# *New Information Reportable to the IRB: Quick Guidance*

*A Tallahassee Memorial HealthCare IRB Guidance Document*

## Purpose

This document provides guidance on reporting new information to the IRB for studies approved by the IRB. This is not a comprehensive list of items, but rather guidance on those topics most commonly submitted to the IRB. If you have questions regarding reportable new information (RNI) items and submission to the IRB, please contact the IRB Office at IRBOffice@tmh.org or 850-431-2522.

## What items do I need to report to the IRB?

| Information or Event | When to report * |
|---|---|
| Breach (or risk of breach) or loss of subject confidentiality or privacy | **Report within 24 hours** |
| Inappropriate access or use of protected health information (PHI) | **Report within 24 hours** |
| Internal harm (adverse event) experienced by a subject which is related (probably, possibly, definitely) AND serious | **Report within 5 business days** |
| Incidental incarceration of a research subject in a study that the IRB has not approved for the inclusion of prisoners and where study activities or data collection will continue while the subject is incarcerated | **Report within 3 business days** |
| TMH IRB is IRB of Record: Unanticipated problem (Internal AND External)<br>TMH IRB is NOT IRB of Record: Unanticipated problem (Internal) | **Report within 5 business days** |
| TMH IRB is IRB of Record: Unanticipated adverse device effect (Internal AND External)<br>TMH IRB is NOT IRB of Record: Unanticipated adverse device effect (Internal) | **Report within 5 business days** |
| Serious non-compliance | **Report within 5 business days** |
| Continuing non-compliance | **Report within 5 business days** |
| Emergency deviation from IRB approved procedures made without IRB review to eliminate an apparent immediate hazard to a subject or others | **Report within 10 business days** |
| Continuation of research after IRB approval has lapsed, because the procedures are of direct benefit to the individual subjects or withholding the research intervention (if any) may increase risks to subjects | **Report within 10 business days** |
| Complaint from a subject or other person about the study, which cannot be resolved by the research team | **Report within 10 business days** |
| Audit, inspection, compliance or safety-related inquiry from a federal agency, sponsor, or External IRB including initial notification of an upcoming audit or inspection | **Report within 2 business days** |
| Information that indicates a new or increased risk or safety issue (or a decrease in study benefits) (e.g. A publication in the literature indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk; revised IB, package insert, or device manual; changes to FDA-approved labeling; FDA withdrawal, restriction, or modification of marketed approval of a drug, device, or biologic used in a research protocol) | **Report within 10 business days** |
| Premature suspension or termination of some or all of the research by the sponsor, researcher, institution, or External IRB | **Report within 10 business days** |
| All safety monitor or DSMB reports indicating new/revised risks, or that study procedures should not continue | **Report within 10 business days** |

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| Changes in relevant licensures, qualifications of study team | **Report within 10 business days** |
| Prospective planned protocol deviation requests (i.e., study requests to deviate from eligibility requirements, etc.) | **1-2 weeks in advance of event** |

Adverse Events & Unanticipated Problems

**Unanticipated Problems** (Internal & External) must ALWAYS be reported to the IRB within 5 business days of learning of the event. An unanticipated problem is defined as:

***Unexpected*** *(in terms of nature, severity, or frequency) given the information provided in research-related documents and the characteristics of the subjects population being studied; AND*
***Related*** *(probably, possibly, or definitely) to participation in the research; AND*
*Suggests that the research places subjects or others at a* ***greater risk of harm*** *than was previously known or recognized.*

The IRB uses the following criteria to determine whether an incidence, experience, or event is an Unanticipated Problem:

Unexpected at the time of IRB approval; AND
Involved new or increased risk to subjects or others; AND
Is Related to the research.

**Adverse Events** that are reportable to the TMH IRB must be related (probably, possibly, or definitely) AND serious.

Non-Compliance (protocol deviations, violations, exceptions, etc.)

**Non-compliance** is defined as any action or activity associated with the conduct or oversight of research involving human subjects that fails to comply with applicable regulations, institutional policies, and/or the determinations and requirements of the TMH IRB.

Non-compliance may range from minor to serious; be unintentional or willful; and may occur once, sporadically, or continuously. The degree of non-compliance is evaluated on a case-by-case basis and considers whether subjects were harmed or placed at an increased risk of harm.

**Minor instances of non-compliance** do not need to be promptly reported to the IRB, but should be logged on the Protocol Deviation Log and submitted at the time of Continuing Review.

*Examples of minor protocol deviations*:

- Out of window visits or procedures
- Subject failure to initial each page of the ICF (as applicable)
- Subject failure to return subject materials (diaries, journals, etc.)
- Administrative hold on a study not related to safety issues

**Serious or Continuing non-compliance**[1] must be promptly reported to the TMH IRB per the above table.

*Examples include*:

- Failure to document informed consent
- Informed consent obtained after initiation of study procedures
- Enrollment of a subject who did not meet all inclusion/exclusion criteria
- Performing study procedures not approved by the IRB
- Failure to report a qualifying internal harm (adverse event) to the IRB and/or sponsor
- Failure to perform a required lab test that, in the opinion of the investigator, may affect subject safety or data integrity

[1] **Serious Non-Compliance** is defined as non-Compliance such that the failure to comply adversely affects the rights, safety, or welfare of a human subject; places a human subject at increased risk of harm; causes harm to a human subject; affects a human subject's willingness to participate in research or significantly damages or compromises the scientific integrity of research data. **Continuing Non-Compliance** is a pattern of non-compliance that indicates a repeated unwillingness to comply or a persistent lack of knowledge of how to comply with applicable regulations, Tallahassee Memorial HealthCare policies and/or the determinations and requirements of the IRB that may affect participants' rights and welfare, increase risk to participants, or may compromise the scientific integrity or validity of the research.