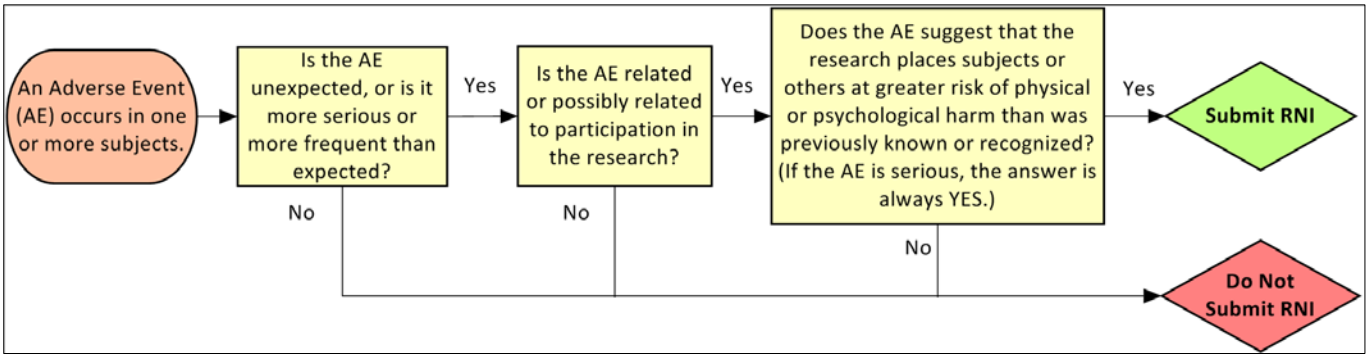
Quick Reference Guide
Reportable New Information (RNI)

This does not replace official guidance from the IRB as noted in SH Policy 15574: "Reportable New Information to the IRB for Previously Approved Research" OR RNI Guidance Document on Protocol Deviations.

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:



- **Unanticipated/Unexpected** means unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related 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 event may have been caused by the procedures involved in the research.
- A **greater risk of harm** includes greater physical, psychological, economic, or social harm related to the research than was previously known or recognized.

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

**OHRP Defines Adverse Event as: "Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research."*

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.

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

- Investigator's Brochure updates identifying new risks (can be reported via a modification xform if changes don't impact risks)
- DSMB/C report identifying new risks
- Drug shortage
- Publications identifying new risks
- Any evidence of a new risk from any other source
- Unauthorized disclosures of subject information
- Unanticipated Adverse Device Effect

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.

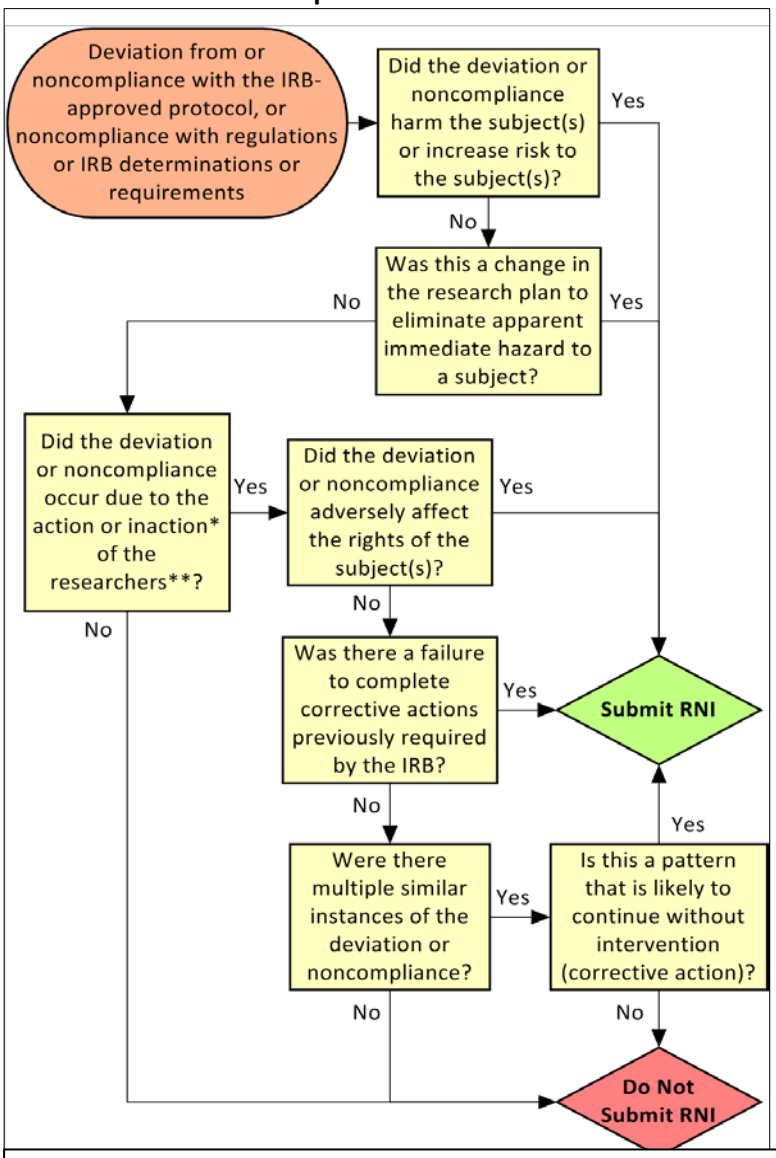
Noncompliance means failure to follow the regulations or the requirements or determinations of the IRB.

A **protocol deviation** occurs when the study departs from the IRB-approved protocol in <u>any</u> way **without the investigator first obtaining IRB approval**.

If the deviation is a one-time deviation from the IRB-approved protocol and it involved no risks, it should be reported to the IRB at the time of continuing review. A **minor deviation** is one that does **not** impact subject safety, compromise the integrity of the study data, or affect subjects' willingness to participate in the study. Minor deviations should be summarized at the time of continuing review on the Protocol Deviation Tracking Log.

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** (Noncompliance that has the potential to increase a physical, psychological, safety or privacy risk to subjects) or **Continuing Noncompliance** (A pattern of non-compliance that indicates a deficiency likely to result in further non-compliance or a circumstance in which an investigator fails to cooperate with investigator or correcting non-compliance); 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 SH IRB oversight.

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.

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**
- **Loss/Breach of Confidentiality, HIPAA Violation, or HIPAA Omission**
- **Items requested by a S.A.F.E. Review**

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.

How do I submit an RNI?

How to report an RNI: In IRB Manager type in the study number in the upper right corner or click on the study from your dashboard

Select the button on your approved study page that says "Start xForm"

Select "Reportable New Information" from the list of xforms

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

How do I submit "new information" that is not "reportable"?

You can use the RNI form to submit **information items** to the IRB even if they do not fit the above categories of Reportable information. Information that fits into this category would include:

- Study Progress Reports or Data Safety Monitoring Reports
- Protocol Deviation Logs
- Publications or Abstracts

***This is information that a sponsor or principal investigator would like reviewed and acknowledged by the IRB but that does not contain any modifications to your project or protocol ***

How do I submit New Information?

How to submit New Information: In IRB Manager type in the study number in the upper right corner or click on the study from your dashboard

Select the button on your approved study page that says "Start xForm"

Select "Reportable New Information" from the list of xforms

When prompted to select a category select category 11- "**N/A Informational Item Only**"

Complete remainder of form

When to report: There is no reporting timeframe for these items, report when needed or prompted by your sponsor or PI