Standard Operating Procedure (SOP)

SOP Number: SOP CW AHC 240	**SOP Name:** Utilization of External IRBs
Location: *Company-Wide Policies	**Responsible Department:** Research Services
Executive Owner: Executive Director of Research Services	**Original Creation Date:** 01/18/2022
Effective Date: 02/16/2023	**Review Date:** 02/16/2023

I. SCOPE: This standard operating procedure (SOP) applies to the Research Personnel and Institutional Review Board (IRB) staff members, chair, and committee members at AdventHealth.

II. PURPOSE: External regulatory and accrediting bodies such as the FDA and AAHRPP expect local IRBs to maintain a minimum amount of oversight for studies that rely upon external IRBs. The purpose of this SOP is to define responsibilities of AdventHealth IRB and Investigators requesting reliance upon external IRBs.

III. QUALIFIED PERSONNEL: IRB Executive Chair, IRB members, IRB staff members, Investigators, and Research Personnel.

IV. TRAINING: Not applicable

V. SUPPLIES & EQUIPMENT: Not applicable

VI. PROCESS/PROCEDURE:

A. AdventHealth relies upon external IRBs for studies on a case-by-case basis. Examples include but are not limited to:
   1. Multi-center, externally sponsored studies
   2. Studies needing single IRB review as required by law

B. Investigators wishing to utilize an external IRB must:
   1. Submit the following documents to AdventHealth IRB via the IRB electronic submission platform:
      a) HRP-200 FORM - Initial Review Application
      b) HRP-201 FORM - Research Personnel
      c) HRP-220 FORM - Request for HIPAA Waiver of Authorization, when applicable[i]
      d) Scientific review documents, when applicable
      e) Protocol
      f) Consent form for local use with required local language[i] (Refer to HRP-507 TEMPLATE: Consent required language (for use with sponsor templates or reliance on other IRBs)
      g) Executed IRB Authorization Agreement, when applicable
      h) Other documents as required by the external IRB
   2. Complete required training to conduct Human Research at AdventHealth in accordance with AdventHealth policies.
   3. Review and agree to follow the external IRB's written polices, SOPs, and/or guidance for Investigators.

C. AdventHealth IRB will review the application in a timely manner not to exceed two business days and provide a letter either accepting or declining external IRB oversight of the study.
   1. If accepted, the Investigator may proceed with review by external IRB.
   2. If declined, a reason will be provided and the Investigator will be given an opportunity to provide additional or clarifying information. In the event that the decision to decline stands on re-review, the Investigator may appeal the decision by contacting the IRB manager. Otherwise, the study will need to be reviewed by AdventHealth IRB.

D. Ongoing responsibilities of the AdventHealth Investigator after study approval:
   1. Follow the external IRB's written policies, SOPs, and/or guidance for Investigators.
   2. On an ongoing basis, submit the following to AdventHealth IRB:
      a) Changes in local study personnel via a revised HRP-201 FORM - Research Personnel log
      b) HRP-204 FORM - Promptly Reportable Information in accordance with CW AHC 111 Prompt Reporting Requirements in Research.
   3. On an annual basis, submit a research personnel log to AdventHealth IRB.
   4. Inform OSP of any changes in the study documents due to, but not limited to, the following:
      a) Administrative changes (e.g. sponsor or clinical research organization change, delegation log change, etc.)
      b) Changes (i.e., adding or removing) to visit and/or tasks in the protocol that may have coverage analysis/billing grid and/or financial implications.
      c) Changes in informed consent related to subject injury, costs, or stipends.
   5. Maintain valid training to conduct research at AdventHealth in accordance with AdventHealth IRB policy.
   6. Submit the external IRB closure letter to AdventHealth IRB upon site closure.

E. Research opened under an external IRB remains subject to AdventHealth policies and procedures related to the conduct of research including, but not limited to, AdventHealth IRB and Research Services policies, procedures, and SOPs.

VII. DEFINITION(S):

For capitalized terms not defined in this SOP, refer to CW AHC 107 Definitions in Human Research.

For abbreviations/acronyms terms not defined in this SOP, refer to CW AHC 102 Abbreviations in Research.

VIII. EXCEPTION(S):

See CW AHC 101 Research Oversight

IX. REFERENCE(S):

Electronic Code of Federal Regulations (e-CFR). (2012). *Title 21: Food and Drugs. Subchapter A, Part 56: Institutional Review Boards.* §56.101 to 56.124.Retrieved from: http://www.ecfr.gov/cgi-bin/text-

idx?SID=1bcd2a8edeb3173c2eeb67de6e0d3d0a&c=ecfr&tpl=/ecfrbrowse/Title21/21cfrv1_02.tpl.

Electronic Code of Federal Regulations (e-CFR). (2012). *Title 45: Public Welfare. Subchapter A, Part 46: Protection of Human Subjects. §46.101 to 46.505.* Retrieved from: http://www.ecfr.gov/cgi-bin/text-idx?SID=1bcd2a8edeb3173c2eeb67de6e0d3d0a&c=ecfr&tpl=/ecfrbrowse/Title45/45cfrv1_02.tpl.

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1979). *The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research.* April 18, 1979. Washington, D.C.: United States Government Printing Office. Retrieved from: The Belmont Report (hhs.gov).

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

- Definitions in Human Research
- Abbreviations in Research
- Research Oversight
- Prompt Reporting Requirements in Research
- Human Research Protection Program
- FORMS are located on in IRBNet
  - HRP-200 FORM - Initial Review Application
  - HRP-201 FORM - Research Personnel
  - HRP-204 FORM - Promptly Reportable Information
  - HRP-220 FORM - Request for HIPAA Waiver of Authorization

[i] External IRBs defer responsibility to local institutions to conduct any reviews necessary under HIPAA. AdventHealth IRB permits required HIPAA language to be incorporated into the consent document or as a stand-alone document at the discretion of the external IRB. AdventHealth researchers must include HRP-507 TEMPLATE language into each consent form for review by the external IRB unless changes are permitted by AdventHealth IRB in writing.