the RNI form on the next page of this guide
- Read the statement at the end of the smart form: “Important! Information that does not fit into one of the categories above does not need to be reported to the IRB as new information.” If the information does not fit a category on the form, you do not have to report it. For example, offsite safety reports, if the information they contain does not meet the criteria of one of the RNI categories, the IRB will not accept them.

Reporting New Information (RNI)

Reportable New Information Smart Form:

Reportable New Information

Only the submitter of this form can respond to the IRB's subsequent inquiries. This is due to the concept that anyone can report concerns. This is not an anonymous means of reporting concerns.

1. **RNI short title:** (uniquely identify this new information report) 

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

3.

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

- 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/deviation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm. This can include deviations from normal practices by institutional persons/groups such as a laboratory or a pharmacy.
 - 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.
- Risk of Harm/Harm:** Any risk of harm or actual harm experienced by a subject or other individual that, in the opinion of the investigator, is unexpected and is related or possibly related to the research procedures.
 - a. A risk of harm or actual 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 risk of harm or actual harm is "**related or possibly related**" to the research procedures if, in the opinion of the investigator, there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research.
- 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.
 - a. Non-compliance can result from system processes or the action/inaction of the investigator, study staff or other institutional persons/groups, including the IRB.
 - b. But protocol deviations that result from the action/inaction of the investigator or study staff should be submitted as a Researcher Error (use Researcher Error box below).
- 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.

Tips:
-Information that does not fit one of these categories does not require reporting
-If the information needs to be reported, you should do so within five business days

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

4. **Briefly describe the new information:**

5. **In the submitter's 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](#)

If revisions are required, describe them above and submit a study modification for review.

6. **Related studies and modifications:**

ID	Short Title	Investigator	State	IRB Office	
STUDY00000152	PLAT-03	Colleen Annesley	Approved	HSPB (IRB Office)	Remove

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

[Add](#)

Name
There are no items to display

Tips:
-View the RNI attachment or the help text to see if the RNI attachment is required

Use one of these templates:

- [HRP-214A RNI Attachment](#)

To send the new information for review, you must select "Submit RNI" under "My Current Actions" on the next page.

Reporting New Information (RNI)

RNI Tips

- Carefully consider each category and check all applicable boxes; you may find yourself checking multiple boxes for a particular incident.
- Use the RNI short title on the form to briefly, but uniquely identify the report. A unique name will be helpful over time in distinguishing between reports for a study.
- For more information on the 5 business days requirement for reporting RNIs, see the section entitled “What are my obligations after IRB approval?” of the Investigator’s Manual (HRP-103)
- Anyone with access to Click can report new information on a study whether they are part of the study team or not.
- Use the “Related studies and modifications” section of the form to relate the RNI to one or more studies. If the RNI requires a modification to complete a corrective action, relate the RNI to that Modification.

More Questions? Contact the Institutional Review Board at irb@seattlechildrens.org or X77804.