AdventHealth

POLICY

Policy # CW AHC 105	**Policy Name** Research Misconduct
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 any person paid by, under the control of, or affiliated with AdventHealth at the time of the alleged misconduct, such as scientists, trainees, technicians and other staff members, guest researchers, volunteers, or collaborators at AdventHealth. This policy may also apply to individuals who were involved in Research that is the subject of an allegation of Research Misconduct, even if they are no longer affiliated with AdventHealth at the time the Allegation is reported.

II. **PURPOSE:** This policy is intended to comply with institutional responsibilities under the Public Health Service Policies on Research Misconduct, 42 CFR Part 93. Other federal agencies have published their own research misconduct regulations; to the extent those regulations apply to an allegation of misconduct and are inconsistent with this policy, AdventHealth shall comply with the applicable regulatory requirements. This policy also applies to research that is not federally funded, although such cases need not be reported to the federal government. The purpose of this policy is to define Research Misconduct and set forth the policies and procedures for the Inquiry, Investigation, adjudication, and reporting of any misconduct, as well as define the roles and responsibilities of those involved in the process.

III. **POLICY:** AdventHealth subscribes to ethical practices and integrity in the conduct of its Research. Quality Research requires adherence to the highest standards of integrity in the proposing, planning, design, conduct, recording, and reporting of Research. Research Misconduct represents a serious breach of AdventHealth policy and the customs of scholarly communities. Therefore, any Allegation is a serious matter to be dealt with deliberately, treated with the utmost seriousness, and examined carefully and responsibly.

AdventHealth will provide opportunities for education and training on this policy to all AdventHealth, and ensure it is made available to all AdventHealth employees for review and reference.

IV. **PROCEDURE/GUIDELINES:**

A. Rights and Responsibilities

1. Research Integrity Officer. The Director of the Office of Research Integrity and Compliance will serve as the Research Integrity Officer (the RIO). The RIO has the primary responsibility for assuring adherence to the implementation of the procedures of this policy, any other AdventHealth procedures adopted to implement this policy, and the Research Misconduct proceedings, as well as maintaining the required institutional assurances with The Office of Research Integrity (ORI), U.S. Department of Health & Human Services (DHHS). The RIO:
   a) Assists the Chief Scientific Officer, Inquiry Committee, and Investigation Committee in implementing these procedures, and in complying with standards imposed by government agencies or external funding sources.
   b) Shall sequester Research Records and Evidence pertaining to any Research Misconduct proceedings. For Public Health Service (PHS) supported Research, the RIO shall notify and communicate with ORI regarding the Allegation(s), Inquiry, Investigation, and findings.
   c) Is responsible for providing any information, documentation, Research Records, Evidence, or clarification requested by ORI to carry out its review of an Allegation or of AdventHealth's handling of such an Allegation, as well as submitting and maintaining annual reports to ORI.
   d) Shall also accept referrals of non-scientific misconduct issues arising from Research Misconduct proceedings.
2. Deciding Official. The Chief Scientific Officer (the CSO) shall serve in the role of the Deciding Official as it relates to Allegations and Research Misconduct proceedings, including Inquiries and Investigations. The CSO is responsible for overseeing and complying with this policy and for safeguarding the integrity of Research at AdventHealth. The CSO is the official authorized to make the final determination on Research Misconduct and oversee all phases of proceedings. The CSO may consult with committee members and other officials as necessary.
   a) Allegations that involve the CSO's Research activities or with individuals who directly report to the CSO will be processed and reviewed via an alternative pathway that will be determined by the AdventHealth legal department.
   b) The services of a consortium or person that AdventHealth reasonably determines to be qualified by practice and experience to conduct Research Misconduct proceedings may be used for this alternative pathway.
      i. A consortium may be a group of institutions, professional organizations, or mixed groups which will conduct Research Misconduct proceedings for other institutions. A consortium or person acting on behalf of AdventHealth must follow this policy in conducting Research Misconduct proceedings.
      ii. Any consortium or person acting on behalf of AdventHealth must also sign a confidentiality agreement, a HIPAA business associate agreement if they will be exposed to protected health information, and any other agreement that AdventHealth requires.
3. Complainant. Complainant is responsible for acting in Good Faith, maintaining confidentiality, and cooperating with the Research Misconduct proceedings.

Complainant may have an opportunity to testify before the Inquiry and Investigation Committees, be informed of the results of the Inquiry and Investigation, and to be protected from retaliation.

4. Respondent. There may be more than one Respondent in any Inquiry or Investigation. Respondent will be informed of the Allegations prior to or when an Inquiry is opened and notified in writing of the final determinations and resulting actions. Respondent is responsible for maintaining confidentiality and cooperating with the conduct of all phases of a Research Misconduct proceeding.
5. General.
   a) Duty to Report Suspected Research Misconduct. Any AdventHealth employee who observes suspected or apparent Research Misconduct is expected to report in accordance with AdventHealth policies CW HR 237 and CW CR 130.
   b) Duty to Cooperate. AdventHealth employees and affiliates involved in Research Misconduct proceedings shall cooperate with the CSO, the RIO, members of the Inquiry and Investigation Committees, and other individuals delegated responsibility in the review of Allegations and the conduct of preliminary assessments, Inquiries, and Investigations. Those AdventHealth employees and affiliates involved shall provide relevant Evidence to the RIO or other officials responsible for reviewing an Allegation. AdventHealth will take all reasonable and practical steps to ensure the cooperation of Respondents and other involved personnel with Research Misconduct proceedings, including, but not limited to, their provision of information, Research Records, and Evidence.
6. Sequestration of the Research Records
   Either before or when AdventHealth notifies the Respondent(s) of the Inquiry, the RIO must immediately take all reasonable and practical steps to obtain custody of all the pertinent Research Records and Evidence needed to conduct the Research Misconduct proceeding, inventory the records and Evidence, and sequester them in a secure manner, except that where the Research Records or Evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or Evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments. The RIO also shall sequester any additional Research Records that become pertinent to an Inquiry or Investigation after the initial sequestration. The need for additional sequestration of records may occur for any number of reasons, including the AdventHealth's decision to investigate additional Allegations, not considered during the Inquiry stage, or the identification of records during the Inquiry process that had not been previously secured. The procedures to be followed for sequestration during the Investigation are the same procedures that apply during the Inquiry.
7. Confidentiality and Access to Records.
   a) Confidentiality will be maintained throughout all stages of the Research Misconduct proceedings for all Respondents, Complainants, those included in the Investigation Committee, the Inquiry Committee, and research subjects identifiable from Research Records or Evidence. Disclosure of the identity of

Respondents and Complainants in Research Misconduct proceedings will be limited, to the extent possible, to those who need to know, and would only be disclosed otherwise as required by law. Reasonable conditions may be established to ensure such confidentiality, such as requiring that the recipient sign a confidentiality agreement.

b) Governmental agencies, including but not limited to ORI or other authorized personnel, will be given access to these records in accordance with the law.

8. Eliminating or Managing Potential Conflicts of Interest. AdventHealth's response to an Allegation includes ensuring that individuals responsible for carrying out any part of the Research Misconduct proceeding do not have unresolved personal, professional, or financial conflicts of interest with the Complainant, Respondent, or witnesses.
9. Opportunity for Respondent to Review and Comment. Throughout all phases of the Research Misconduct proceedings, when a formal report is prepared, such as the written Inquiry Report or written Investigation Report, the Respondent must have the opportunity to review these report(s) while still in *draft* form and respond with comments if desired prior to the report(s) being finalized. The Respondent's comments should be attached to the corresponding report and kept with the records.
10. Non-retaliation. AdventHealth will take all reasonable and practical steps to protect or restore the position and reputations of Complainants, witnesses, committee members, and other AdventHealth employees involved in the Research Misconduct proceedings, to counter potential or actual retaliation against them by Respondents or other AdventHealth employees, in accordance with AdventHealth policy CW HR 237.
11. Restoration of Reputation. If the report of the Inquiry Committee finds that an Investigation is not warranted, or the Investigation Committee finds the charges of Research Misconduct to be inconclusive, unfounded, or otherwise unsubstantiated and does not result in a determination of Research Misconduct; AdventHealth shall take all reasonable and practical efforts, if requested and as appropriate, to protect or restore the position and reputation of the Respondent(s) against whom the Allegations were made.

B. Requirements

1. Time Limitations
   a) Federal law imposes specific time limits upon some of the steps of the Research Misconduct proceedings. These time limitations should be adhered to whenever possible unless a delay is clearly justified or warranted. When delays are necessary, the reason should be documented, and an extension must be requested from ORI for federally funded studies. These time limits include:
      i. Completion of the Inquiry process within 60 days of the initiation of the process.
      ii. If the decision is made to move forward with an Investigation, it must be initiated within 30 days of completion of the Inquiry phase.
      iii. The final report of the Investigation must be submitted to the federal sponsor within 120 days of initiation of the Investigation.

b) The Allegation(s) must have occurred within six (6) years of the date of the receipt of the Allegation(s) with the following exceptions:
   i. Respondent continues or renews an incident of alleged Research Misconduct (e.g., through citation, republication, or reuse of the Research); or
   ii. If AdventHealth or ORI determines that the alleged misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public.

2. Finding of Research Misconduct. To make a determination of Research Misconduct, the following requirements must be satisfied:
   a) There must be a serious deviation or significant departure from accepted practices of the relevant research community; and
   b) The misconduct be committed intentionally, knowingly, or recklessly; and
   c) The Allegation must be proven by a preponderance of the Evidence, which means that the Evidence demonstrates that it is more likely than not, or more probably true than not true (evidentiary standard of 50%), that the Respondent did commit Research Misconduct as defined in this policy.
3. Reporting
   Reporting of Research Misconduct to ORI may be required under certain circumstances and at certain stages of the Research Misconduct proceedings.
4. Records Management and Retention
   The RIO will maintain a complete file including records of Research Misconduct proceedings, Allegations, Inquiries, and Investigations and all copies of documents and other materials related to these activities, regardless of whether they resulted in a finding of Research Misconduct. These documents will be retained for a period of seven (7) years from the date of the receipt of the Allegation. Governmental agencies, including but not limited to ORI or other authorized DHHS personnel, will be given access to these records when required by law.

C. Procedures

1. Allegation. Allegations may be communicated by oral or written statement or other means of communication and to different people or entities within AdventHealth or directly to ORI as follows:
   a) Reports may be made to your supervisor or department manager, the designated institutional CSO or RIO, Research Executive Directors, Directors, or the AdventHealth Office of Research Integrity and Compliance at 407-200-1615, or email at researchcompliance@AdventHealth.com
   b) AdventHealth Corporate Responsibility at 407-303-9659
   c) GuideLine at 1-888-92-GUIDE, or 1-888-924-8433. GuideLine is toll-free and available 24 hours a day, seven days a week. All calls are confidential, and you may call anonymously if you choose, in accordance with AdventHealth policy CW HR 237.
2. Inquiry. The Inquiry is the preliminary information gathering and fact-finding phase.

3. Investigation. The Investigation is the formal development of a factual record and the examination of that record leading to a decision, which may include a recommendation for other appropriate actions, including administrative actions.
4. Reporting. Reporting of Research Misconduct to ORI is required when funded by PHS. ORI must be notified of an Inquiry's finding that an Investigation is warranted; the decision to begin an Investigation; and the Investigation's findings and actions. AdventHealth's legal counsel should be consulted to determine if specific instances of Research Misconduct are reportable.

D. Initial Review of the Allegation

1. Allegation Review. If received in written format, it is forwarded to the CSO for initial review. If the Allegation is received by oral statement, the person to whom it is disclosed will provide a written summary of the oral statement that can be forwarded to the CSO for initial review. To the extent possible, the Allegation should be detailed and specific to allow ample information for reviewing the Allegation.
2. Standard for Determination to Conduct an Inquiry. Upon receipt of the Allegation, the CSO will determine if the Allegation:
   a) Falls within 6-year time limitation or meets an exception;
   b) Falls within the definition of Research Misconduct;
   c) Is made in Good Faith; and
   d) Is sufficiently credible and specific so that potential Evidence of Research Misconduct may be identified.
3. Determination to Dismiss an Allegation. If the CSO determines that the Allegation does not warrant an Inquiry (using the criteria above), the CSO will document any decision not to proceed past the initial review of the Allegation and the rationale for the decision.
4. Determination to Conduct an Inquiry. If the CSO determines that the Allegation warrants an Inquiry (using the criteria above), the CSO will:
   a) Provide notice to the Respondent. Before beginning an Inquiry, the CSO must make a Good Faith effort to notify the Respondent, in writing. If the Inquiry subsequently identifies additional Respondents, the CSO must notify them.
   b) Provide notice to the RIO to take custody of Research Records through sequestration.
   c) Provide notice to the RIO if the Allegation that warrants an Inquiry is related to applications for PHS support, proposals for PHS support, or actual PHS support for biomedical or behavioral extramural or intramural research, research training or activities related to that research or research training; plagiarism of Research Records produced in the course of PHS supported research, research training or activities related to that research or research training, as this creates a requirement to report to the ORI.
5. Allegations Not Made in Good Faith. If relevant, the CSO will determine whether the Complainant's Allegations were made in Good Faith. If the CSO determines that there was an absence of Good Faith, they will determine whether any administrative action should be taken against that person.

E. Inquiry

1. Purpose. The purpose of an Inquiry is to conduct an initial review of the Evidence to determine whether to conduct an Investigation. An Inquiry does not require a full review of all the Evidence related to the Allegation(s).
2. Timeframe. The Inquiry Committee must complete the Inquiry within sixty (60) calendar days of its initiation unless circumstances clearly warrant a longer period. If the Inquiry takes longer than sixty (60) calendar days to complete, the Inquiry record must include documentation of the reasons for exceeding the sixty (60)-day period.
3. Inquiry Committee and Notification. The CSO will notify the Respondent in writing of the proposed Inquiry Committee membership. The Respondent will be given an opportunity to object to any proposed member based on a personal, professional, or financial conflict of interest. The Respondent will submit any objections within seven (7) calendar days of notification of the potential Inquiry Committee membership. The CSO makes the final determination of whether any such conflict exists.
4. The Charge to the Inquiry Committee. The RIO will prepare and present a charge to the Inquiry Committee that:
   a) Sets forth the time for completion of the Inquiry;
   b) Describes the Allegation(s) and any related issues identified during the initial review of the Allegation(s);
   c) States that the purpose of the Inquiry is to conduct an initial review of the Evidence to determine whether an Investigation is warranted, not to determine whether Research Misconduct definitely occurred or who was responsible;
   d) States the standard for determining whether to conduct an Investigation as described below;
   e) Informs the committee of the importance of maintaining confidentiality; and
   f) Informs the committee that they are responsible for preparing or directing the preparation of a written report of the Inquiry that meets the requirements of this policy.
5. Responsibilities of the Inquiry Committee. The Inquiry Committee shall review the available Research Records and Evidence to determine if the criteria below are met, warranting an Investigation. The Inquiry Committee may also request to interview the Complainant, Respondent, and others as necessary and appropriate in making this determination. The Inquiry Committee may also identify, in the course of its duties, if there are issues which would justify broadening the scope of the Research Misconduct proceeding beyond the initial Allegation. The Inquiry Committee is not responsible for making a final determination based on the merits of the Allegation(s).
6. Standard for Determination to Conduct an Investigation. An Investigation is warranted if there is a reasonable basis for concluding that the Allegation(s) falls within the definition of Research Misconduct, and preliminary information-gathering and preliminary fact-finding from the Inquiry indicates that the Allegation may have substance.
7. Inquiry Report. The Inquiry Committee must prepare a written Inquiry Report. At a minimum, the Inquiry Report should include:

a) Name and position of the Respondent.
b) A description of the Allegation(s).
c) Whether the Allegation(s) involved PHS support, including, for example, grant numbers, grant applications, contracts, and publications listing PHS support.
d) The basis for recommending that the Allegation(s) does or does not warrant an Investigation, including whether it:
   i. Falls within the definition of Research Misconduct.
   ii. Is sufficiently credible and specific so that potential Evidence of Research Misconduct may be identified.
e) If there is a recommendation for an Investigation, a list of the charges for the Investigation to consider. The charges may include some or all of the Allegation(s).
f) Any commentary on the *draft* Inquiry Report by the Respondent or Complainant.
g) Inventory of Research Records and Evidence reviewed.
h) The process used.

8. Review of Draft Inquiry Report.
   a) The Inquiry Committee must provide the Respondent an opportunity to review and comment on the *draft* Inquiry Report. The Respondent must provide any written comments within fifteen (15) calendar days of receipt of the *draft* Inquiry Committee report. The Inquiry Committee may revise the *draft* Inquiry Report as appropriate as the final Inquiry Report is prepared. The Inquiry Committee must attach any of the Respondent's comments received to the final report.
   b) The Inquiry Committee may provide the Complainant an opportunity to review and comment on the *draft* Inquiry Report or relevant portions of it. The Complainant must provide any written comments within fifteen (15) calendar days of receipt of the *draft* Inquiry Report. The Inquiry Committee may revise the *draft* report as appropriate as the final report is prepared. The Inquiry Committee must attach any of the Complainant's comments received to the final report.
   c) In distributing the *draft* Inquiry Report, or portions thereof, the Inquiry Committee will inform the recipient of the confidentiality under which the *draft* Inquiry Report is made available.
9. Notification. The Inquiry Committee will submit the *final* Inquiry Report with all attachments to the CSO.
10. Decision to Not Investigate. If the *final* Inquiry Report concludes that an Investigation is not warranted, and CSO concurs, the CSO will formally dismiss the Allegation(s). The CSO, with assistance from applicable parties, shall take all reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputation of the Respondent. The CSO, with assistance from applicable parties, shall take all reasonable and practical efforts, if requested and as appropriate, to protect or restore the position and reputation of any Complainant, witness, or committee member and to counter potential or actual retaliation against these Complainants, witnesses, and committee members. Depending on the particular circumstances and the views of the Respondent, Complainant, witness, or committee member, AdventHealth may consider notifying those individuals aware of or involved in the Inquiry of the final

outcome, publicizing the final outcome in any forum in which the Allegation(s) was previously publicized, and expunging all reference to the Allegation(s) from the Respondent's personnel file.

11. Decision to Investigate. If the *final* Inquiry Report concludes that an Investigation is warranted, and the CSO concurs, the CSO will formally convene an Investigation.
12. Notice of Decision to Respondent. The CSO must notify the Respondent whether the Inquiry Committee found that an Investigation is warranted. The notice must include a copy of the *final* Inquiry Report, a copy of or reference to 42 CFR 93 (if applicable), and this policy.
13. Notice of Decision to Complainant. The CSO may notify the Complainant who made the Allegation whether the Inquiry found that an Investigation is warranted. The CSO may provide a copy of the *final* Inquiry Report or relevant portions of the report to the Complainant. If the CSO elects to notify the Complainant, the CSO will inform the Complainant of the confidentiality under which the report is made available.
14. Notice of Decision to ORI. When required, the RIO will make a report to ORI on the decision to initiate an Investigation within thirty (30) calendar days of the finding that an Investigation is warranted. The following must be included:
    a) Inquiry Report, including any attachments and comments on the report by Respondent or Complainant;
    b) AdventHealth policies and procedures under when the Inquiry was conducted; and
    c) Research Records and Evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents.

F. Investigation

1. Purpose. Once AdventHealth determines that the criteria for an Investigation have been met, the CSO initiates the Investigation process. The purpose of the Investigation is to determine whether Research Misconduct has occurred and, if so, to determine the responsible person and the nature and seriousness of the Research Misconduct.
2. Time Frame. The Investigation must begin within thirty (30) calendar days after determining that an Investigation is warranted. All aspects of the Investigation, including the *final* Investigation Report, findings for each Allegation, and (if required) submitting the Investigation Report to ORI, should generally be completed within one-hundred and twenty (120) calendar days after convening the Investigation.
3. Notice of Formal Investigation to Respondent. The CSO will notify the Respondent in writing of the Allegation(s) within a reasonable amount of time after determining that an Investigation is warranted, but before the Investigation begins. The CSO must give the Respondent written notice of any new Allegations within a reasonable amount of time of deciding to pursue Allegation(s) not addressed during the Institutional Inquiry or in the initial notice of Investigation.
4. Notice of Investigation to ORI. If required by law, the RIO will notify ORI of the decision to begin an Investigation on or before the date the Investigation begins and provide an Inquiry Report, if not already provided to ORI.
6. Selection of the Investigation Committee.

a) The CSO shall appoint an Investigation Committee of not less than three (3) members who shall not have been members of the Inquiry Committee and appoint a committee chair.
b) The Respondent will be notified, in writing, of the proposed Investigation Committee membership. The Respondent will be given an opportunity to object to any proposed member based on a personal, professional, or financial conflict of interest. The Respondent will submit any objections within seven (7) calendar days of notification of the potential Investigation Committee membership. The CSO makes the final determination of whether any such conflict exists.

7. Charge to the Investigation Committee. The RIO will prepare and present a charge to the Investigation Committee that:
   a) Describes the Allegation(s) and related issues identified during the Inquiry;
   b) Identifies the Respondent(s);
   c) Informs the Investigation Committee that it must conduct the Investigation and make a determination as to whether Research Misconduct occurred and, if so, the type and extent of it and who was responsible, as prescribed in this policy;
   d) Defines Research Misconduct;
   e) Informs the Investigation Committee that it must prepare or direct the preparation of a written Investigation Report that meets the requirements of this policy; and
   f) Informs the Investigation Committee of the importance of maintaining confidentiality.
8. Responsibilities of the Investigation Committee. The Investigation Committee shall:
   a) Undertake a thorough and diligent examination of the:
      i. Charges;
      ii. Research Records;
      iii. Interviews; and
      iv. Other Evidence.
   b) Interviews. The Investigation Committee, or one or more of its members, must interview each Respondent, Complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the Investigation, including witnesses identified by the Respondent or Complainant. Interviews are recorded or transcribed and provided to the interviewee for correction and include the recording or transcript in the record of the Investigation.
   c) Pursue Leads. Pursue diligently all significant issues and discovered leads that are determined to be relevant to the Investigation, including any Evidence of additional instances of possible Research Misconduct beyond the initial Allegation(s), and continue the Investigation to completion.
   d) Ensure a Fair Investigation. Take reasonable steps to ensure an impartial and unbiased Investigation to the maximum extent practicable, including participation of persons with appropriate scientific expertise who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the Inquiry or Investigation.
   e) Give the Respondent(s) the opportunity to admit that Research Misconduct

occurred and that they committed the Research Misconduct. With the advice of the RIO, the CSO, and other applicable AdventHealth members, the Investigation Committee may terminate review of an Allegation that has been admitted, if acceptance of the admission and any proposed settlement is approved by the CSO and ORI.

f) Determine if the following requirements are met for a finding of Research Misconduct:
   i. There must be a significant departure from accepted practices of the relevant research community;
   ii. The Research Misconduct must be committed intentionally, knowingly, or recklessly; and
   iii. The Allegation(s) must be proven by a preponderance of Evidence.

9. Legal Representation. During its proceedings, the Investigation Committee may consult legal counsel. The Respondent and the Complainant may each be accompanied by an adviser, who may be a lawyer, but who may not participate in the proceedings. Except in unusual cases, the Respondent and the Complainant should not appear before the Investigation Committee at the same time.
10. Review of Draft Investigation Report.
    a) The Investigation Committee must give the Respondent a copy of the *draft* Investigation Report and, concurrently, a copy of, or supervised access to, the Evidence on which the Investigation Report is based. The comments of the Respondent on the *draft* report, if any, must be submitted within thirty (30) calendar days of the date on which the Respondent received the *draft* Investigation Report. The Investigation Committee must consider the comments of the Respondent and may revise the *draft* Investigation Report as appropriate as it prepares its final report.
    b) The Investigation Committee may provide the Complainant a copy of the *draft* Investigation Report or relevant portions of that report. The comments of the Complainant, if any, must be submitted within thirty (30) calendar days of the date on which the Complainant received the *draft* Investigation Report or relevant portions of it. If provided, the Investigation Committee must consider the comments of the Complainant and may revise the *draft* Investigation Report as appropriate as it prepares its final report.
    c) In distributing the *draft* Investigation Report, or portions thereof, the Investigation Committee will inform the recipient of the confidentiality under which the *draft* Investigation Report is made available.
11. The *final* Investigation Report must be provided in writing and include:
    a) Allegations. Describe the nature of the Allegation(s), including the identification of the Respondent.
    b) If applicable, PHS support. Describe and document the PHS support, including, for example, any grant numbers, grant applications, contracts, and publications listing PHS support.
    c) Charge. Describe the specific Allegation(s) for consideration in the Investigation.
    d) Policies and procedures. If not already provided to ORI with the Inquiry Report,

include the AdventHealth policies and procedures under which the Investigation was conducted.

e) Research Records and Evidence. Identify and summarize the Research Records and Evidence reviewed, and identify any Evidence taken into custody but not reviewed. Recordings or transcripts from all interviews must be attached to the *final* Investigation Report.

f) Statement of Findings. For each separate Allegation identified during the Investigation, provide a finding as to whether Research Misconduct did or did not occur, and if so—

i. Identify whether the Research Misconduct was Falsification, Fabrication, or Plagiarism, describe why it is a serious deviation or departure from accepted and professional research practices, and explain if it was intentional, knowing, or in reckless disregard;

ii. Summarize the facts and the analysis which support the conclusion and consider the merits of any reasonable explanation by the Respondent;

iii. Identify the specific PHS support;

iv. Identify whether any publications need correction or retraction;

v. Identify the person(s) responsible for the Research Misconduct; and

vi. List any current support or known applications or proposals for support that the Respondent has pending with non-PHS federal agencies.

g) Comments. Include and consider any comments made by the Respondent and Complainant on the *draft* Investigation Report.

12. Other Administrative Matters Report. At the direction of AdventHealth legal counsel, the Investigation Committee may also prepare a written report detailing all issues not meeting the definition of Research Misconduct but discovered during the Research Misconduct proceedings, with recommendations and suggestions on resolving such issues. This report shall be stamped CONFIDENTIAL – INTERNAL ONLY and is protected under the attorney-client privilege. The Investigation Committee will provide this report to the Research Oversight Committee (ROC).
13. Notification. The Investigation Committee will submit the *final* Investigation Report with all attachments to CSO.
14. Finding of No Research Misconduct. If the report of the Investigation Committee finds the charges to be unfounded and does not result in a finding of Research Misconduct, and the CSO concurs, the CSO, with assistance from applicable parties, shall take all reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputation of the Respondent. The CSO, with assistance from applicable parties, shall take all reasonable and practical efforts, if requested and as appropriate, to protect or restore the position and reputation of any Complainant, witness, or committee member and to counter potential or actual retaliation against these Complainants, witnesses, and committee members.
15. Finding of Research Misconduct. If the report of the Investigation Committee finds the charges against the Respondent to be substantiated, and CSO concurs, the CSO shall proceed to impose penalties or work with AdventHealth leadership to impose penalties that are appropriate to the seriousness of the offense, in accordance with

AdventHealth policies and procedures, Medical Staff By-Laws, and which take into consideration the previous record of complaints against the Respondent. Actions may include, but are not limited to:

a) Suspension or termination in the case of serious offenses to removal from a particular project
b) A letter of reprimand
c) Special monitoring of future work
d) Probation
e) Reduction of salary
f) Reduction in rank

16. Notice of Decision to Respondent. The CSO will notify the Respondent in writing of the results of the Investigation, including a copy of the *final* Investigation Report with all attachments. The notification will outline plans for any pending disciplinary action against the Respondent.
17. Notice of Decision to Complainant. The CSO may notify the Complainant who made the Allegation(s) of the results of the Investigation. The CSO may provide a copy of the *final* Investigation Report or relevant portions of the report to the Complainant. If the CSO elects to notify the Complainant, the CSO will inform the Complainant of the confidentiality under which the report is made available.
18. Notice of Decision to ORI. If required by law as described in this policy, the RIO must give ORI the following:
    a) The Investigation Report (including all attachments, and appeals);
    b) Final institutional action (state whether AdventHealth found Research Misconduct, and if so, who committed the misconduct);
    c) Findings (state whether AdventHealth accepts the Investigation findings); and
    d) AdventHealth administrative actions (describe any pending or completed administrative actions against the Respondent).

G. Administrative Actions & Notifying ORI of Special Circumstances

1. Notification to External Agencies. AdventHealth will comply with the requirements and regulations of its funding agencies. Where false or misleading data has been published as the result of Research Misconduct, AdventHealth may disclose relevant information to affected scholarly and scientific publications or agencies.
2. ORI. The RIO will provide ORI with legally required notifications at any stage of an Inquiry or Investigation. AdventHealth will accept ORI's assistance with Research Misconduct proceedings.
3. Notifying ORI of Special Circumstances. The RIO will review the situation throughout the Research Misconduct proceedings to determine if there is any threat of harm to public health, federal funds and equipment, or the integrity of the PHS supported research process. In the event of such a threat, the RIO will, in consultation with the CSO, other applicable AdventHealth members, and ORI, take appropriate interim action to protect against any such threat. Interim action might include additional monitoring of the research process and the handling of federal funds or equipment, reassignment of personnel, or of the responsibility for the handling of federal funds and equipment, additional review of research data and results, or delaying

publication. The RIO shall, at any time during a Research Misconduct proceeding, notify ORI immediately if they have reason to believe that any of the following conditions exist:

a. Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
b. PHS resources or interests are threatened;
c. Research activities should be suspended;
d. There is a reasonable indication of possible violations of civil or criminal law;
e. Federal action is required to protect the interests of those involved in the Research Misconduct proceeding;
f. The Research Misconduct proceeding may be made public prematurely and ORI action may be necessary to safeguard Evidence and protect the rights of those involved; or
g. The research community or public should be informed.

4. Separation Prior to Completion of Process. Generally, all Inquiries and Investigations will be carried through to completion and all significant issues will be pursued diligently. The termination of a Respondent's employment or association by resignation or otherwise, before or after an Allegation has been reported, will not preclude or terminate the Inquiry or Investigation. If the Respondent refuses to participate in the process after resignation, the CSO will use reasonable efforts to reach a conclusion concerning the outstanding Allegation, noting in the *final* Investigation Report the Respondent's failure to cooperate and its effect on the review of all Evidence.

V. DEFINITION(S):

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

Allegation(s): Any written or oral report of possible Research Misconduct to an AdventHealth or HHS official.

Complainant(s): A person who in Good Faith makes an Allegation.

Evidence: Any document, tangible item, electronic data, digital images, or testimony offered or obtained during a Research Misconduct proceeding that tends to prove or disprove the existence of an alleged fact.

Good Faith: Made with the honest belief that Research Misconduct may have occurred. An Allegation is not in Good Faith if it is made with knowing or reckless disregard for facts that would negate the Allegation or testimony.

Inquiry: Preliminary information gathering and fact-finding to determine whether an Allegation warrants an Investigation.

Inquiry Committee: The committee authorized and appointed by the CSO to conduct the institutional Inquiry into an Allegation. At their discretion, the CSO may conduct the

Inquiry by themself or may appoint an Inquiry Committee consisting of at least two members who are not members of the same department as, or collaborators with, the Complainant or Respondent. The members of the Inquiry Committee should be unbiased (*e.g.* no personal, professional, or financial conflicts of interests with the Complainant or Respondent), qualified by practice and experience to assist in the conduct of Research Misconduct proceedings, and have appropriate backgrounds to judge the issues being raised. When appropriate, the CSO may appoint Inquiry Committee members from outside AdventHealth's community.

Inquiry Report: A report from the Inquiry Committee providing documentation of the decision whether to conduct an Investigation. The report must be sufficiently detailed to permit a later assessment by ORI of the reasons why the Inquiry Committee made their determination.

Investigation: The formal development of a factual record and the examination of that record leading to a decision not to make a finding of Research Misconduct or to a recommendation for a finding of Research Misconduct which may include a recommendation for other appropriate actions, including administrative actions.

Investigation Committee: The committee authorized and appointed by the CSO to conduct a formal Investigation into an Allegation(s). The members of the Investigation Committee should be unbiased (*e.g.*, no personal, professional, or financial conflicts of interests with the Complainant or Respondent), qualified by practice and experience to assist in the conduct of Research Misconduct proceedings, and have appropriate backgrounds to judge the issues being raised. When appropriate, committee members may be appointed from outside AdventHealth's community.

Investigation Report: A written report of the Investigation Committee's findings, provided at the conclusion of an Investigation.

Respondent(s): The person against whom an Allegation is directed or who is the subject of a Research Misconduct proceeding.

Research: Any systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge or specific knowledge by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, the matters to be studied.

Research Misconduct: Includes Fabrication, Falsification, or Plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- **Fabrication:** Making up data or results and recording or reporting them.
- **Falsification:** Manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the Research Records.

- **Plagiarism:** The appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Research Misconduct does not include honest error or differences of opinion.

Research Records: The record of data or results that embody the facts resulting from scientific Inquiry, including but not limited to, research proposals, grant applications, laboratory records, both physical and electronic, digital images, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to DHHS or an institutional official by a Respondent in the course of the Research Misconduct proceeding.

VI. EXCEPTION(S): This policy does not apply to authorship or collaboration disputes and does not include honest error or differences of opinion.

See CW AHC 101 Research Oversight

VII. REFERENCE(S):
42 CFR Part 93 Public Health Service Policies on Research Misconduct ORI
Sample Policy and Procedures for Responding to Allegations of Research Misconduct

RELATED DOCUMENT(S) / ATTACHMENT(S):
- CW CR 130 Corporate Responsibility
- CW HR 237 Workforce Member Conduct
- CW AHC 101 Research Oversight
- CW AHC 102 Abbreviations in Research
- CW AHC 103 Designations in Research