Standard Operating Procedure (SOP)

SOP Number: SOP CW AHC 201	**SOP Name:** Regulatory Review
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 Research Personnel and Institutional Review Board (IRB) staff members, chair, and committee members at AdventHealth.

II. PURPOSE: This procedure establishes the process to review IRB submissions for regulatory issues. This procedure begins when an IRB submission for a review or determination has been checked by office staff. This procedure ends when the Regulatory Reviewer has completed the review, or an Investigator has withdrawn the submission.

III. QUALIFIED PERSONNEL: Regulatory Reviewers; IRB staff members

IV. TRAINING: Not Applicable

V. SUPPLIES & EQUIPMENT: Not Applicable

VI. PROCESS/PROCEDURE:

A. As part of IRB review, all submissions are reviewed by a Regulatory Reviewer to:

1. Identify submissions with missing materials
2. Identify and document the determinations that the IRB needs to make in order to approve research. (For example. waiver of consent, children, prisoners)
3. Identify, make, and document regulatory determinations that the institution needs to make in order to approve research (For example, IND/IDE requirements)
4. Identify any relevant local, state, or international requirements
5. Arrange for consultation to resolve local, state, or international requirements.
6. Identify other special review issues.
7. Determine the likely level of review (Committee Review versus Non-Committee Review)
8. Follow applicable work instructions for review of initial application

B. The Regulatory Reviewer documents Regulatory Review findings on HRP-420 WORKSHEET – Regulatory Review or equivalent.

C. The Meeting Chair ensures that issues raised by Regulatory Review are covered at meetings.

D. The addition of a site to a previously approved study is considered a modification to previously approved research.

E. If the Investigator is Restricted and the submission satisfies all outstanding delinquent submissions, remove the Investigator's Restricted status.

F. If the Investigator is Restricted and the submission is an initial submission, notify the submission contact of IRB policy to disapprove those submissions:

   1. If the submission contact wants to address the Restricted status, have the contact provide additional information as appropriate to resolve the issues, or withdraw the submission and resubmit when complete.
   2. If the submission contact does not want to address the Restricted status, note this and continue processing.

G. If the submission is a response to a decision to conditionally approve research:

   1. Evaluate whether the submitted materials meet the conditions necessary for approval and evaluate if any other changes have been made.
   2. If the submitted materials meet the conditions necessary for approval and nothing else in the submission has changed, document that the submission is approved and follow SOP CW AHC 211 Post-Review to issue an approval. Otherwise, process as a modification.

H. Determine whether the submission is initial, continuing, or modification. If both continuing and modification, follow both procedures.

   1. For initial submission:

      a) Use HRP-420 WORKSHEET – Regulatory Review or SOP CW AHC 232 External IRB Screening
      b) Document any Regulatory Review findings.
      c) Confirm a research review application has been submitted to the Office of Sponsored Programs.

   2. For a modification submission:

      a) Determine whether the submission includes information that might represent an Unanticipated Problem Involving Risks to Subjects or Others, Serious Noncompliance, Continuing Noncompliance, Suspension of IRB Approval, or Termination of IRB Approval.
      b) If so, additionally process under SOP CW AHC 212 New Information.
      c) Review the Regulatory Review findings associated with prior approval(s).
      d) Use HRP-420 WORKSHEET – Regulatory Review.
      e) Update Regulatory Review findings as needed.

   3. For request to transfer an existing study to another IRB, follow SOP CW AHC 232 External IRB Screening and then and follow SOP CW AHC 211 Post-Review to notify the Investigator.

I. For continuing submission:

1. Determine whether the submission includes information that might represent an Unanticipated Problem Involving Risks to Subjects or Others, Serious Noncompliance, Continuing Noncompliance, Suspension of IRB Approval, or Termination of IRB Approval. If so, additionally process under SOP CW AHC 212 New Information.
2. If the submission meets HRP-413 WORKSHEET – Closure Criteria, close the study, follow SOP CW AHC 211 Post-Review to notify the investigator, and stop further processing.
3. Check whether consent document(s) and script(s) being used are the currently approved versions. If not, additionally process under SOP CW AHC 212 New Information as Noncompliance.
4. Review the Regulatory Review findings associated with prior approval(s).
5. Use HRP-420 WORKSHEET – Regulatory Review.
6. Update Regulatory Review findings as needed.

J. Communicate with the submission contact for any potentially resolvable contingencies.

1. If the submission contact wants to address the contingencies, have the contact provide additional information as appropriate to resolve the issues, or withdraw the submission and resubmit when complete.
2. If the submission contact does not want to address the contingencies, note this and continue processing.

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

VIII. EXCEPTION(S):

See CW AHC 101 Research Oversight

IX. REFERENCE(S):

Not Applicable

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

- CW AHC 101 Research Oversight
- CW AHC 107 Definitions in Human Research
- CW AHC 108 Human Research Protections Program
- SOP CW AHC 211 Post-Review
- SOP CW AHC 232 SOP External IRB Screening
- SOP CW AHC 212 SOP New Information
- WORKSHEETS are located on the AdventHealth Research Institute website
  - HRP-413 WORKSHEET – Closure Criteria
  - HRP-420 WORKSHEET – Regulatory Review