Submitting an RNI (Reportable New Information) in eIRB+

RNI Basics

During the course of a research study, Unanticipated Problems Involving Risk to Subjects or Others (UPIRSOs) and non-compliance may occur and need to be reported to the NU IRB. The NU IRB website contains detailed guidance on the types of scenarios that require reporting to the IRB as well as the appropriate procedures for doing so: https://irb.northwestern.edu/process/reportable-new-information

Specifically, the following events are considered reportable. More information/examples of each of these can be found on the IRB website linked above.

- **Risk**: Information that indicates a new or increased risk, or a safety issue. This includes a chance that something bad could happen.

- **Harm/Death**: Any harm (including death) experienced by an NU subject or other individual(s) that, in the opinion of the investigator, is unexpected and at least probably related to the research procedures. Harms can include psychological, economic, legal, and other non-physical harms.

- **(Reportable) Non-compliance**: Serious and/or continuing non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB that causes harm, increases the risk of harm, adversely affects the rights or welfare of participants or undermines the scientific integrity of the data, or an allegation of such non-compliance. Incidents of non-compliance on the part of research participants which do not involve risk need not be reported to the IRB (i.e., failure to turn in medication diary).

- **Audit**: Audit, inspection, or inquiry by a federal agency and any resulting reports (e.g., FDA Form 483)

- **Reports**: Only certain written reports of study monitors must be reported. Prompt reporting (within 5 days) is required for monitoring reports for which the industry sponsor determines the findings could affect the safety of participants or influence the conduct of the study.

- **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**: A participant at a non-Northwestern site has experienced a severe and unexpected reaction to the study drug. The sponsor thinks this may be related to the study drug and instructs sites to promptly lower the drug dosage to eliminate an immediate hazard to participants. In this case, the PI should immediately implement the dosage change prior to IRB approval and then submit an RNI to notify the IRB.

- **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.
• **Investigational Pharmacy Error:** An error involving the investigational pharmacy that puts participants' rights and/or welfare at risk or undermines the scientific integrity of the data. Please also notify the Investigational Pharmacy at INVdrugser@nm.org to get additional information for your RNI (e.g., Corrective Action Plan).

• **Short Form:** If using a translated short form from the IRB website and the English language consent document as the written summary, the short form consent process may take place prior to IRB review. An RNI should be submitted to the IRB within 10 days, to report the use of the short form consent process. The RNI should contain the documents and confirmations previously described above. Additional guidance on short forms can be found [here](#).

Information that does not fit into one of the categories above does not need to be submitted, per NU IRB’s requirements, but may still be submitted at the PI or study team’s discretion.

**UPIRSOs**
(U[nanticipated] P[roblems] I[nvolving] R[isk] to S[ubjects] or O[thers])

If a sponsor issues a study-wide safety report, and the NU principal investigator determines that the incident, experience, or outcome fits ALL of the following conditions (i.e. the 3 UPIRSO criteria), an RNI should be submitted:

1. is **unexpected** (in terms of nature, severity, or frequency) given the procedures described in the research protocol documents (e.g., the IRB-approved research protocol and informed consent document) and the characteristics of the human subject population being studied;

2. is **related or possibly related** to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

3. suggests that the research places human subjects or others at a **greater risk of harm** (including physical, psychological, economic, or social harm) than was previously known or recognized, even if no harm has actually occurred.

In addition, all subsequent follow-up safety reports for that initial report/event for that specific subject/report number, regardless of whether or not they meet the UPIRSO criteria, will need to be submitted as RNIs as well.

**Time Frames for Reporting and Submission**

Reporting requirements at NU IRB are separated into two distinct categories:

1. Death of an NU/NU Affiliate research participant
2. RNI

The death of an NU/NU Affiliate research participant for a reason that is unanticipated and related to the research must be reported within **24 hours** of knowledge or notification.

**Reporting the death of non-NU/NU affiliate research participants is not required.**

Any of the above events that are considered RNIs must be reported within **5 business days** of knowledge or notification.
Process for RNI Submission, Review, and Acknowledgement

If an event meets the criteria described above and must be reported to the IRB as an RNI, please follow the instructions linked below. For additional information, visit the NU IRB website here: https://irb.northwestern.edu/process/reportable-new-information/preparing- rni-eirb

1. Start the RNI Submission
   a. Go to the main page for eIRB+ and log-in. Once in the system you will be brought to your inbox.
   b. On the left side of the page, select “Report New Information”.
   c. You will be brought to the main page of the RNI submission
   d. Create an RNI short title – ensure the NUCATS#, PI name, protocol #, sponsor (if applicable), and event are listed in the title
      For example: 18-133 Amin AbbVie M16-766 – Consenting Error
   e. Enter the date you became aware of the information/were notified by the study team of an event. Enter the date the PI became aware that the reportable event occurred. This date should be within the appropriate reporting time frame as described above. Please explain any delays that may have occurred between the PI being informed of the reportable event and subsequently informing the regulatory coordinator for submission.
Reportable New Information

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

2. Date you became aware of the information:

f. Select the appropriate category that represents the information (multiple categories can be selected). See section above under RNI Basics for more information.

- Risk: Information that indicates a new or increased risk, or a safety issue. This includes a chance that something bad could happen. 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 unveils 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 that harmed subjects or others that indicates subjects or others might be at increased risk of harm.
  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.

- Harm/Death: Any harm (including death) experienced by an NI subject or other individual that, in the opinion of the investigator, is unexpected and at least probably related to the research procedures. Harms can include psychological, economic, legal, and other non-physical harms. For example:
  a. A participant at the Northwestern site has experienced a severe and unexpected reaction to the study drug. The PI thinks this is possibly related to the study drug.
  b. An investigator finds out that the study involves a currently approved drug that may cause renal failure according to newly published literature. An interim analysis or safety monitoring report indicates that frequency or magnitude of harms or benefits may be different than those initially presented to the IRB.
  c. Change in FDA labeling or withdrawal from marketing of a drug, device, or biologic used in a research protocol.
  d. An investigator realizes participants have accidentally been given study drug at a higher dose than was approved by the IRB. While no side effects were reported, the increase in dosage places the subjects at potential risk of harm.
  e. Four weeks into the study of a new asthma drug, a participant informs the research staff that she is pregnant although the pregnancy test done at screening was negative. Pregnancy is an exclusion factor in the study.
g. Inform the IRB if the incident occurred at NU or was external from NU.

h. Describe the event/new information. Include a brief description (no more than 1-4 paragraphs) describing the RNI. Be sure to include what occurred, the date that the event occurred, why the event is reportable, and if applicable what is being done as follow-up to the event and/or what is done to make sure it doesn’t occur in the future (i.e. the Corrective Action Plan, or “CAP”).
i. Select “yes” or “no” to the following three questions:

5. In the PI/submitter’s opinion:
   a. * Does this information indicate a new or increased risk, or a safety issue?
      - Yes
      - No
   b. * Does the study need revision?
      - Yes
      - No
   c. * Does the consent document need revision?
      - Yes
      - No

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

If you select “yes” to any of the above questions, modifications to study documents (such as the consent) or study procedures may be required by the IRB. These will need to be submitted and reviewed separately. The RNI # should be referenced in each subsequent, related submission for purposes of continuity.

j. Indicate what study(s) the RNI applies to. Find a study by typing in any part of the short title or PI’s name. A list of studies will generate; select the study the RNI applies to.

k. Upload any and all supporting information

Attach any additional documents that are relevant to the RNI event. This includes the sponsor-issued safety report/SUSAR document or additional information clarifying the RNI event.
When you are finished completing the RNI submission, select complete in the bottom-right corner of the page to be re-routed to the main study page.

Forward to the PI to submit the RNI.

RNIs are unique submissions because they must be forwarded to the PI to submit and the individual completing the RNI or personnel with proxy are not able to initially submit. The individual completing the RNI may submit if subsequently any clarifications are requested by the IRB.

**RNI Review:** RNIs are not “approved” in the same way that modifications or new study submissions are approved. Instead, RNIs are acknowledged once the IRB panel reviews and all clarification requests have been addressed.
There are instances in which multiple RNIs for a specific study, or insufficient action taken by the study team described in an RNI, may lead to a need for study revision or an updated corrective action plan. If such a case occurs, the IRB will request a corrective action plan (CAP) and/or any other revision needed in the IRB RNI acknowledgment letter. A new RNI may need to be submitted to address such requests.

The IRB requests the following additional information. This can be submitted as a new RNI (be sure to reference this RNI number in that submission):

1. Provide a detailed corrective action plan, specifically how eligibility criteria is assessed and plans to avoid missed procedures.
2. Also a corrective action plan for the timely submission of RNIs is needed.
3. Please notify the subject of the error and report back to the IRB how the subjects reacted to this information.