AdventHealth

POLICY

Policy # CW AHC 112	**Policy Name** Investigator Obligations in Research
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 04/04/2022	**Policy Review Date** 04/04/2022

I. **SCOPE:** This policy applies to all Investigators conducting Human Research overseen by AdventHealth.

II. **PURPOSE:** This policy describes the obligations of all Investigators conducting Human Research overseen by AdventHealth's Institutional Review Board (IRB). For research overseen by an IRB other than AdventHealth's, Investigators will follow the requirements of that IRB.

III. **POLICY:** Investigators are responsible for protecting human subjects and ensuring the integrity of the data from clinical investigations and will abide by the obligations outlined in this policy.

IV. **PROCEDURE/GUIDELINES:**

A. Human Research will not commence until the IRB approval letter is provided as well as all other required approvals, such as Institutional Clearance, radiation safety approval, biosafety approval, and approvals of departments or divisions that require approval to use their resources. If there are any questions about conducting research involving human subjects, contact the IRB before commencing the study.
B. Comply with all requirements and determinations of the IRB.
C. Ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient Investigator time, appropriately qualified research team members, equipment, and space.
D. Ensure that research staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study. Investigators and research staff are required to complete initial training and continuing training at least every three years.
E. Personally conduct or supervise the research.
F. Conduct Human Research in accordance with the relevant current protocol approved by the IRB.
G. Protect the rights, safety, and welfare of subjects involved in the research.
H. Submit proposed modifications to the IRB prior to their implementation.
I. Do not make modifications to the research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.

J. Submit continuing reviews when requested by the IRB.
K. Submit a continuing review to close research (end the IRB's oversight) when:
    1. The protocol is permanently closed to enrollment
    2. All subjects have completed all protocol related interventions and interactions
    3. For research subject to federal oversight other than FDA:
        a) No additional identifiable private information about the subjects is being obtained
        b) Analysis of private identifiable information is completed
L. If research approval expires, stop all research activities and immediately contact the IRB.
M. Promptly report to the IRB the information items listed in CW AHC 111 Prompt Reporting Requirements in Research.
N. Do not accept or provide payments to professionals in exchange for referrals of potential subjects ("finder's fees.")
O. Do not accept payments designed to accelerate recruitment that were tied to the rate or timing of enrollment ("bonus payments") without prior IRB approval.
P. For studies regulated by a federal department or agency, follow the additional obligations, as applicable:
    1. HRP-810 INVESTIGATOR GUIDANCE – Additional DOD Obligations
    2. HRP-811 INVESTIGATOR GUIDANCE – Additional DOE Obligations
    3. HRP-812 INVESTIGATOR GUIDANCE – Additional DOJ Obligations
    4. HRP-813 INVESTIGATOR GUIDANCE – Additional ED Obligations
    5. HRP-814 INVESTIGATOR GUIDANCE – Additional EPA Obligations
    6. HRP-815 INVESTIGATOR GUIDANCE – Additional FDA Obligations
Q. For studies where ICH-GCP compliance is required, follow additional the obligations in HRP-816 INVESTIGATOR GUIDANCE – Additional ICH-GCP Obligations.
R. Unless the IRB affirmatively approved a protocol to include the following populations, such subjects may not be enrolled:
    1. Adults unable to consent
    2. Children
    3. Neonates of Uncertain Viability
    4. Nonviable Neonates
    5. Pregnant Women
    6. Prisoners
    7. Individuals unable to speak English
S. When consent, permission, or assent are required by the IRB, ensure that they are obtained and documented in accordance with the relevant current protocol as approved by the IRB.
T. Follow AdventHealth requirements to disclose financial interests in research.
    1. Disclose financial interests on submission of an initial review.
    2. Disclose changes to financial interests.
        a) On submission of continuing review
        b) Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest that would have required disclosure on initial review
U. Retain research records (including signed consent documents) for the greater of:
    1. Seven years after completion of the research;
    2. The retention period required by the sponsor;
    3. The retention period required by local, state, or international law;

4. The retention period required by a site that is not part of AdventHealth; or
5. HIPAA requires signed authorizations to be retained for six years from the date signed or the date when it last was in effect, whichever is later.

V. Employ sound study design in accordance with the standards of a discipline and design studies in a manner that minimizes risks to subjects.
W. Update the IRB with any changes to study personnel.
X. Lead Investigators, of a multi-site study, will ensure there is a plan to manage information that is relevant to the protection of subjects, such as Unanticipated Problems Involving Risks to Subjects or Others, interim results, and protocol modifications, and submit that plan to the IRB.
Y. For plans to conduct community-based participatory research, contact the IRB for information about:
1. Community-based participatory research design
2. Community advisory boards
3. Subject advocates
4. Partnerships with community-based organization

V. DEFINITION(S):

For capitalized terms not defined in this policy, refer to CW AHC 107, Definitions in Human Research

For abbreviations/acronyms not defined in this policy, refer to CW AHC 102, Abbreviations in Research

VI. EXCEPTION(S):

See CW AHC 101 Research Oversight

VII. REFERENCE(S):

Electronic Code of Federal Regulation (*e-CFR™*). (June 18, 2015). 21 CFR, §50, §56: IRB Review of Research. Retrieved from: Click here and here.

Electronic Code of Federal Regulation (*e-CFR™*). (June 18, 2015). 45 CFR, §46: IRB Review of Research. Retrieved from: Click here.

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

- CW AHC 101 Research Oversight
- CW AHC 107 Definitions in Human Research
- CW AHC 102 Abbreviations in Research
- CW AHC 108 Human Research Protection Program
- CW AHC 111 Prompt Reporting Requirements in Research
- CW AHC 110 Legally Authorized Representatives, Children and Guardians in Research
- INVESTIGATOR GUIDANCES are located on the AdventHealth Research Institute website
  - HRP-810 INVESTIGATOR GUIDANCE – Additional DOD Obligations
  - HRP-811 INVESTIGATOR GUIDANCE – Additional DOE Obligations
  - HRP-812 INVESTIGATOR GUIDANCE – Additional DOJ Obligations
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  - HRP-816 INVESTIGATOR GUIDANCE – Additional ICH-GCP Obligations