

## Quick Reference Guide Reportable New Information (RNI)

This Quick Guide is a supplement to **HRP-801 INVESTIGATOR GUIDANCE: Prompt Reporting Requirements and HRP-112 SOP: New Information**.

### 1. What is Reportable New Information? How and when do I submit it to the IRB?

Reportable New Information (RNI) is any information that might meet the regulatory definition of an Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO) or Serious or Continuing Noncompliance, or otherwise might impact the criteria for IRB approval. The IRB makes these regulatory determinations.

To help the IRB get the information it needs, IRB policy outlines **four general categories of RNI**, below. *An event or series of events may fit more than one category, but you only need to submit one RNI.*



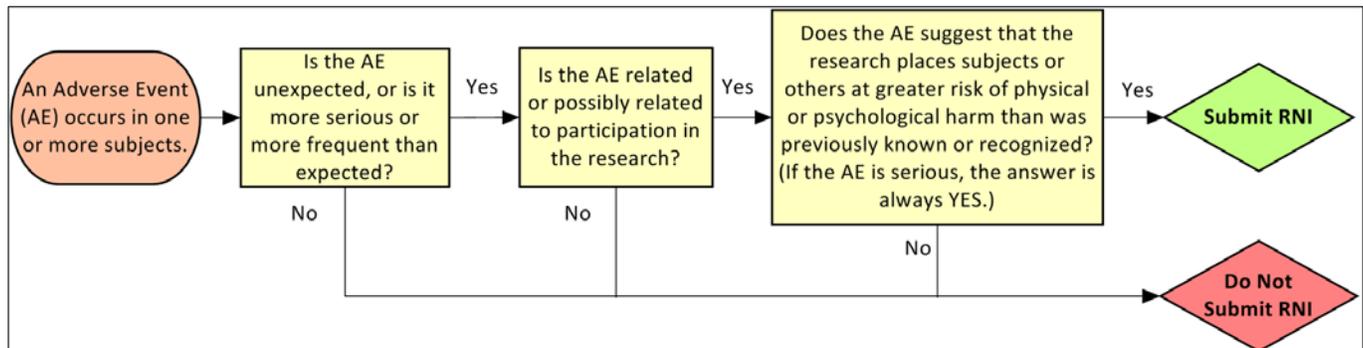
See **HRP-801 INVESTIGATOR GUIDANCE: Prompt Reporting Requirements** for a complete list of things that must be reported to the IRB as RNI. This Quick Guide provides additional guidance on some of the listed items.

**How to report:** In eIRB, select the button on your approved study page that says “Report New Information.”

**When to report:** Within **5 business days** of discovering the information.

### 2. When do I need to report an Adverse Event (AE) as a new risk?

The flow chart below can help the Principal Investigator decide whether to submit an RNI report for an AE:



- **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.

**It is up to the Principal Investigator to determine whether an AE represents a new risk.**

*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.*

**3. Besides AEs that meet the above criteria, what else might indicate that a new risk needs to be reported?**

Submit an RNI report if any of the following indicate that subjects or others may be at higher risk than previously recognized.

- Investigator’s Brochure updates identifying new risks (RNI report not required if changes don’t impact risks)
- New FDA Black Box Warning
- DSMB/C report identifying new risks
- Publications identifying new risks
- Any evidence of a new risk from any other source
- Unauthorized disclosures of subject information
- Unanticipated Adverse Device Effect

For **example scenarios** that illustrate when an event is considered a new risk, see the OHRP guidance [here](#).

**4. When do I need to report protocol deviations or noncompliance to the IRB?**

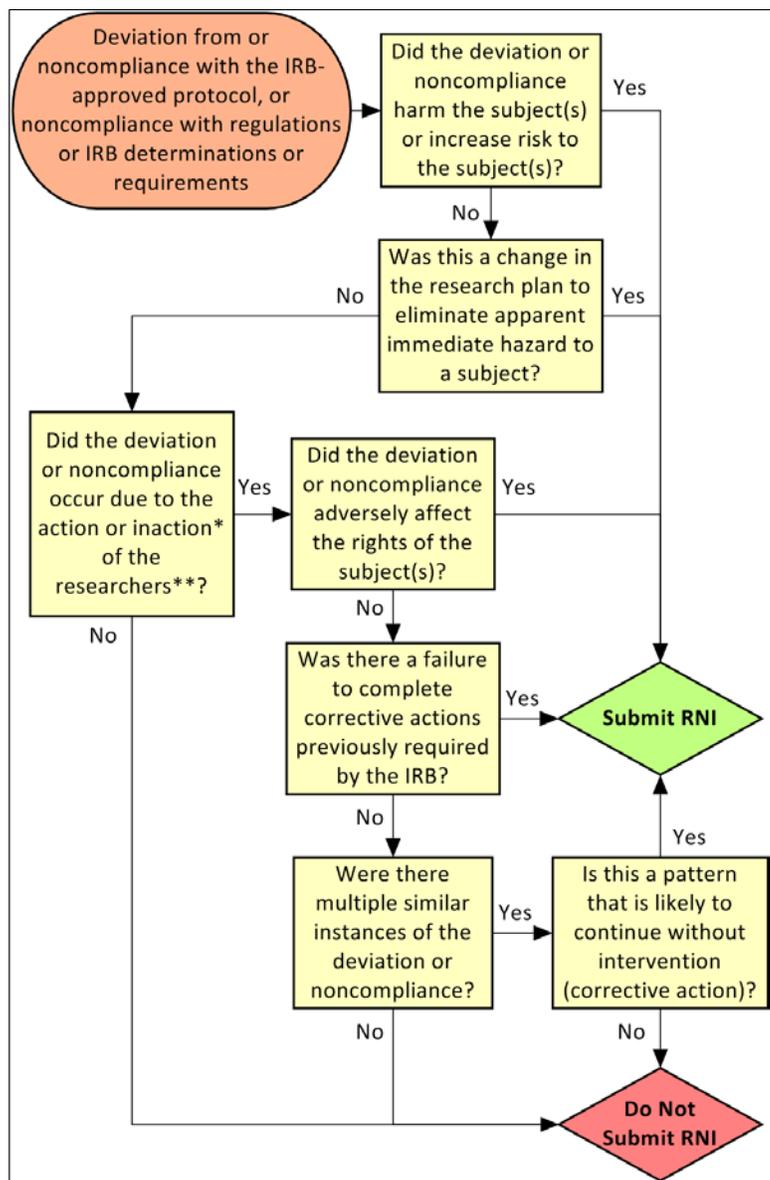
The flow chart to the right provides an algorithm for determining whether to submit an RNI report for protocol deviations or noncompliance.

**Noncompliance** means failure to follow the regulations or the requirements or determinations of the IRB.

The IRB does not define **protocol deviation** because individual protocols/sponsors may define it differently.

In general, the following need to be reported to the IRB:

- Events that harmed a subject or increased risk of harm;
- Events that 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); or
- Deviations from the research plan made to avoid apparent immediate hazard to a subject.



\*Regardless of intent.

\*\*Including anyone engaged in the research under OHSU IRB oversight.

## 5. What written reports must I submit as RNI?

- Audits, inspections, or inquiries by a **federal agency** (FDA, DOD, etc.), regardless of findings
- Any other report by any other entity (monitor, state agency, etc.) that includes **at least one finding of deficiency**

Submit **one single RNI** for the entire report, regardless of how many findings it contains.

*Audit or monitoring reports with no findings should be submitted with your continuing review and not as RNI.*

## 6. What other things require an RNI report?

- **Significant or unresolved subject complaint** (examples: subject feels his/her rights have been violated, subject accuses research team of unethical conduct, subject/researcher cannot resolve a dispute after reasonable effort)
- **Suspension or premature termination of the study** by the sponsor, investigator, or institution (does not include planned suspensions for interim analysis, etc., or termination in accordance with a contingency already described in the protocol)
- **Incarceration of a subject when the study is not approved to involve prisoners** (see **Help Sheet: Vulnerable Populations – Prisoners** for further guidance on prisoners in research)
- **State medical board or hospital Medical Staff actions** against a study team member

## 7. Do I also need to submit a modification?

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 (such as consent forms, protocol, investigator's brochure, recruitment materials, or letters to subjects). You can upload documents to an RNI submission to provide the IRB with extra information, but these documents will not be "approved" or finalized.

## 8. What happens after the IRB receives my RNI report?

The IRB follows **HRP-112 SOP: New Information** in reviewing your report to determine whether it represents an Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO) and/or Serious or Continuing Noncompliance. You will receive a memo via the eIRB detailing the IRB's determination and any corrective actions the IRB requires.

If the IRB determines that your RNI represents a UPIRTSO or Serious or Continuing Noncompliance:

- The IRB will review the event at a convened meeting, along with any corrective and preventative actions you have proposed (including a modification to your study if you have submitted one), and determine whether any further actions are needed in order to protect subjects.
- The IRB office may be required to report the event to the federal authorities that regulate your study, such as the FDA or the Office for Human Research Protections (OHRP). The IRB will also report certain events to institutional authorities as required by IRB policy.
- You are responsible for reporting the event to sponsors/funding agencies as required by your protocol, and if you are the IND or IDE holder, to the FDA as required by the applicable regulations (see **HRP-815 INVESTIGATOR GUIDANCE: Additional FDA Obligations**).