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**Program for the Protection
of Human Subjects**

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ISMMS Guidance on Reportable New Information (RNI)

The following guidance provides information on ISMMS IRB's requirements for reporting new information for projects that rely on the ISMMS IRB. The instruction below is not a complete list of events that require reporting to the IRB. For a complete list of reporting categories, refer to the Investigator Manual, or the RUTH RNI smart form. The expectation is that events that meet the reporting criteria are reported within 5 business days of learning of the event (unless defined otherwise below).

If the new information does not meet the below reporting criteria, it does not need to be submitted to the ISMMS IRB. If you are unsure about whether something meets the criteria, please contact the PPHS at IRB@mssm.edu.

Adverse Event Reporting:

- Report all **unexpected and related adverse event(s)** regardless of other reporting (i.e. reports to sponsor or outside entities that has occurred).
- Report all **related, serious adverse event(s)** as defined below. Reporting to the ISMMS IRB must occur within 24 hours of learning of the event:
 - Death
 - Life-threatening
 - Hospitalization (initial or prolonged)
 - Disability or Permanent Damage
 - Congenital Anomaly/Birth Defect
 - Required Intervention to Prevent Permanent Impairment or Damage (Devices)
 - Any serious psychological and emotional distress resulting in study participation (suggesting need for professional counseling or intervention)
 - Other Serious (Important Medical Events) as determined by the PI

For more information on reporting serious adverse events, [click here](#).

- If event(s) was expected and the research team has followed their monitoring plan and have reported the event to their DSMB or DMC, reporting an annual AE log to the ISMMS IRB occurs at the time of continuing review or final report.
- If the event(s) was expected but during regular oversight the research team identified a higher rate of frequency or severity of said event(s), reporting to the ISMMS IRB must occur within five (5) days of that discovery.
- If the event(s) is not related to the research at all, do not report to the IRB even at the request of the sponsor or others. If the event(s) is not related, it is not reportable.

Non-Compliance/Failure to Follow the Protocol Reporting:

- ISMMS does not use terms such as "major" or "minor" deviation when identifying reportable new information to PPHS.

- All instances of non-compliance must be reported along with a root cause analysis and corrective action plan signed by the Principal Investigator. In your plan, include information that is:
 - Specific: Identify the actions you or others will take to address the root cause
 - Timely: Include the date(s) when you or others will complete the actions.
 - Measurable: Include a process of assessing the action plan effectiveness and a process by which the plan will be amended if it is not effective.

Other Reporting Considerations:

- Any change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject must be reported to the IRB.
- The IRB does not prospectively approve deviations that have not yet occurred. The expectation is that your protocol is formally amended via a modification submission if any changes are being proposed to your study. Do not submit a RNI asking the PPHS to approve a “waiver” or “exception” to a protocol. Immediate safety concerns should trigger a change to the protocol prior to PPHS review. Please contact the PPHS if there is a specific scenario to discuss.
- Any written report of study monitors, internal or external audit reports, DSMB reports, notices of suspensions and/or termination must be submitted to the IRB.
- Any breach of confidentiality must be reported to the IRB and submitted to the HIPAA Privacy Officer (if applicable).
- Any subject complaint that cannot be resolved by the research team must be reported to the IRB.
- Incarceration of a subject in a study that has not previously been approved by the IRB under Subpart C to involve prisoners, must be reported to the IRB.
- If an individual becomes pregnant in a study that has not been previously approved by the IRB under Subpart B to enrolling pregnant individuals, must be reported to the IRB if the PI wishes to have the individual continue in the research.
- For studies relying on an external IRB, please see document “[Guidance - R2R Reportable New Information \(RNI\)](#)” for further instruction