University of Massachusetts UMASS Medical School

INVESTIGATOR GUIDANCE: Prompt Reporting Requirements

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1. PURPOSE

1.1. This guidance describes the information to promptly report to the [Organization's] local IRB when the research is subject to oversight by the [Organization's] local IRB.

1.2. For research overseen by an IRB other than [Organization's] local IRB, investigators should follow the requirements of that IRB.

2. GUIDANCE

2.1. Report the following information items to the IRB within 5 days of becoming aware of the information:

- 2.1.1. New or increased risk[1]
- 2.1.2. Protocol deviation due to the action or inaction of the investigator or research staff
- 2.1.3. Protocol deviation that harmed a subject or placed subject at risk of harm
- 2.1.4. Protocol deviation made without prior IRB approval to eliminate an immediate hazard to a subject
- 2.1.5. Audit, inspection, or inquiry by a federal agency
- 2.1.6. Written report of a federal agency (e.g., FDA Form 483)
- 2.1.7. <Allegation of Noncompliance> or <Finding of Noncompliance>
- 2.1.8. Unauthorized disclosure of confidential information
- 2.1.9. Unresolved subject complaint
- 2.1.10. Suspension or premature termination by the sponsor, investigator, or institution
- 2.1.11. Incarceration of a subject in a research study not approved to involve prisoners
- 2.1.12. Adverse event or IND safety report that requires a protocol or consent change
- 2.1.13. State medical board or hospital medical staff actions
- 2.1.14. Unanticipated adverse device effect[2]
- 2.1.15. Updated investigator brochure

2.2. When relying on an external IRB report the following information items to the HRPP Office within 5 days:

- 2.2.1. Audit, inspection, or inquiry by a federal agency
- 2.2.2. Written report of a federal agency (e.g., FDA Form 483)
- 2.2.3. Unauthorized disclosure of confidential information
- 2.2.4. State medical board or hospital medical staff actions

2.3. Information not listed above does not require prompt reporting to the [Organization's] local IRB.

3. REFERENCES

3.1. 21 CFR §56.108(b)

3.2. 45 CFR §46.103(b)(5)

[1] For example, publications indicating a new risk, new risk in an investigator brochure, FDA black box warning, new risk identified in a data safety monitoring report, information or change that adversely affects subject safety, or information or change that adversely affects the conduct of the research.

[2] Unanticipated adverse device effect means any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.