Reportable New Information (RNI) FAQs

1. **When should an updated Investigator Brochure be reported?**

Submit an RNI report if the changes to the IB indicate a new or increased risk than previously recognized. RNI report is not required if the changes do not impact risks.

(NOTE: The assessment of risk should be made by the Principal Investigator and not solely based on the sponsor’s assessment of the risk to benefit ratio.)

**Do I also need to submit a modification?**

RNIs do not process study document changes. You can upload documents to an RNI submission to provide the IRB with extra information, but these documents will not be “approved” or finalized.

You need to submit a modification **in addition to the RNI** if you need to make changes or add to your final approved study documents.

*When to report:* Within **5 business days** of receiving the updated IB.

If a sponsor template with revisions to the consent or protocol are still forthcoming at time of IB receipt, **DO NOT wait to submit the RNI for the updated IB**. Instead include within your RNI report a statement stating the site is still pending receipt of the sponsor revised study documents and a modification will be submitted once received.

2. **When should a Safety Report/ SUSAR be reported as an RNI?**

Adverse events that the Principal Investigator has determined to meet **ALL** the following criteria should be reported:

- **Unexpected** means unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the study documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied.
- **Related or possibly related** to participation in the research means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research.
- **A greater risk of harm** includes greater physical, psychological, economic, or social harm than was previously known or recognized.

Adverse events that do not meet all three of these criteria for prompt reporting as RNI must be reported at Continuing Review via a summary on the Continuing Review form.
(NOTE: If the Principal Investigator determines the adverse event meets all the 3 criteria above and no revisions to the study or consent form are made, justification must be provided.)

3. When do events noted on an audit or monitoring report need to be submitted as a separate RNI?

Although any monitoring report that includes at least one finding of deficiency should be submitted as an RNI, a separate RNI report should be submitted in addition to the monitoring report if the event could otherwise be considered **Serious Noncompliance** (may adversely affect subject rights or welfare) or **Continuing Noncompliance** (pattern of noncompliance likely to continue without intervention, or failure to work with the IRB to resolve noncompliance).

**For example:** A procedure, treatment, or visit specified in the protocol is conducted outside of the required time frame and has clinical consequence and/or poses risk of harm to subject or others.

- Subject receives additional or higher dose of study drug not dictated by study protocol
- Safety labs were missed

**Continuing Noncompliance** (a pattern or unrectified instance of noncompliance by an investigator or research staff)

- Protocol deviations and/or findings on multiple monitoring letters that have not been addressed
- Repeated informed consent discrepancies (i.e. missing patient signatures in consent documents, lack of reconsent on multiple subjects)

**Deficiencies** are not limited to subject-related findings.

If a monitoring report only notes deficiencies regarding regulatory items (regulatory binder missing documents, missing training documentation), the monitoring report should still be submitted as an RNI.

4. What if the event meets the RNI criteria but the event did not take place at OHSU?

Any adverse event, even those that do not occur at OHSU, should be reported as a RNI if it meets the RNI criteria.
5. **Do I still need to submit an RNI if the study is closed to enrollment?**

All events that meet the RNI reporting criteria should be submitted regardless of the study enrollment status.

A RNI report is not needed if **ALL** the following apply:

- The study is closed to enrollment **AND**
- No subjects are on study drug/device/treatment **AND**
- The new risk is not a long-term side effect

If the above criteria are met, the event does not represent an unanticipated problem involving risks to subjects or others because although unanticipated, **there are no subjects at OHSU who could be at risk.**

6. **What if the event meets the RNI criteria but the event only took place with one subject?**

Regardless if the event occurred with only one subject or multiple subjects, if the event meets the RNI reporting criteria, a RNI report should be submitted.

Federal regulations require investigators to report to the IRB any information that may be considered an unanticipated problem involving risks to subjects or others.

7. **For RNI reports involving specific OHSU subjects, how much information is needed?**

For RNI reports where OHSU subjects are involved, the IRB will need at a minimum the following information in order to determine whether the event represents an Unanticipated Problem and/or Serious or Continuing Noncompliance:

- Dates
- Timeline of events and corrective action
- Address how or if the event has affected the subject’s safety
- Current status of the subject
- Corrective action plan

REMINDER: Do NOT include subject identifiers (name, MR#, etc.) when submitting reportable new information to the IRB.
8. **When should I submit an RNI for a waived study?**

RNIs should be submitted directly to the overseeing IRB per their reporting policies.

RNI reports should be submitted for OHSU IRB review when the overseeing IRB acknowledgement is received where the findings involve:

- Determined that the event was unanticipated problem
- Serious or continuing noncompliance
- Suspension of study approval
- Termination of study approval

If you have an acknowledgement memo/letter from the overseeing IRB that they have made any of these findings, please include this with your submission.

Otherwise, RNI reports are not submitted for OHSU IRB review for studies where OHSU has waived IRB oversight to a Central IRB.