SOP: Incident Reporting by Researcher				
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1 PURPOSE

1.1. This procedure establishes the procedures that researchers follow for identifying and reporting Incidents to the TMH IRB.

1.2. The process begins when the researcher is notified of a qualifying event or information.

1.3. The process ends when the researcher has been notified by the TMH IRB of the Incident Report outcome.

2 REVISIONS FROM PREVIOUS VERSION

2.1. None

2.2. Revisions to align with Cayuse transition, administrative alignment. 14JUN2023

3 POLICY

3.1. This applies to any researcher whose research is being reviewed by the TMH IRB, including non-TMH researchers whose sites or institutions are relying on the TMH IRB for review.

3.2. TMH researchers whose research is reviewed by an External IRB (as documented in a formal agreement with the TMH IRB Office) should follow the reporting policies and procedures of the External IRB and the TMH IRB (if applicable). The following items must be reported to the TMH IRB in addition to the External IRB (as applicable):

3.2.1. Unanticipated problems (Internal)

3.2.2. Breach (or risk of breach) or loss of subject confidentiality or privacy

3.2.3. Serious and/or Continuing non-compliance

3.2.4. Audit, inspection, compliance or safety-related inquiry from a federal agency, External IRB, or sponsor including initial notification of an upcoming audit or inspection.

3.2.5. Suspension or termination of some or all of the research by sponsor, researcher, or External IRB.

4 RESPONSIBILITIES

4.1. Any member of the study team responsible for submitting the IRB application, or anyone who has access to the Cayuse system is responsible for submitting Incident Reports.

5 PROCEDURE

5.1. The attached table indicates events and incidents that are reportable. The nature of the information determines how quickly it must be reported. The reporting “clock” begins when the researcher (i.e., any member of the research team) becomes aware of the information.

5.2. Reporting is done through Cayuse utilizing the Incident submission form. The report should include:

5.2.1. Completed submission form (all applicable fields)

5.2.2. DSMB or other safety monitoring report (if applicable)

5.2.3. Audit or compliance report (if applicable)

5.2.4. Any additional relevant supporting documentation

5.3. The TMH IRB may send requests for additional information or changes, request additional actions, or request additional documentation to the Incident submission. Respond to the requests in a timely manner.

5.4. The TMH IRB will notify the study team of the outcome of the Incident submission.

6 MATERIALS

6.1. FORM: Incident

7 REFERENCES

7.1. 45 CFR 46.103(a), 103(b)(5), and 111(a,b) (Pre-2018 regulations)

7.2. 45 CFR 46.103(a), 108(a)(4), and 111(a,b) (2018 regulations)

7.3. 21 CFR 56.108(b)

7.4. OHRP guidance, “Reporting Incidents to OHRP”; June 20, 2011

7.5. OHRP guidance, “Unanticipated Problems Involving Risks and Adverse Events”; 2007

7.6. FDA guidance, "Adverse Event Reporting to IRBs – Improving Human Subject Protection"; January 2009

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) 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) 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**
Changes in relevant licensures, qualifications of study team	**Report within 10 business days**

Information or Event	When to report *
Prospective planned protocol deviation requests (i.e., study requests to deviate from eligibility requirements, etc.)	**1-2 weeks in advance of event**