

Policy # CW AHC 101	Policy Name Research Oversight
Policy Location *Company-Wide Policies	Responsible Department Research Services
Executive Owner: Executive Director of Research Services	Original Creation Date 01/18/2022
Policy Effective Date 03/28/2022	Policy Review Date 03/28/2022

- I. SCOPE:** This policy applies to all Research conducted at or under the auspices of facilities owned or managed by AdventHealth, regardless of funding source, and to all individuals participating in Research at or under the auspices of AdventHealth.
- II. PURPOSE:** This policy addresses the authority of AdventHealth’s Chief Scientific Officer (CSO) to establish, coordinate, and manage AdventHealth’s Research Oversight program, utilizing AdventHealth Research Institute (AHRI). This policy provides the framework and key elements for AHRI; promotes and supports ethical conduct by AdventHealth researchers and staff; and supports AdventHealth’s commitment to compliance with applicable laws, regulations, company, and departmental policies.
- III. POLICY:** All members of AdventHealth are expected to satisfy institutional stewardship obligations and conduct Research in compliance with federal, state, and local laws, and with the policies and procedures of AdventHealth. Many departments contribute to the advancement of Research by engaging in activities that enhance and protect AdventHealth’s Research efforts. This policy sets forth AHRI’s authority and responsibility for Research Oversight, throughout AdventHealth. AHRI, with guidance from the AdventHealth Research Council (ARC), is responsible for developing a system-wide Research Oversight program that will promote compliance with all applicable legal requirements and institutional policies, ensure ethical conduct, and provide education, training, and guidance. AHRI manages the following system-wide programs for AdventHealth:
- Human Research Protection Program (HRPP): including Institutional Review Board (IRB)
 - Research Billing Compliance
 - Financial Conflicts of Interest in Research
 - Auditing and Monitoring (research related activities)
 - Research Regulatory Submissions & Maintenance.
 - Research Misconduct
 - Research Education and Training

ARC, the multi-divisional committee, as delegated by the CSO, will endeavor to harmonize Research policies and procedures, strategies, systems, and workflows, to

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standardize and streamline Research across AdventHealth.

IV. PROCEDURE/GUIDELINES: Specific procedures and guidelines are outlined in the individual policies. When necessary, each AdventHealth facility shall develop and implement facility-specific procedures or other protocols to implement the corporate-wide policies and procedures, while integrating local governmental rules and regulations and adhering to corporate-wide and industry best practices.

Information, Education, and Training

AHRI is committed to communicating our standards for ethical conduct and AdventHealth policies to individuals participating in Research at AdventHealth. AHRI provides education and training to develop Research Oversight awareness and commitment. Specific training is required for investigators and other research personnel.

Research Compliance Internal Monitoring and Auditing – AHRI will establish internal Research Oversight monitoring (process review) and auditing processes to evaluate the effectiveness of AdventHealth’s Research Oversight program, validate compliance with laws and regulations and to promote continuous improvement/best practices.

V. DEFINITION(S):

Research: is any systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge, including basic and applied research (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test, drug or device), and non-research projects such as training, clinical services, educational conferences, exhibitions, performances, archives, workshops, and library projects for which external funding is received.

Research also includes any such activity for which a proposal is submitted for funding from external sources through a grant, contract, or agreement, including, but not limited to, research grants, career development awards, center grants, individual fellowship awards, infrastructure awards, institutional training grants, program projects and research resources awards. Research also includes projects that are internally funded (i.e., funded by AdventHealth), as well as research for which approval of an IRB (or IRB exemption) or Institutional Animal Care and Use Committee (IACUC) is required.

VI. EXCEPTION(S): In the event, a division or affiliate is unable to comply with the procedure outlined in a specific corporate policy or procedure, due to lack of the necessary infrastructure, software, programmatic components, or other resources, an exception may be made for that specific procedure, contingent upon the division or affiliate's ability to provide an alternate process or procedure to comply with the policy.

When a division or affiliate has a Research Oversight procedure that deviates from one or more of the corporate-wide Research Oversight policies, it shall submit the applicable procedures to AHRI’s Director of Research Integrity, for review and approval. If the proposed procedures comply with applicable laws and regulations, the division or affiliate

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may provisionally retain use of the proposed procedure.

If the proposed procedures do not comply with applicable laws and regulations, the division or affiliate may be required to update the proposed procedure prior to approval. Alternative arrangements may be necessary to enable AHRI to fulfill the division or affiliate's Research Oversight obligations.

VII. REFERENCE(S): Not Applicable

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

- AdventHealth Research Council (ARC) Charter
- Research Oversight Committee (ROC) Charter
- CW AHC 102 Abbreviations in Research
- CW AHC 103 Designations in Research
- CW AHC 104 Financial Conflict of Interest in Research – Individual
- CW AHC 105 Research Misconduct Policy
- CW AHC 106 Billing Compliance in Clinical Research
- CW AHC 108 Human Research Protection Program (HRPP)

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