



POLICY: Prompt Reporting Requirements

Document No.:	Edition No.:	Effective Date:	Page:
IBC-071	1.0	01/21/2019	Page 1 of 1

1. PURPOSE

- 1.1. This policy 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:
 - 2.1.1. Audit, inspection, or inquiry by a federal agency
 - 2.1.2. Written report of a federal agency (e.g., FDA Form 483)
 - 2.1.3. State medical board or hospital medical staff actions
 - 2.1.4. <Allegation of Noncompliance> or <Finding of Noncompliance>
 - 2.1.5. Suspension or premature termination by the sponsor, investigator, or institution
 - 2.1.6. Incarceration of a subject in a research study not approved to involve prisoners
 - 2.1.7. New or increased risk¹
 - 2.1.8. Change in financial interest disclosure.
 - 2.1.9. Protocol deviation that harmed a subject or placed subject at risk of harm
 - 2.1.10. Protocol deviation due to the action or inaction of the investigator or research staff
 - 2.1.11. Protocol deviation made without prior IRB approval to eliminate an immediate hazard to a subject
 - 2.1.12. Breach of confidentiality
 - 2.1.13. Subject complaint that cannot be resolved by the research team
 - 2.1.14. Adverse event or IND safety report that requires a protocol or consent change
 - 2.1.15. Unanticipated adverse device effect²
 - 2.1.16. Written report of a study monitor
- 2.2. Information not listed above does not require prompt reporting to the [Organization's] IRB.

3. REFERENCES

- 3.1. 21 CFR §56.108(b)
- 3.2. 45 CFR §46.107(a)(4)

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.