AdventHealth Orlando

Policy

Policy#: 400.069	HRP-069 Prompt Reporting Requirements in Research	
Executive Owner: Vice President of Research Operations		**Effective Date:** 6/11/2018 **Review Date:** 6/11/2018

Scope

This policy applies to Investigators conducting <Human Research> overseen by AdventHealth Orlando.

Purpose

This policy describes the information to promptly report to AdventHealth Orlando's local Institutional Review Board (IRB) when the research is subject to oversight by AdventHealth Orlando's local IRB. For research overseen by an IRB other than AdventHealth Orlando's local IRB, investigators will follow the requirements of that IRB.

Policy

A. Report the following information items to the IRB office within 10 days:

1. New or increased risk[1]
2. Protocol deviation due to the action or inaction of the investigator or research staff
3. Protocol deviation that harmed a subject or placed subject at risk of harm
4. Protocol deviation made without prior IRB approval to eliminate an immediate hazard to a subject
5. Audit, inspection, or inquiry by a federal agency
6. Written report of a federal agency (e.g., FDA Form 483)
7. Written report of a study monitor
8. <Allegation of Noncompliance> or finding of <Noncompliance>
9. Unauthorized disclosure of confidential information
10. Unresolved subject complaint
11. Suspension or premature termination by the sponsor, investigator, or institution
12. Incarceration of a subject in a research study not approved to involve prisoners
13. Adverse event or IND safety report that requires a protocol or consent change
14. State medical board or hospital medical staff actions
15. <Unanticipated Adverse Device Effect>

B. When relying on an external IRB report the following information items to the IRB Office within 10 days:

1. Audit, inspection, or inquiry by a federal agency
2. Written report of a federal agency (e.g., FDA Form 483)
3. Written report of a study monitor
4. Unauthorized disclosure of confidential information
5. State medical board or hospital medical staff actions

[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.

C. Information not listed above does not require prompt reporting to AdventHealth Orlando's local IRB.

Definition(s)

For <Angle Brackets> refer to Policy 400.001 HRP-001 Definitions
For [Square Brackets] refer to Policy 400.003 HRP-003 Designations

Allegation of Noncompliance: An unproven assertion of <Noncompliance>.

Noncompliance: Failure to follow the regulations or the requirements or determinations of the IRB.

Unanticipated Adverse Device Effect - Unanticipated adverse device effect is any serious adverse effect on health or safety, 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 application; or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

Reference(s)

21 CFR §56.108(b)
45 CFR §46.103(b)(5)

Related Document(s)

Not Applicable

Keywords

HRP-069