Standard Operating Procedure (SOP)

SOP Number: SOP CW AHC 228	**SOP Name:** Annual Tasks
Location: *Company-Wide Policies	**Responsible Department:** Research Services
Executive Owner Executive Director of Research Services	**Original Creation Date:** 01/18/2022
Effective Date: 04/04/2022	**Review Date:** 02/12/2024

I. SCOPE: This standard operating procedure (SOP) applies to the Organization Official and designated individuals.

II. PURPOSE: This procedure establishes the process to conduct annual tasks related to the Human Research Protection Program (HRPP). This procedure begins every year in July. This procedure ends when evaluations and corrective actions are completed.

III. QUALIFIED PERSONNEL: The Organization Official delegates individuals to carry out these procedures.

IV. TRAINING: Not applicable

V. SUPPLIES & EQUIPMENT: Not applicable

VI. PROCESS/PROCEDURE:

A. The subject outreach program for enhancing the understanding of subjects, prospective subjects, and communities is accomplished by making subject information available on AdventHealth Research Institute's website.

B. Obtain updated résumés or curricula vitae from each IRB member and IRB staff member (or confirmation that the existing one is still accurate).

C. Evaluate in consultation with the IRB Executive Chair and HRPP Administrator as appropriate:

1. General performance of the HRPP, such as:

a) Feedback from Investigators, research staff, sponsors, and subjects
b) The subject outreach plan
c) Results of regulatory audits
d) Results of continuous improvement activities
e) New requirements
f) Compliance with policies and procedures
g) Compliance with regulatory requirements
h) Status of action items from previous reviews

2. HRPP resources for:

a) Space
b) Personnel
c) HRPP educational program
d) Legal counsel

e) Conflicts of interests
f) Quality improvement

3. Whether the number of IRB panels is appropriate to the volume and types of research reviewed
4. Whether the composition of IRBs meets the requirements in HRP-430 WORKSHEET – IRB Composition
5. Whether the IRB and organizational registrations have been updated in the past two years
6. The knowledge and performance of each IRB member, IRB Executive Chair, IRB vice-chair, and IRB staff. Consult with the IRB Executive Chair on the performance of IRB members and IRB staff members.
7. Whether IRB members, IRB Executive Chair, IRB vice-chairs, and IRB staff members have completed required training
8. The effectiveness of the subject outreach plan

D. Provide a copy of the evaluation to the Organization Official.

E. Take actions as needed to:

1. Reallocate HRPP resources
2. Modify the number of IRBs
3. Modify the composition of IRBs
4. Remove individuals with persistent knowledge and performance gaps
5. Correct knowledge and performance gaps of individuals
6. Arrange for individuals to take missing training
7. Modify the subject outreach plan
8. Modify policies and procedures
9. Provide additional training or modify existing activities

F. Provide each individual with a summary of the individual's evaluation

G. If a member is recommended for reappointment, send letter thanking them for their service, inviting them to accept reappointment for the year, and offering them an opportunity to obtain feedback on their performance for the previous year.

H. Update IRB registrations at http://ohrp.cit.nih.gov/efile/.

I. Update organizational registrations more than four years old at http://ohrp.cit.nih.gov/efile/FwaRenew.aspx.

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

For capitalized designations not defined in this policy, refer to CW AHC 103 Designations in Research.

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

IX. REFERENCE(S):

21 CFR §56.106 and §56.107

45 CFR §46.107 and 45 CFR §46 Subpart E

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

- CW AHC 107 Definitions in Human Research
- CW AHC 103 Designations in Research
- CW AHC 101 Research Oversight
- CW AHC 108 Human Research Protection Program
- WORKSHEETS are located on the AdventHealth Research Institute website
  - HRP-430 WORKSHEET – IRB Composition