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):** N/A
Effective Date: 11/28/2022	**Review Date:** 11/28/2022

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, 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 and IRBNet.

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. Students and Volunteers may be considered Research Personnel based on their role on the study. These roles need to 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 (HIPS)
   c) Good Clinical Practice (GCP), required for those conducting a clinical trial involving

a drug or device.
d) Refresher 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 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, 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 regulatory binders
5. Other trainings may be applicable based on research activity, e.g., International Air Transport Association/IATA, etc.

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.

D. Research Personnel Qualifications

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 assigned. This qualification assessment is documented in using the following methods:

1. 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.
2. CVs/Resumes: All Research Personnel on a DOA Log must maintain their CVs or resumes and file them in Florence.
   a) The time frame for Research Personnel to sign and verify their CV is every two years.
   b) CVs/resumes are generally not required for student or volunteer researchers, unless necessary to document specific qualifications necessary to conduct the research.
3. Licenses or Certifications: All Research Personnel must maintain applicable licenses or certification and file them in Florence or other study binder.
   a) Licenses and certifications should be updated prior to their expiration date.
   b) 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.

E. AdventHealth IRB Submission Requirements

The DOA Log (dependent on study activation date) must be submitted to AdventHealth IRB at the following time points:

1. Study initiation - Clinical operations must provide Research Regulatory Services with a list of Research Personnel on the DOA Log prior to IRB submission.
2. Research Personnel added/changes to DOA Log
   a) When Research Personnel are added to the DOA Log.
   b) When FCOI management plans are created or modified.
   c) Other circumstances that necessitate prompt reporting
3. Research Personnel removed from DOA Log
   a) The end date must be added to the DOA Log and Research Personnel log (if Legacy Study), and IRBNet access should be removed in real time for Research Personnel that are removed from a study.
   b) Personnel removals are only required to be submitted to the AdventHealth IRB at continuing review or other study changes/notifications that would require a new submission. The following scenarios would require promptly reporting:
      i. Research Personnel with an FCOI management plan
      ii. Other circumstances that necessitate prompt reporting
4. PI changes - The revised DOA Log will be promptly submitted to AdventHealth IRB.
5. Continuing review - At the time of continuing review, the DOA Log or Research Personnel log (if Legacy Study) must be submitted to AdventHealth IRB.

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

Delegation of Authority Log (DOA Log): a comprehensive list of study staff members and the duties that have been delegated to them by the PI used by the study team, sponsor, and IRB to confirm who is listed as Research Personnel of a study.

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. Individuals do not contribute to the design, governance or analysis of the study. Individuals are not recognized as Research Personnel and are not required to be listed on the DOA log. (Examples include but are not limited to: Bedside nurse completing standard of care procedures, Infusion Nurses (starting and monitoring the infusion), Phlebotomist, ECG technician, Radiologist or Radiology Technician, Pathologist, Lab Personnel, Nutrition Services, Pharmacy (if applicable)).

Students: Employees or Non-Employees conducting research in a student capacity who are enrolled students at a college or university to satisfy educational requirements to receive credit for a course or to meet a degree requirement. All students must have a research collaboration agreement fully executed between AdventHealth and their educational institution.

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.

Treating Physician: An individual who, working under the guidance of the Principal Investigator, conducts research, that is outside standard of care. This investigator may make medical decisions, but is not performing critical study functions, and is not making a direct and significant contribution to study data.

Volunteers: Upon onboarding by the Volunteer Services Department, an approved AdventHealth Volunteer may only serve on a research team through being vetted by an established AdventHealth Research Institute department.

a. May not serve as a PI. May serve in other roles on the research team with the appropriate background training, education, and experience.
b. May not obtain informed consent or sign legal documents,
c. May not document in medical records per AdventHealth policy.

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
- SOP CW AHC 241 AHRI Personnel Financial Interest
- 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
- WORKSHEETS are located on the AdventHealth Research Institute Website
  - HRP-422 WORKSHEET - Engagement