AdventHealth

POLICY

Policy #	Policy Name
CW AHC 111	Prompt Reporting Requirements in Research
Policy Location	**Responsible Department**
*Company-Wide Policies	Research Services
Executive Owner:	**Original Creation Date**
Executive Director of Research Services	01/18/2022
Policy Effective Date	**Policy Review Date**
04/04/2022	04/04/2022

I. **SCOPE:** This policy applies to Investigators and Research Personnel conducting Human Research overseen by AdventHealth.

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

III. **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 Personnel
   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 reports as follows: industry or internal monitoring reports; data monitoring board reports or IRB required internal or external audit reports
   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 AdventHealth
   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 AdventHealth's

[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.

IRB within 10 days:

1. Allegation of Noncompliance or finding of Noncompliance as it relates to local requirements.
2. Audit, inspection, or inquiry by a federal agency
3. Written report of a federal agency (e.g., FDA Form 483)
4. Written reports as follows: industry or internal monitoring reports; data monitoring board reports or IRB required internal or external audit reports
5. Unauthorized disclosure of confidential information
6. State medical board or hospital medical staff actions

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

IV. PROCEDURE/GUIDELINES: Not Applicable

V. DEFINITION(S): For capitalized terms not defined in this policy, refer to CW AHC 107 Definitions in Human Research.

For abbreviations not defined in this policy, refer to CW AHC 102 Abbreviations in Research.

VI. EXCEPTION(S): See CW AHC 101 Research Oversight

VII. REFERENCE(S):

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

VIII. RELATED DOCUMENT(S) / ATTACHMENT(S):

- CW AHC 101 Research Oversight
- CW AHC 102 Abbreviations in Research
- CW AHC 107 Definitions in Human Research
- CW AHC 108 Human Research Protection Program policy
- CW AHC 112 Investigator Obligations in Research
- CW AHC 110 Legally Authorized Representatives, Children and Guardians in Research