Standard Operating Procedure (SOP)

SOP number: SOP CW AHC 255	**SOP Name:** External Site Reliance on AdventHealth IRB
Location: *Company-Wide Policies	**Responsible Department:** Research Services
SOP Owner/Executive Owner: Executive Director of Research Services	**Original Creation Date (If applicable):** Not Set
Effective Date: 02/16/2023	**Review Date:** 02/16/2023

I. **SCOPE:** This standard operating procedure (SOP) applies to studies for which AdventHealth Institutional Review Board (IRB) serves as the IRB of record for sites external to AdventHealth.

II. **PURPOSE:** The purpose of this SOP is to provide the process for IRB review of external research sites where AdventHealth IRB is the reviewing IRB.

III. **QUALIFIED PERSONNEL:** IRB staff and regulatory personnel carry out these tasks

IV. **TRAINING:** N/A

V. **SUPPLIES & EQUIPMENT:** Access to IRB Reliance Exchange (IREx) and the AdventHealth IRB electronic submissions platform

VI. **PROCESS/PROCEDURE:**

A. The SmartIRB Agreement will be the preferred agreement for sites relying on AdventHealth IRB. Other agreement options may be considered on a per-study basis.
B. The lead, or coordinating site, will submit an HRP-200 FORM - Initial Review Application and supporting documents in the IRB electronic submissions platform for AdventHealth IRB review. Upon approval of the lead site, AdventHealth IRB will provide:
    1. Approval letter
    2. Approved documents for lead site
C. When an external site is identified, the following must occur:
    1. The IREx platform will be the preferred platform used to track external site agreements and reliance decisions
        a) AdventHealth IRB staff, with the regulatory team, will create the study in IREx
        b) Each Relying Site will complete the following in IREx:
            i. Institutional Profile
            ii. Human Research Protections (HRP) Survey
            iii. Principal Investigator (PI) Survey
    2. The AdventHealth regulatory team will submit the following in the IRB electronic submissions platform for each Relying Site as an amendment to the initial approval of the lead site:
        a) HRP-203 FORM - Modification Application
        b) Consent with site specific changes
        c) The completed Institutional Profile, HRP Survey, and PI Survey from IREx
        d) IRB Authorization Agreement, if not using the SmartIRB Agreement
        e) Other site-specific documents, i.e. recruitment material, etc.

3. Upon approval of a Relying Site, AdventHealth IRB will provide:
   a) Approval letter
   b) Approved documents for the Relying Site
   c) Executed IRB Authorization Agreement, if applicable
4. The AdventHealth regulatory team will be responsible to enter the appropriate information and documentation in IREx for each Relying Site.

D. For continuing review, the study expiration date will be the same for the lead site and all Relying Sites. Each site will be expected to provide the following information to the lead site for submission to AdventHealth IRB:
   1. HRP-202 FORM - Continuing Review Application
   2. Current approved consents for all sites

E. For closure, the lead site must remain open until all Relying Sites are closed.
   1. Each site must meet criteria for closure according to HRP-413 WORKSHEET - Closure Criteria.
   2. Closure of lead and all Relying Sites may occur at the same time.

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

Human Research Protections Survey: The survey completed by the human research protection program of the Relying Site for each study. It is completed within IREx.

Institutional Profile: The survey completed by each institution that is a member of IREx. It is completed within IREx.

IRB Reliance Exchange (IREx) **:** An electronic platform, used nationally, to capture reliance decisions and facilitate communication between the Lead/Coordinating Site/PI, Relying Site or IRB, and the Reviewing IRB.

Lead/Coordinating Site/PI: The lead multisite Principal Investigator with ultimate responsibility for the conduct and integrity of research (generally, the initiating Principal Investigator or funding Principal Investigator, as applicable). Generally, the Lead/Coordinating Site/PI is at the Reviewing IRB's institution. In collaboration with the Reviewing IRB, ensures coordination of communication to and from all Relying Sites, routing all IRB submissions to the Reviewing IRB and communicating IRB determinations to all sites.

Principal Investigator Survey: They survey completed by the PI or coordinator of the Relying Site for each study. It is completed within IREx.

Relying Site or IRB: A participating institution that cedes IRB review to a Reviewing IRB for a specific study.

Reviewing IRB: The "IRB of record" to which authority for IRB review and oversight has been ceded by another institution for a specific study.

SmartIRB Agreement: An IRB Authorization Agreement, used nationally, for the

harmonization of multicenter research when federal regulations or local policies require a single Reviewing IRB for the oversight of such studies.

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

VIII. REFERENCE(S): 45 CFR 46

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

- Research Oversight
- Definitions in Human Research
- Human Research Protection Program
- Investigator Obligations in Research
- FORMS are located in IRBNet
  - HRP-200 FORM - Initial Review
  - HRP-202 FORM - Continuing Review Application
  - HRP-203 FORM - Modification Application
- WORKSHEETS are located on the AdventHealth Research Institute Website
  - HRP-413 WORKSHEET - Closure Criteria