	GUIDANCE: RNI Reporting for R2Rs		
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All study teams under the purview of an External IRB will follow the External IRB's policies and procedures for reportable events (e.g., what requires reporting, reporting timeframes, and mechanism for reporting). The External IRB will conduct reviews of reportable events in accordance with the Reliance Agreement as well as its own policies and procedures. Occasionally, Mount Sinai Study Teams are required to also report to PPHS.

**Below are examples of types of events/information that must also be reported to PPHS. This list is not exclusive. If you have any questions about reporting to PPHS for R2R studies, please contact the PPHS office at irb@mssm.edu.*

PROCESS

1. Report information/incident to the external IRB.
2. Determine if the information/events needs to be reported to PPHS using the examples below. *This list is not exclusive. If you have any questions about reporting to PPHS for R2R studies, please contact the PPHS office at irb@mssm.edu.*
3. If so, log into RUTH. Click REPORT NEW INFORMATION.
4. In the RNI Title field, use the format "R2R – unique description of information/incident" (i.e., R2R-SAE Subject 0098).
5. Fill out the rest of the RNI SmartForm.
6. Attach any applicable documents, including letters or documentation from the External IRB, regarding the incident/information.

EXAMPLES:

RISK: Information that indicates a new or increased risk, or a safety issue. For example:

1. Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol.
2. Protocol violation that harmed or had a real possibility of harming Mount Sinai subjects or others associated with Mount Sinai.
3. Any protocol violation determined to be serious or continuing noncompliance. This does not include minor protocol violations that were not judged to be serious, continuing or impacting subject safety.

Note: Any reports or new information that indicates a significant change, a new risk or increase in frequency or magnitude of a previous risk should be submitted to PPHS (after External IRB approval) as an Update Study Details submission if it impacts local context. The HRP-388 can be used to determine if local context is impacted.

HARM: Any harm experienced by a Mount Sinai subject or other individual associated with Mount Sinai that, in the opinion of the investigator, is unexpected and at least probably related to the research procedures.

1. A harm is "**unexpected**" when its specificity or severity are not accurately reflected in the consent document.
2. A harm is at least "**probably related**" to the research procedures if, in the opinion of the investigator, the research procedures more likely than not caused the harm.

EXTERNAL REPORTING: Any external report to a Federal agency due to incidents that occurred at a Mount Sinai site or that involved a Mount Sinai subject or other affiliate. For example:

1. **NON-COMPLIANCE:** Non-compliance by the Mount Sinai research staff, that the external IRB determines to be either serious or continuing, with the federal regulations governing human research or with the requirements or determinations of the IRB.
2. **UNANTICIPATED PROBLEM INVOLVING RISK TO SUBJECTS OR OTHERS (UPIRTSO)**: Any incident that occurred at a Mount Sinai site or that involved a Mount Sinai subjects or other affiliate, that the external IRB determines to be a UPIRTSO.

AUDIT: Audit, inspection, or inquiry by a federal agency.

RESEARCHER ERROR: Failure to follow the protocol due to the action or inaction of the Mount Sinai investigator or Mount Sinai research staff.

CONFIDENTIALITY: Breach of confidentiality that involves or may involve Mount Sinai data or PHI.

INCARCERATION: Incarceration of a Mount Sinai subject in a study not approved by the IRB to involve prisoners.

COMPLAINT: Complaint of a Mount Sinai subject that cannot be resolved by the research team.

SUSPENSION: Premature suspension or termination of the research by the sponsor, or the investigator.

POTENTIAL RESEARCH MISCONDUCT: The Research Integrity Officer should be notified of any potential research misconduct or allegation of same that occurred at the Mount Sinai site(s) or involves the Mount Sinai research team.