Standard Operating Procedure (SOP)

SOP number: SOP CW AHC 252	**SOP Name:** Research Personnel
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: 11/20/2024	**Review Date:** 11/20/2024

I. SCOPE: This standard operating procedure (SOP) describes the minimum requirements for Research Personnel listed on a Delegation of Authority Log (DOA Log) and applies to all those conducting human subjects research at AdventHealth. Individual departments may create additional work instructions to support this SOP. Requirements and procedures for unique activities are addressed in separate SOPs or guidances, including: Humanitarian Use Device (HUD), Expanded Access Program (EAP), and Compassionate Use.

II. PURPOSE: The purpose of this SOP is to identify Research Personnel, the associated training requirements, and the submission timelines and requirements to the AdventHealth Institutional Review Board (IRB). There will be one DOA Log for each new study, encompassing both sponsor and AdventHealth IRB requirements. This log will be maintained as an eLog in Florence eBinders™ (Florence) and signatures are required for applicable clinical trials.

III. QUALIFIED PERSONNEL: Research Personnel

IV. TRAINING: Florence, Collaborative Institutional Training Initiative (CITI), International Air Transport Association (IATA), informed consent, research billing compliance, conflict of interest.

V. SUPPLIES & EQUIPMENT: Florence and IRBNet.

VI. PROCESS/PROCEDURE:

A. Role Types for Research Personnel

1. AdventHealth recognizes various roles for Research Personnel associated with a research study. These roles may be filled by AdventHealth employees and non-employees.
2. The same person may perform various roles for different research studies.
3. The role for each person is not necessarily tied to a job description or title, but rather the role they are assigned in the study and their level of involvement.
4. Members of Centralized Teams are not required to be listed on a DOA Log.
   a) Centralized Teams only perform research specific procedures in connection with the protocol follow the scope of practice assigned to their standard role.
   b) Manager/Supervisor of team will be the only person added to DOA Log.
   c) A separate log for each Centralized Team will be maintained to list the individuals on the team. Start and end date of individuals in these teams will be recorded on the Centralized Team log. These logs will be made available upon request and will be kept in Florence.

5. Research Learners may be considered Research Personnel based on their role on the study. The Research Learner role must be designated on the DOA Log to ensure appropriate AdventHealth credentialing and training is in place.

B. Specific Training Requirements

1. AdventHealth IRB Requirements: Collaborative Institutional Training Initiative (CITI) courses are required for Research Personnel. They include:
   a) Basic Ethics Research course (Biomedical or Social Behavioral, as applicable.)
   b) HIPAA training course Health Information Privacy and Security (HIPS)
   c) Good Clinical Practice (GCP), required for those conducting non-exempt research and/or a clinical trial involving a drug or device. Those who are participating in studies that fit exempt categories, would not be required to complete this training.
   d) Refresher CITI training courses are required every 3 years for all Research Personnel listed on an IRB approved study.
2. Protocol specific training: Any protocol specific training provided by the Principal Investigator (PI) or the appropriate delegate(s), sponsor, or sponsor representative(s) to specific Research Personnel or the whole study team. This would include all aspects of the protocol necessary to perform said specified tasks per their role(s) designated on the DOA Log. This may include but is not limited to the site initiation visit, study team meetings, unit manager overview, etc. After IRB approval of protocol amendments, any applicable training should occur and be documented.
3. Conflict of interest training and disclosure unless an exemption applies by CW AHC 104 Financial Conflict of Interest (FCOI) in Research - Individual policy.
4. Florence eRegulatory binders
5. Additional trainings are required based on the individual's role or delegated task(s) in a study:
   a) Informed consent training – every 3 years
      i. Investigator specific training – Required training for Investigators participating in human subjects research.
      ii. Comprehensive training - Required for research coordinators and any staff who obtain informed consent. Investigators may complete the Comprehensive training in lieu of the Investigator specific training.
   b) International Air Transport Association (IATA) – every 2 years
   c) Research Billing Compliance Training as required in CW AHC 106 Billing Compliance in Clinical Research Policy and SOP CW AHC 257 Research Billing Compliance.

C. Documentation of Training

1. Documentation of training is generally maintained in the eBinder in Florence. A training log may be used for documentation of training.
2. Office of Research Integrity and Compliance will ensure all Research Personnel are properly credentialed to assist on research teams by utilizing the Florence eBinders. Credentialing documents for Research Personnel stored in Florence are available upon request.
3. Legacy Studies will have a Research Personnel log on file and may also have a DOA Log, based on study sponsor requirements.
4. Protocol training documentation for Centralized Teams:
   a) The individual signing the DOA Log representing the Centralized Team will also

sign the Protocol Training Log on behalf of the team as required for those teams who will perform protocol specific tasks.

b) Those Centralized Teams that do not perform protocol specific tasks are not required to complete protocol training.

D. Research Personnel/DOA Logs – Additions and Removals

Individuals meeting the definition of Research Personnel must meet specific criteria necessary to complete the specific tasks on a research study for which they have been delegated. This qualification assessment is documented in using the following methods:

1. Additions – Qualifications:
   a) Job Descriptions/Roles/Titles: Qualifications for a person's level of involvement in a research study may be met through a job description or a curriculum vitae (CV). The Research Personnel education, experience, and background must be appropriate for their delegated role on the study, and within the scope of any licensure or certification they may have.
   b) CVs/Resumes: All Research Personnel on a DOA Log must maintain their CVs or resumes and file them in Florence.
      i. Research Personnel must review and sign their CV every two years verifying it is current and making any revisions necessary.
      ii. CVs/resumes are generally not required for Research Learners unless necessary to document specific qualifications required for the task they are delegated.
   c) Licenses or Certifications: All Research Personnel must maintain applicable licenses or certification and file them in Florence or other study binder.
      i. Licenses and certifications should be updated prior to their expiration date.
      ii. Individuals are responsible for maintaining the required training, education, licensure or any certification necessary for the role and tasks in which they are assigned on the study they are listed.
2. Removals:
   a) The end date must be added to the DOA Log and Research Personnel log (if Legacy Study).
   b) IRBNet access should be removed for Research Personnel in real time.

E. AdventHealth IRB Submission Requirements

The DOA Log (dependent on study activation date) must be submitted to AdventHealth IRB as follows:

1. Study initiation: Clinical operations must provide Research Regulatory Services department with a list of Research Personnel on the DOA Log prior to IRB submission.
2. Research Personnel changes:
   a) FCOI management plans are created or modified.
   b) Investigator changes.
   c) Removal of any Research Personnel due to FCOI management plan requirement.
   d) Other circumstances requiring notification to the IRB.
3. At continuing or annual review: Submit the DOA Log or Research Personnel log (if Legacy Study) ensuring it reflects any Research Personnel changes since prior submission.

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 policy, refer to CW AHC 102 Abbreviations in Research

Academic Affiliation Agreement: Agreement initiated between AdventHealth and an academic institution for the purposes of outlining roles, responsibilities and procedures for a Student's academic experience at AdventHealth.

Centralized Team(s): Teams providing research services in support of study teams to conduct clinical trials/research studies. These teams perform research specific procedures in connection with the protocol following the scope of practice assigned to their standard role. (e.g. phlebotomist, research laboratory personnel, pathologist, ECG technician, investigational drug services (IDS) pharmacy, centralized research regulatory, exercise, calorimetry, nutrition services, radiologist or radiology technician and imagine core).

Delegation of Authority Log (DOA Log):
A form that provides a comprehensive list of study staff members and the duties that have been delegated to them by the PI. It is required for both observational and interventional clinical research studies.

Legacy Study(ies): Studies opened prior to the regular use of the e-regulatory software Florence. If an eBinder is/was created during the life of the study, then the normal process should be followed as practical.

Non-Research Personnel: Ancillary individuals who may interact with research subjects during a research study, but only within the scope of his/her regular employment capacity. Involvement in the research study of this level merits neither professional recognition nor publication privileges. These individuals do not contribute to the design, governance or analysis of the study. Additionally, these individuals are not recognized as Research Personnel and should not be listed on the DOA log. Examples include but are not limited to: Centralized Teams (as defined above), Bedside nurse completing standard of care procedures, Infusion Nurses (starting and monitoring the infusion

Research Administration: Central coordinating office for Research Learner activities.

Research Learner: An employed or non-employed individual engaging in a research experience for the purposes of professional development and/or obtaining credit towards a degree program. Must be at least 18 years of age. Research Learner categories are defined as follows:

1. Unpaid Research Intern ("Intern") – A non-credit seeking, non-sponsored individual; may or may not be enrolled in an academic degree program. Must have an active Unpaid Intern Agreement executed with AdventHealth.
2. Credit-Seeking Student ("Student") - A currently enrolled student engaging in research for academic credit. Must have an active Academic Affiliation Agreement executed with AdventHealth.

3. Visiting Research Scholar ("Scholar") - A Masters, PhD, or MD scholar with sponsorship from their home institution. Must have an active Visiting Researcher – Scholar Agreement executed with AdventHealth.

Research Learners must be approved by Research Administration, successfully complete the Research Administration onboarding process, and fulfill all research credentialing requirements prior to serving on a research study team. Upon onboarding through Research Administration, an approved Research Learner may only serve on a research team through being vetted by an established AdventHealth Research Institute department.

1. May not serve as a Principal Investigator or Sub-Investigator*. May serve in other roles on the research team with the appropriate background training, education, and experience.
2. May not obtain informed consent or sign legal documents, participate in any portion of the consent process, including witnessing a signature.*
3. May not participate in industry-sponsored research or clinical trials.
4. May not document in medical records per AdventHealth policy.
5. May not assist patients to get out of bed/chair or lift a patient.
6. May not provide medical advice.
   *An exception may be made in cases where the Research Learner is an AdventHealth employee.

Sub-Investigator: An individual who, working under the guidance of the Principal Investigator, conducts research. The Sub-Investigator should report directly to the Principal Investigator for the site (i.e., the PI should have clear responsibility for evaluating the Sub-Investigator's performance and the authority to terminate the Sub-Investigator's involvement with the study) and the Sub-investigator should not be delegated the primary supervisory responsibility for the site.

Unpaid Intern Agreement: Document initiated between AdventHealth and an Intern for the purposes of outlining roles, responsibilities and expectations related to the Intern's research experience.

Visiting Researcher – Scholar Agreement: Document initiated between AdventHealth and a Scholar for the purposes of outlining roles, responsibilities and expectations related to the Scholar's research experience.

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

REFERENCE(S):

FDA Guidance for Industry Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects

FDA Code of Federal Regulations: 21 CFR, Part 312.53

Department of Health and Human Services (DHHS) 42 CFR 50.603, 604, 605, & 606
E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry

IX. 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 104 Financial Conflict of Interest in Research - Individual
- CW AHC 112 Investigator Obligations in Research
- CW AHC 108 Human Research Protection Program
- CW AHC 106 Billing Compliance in Clinical Research Policy
- SOP CW AHC 241 AHRI Personnel Financial Interests
- SOP CW AHC 216 Informed Consent Process and Written Documentation of Informed Consent
- SOP CW AHC 234 Florence eRegulatory Essential Documents Maintenance
- SOP CW AHC 240 Utilization of External IRBs
- SOP CW AHC Research Billing Compliance
- FORMS are located in IRBNet
- WORKSHEETS are located on the AdventHealth Research Institute website
  - HRP-422 WORKSHEET – Engagement