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

   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

   2.1.15. 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)

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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.