Standard Operating Procedure (SOP)

SOP number SOP CW AHC 256	**SOP Name** Principal Investigator Oversight in Research
Location *Company-Wide Policies	**Responsible Department** Research Services
SOP Owner/Executive Owner: Executive Director of Research Services	**Original Creation Date** 3/7/2022
Effective Date: 02/16/2023	**Review Date** 01/24/2025

I. **SCOPE:** This standard operating procedure (SOP) outlines the process that Principal Investigators (PI) must follow to ensure oversight is conducted for all research at AdventHealth. The PI oversight process will follow all federal regulations and AdventHealth policies and procedures (FDA, DHHS/OHRP, and ICH-GCP (E6) (R2) guidelines including future revisions when applicable).

II. **PURPOSE:** The SOP describes the process for providing PI oversight and documentation requirements for all human subject research studies conducted at AdventHealth.

III. **QUALIFIED PERSONNEL:** This SOP applies to all principal investigators conducting a research study under the purview of AdventHealth Research Institute (AHRI) or collaborators and those participating at affiliated sites.

IV. **TRAINING:** See CW AHC 112 Investigator Obligations in Research, CW AHC 106 Billing Compliance in Clinical Research policy, and CW AHC 104 Financial Conflict of Interest in Research - Individual.

V. **SUPPLIES & EQUIPMENT:** Florence eBinders™ (Florence)

VI. **PROCESS/PROCEDURE:** PI oversight begins during the planning process of the study and continues throughout the life of the research study. For PIs of multi-site studies, the oversight responsibilities extend to all sites participating. Oversight is accomplished by the demonstration of the following:

A. Ensuring all Institutional Review Board (IRB) and AHRI approvals have been obtained prior to study initiation.
B. Delegation of tasks to all Research Personnel on the research study.
C. Involvement in protocol training and meetings including kick off meetings, site initiation meetings, monitor site visit meetings, etc.
D. Ensuring study protocol is being followed and participants' safety, wellbeing, and rights are being protected. This can be accomplished by overseeing study events and review of the following as applicable:
    1. Adverse events (AE)/serious adverse events (SAE) and immediate review and assessment of SAEs
    2. Appropriate informed consent process
    3. Assessing significant laboratory values that might jeopardize the participants' health and wellbeing
    4. Investigational product accountability

5. Review and sign *off* on participant eligibility requirements and randomization documents for Clinical Trials
6. Protocol deviations and unanticipated problems

E. Review of investigational new drug (IND) safety reports and assessment of re-consent if applicable.

F. Review of electronic data capture (EDC) system and sign *off* in a timely manner. Delegated Research Personnel can perform this task however the PI remains ultimately responsible.

G. Ensuring any data sets separate from EDC data entry are provided to external collaborators in a Health Insurance Portability and Accountability Act (HIPAA") compliant manner.

H. Ensuring they have oversight of AdventHealth selected external vendors used on the study. This can be accomplished by obtaining vendor policies/SOPs related to the service they will be providing for the study and file in (Florence). For example, external IRB policies and SOPs, central laboratory license and certifications and reference lab ranges, central imaging services manual of operations.

I. PI is to conduct PI oversight meetings or equivalent (such as regular connections with the study team), which must occur with applicable Research Personnel. Frequency of these meetings will be dependent on the enrollment and complexity of study. It should include the following assessments:

1. **For Clinical Trials:**
   a) AE/SAE for participants
   b) Unanticipated Problems Involving Risks to Subjects or Others
   c) Recruitment status and potential obstacles
   d) Eligibility issues or clarification
   e) Protocol amendment review and retraining of study staff
   f) Research Personnel review, addition, removal, and task assignment
   g) Concerns or deficiencies along with possible resolution, corrective and preventative action plan (CAPA) to be discussed and assigned to Research Personnel, ensure follow through with implementation.
   h) Review all monitoring reports and letters and provide documentation of that review. All documentation should include date reviewed. Methods may include:
      i. Signing monitoring report
      ii. Document the review in meeting settings through agenda or minutes. Document informal conversations in a research study specific note signed and dated.
   i) PI or delegate must review and sign/co-sign on eligibility, physical exam, laboratory assessments, AE logs, etc. If PI is a non-physician, the medical investigator will conduct physician assessments and the PI will oversee the information.
   j) Ensure research records demonstrate the protocol was followed including

methods for data de-identification, storage, retention, quality and sharing.
k) Ensure there are source documents for all data collected.

2. **For Studies that are not Clinical Trials:**
   a) Unanticipated Problems Involving Risks to Subjects or Others or data
   b) Recruitment status
   c) Eligibility issues
   d) Data review and protection (limited access)
   e) Protocol amendment review and retraining of study staff
   f) Research Personnel review, addition, removal, and task assignment
   g) Concerns or deficiencies along with possible resolution, corrective and preventative action plan (CAPA) to be discussed and assigned to Research Personnel, ensure follow through with implementation.

J. Documentation of meetings must be documented in any of the following ways and filed in Florence for each study:
(All documentation must include study identifiers such as protocol or IRBNet number or study title)
   a) Meeting minutes
   b) Detailed agenda with name of all attendees
   c) PI oversight meeting log, which includes who attended and cases or items reviewed
   d) All documentation must be signed and dated contemporaneously by PI and applicable research personnel in attendance such as lead coordinator. If Microsoft Teams or another approved method of virtual meeting system is used, meeting minutes with screenshot of attendees, do not require a signature.

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

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

Clinical Trials: Common Rule definition: A Research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

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

IX. REFERENCE(S):
Investigator Guidance; Additional FDA Obligations
Investigator Guidance: Additional ICH-GCP Obligations

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

- Research Oversight
- Abbreviations in Research
- Definitions in Human Research
- Human Research Protection Program
- Investigator Obligations in Research