Standard Operating Procedure (SOP)

SOP number	SOP Name
851.001	Standard Operating Procedure for AdventHealth Orlando Research Institute Standard Operating Procedures (SOPs)
Location	**Responsible Department**
AdventHealth Orlando	Research Services
SOP Owner/Executive Owner	**Original Creation Date (If applicable)**
Executive Director of Research Services	Not applicable
Effective Date	**Review Date**
3/3/2021	3/3/2021

I. SCOPE: This Standard Operating Procedure (SOP) describes the process for writing, reviewing, revising, approving, training, disseminating, implementing, and maintaining the Standard Operating Procedures (SOPs) for AdventHealth Orlando Research Institute as issued by the AdventHealth Orlando Office of Research Integrity (ORI).

The ORI is committed to research compliance and integrity. Properly developing, maintaining, training, and disseminating of SOPs are necessary to help ensure consistency, compliance, accountability, and efficiency of the Principal Investigator (PI) and the entire research team while conducting research. SOPs will assist in maximizing subject's safety while minimizing risk to AdventHealth Orlando researchers, AdventHealth Orlando research departments, and/or AdventHealth Orlando affiliates conducting research under the auspices of AdventHealth Orlando Research Institute and at the same time help AdventHealth Orlando researchers satisfy the many Federal regulations, guidelines, and State laws that are applicable to clinical research.

II. PURPOSE: The AdventHealth Orlando Research Institute Standard Operating Procedure (SOP) on SOPs is to ensure that all AdventHealth Orlando Research Institute staff follow institutional policies, and there is a formal process to review, approve, and to implement SOPs. All SOPs must comply with all applicable state and federal regulations and laws and international guidelines. This SOP on SOPs will replace any individual department SOP on SOPs previously created.

III. QUALIFIED PERSONNEL: This SOP applies to all employees and agents of AdventHealth Orlando conducting Human Research. All <Research Personnel>, <HRPP Personnel> (as defined by Policy 400.001 HRP-001) and agents conducting research at an AdventHealth Orlando facility must comply with AdventHealth Orlando Research Institute SOPs.

IV. TRAINING: All <Research Personnel>, <HRP Personnel> and agents conducting research at an AdventHealth Orlando Facility should review this SOP as part of their orientation process.

V. SUPPLIES & EQUIPMENT: Not applicable

VI. PROCESS/PROCEDURE:

A. Writing the SOP:

1. Draft an outline of the procedure.
   (a) Review, interpret, and apply all of the following (as applicable) to the SOP: applicable federal regulations (including, but not limited to: FDA, DHHS/OHRP, and ICH (E-6) GCP guidelines), State laws, and/or AdventHealth Orlando Policies, Procedures, or guidelines. The SOP should meet these requirements and also maintain some flexibility for all <Research Personnel>, <HRPP Personnel>, and agents to be able to operationalize SOPs. When needed, seek input from other stakeholders, such as: Core Lab, Pharmacy Investigational Drug Services (IDS), AdventHealth Information Technology (AIT), and Materials Management.
   (b) Utilize AdventHealth Orlando Legal and/or AdventHealth Orlando Corporate Compliance to assist with resolving any differences between federal laws and local laws as they relate to research when necessary.
   (c) The SOP should be written from a user's point of view presenting step-by-step instructions in a logical or chronological order for all necessary actions.
   (d) Complete a draft version and the SOP Committee Checklist (See Appendix A).
   (e) Review and approval process through the SOP Committee.

B. Standard Format of the SOP:

1. The SOP will follow the SOP template provided by the Document and Knowledge Portal. The SOP header will be completed per the research chapter numbering guide provided by the Document and Knowledge Portal.

C. Review and/or Revision of an existing SOP:

1. Each SOP will be reviewed on a biannual basis, after the approval date, unless otherwise necessary. Each SOP must be reviewed for accuracy, completeness, any organizational and/or necessary procedures changes, and to ensure that SOPs based upon regulations that may have changed, continue to be up-to-date and satisfy current regulations. SOPs may be reviewed more often as necessary due to new or revised federal regulations, or at the discretion of the Research Services Executive Director, ORI Director, Research Oversight Committee (ROC), and/or the SOP committee.
2. The review and approval process require a quorum of the SOP Committee, including stakeholders' recommendations with subject matter expertise. Changes will be made per the AdventHealth Orlando Document and Knowledge requirements.
3. For revisions, a gatekeeper from the SOP Committee will submit the SOP and corresponding checklist to the AdventHealth Orlando Document & Knowledge inbox. Follow all additional steps as required by the AdventHealth Orlando Document & Knowledge team.

Revision history will be noted in each document and managed as follows:

Document Action	**Effective Date**	**Training Required**
New Document	New	Yes
Reviewed; no change	No change	No
Reviewed; edited (no changes to the practice or procedure, formatting/clarification changes only)	No change	No

Reviewed; revised (content changes to the practice or procedure	New	Yes

D. The Approval process of the SOP

1. The Author submits the SOP and SOP Checklist to the SOP Committee for review. Once the approval process and voting have been completed, a final "clean copy" will be saved.
2. If required per the SOP checklist, the SOP will be sent to the Research Oversight Committee. Any Research Oversight Committee requested changes will be made prior to finalization.
3. The SOP will then be sent to the Document and Knowledge Portal and follow the gatekeeper process for submission.
4. All SOPs that govern generalized institute wide operations must come through the SOP committee for review, approval and submission to the Document & Knowledge Portal in SharePoint. Once the SOP is approved by the AdventHealth Orlando Document and Knowledge team, the SOP will be disseminated among AdventHealth Orlando Research Institute, education will be provided, and the SOP will be maintained in Florence.
5. All other individual clinical departmental SOPs must come through the SOP committee for review, acknowledgement and submission to the Document & Knowledge Portal in SharePoint.
6. Deletion of an SOP requires stakeholder approval as noted above to ensure that the process is no longer needed. All deleted SOPs will be archived as a resource.

E. Filing and Maintaining the SOP:

1. All approved versions of the SOPs are stored securely in electronic format. The official copy is the document that lives in the Document and Knowledge Portal. SOPs will also be housed in Florence.

F. Training and Dissemination of the SOP:

1. AdventHealth Orlando Research Institute will be notified via the AdventHealth Orlando Research Institute All email list when new SOPs are implemented (or existing SOPs are deleted and/or revised) and will be provided with a link to the newly published SOP in the Document & Knowledge Portal.
2. Members of the SOP Committee, in partnership with the Research Education department, and Clinical Operations Managers will determine role-based training approach. Training formats may include independent review of the SOP, watching a recorded introduction and explanation of the new SOP, participating in live meetings or presentations, etc. Any training recordings will be posted to the Research Services SharePoint Website for future training needs.
3. AdventHealth Orlando Research Institute will comply with AdventHealth Orlando Policy# 800.426, Staff Education and Training. Once documents are approved and accessible, all applicable AdventHealth Orlando Research Institute personnel will be notified and training on the Policy/SOP/Work Instruction (WI)/Study Specific Procedure (SSP) will take place. Applicable personnel for training will be determined based on respective job description and requirements. Each employee's immediate supervisor will ensure that Policy/SOP/WI/SSP training has been completed and training documentation is maintained.

G. Implementation of the SOP:

1. Each employee's immediate supervisor will be responsible for ensuring that all their research staff review and follow all applicable AdventHealth Orlando Research Institute SOPs.
2. AdventHealth Orlando Research Institute SOPs will be reinforced through the following:
   - Educational Offerings as applicable by class topic
   - Completion of quizzes when required
   - Internal Monitoring & Auditing

VII. DEFINITION(S):

Approver/Executive Owner: The Executive Director of Research Services serves as the Approver of AdventHealth Orlando Research Institute SOPs, and is the only person with signatory authority for AdventHealth Orlando Research Institute that may designate an SOP as approved in the Document and Knowledge Portal. The Approver is responsible for ensuring the integrity and accuracy of the SOP, and that the SOP is adequate to meet the needs for its intended use as defined by current practices, AdventHealth Orlando, State, and Federal policies, as well as consistency with existing SOPs and policies and procedures.

Committee Charter: A document that defines the authority and functions of committees established by AdventHealth Orlando's governing body or leadership

Gatekeeper: Staff member with responsibility to load, update, delete, and initiate electronic signature for documents in the document management system.

HRPP Personnel: Individuals involved in the oversight of research.

Policy: A document that defines non-negotiable rules for compliance and decision-making.

Research Personnel: Individuals involved in designing, conducting, or reporting of research.

SOP Effective Date: Date the SOP Committee assigns as the effective date of the final version of the SOP.

SOP Review Committee: The committee is made up of the SOP Chair and Co-Chair, and other members of the AdventHealth Orlando research community from various departments, as described in depth in the SOP Committee Charter. Also, relevant stakeholders are invited to specific SOP Review Committee meetings. The primary purpose of the SOP Review Committee is to provide specific SOP support, creation, and education guidelines and resources for the research compliance elements for the AdventHealth Orlando Research Institute. The SOP Committee members make suggestions and provide feedback for SOP drafts, and then the Committee votes, approves, and submits the SOP per the SOP Committee Charter.

Standard Operating Procedure (SOP): A document that identifies a consistent way to carry out a process or procedure from beginning to end. An SOP can be a written document, flowchart, or graphic.

Work Instruction: A document that provides details for carrying out a job responsibility in a consistent way from beginning to end.

VIII. EXCEPTION(S): Not applicable

IX. REFERENCE(S):

FDA Code of Federal Regulations: 21 CFR Parts 11.10, 50, 54, 56.108, 56.109, 56.113, 312.53, 314, 600, 601, 812 and 814

45 CFR 46.103, 46.108

International Conference on Harmonization (ICH) Guidelines (E6) for Good Clinical Practices (GCPs): 1.55, 2.13, 2.8, 4.9.3, and 5.18.5

X. RELATED DOCUMENT(S) / ATTACHMENT(S): HRP 001 400.001; EDU.042.0026