Standard Operating Procedure (SOP)

SOP Number: SOP CW AHC 210	**SOP Name:** Consultation
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 Institutional Review Board (IRB) staff members and Designated Reviewers at AdventHealth.

II. PURPOSE: This procedure establishes the process to obtain consultation. This procedure begins when the IRB requires competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. This procedure ends when the IRB is informed of the consultation.

III. QUALIFIED PERSONNEL:
For Committee Review, IRB staff members carry out these procedures.
For Non-Committee Review, the Designated Reviewer carries out these procedures.

IV. TRAINING: Not applicable

V. SUPPLIES & EQUIPMENT: Not applicable

VI. PROCESS/PROCEDURE:

A. Identify a consultant with the required expertise who can provide a review. Identify individuals as follows:
   1. IRB members
   2. Employees
   3. External consultants

B. Contact the consultant and determine availability for review.

C. Determine whether the consultant has a Conflicting Interest. If so, inform the Meeting Chair or the Designated Reviewer.

D. Obtain the agreement of the consultant to maintain confidentiality of information provided.

E. Use CW AHC 109 IRB Member Review Expectations to determine which documents to make available to the consultant so the IRB can obtain the additional expertise needed and make these documents available to the consultant. If the additional expertise needed does not require review of any materials, no materials need be provided.

F. For review Committee Review:
   1. If the consultant provided a written report, make the report available to the IRB members attending the meeting.
   2. If the consultant did not provide a written report, invite the consultant to the IRB meeting.

3. If requested by an IRB, invite the consultant to the IRB meeting.

G. For Non-Committee Review:

1. Directly obtain the information (oral or written) from the consultant.
2. Document information received with the name of the consultant.

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

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

IX. REFERENCE(S): Not applicable

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

- CW AHC 107 Definitions in Human Research
- CW AHC 101 Research Oversight
- CW AHC 108 Human Research Protection Program
- CW AHC 109 IRB Member Review Expectations