COMMONSPIRIT HEALTH
ADMINISTRATIVE POLICY

SUBJECT: Reporting and Investigating Allegations of Research Misconduct

POLICY NUMBER: Corporate Responsibility A-007

EFFECTIVE DATE: January 6, 2022

ORIGINAL EFFECTIVE DATE: January 6, 2022

_X_ National/System Offices _X_ Acute Care Facilities _X_ Non-Acute Care Facilities

PURPOSE

It is the purpose of this Policy to establish standards and procedures for the reporting and investigation of allegations of research misconduct to promote a culture of integrity and ethical conduct in research and maintain responsible stewardship of research funding.

It is essential to the Core Values of CommonSpirit Health Entities that researchers conduct research with integrity and in compliance with CommonSpirit Administrative Policy Corporate Responsibility A-001, *CommonSpirit Health Standards of Conduct: Our Values in Action Policy and Reference Guide,* and federal research misconduct regulations.

POLICY

It is the policy of CommonSpirit that all employees and researchers comply with the requirements set forth in the Reporting and Investigating Allegations of Research Misconduct Policy and Procedure.

AFFECTED AREAS OR DEPARTMENTS

This Policy applies to CommonSpirit and its Direct Affiliates[1] and wholly owned Subsidiaries,[2] as well as any non-wholly owned Subsidiary or other related entity whose governing documents expressly require or provide for such Subsidiary or entity(ies) to comply with CommonSpirit's policies and procedures (Conforming Entity).

REFERENCES

CommonSpirit Administrative Policy	Corporate Responsibility A-001, *CommonSpirit Health Standards of Conduct: Our Values in Action Policy and Reference Guide*

STATUTORY/REGULATORY AUTHORITIES

- Executive Office of the President; Office of Science and Technology; "Federal Policy on Research Misconduct"
- Public Health Services "Policies on Research Misconduct" regulation at 42 CFR Part 93
- National Science Foundation "Research Misconduct" regulation at 45 CFR Part 689

[1]A Direct Affiliate is any corporation of which CommonSpirit Health is the sole corporate member or sole shareholder, as well as Dignity Community Care, a Colorado nonprofit corporation.

[2] A Subsidiary refers to *either* an organization, whether nonprofit or for-profit, in which a Direct Affiliate holds the power to appoint fifty percent (50%) or more of the voting members of the governing body of such organization or holds fifty percent (50%) or more of the voting rights in such organization (as evidenced by membership powers or securities conferring certain decision-making authority on the Direct Affiliate) or any organization in which a Subsidiary holds such power or voting rights.

COMMONSPIRIT HEALTH
ADMINISTRATIVE PROCEDURE

SUBJECT: Reporting and Investigating Allegations of Research Misconduct

PROCEDURE NUMBER: Corporate Responsibility A-007P **EFFECTIVE DATE:** October 31, 2025

X National/System Offices X Acute Care Facilities X Non-Acute Care Facilities

ASSOCIATED DOCUMENTS:

CommonSpirit Health Administrative Policy	Corporate Responsibility A-007, *Reporting and Investigating Allegations of Research Misconduct*

AFFECTED AREAS OR DEPARTMENTS

All CommonSpirit Health employees and Affiliates conducting research in hospitals, clinics, preclinical and basic science laboratories, administrative offices and other entities.

PURPOSE

The purpose of this Procedure is to establish procedures for reporting and investigating Allegations of Research Misconduct.

SCOPE

This Procedure applies to Research conducted by CommonSpirit Employees and Affiliates at CommonSpirit Facilities. The obligations to report Research Misconduct applies to all individuals engaged in Research at CommonSpirit. The procedural rights and processes in this Procedure apply only to Federally Sponsored Research. The Deciding Officer, may, after consultation with the Research Integrity Officer (RIO), apply any of the procedural rights and processes of this Procedure to non-Federally Sponsored Research and Notice of such decision and the applicable sections of this Procedure shall be provided to the Respondent by the RIO, within 10 days of such decision. If a research misconduct proceeding involves multiple institutions, the RIO shall coordinate with the external institution's RIO to determine the lead institution.

This Procedure only governs Complaints of Research Misconduct. This Procedure does not apply to Complaints of fiscal impropriety, violation of human or animal subject regulations, intentional misrepresentation of credentials, abuse of confidentiality, violation of regulations applicable to Research, or conflicts of interest; or to authorship disputes among Research collaborators, except to the extent that the facts giving rise to these excluded types of conduct independently constitute a basis for an Allegation of Research Misconduct. When such an excluded type of Complaint is made against CommonSpirit, where appropriate, it shall be addressed as provided for in other CommonSpirit policies and procedures.

PROCEDURE:

A. Rights and Responsibilities

1. Responsibilities of the RIO: Because of the importance of Research Misconduct to the operations of CommonSpirit and the expertise required to address such issues, CommonSpirit has designated RIOs who are responsible for initiating and coordinating CommonSpirit's handling of Research Misconduct Allegations with the Legal Team. RIOs evaluate Research Misconduct Complaints and, when appropriate, conduct inquiries to determine, in consultation with the Deciding Officer, when an Investigation is warranted. RIOs advise the Deciding Officer on Investigations and procedural matters. RIOs are not advocates for the Complainant or the Respondent. RIOs are responsible for communicating with any funding agencies on behalf of CommonSpirit regarding Research Misconduct. RIOs shall work with the Corporate Responsibility department and the Legal Team when appropriate.

2. Duty to Report Research Misconduct: All CommonSpirit Employees and Affiliates must report, either in writing or orally, what they perceive to be Research Misconduct. Allegations of Research Misconduct are to be reported to CommonSpirit RIO who is the Corporate Responsibility System Research Compliance Director and may also be reported to any of the following, who upon receipt of the Allegations must immediately reported to the RIO:

    a. CommonSpirit Research Institute/Center Director
    b. CommonSpirit Region /System Corporate Responsibility leadership
    c. CommonSpirit Institutional Official for Research
    d. CommonSpirit Legal Team
    e. CommonSpirit Institutional Review Board (IRB) or Institutional Animal Care and Use Committee Chair

3. Duty to Cooperate: CommonSpirit Employees and Affiliates shall cooperate with the Deciding Officer or RIO or other individuals delegated responsibility in the review of Research Misconduct Allegations and the conduct of preliminary Assessments, Inquiries and Investigations. Individuals shall provide relevant evidence to the RIO or other individuals responsible for reviewing an Allegation of Research Misconduct.

4. Confidentiality: The RIO will take all reasonable steps to protect the confidentiality of the preliminary Assessment, Inquiry and Investigation process and to protect the identities of those who participate in these processes. If a Complainant requests anonymity, an effort will be made to honor the request during the preliminary Assessment or Inquiry to the greatest extent possible and in compliance with applicable policies, regulations and federal, state and local laws. The Complainant will be advised that if the matter is referred to an Investigation committee and an interview with the Complainant is required, anonymity may no longer be guaranteed.

5. Protecting Identity of Participants: CommonSpirit Employees and Affiliates who make, receive or learn of an Allegation of Research Misconduct will protect, to the greatest extent possible, the confidentiality of information regarding the Complainant, the Respondent and other affected individuals.

    Disclosure of the identity of respondents and complainants in research misconduct proceedings is limited, to the extent possible, to those who "need to know". Those who

"need to know" may include institutional review boards, journals, editors, publishers, co-authors, and collaborating institutions. The limitation on disclosure of the identity of respondents, complainants, and witnesses no longer applies once CommonSpirit makes a final determination of research misconduct.

6. Protection from Retaliation: CommonSpirit Employees and Affiliates who receive or learn of an Allegation of Research Misconduct will treat the Complainant who makes a good faith Allegation of Research Misconduct and others involved in the preliminary assessment, Inquiry or Investigation of Research Misconduct who act in good faith with fairness and respect. The RIO will take reasonable steps to protect the position and reputation of such individuals and protect them against retaliation. CommonSpirit Employees and Affiliates shall immediately report any alleged or apparent retaliation to the RIO, who will review instances of alleged retaliation for appropriate action.

7. Protection of Research Subjects: To the extent required by state or federal law, the identity of any research subject and any other protected health information shall be kept confidential, with disclosure being limited to those who have a need to know in order to carry out the Research Misconduct proceeding.

8. Restoration of Reputation: If neither CommonSpirit nor the Federal Sponsor finds evidence of Research Misconduct, and if requested by the Respondent, CommonSpirit will undertake reasonable and practical efforts to protect or restore the Respondent's reputation. Similar efforts will be employed when requested and when necessary to protect or restore the reputation of a Complainant, witness or committee member.

9. Respondent's Right to an Advisor: The Respondent is entitled to utilize an advisor of the Respondent's choosing throughout the Research Misconduct proceeding, which advisor may be present during the Respondent's interview. This advisor shall be provided at the Respondent's expense and may, for example, be a CommonSpirit Employee or Affiliate, who agrees to serve in that role, or a personal attorney, if the Respondent so chooses. The advisor is required to abide by and honor the confidentiality requirements and protections set forth in this Procedure. The advisor has no right to directly participate in the proceeding (e.g., the advisor cannot directly address the Investigation Committee), but the Respondent can consult with the advisor throughout the process. The Respondent is required personally to participate fully in the Research Misconduct proceeding.

B. Procedural Standards

1. Finding of Research Misconduct: A finding of Research Misconduct requires:
   a. A conclusion that Fabrication, Falsification, or Plagiarism in proposing, performing or reviewing Research, or reporting Research results has occurred; and
   b. That there was a significant departure from accepted practices of the relevant research community;
   c. The misconduct was Intentional, Knowing, or Reckless, and
   d. The allegation be proven by a Preponderance of the Evidence.

2. Exclusions from Research Misconduct: Research Misconduct does not include honest error or differences of opinion.

3. Time Limitations: This Procedure applies only to Research Misconduct occurring within the six years preceding the date CommonSpirit receives a Complaint of Research Misconduct, with the following exceptions:

a. Subsequent Use. If the Respondent continues or renews any incident of alleged Research Misconduct that occurred before the six-year limitation has run, through the citation, republication or other use for the Respondent's potential benefit of the Research Record that is alleged to have been Fabricated, Falsified, or Plagiarized. Application of the Subsequent Use Exception requires a citation to the portion(s) of the research record (e.g., processed data, journal articles, funding proposals, data repositories) alleged to have been fabricated, falsified, or plagiarized, for the potential benefit of the respondent.
b. Health or Safety of Public. If CommonSpirit, following consultation with any applicable Federal Sponsor, determines that the alleged misconduct, if it occurred, is having or could have a substantial adverse effect on the health or safety of the public.

4. Burden of Proof:

   a. CommonSpirit. CommonSpirit has the burden of determining whether the elements of Research Misconduct have been established by a Preponderance of the Evidence.
   b. The Respondent. The Respondent has the burden of proving, by a Preponderance of the Evidence, honest error or differences of opinion or any other affirmative defense. Due consideration shall be given to any admissible, credible evidence presented by the Respondent.

5. Research Records as Evidence: The destruction of, , or the Respondent's failure to provide Research Records adequately documenting the questioned Research may be considered as Evidence of Research Misconduct where CommonSpirit establishes, by a Preponderance of the Evidence, that both:

   a. The Respondent had Research records and Intentionally, Knowingly, or Recklessly destroyed them; or
   b. Maintained Research Records and failed to produce them in a timely manner; and
   c. The Respondent's conduct constitutes a significant departure from the accepted practices of the relevant research community.

6. Procedural Concerns: The Respondent must present any concern regarding procedure or process to the RIO in a timely manner before the Deciding Officer issues the Deciding Officer's decision.

   a. A concern regarding a Conflict of Interest must be raised within 14 days of the date when the Respondent knew or should have known of that potential Conflict of Interest.
   b. A concern regarding any other procedure or process that occurred at any point up through the conclusion of the Inquiry must be presented no later than the time for submission of the Respondent's comments on the Inquiry report, or 14 days from the date when the Respondent knew or should have known of the concern, whichever is later.

7. Extensions of Time: The timelines set forth in this Procedure may be extended by RIO, after consulting with the Deciding Officer, when deemed reasonable and necessary. If a Federal Sponsor has established a mandatory timeline for a Research Misconduct proceeding and that Federal Sponsor's approval is required before an extension of time can be granted, the RIO is responsible for seeking such an extension on behalf of CommonSpirit. Any extension of time shall be documented in a writing that includes the reason for the extension. Notice of the extension shall be given to the Respondent.

8. Admission or Settlement: The Deciding Officer can agree to close a Research Misconduct proceeding at the Inquiry or Investigation stage if the Respondent admits to having engaged in Research Misconduct, a settlement has been reached between CommonSpirit and the Respondent, or for other good reason as determined by the Deciding Officer. Prior to agreeing to such a closure of the Research Misconduct proceeding, the RIO shall provide any applicable Federal Sponsor with notice, if such is required by the Federal Sponsor, and comply with other applicable Federal Sponsor requirements.

9. Maintenance of the Record: The RIO and the Deciding Officer shall collaborate in maintaining a record of the Research Misconduct proceeding. This record shall be retained consistent with CommonSpirit and applicable state and federal record retention requirements.

10. Ongoing Cooperation with Federal Sponsor: CommonSpirit, and its Employees and Affiliates are required to fully cooperate with the reasonable requests of any Federal Sponsor at issue throughout the Research Misconduct proceeding; and during any proceeding, oversight review, administrative hearing, or appeal provided for by the funding entity's process. This includes providing the Federal Sponsor with relevant Research Records and Evidence in CommonSpirit's control, custody, or possession, and with access to all persons within CommonSpirit's authority who are necessary to develop a complete record of relevant Evidence.

11. Issues that do not Qualify as Research Misconduct: If, in the course of a Research Misconduct proceeding, a concern (other than a Research Misconduct concern) is identified that is reasonably believed to require further action, the concern shall be communicated to the appropriate person or office within CommonSpirit for evaluation and action, including the Corporate Responsibility department and the Legal Team, as appropriate. Other offices shall consult with the RIO to minimize the effect of the concern on any pending Research Misconduct proceeding, and shall involve other CommonSpirit departments and divisions, as needed, in addressing the concern.

12. Activities to Protect Research: During a Research Misconduct proceeding, CommonSpirit, where reasonable, is authorized to take such interim actions as are necessary and prudent to protect the public health and safety, Research funds and equipment, and the integrity of the Research process; to prevent potential or immediate health hazards; and to prevent and report any possible criminal violation.

C. Receipt and Preliminary Assessment of Complaint

1. Receipt of Complaint: A Complaint of Research Misconduct shall be provided to or forwarded to the RIO if the Complaint appears to constitute an Allegation of Research Misconduct. A prospective Complainant may discuss a concern with the RIO or with an appropriate Deciding Officer, the RIO or any other person to whom Complaints can be submitted, without submitting a Complaint.

    a. Written Complaints allow for careful, considered, documented statement of the concern and the relevant facts and are preferred by CommonSpirit. Upon receipt of a Complaint, the RIO shall review the matter, including possible Conflicts of Interest, and take appropriate action as set forth in this Procedure.

b. A Complaint must be filed in good faith. The RIO will report to the Deciding Officer any Allegation determined by the RIO not to have been made in good faith for appropriate action.

c. If the Complainant is a person charged with oversight of some aspect of the research integrity process, they should not participate in the Inquiry or Investigation of the issue other than to provide relevant information to the RIO and Inquiry or Investigation committees. In the event that the Complainant who is charged with oversight responsibilities has pertinent work products or information predating the Allegation, that material may be reviewed by the RIO or their designee.

d. An Allegation may involve overlapping or related concerns of Falsification, Fabrication, or Plagiarism. When this occurs, the RIO may include these concerns in a single Allegation or set them forth in separate Allegations.

2. **Preliminary** Assessment of Complaint: The RIO shall assess whether a Complaint constitutes an Allegation of Research Misconduct by determining whether:

   a. The described actions appear to constitute Research Misconduct; and
   b. The Complaint is sufficiently credible, specific, and significant to both permit and warrant an Inquiry.

   In conducting its preliminary assessment, the RIO may talk to the Complainant and others with knowledge of facts relevant to the Complaint, but it is not required to do so. The RIO may seek such advice as is necessary, including the advice of the appropriate Deciding Officer, during the preliminary assessment.

3. Assessment Decision: If the RIO determines that a Complaint comprises an Allegation of Research Misconduct, the RIO shall inform the appropriate Deciding Officer and, in consultation with the Deciding Officer, shall initiate an Inquiry into the Allegation.

D. Inquiry

1. **Standard:** The purpose of the Inquiry is to conduct an initial review of the Allegation and the Respondent's response, as well as other Evidence as appropriate, to determine whether an Investigation is warranted. An Inquiry shall lead to an Investigation if, after consultation with the Deciding Officer, the RIO determines:

   a. There is a reasonable basis for concluding that the Allegation falls within the definition of Research Misconduct; and
   b. Preliminary information from the Inquiry indicates that the Allegation has sufficient substance to warrant an Investigation, or the available Research Record is inadequate to make such a determination so that a more detailed analysis is required.
   c. The RIO's decision as to whether an Investigation is warranted is final and is not subject to review.

2. Respondent Notification: Absent extraordinary circumstances, the RIO shall provide Notice to the Respondent, within 7 days of the RIO’s decision to conduct an Inquiry, that an Allegation of Research Misconduct has been made against the Respondent, provide the Respondent with a written summary of the Allegation and a copy of this Policy, and explain the process for addressing the Allegation. The RIO shall make reasonable efforts to notify

the Respondent of the Allegation in a face-to-face or video meeting, which generally will be attended by a representative of the Deciding Officer's office.

3. Respondent Response: Within 14 calendar days of receiving Notice of the Allegation from the RIO, the Respondent shall provide the RIO with a detailed written response to the Allegation(s), unless an extension of time has been granted. The response shall address the substance of the Allegation in detail, specifically referencing any Research Records that support the response in order to allow the RIO to fully understand the Respondent's position and the basis for it, and locate and consult the relevant portions of the records. Upon being notified of the Allegation, the Respondent shall provide the RIO with the Respondent's current home and email addresses, and phone number. The Respondent shall immediately advise the RIO in writing if this information changes at any time during the Research Misconduct proceeding.

4. Certification Relating to Records: No later than 10 calendar days after Respondent's deadline for providing RIO with an initial written response to the Allegation, the Respondent shall submit a signed certification to RIO:

    a. Explaining all efforts that were made to locate all potentially relevant Research Records and Evidence, including in this explanation the identity of all places where such records were located in the past, all places that were searched, and all places where such records were found;
    b. Declaring that all such Research Records that were located during this search have been provided to the RIO;
    c. Identifying and describing any such Research Records that cannot be located; and
    d. Providing a full and clear explanation of where and when the missing Research Records were created and stored, when they were last seen, and why they are missing.

5. Obligation of CommonSpirit Personnel to Provide Records: The RIO is specifically charged and authorized to take custody of all relevant Research Records and Evidence from the files and laboratories of the Respondent and other CommonSpirit Employees and Affiliates. Such persons are required to provide the RIO with all original data books, laboratory notes, electronic records, and other records that the RIO believes are potentially relevant to a Research Misconduct proceeding; and submit to the RIO, upon request, the type of signed certification that is described in this Procedure. If the RIO determines that providing such records may significantly disrupt the Research of an investigator, the RIO may arrange for a copy to be made for use by such an investigator. An investigator may be allowed access to the original material if the RIO determines such access can be provided while maintaining the integrity of the record.

6. Sequestration: On or before the date when the Respondent is notified of the Allegation by the RIO, the RIO shall take all reasonable and practical steps to take custody of and appropriately sequester, secure and preserve all potentially relevant Evidence. Where the Evidence encompasses scientific instruments, computer systems, or other equipment shared by multiple users, custody may be limited to copies of the data or Evidence on such equipment, so long as those copies are substantially equivalent in evidentiary value to the originals. At any point in the Research Misconduct proceeding, the RIO may undertake additional sequestrations. The RIO may act through an agent when appropriate. The affected CommonSpirit Facility, research institute and regions shall assist with the sequestration. During the sequestration, the Respondent shall be instructed by the RIO to

provide all potentially relevant Research Records that relate to the Allegation. The Respondent must identify and arrange to immediately provide the RIO with all such records that could reasonably relate to the research that is the subject of the Allegation, regardless of where the Research Records are located. The Respondent has a continuing obligation to identify and provide such Research Records during the Research Misconduct proceeding. The RIO may also sequester research records and evidence whenever additional items become known or relevant to the inquiry or investigation. Where appropriate, the Respondent shall be provided with copies of, or reasonable supervised access to the Research Record.

7. Additional Allegations: If the RIO becomes aware of information during the course of the Inquiry that gives rise to an additional Allegation of Research Misconduct, that Allegation may be added to the Inquiry as appropriate. The RIO shall inform the Respondent in writing of the additional Allegation and allow the Respondent 14 calendar days to provide a detailed written response to it, following the procedure set forth in this Procedure. The RIO can include the additional Allegation in any current Allegation, or it can be set forth in a separate Allegation.

8. Scope of Inquiry: During the Inquiry, the RIO has the discretion to talk to such witnesses and review such Evidence as the RIO believes is necessary to make the Inquiry decision. However, the RIO is not obligated to conduct any such witness interviews or to perform an exhaustive review of all the Evidence as part of the Inquiry process.

9. Inquiry Report: The Inquiry shall be completed within 90 calendar days after the Respondent receives notice of the Allegation, unless an extension of time has been granted. The RIO, after consulting with the Deciding Officer, shall prepare an Inquiry report that indicates whether an Investigation is warranted. The report shall comply with the requirements of any applicable Federal Sponsor and generally will include the name and position of the Respondent; the specific Allegations of Research Misconduct that were considered; a description of analyses conducted; transcripts of any interviews that were transcribed; a timeline and procedural history; an inventory of sequestered research records; any institutional actions implemented; the identity of any federal support for the research at issue; the identity of CommonSpirit and any federal policies and procedures under which the Inquiry was conducted; a determination of whether the alleged Research Misconduct warrants an Investigation; and the basis for any such determination.

   The Respondent shall be provided with a copy of the Inquiry report and given 10 days to submit written comments on it to the RIO. These comments shall be attached to the final Inquiry report. The RIO also may, at the RIO's discretion, provide relevant portions of the Inquiry report to the Complainant for comment. The reports may be redacted as deemed necessary to protect confidentiality and to prevent the Complainant from accessing information not pertinent to his/her participation in the review of the Allegation.

10. Inquiry Decision: The Deciding Officer after receiving the Inquiry report and consulting with the RIO or other CommonSpirit officials, decide if an Investigation is warranted. If so, the Deciding Officer shall notify the RIO and the Respondent of the Deciding Officer's decision and provide the Respondent with a copy of the Inquiry report.

    The Deciding Officer may instruct the RIO, as deemed appropriate, to inform the Complainant or others of the result of the Inquiry. When an Investigation is found to be warranted, the RIO shall forward a copy of the final Inquiry report to any applicable Federal

Sponsor, if the agency so requires. Notice of the pending Investigation also may be confidentially communicated by the RIO or the Deciding Officer's office, as appropriate, to anyone who intends to publish or otherwise disseminate the results of the Research to which the Allegation relates.

If the Deciding Officer concludes that an Investigation is not warranted, the Respondent may request that CommonSpirit take such reasonable and practical efforts as CommonSpirit believes are appropriate to restore the Respondent's reputation, if it has been damaged as a result of the Research Misconduct proceeding.

E. Investigation

1. Overview of Investigation: During the Investigation, an Investigation Committee formally develops the factual record, examines that record, and, in consultation with the RIO, makes an informed recommendation to the Deciding Officer concerning whether the Respondent engaged in Research Misconduct, applying the relevant standards set forth in this Procedure. The Investigation process must begin within 30 calendar days after RIO's issuance of the final Inquiry report, unless an extension of time has been granted.

2. Appointment of Investigation Committee: Upon issuance of the final Inquiry report that concludes an Investigation is necessary, the Deciding Officer, in consultation with RIO, shall select a proposed “Investigation Committee”, which shall consist of at least three individuals who are not reasonably known to have any Conflict of Interest with the Complainant or the Respondent that would interfere with their service on the Investigation Committee, as determined by the Deciding Officer in consultation with RIO. At least two members of the Investigation Committee shall possess expertise that is determined by the Deciding Officer to be relevant to the Research at issue in the Allegation; and at least one member shall be an individual with the same CommonSpirit Employee and Affiliate status as the Respondent.

3. Notice to Respondent Identifying Committee Members: The Deciding Officer shall notify the Respondent of the identity of the proposed Investigation Committee members.

4. Respondent Objections to Committee Members: Within 7 days after being advised of the identity of the proposed Investigation Committee, the Respondent can object to the appointment of any Investigation Committee member on grounds of a Conflict of Interest. The Respondent shall notify the Deciding Officer in writing of the objection and shall clearly state the basis for the objection, providing a copy of this objection to RIO.

5. Deciding Officer’s Decision on Objections: The Deciding Officer, in consultation with RIO, shall determine whether the Respondent's objection sets forth a basis for declining to appoint the proposed member to the Investigation Committee. If the Deciding Officer determines it is appropriate to select a different member for the Investigation Committee, the Respondent shall be notified of this new selection and provided with the same opportunity to object as was provided with respect to the initially proposed Investigation Committee members.

6. Investigation Committee Charge: After appointing the Investigation Committee and consulting with RIO, the Deciding Officer shall issue a letter to the Investigation Committee that outlines the Research Misconduct Allegation and the Investigation Committee's

responsibilities during the Investigation. The Respondent shall be provided with a copy of the Deciding Officer's letter.

7. Role of Investigation Committee: The Investigation Committee shall review such records and Evidence, interview such persons, and obtain such additional evidence as it believes is necessary to make an informed recommendation to the Deciding Officer on the merits of the Allegation. The Investigation Committee shall interview the Respondent, the Complainant, and any other available witness who has been identified as having information regarding any relevant aspect of the Investigation, including witnesses identified by the Respondent. Interviews shall be transcribed or recorded, and the transcript or recording shall be provided to the witness for correction and included in the record of the Investigation.

8. Additional Issues: The Investigation Committee is expected to diligently pursue all significant issues that are determined to be relevant to the Investigation, including any Evidence of additional instances of possible Research Misconduct. If the Investigation Committee becomes aware of information during the course of the Investigation that gives rise to an additional possible Allegation of Research Misconduct, the Investigation Committee shall ask the Deciding Officer to determine whether the Allegation should be added to the current Investigation. The Deciding Officer shall consult with the RIO when determining whether to add the Allegation to the current Investigation or addressed in a separate Allegation.

   In the event that the Deciding Officer instructs the Investigation Committee to add the Allegation to the Investigation, the RIO shall inform the Respondent in writing of the additional Allegation and allow the Respondent 14 calendar days to provide a detailed written Response to the Allegation, with such response complying with the requirements of this Procedure. The Respondent shall provide all relevant Research Records that have not yet been produced and shall submit a signed certification about the records that relate to the additional Allegation, in accordance with this Procedure.

9. Procedural Matters: The Investigation Committee shall operate in closed session. The Investigation Committee may request the assistance of the RIO and the Deciding Officer's office during the Investigation Committee's deliberations and its preparation of the Investigation report, but neither the RIO nor the Deciding Officer's office shall participate in the Investigation Committee's deliberations or vote on whether Research Misconduct occurred.

10. Investigation Report: The Investigation Committee shall prepare and provide the Respondent, through the RIO, a draft Investigation report that includes the Investigation Committee's recommendation to the Deciding Officer concerning each Allegation of Research Misconduct. The draft Investigation report generally shall include an inventory of sequestered materials and how sequestration was conducted, transcripts of all interviews, and any scientific or forensic analysis conducted. The Investigation report shall be accompanied by a copy of any Evidence on which the report is based that has not already been provided to the Respondent, or the Respondent shall be given supervised access to this Evidence. Both the draft and the final Investigation report shall comply with the requirements of any applicable Federal Sponsor and shall include:

    a. A description of the type of Research Misconduct alleged (i.e., fabrication, falsification, or plagiarism);

b. The specific Allegations of Research Misconduct that were considered;
c. A description of any federal support for the Research at issue;
d. The identity of CommonSpirit investigation committee including name(s), position(s), and subject matter expertise, and any institutional policies and procedures under which the Investigation was conducted;
e. An inventory of sequestered materials and how sequestration was conducted;
f. Transcripts of all interviews;
g. Any scientific or forensic analysis conducted;
h. The identity and a summary of the Research Records and Evidence that were reviewed;
i. The identity of any Evidence taken into CommonSpirit's custody but not reviewed;
j. The Investigation Committee's recommended finding relative to each Research Misconduct Allegation;
k. The rationale for each recommended finding, with appropriate references to the Evidence.

11. Recommendations to Find Research Misconduct: For each Allegation for which the Investigation Committee recommends a finding of Research Misconduct, the Committee shall include the following in its report:

    a. A statement of whether the Research Misconduct was found to constitute Falsification, Fabrication or Plagiarism, and whether it was found to have been committed Intentionally, Knowingly or Recklessly;
    b. A summary of the facts and the analysis supporting the Committee's recommendation, including a discussion of the merits of any reasonable explanation given by the Respondent;
    c. The identity of the funding source for the Research at issue;
    d. A discussion of whether any publications need to be corrected or retracted and, if so, which ones and how;
    e. The identity of the person responsible for the Research Misconduct; and
    f. A list of any current funding and known applications or proposals for funding that the Respondent has pending.

12. Respondents Review of Committee’s Recommendations: The Respondent shall be allowed 30 calendar days to review the draft report and provide written comments to RIO, who shall immediately forward the comments to the Investigation Committee. The Investigation Committee shall consider these comments and address them in its final Investigation report. The Investigation Committee, through the RIO, also may provide relevant portions of the draft Investigation report to the Complainant for comment. Any comments on the draft report shall be submitted by the Complainant to the RIO for consideration by the Investigation Committee within 14 calendar days.

13. Final Investigational Report: The final Investigation report shall be issued within 180 calendar days of the initiation of the Investigation, unless an extension of time has been granted by the Federal sponsor. The Respondent's comments and copies of recorded testimony and transcripts, where available, and the Complainant's comments, if any shall be attached to the final report. Copies of the final Investigation report shall be provided to the Deciding Officer, the Respondent, the RIO, and any applicable Federal Sponsor, if the Federal Sponsor so requires.

F. Deciding Officer’s Decision

1. Overview of Deciding Officer's Decision: The Deciding Officer determines whether the Respondent engaged in Research Misconduct and whether corrective or disciplinary action is appropriate. The Deciding Officer's decision is the final decision of CommonSpirit with respect to whether Research Misconduct occurred.

2. Basis for Decision: The Deciding Officer shall consider the report of the Investigation Committee and the Respondent's comments, as well as any other material the Deciding Officer believes is relevant. At the Deciding Officer's request, the Respondent shall meet with the Deciding Officer to present any information that the Respondent believes is pertinent to the Deciding Officer's decision. Before reaching a final decision, the Deciding Officer shall meet with the Investigation Committee. If the Deciding Officer is considering departing from the Investigation Committee's recommendation on whether Research Misconduct should be found, the Deciding Officer shall explain to the Committee the reasons for the contemplated departure and obtain the Committee's feedback. The Deciding Officer then shall decide, for each Allegation, whether the Respondent engaged in Research Misconduct. This decision, along with its rationale, shall be documented in writing by the Deciding Officer.

3. The Decision:
    a. No Finding of Research Misconduct. If the Deciding Officer does not find that the Respondent engaged in Research Misconduct, the Research Misconduct proceeding shall be closed. The Deciding Officer shall decide, after consultation with the Respondent, what reasonable actions, if any, need to be taken to restore the Respondent's reputation, if it has been damaged due to the Research Misconduct proceeding. The Deciding Officer then shall implement those actions as appropriate, including issuing a statement of exoneration if the Deciding Officer believes this is reasonably required.
    b. Finding of Research Misconduct. If the Deciding Officer finds that the Respondent engaged in Research Misconduct, the Deciding Officer shall impose such corrective or disciplinary action as the Deciding Officer finds appropriate, consistent with this Procedure. This may include a requirement that publications be corrected or retracted, a return of research funds, removal of the Respondent from Research or a process of oversight of the Respondent’s Research activities. The disciplinary/corrective action process shall be overseen by the Deciding Officer's office, who will work with the appropriate administrative or Medical Staff office responsible for discipline or administrative action pursuant to the appropriate CommonSpirit policies, procedures, Medical Staff bylaws or agreements.

4. Request for Review: The Respondent may request review of the Deciding Officer’s finding of Research Misconduct. Grounds for review are limited to Allegations of material and substantive procedural error in the process afforded the Respondent. The Respondent must request a review in writing and describe the alleged procedural error to the RIO within 10 calendar days of receiving the final Investigation report from the Deciding Officer. The review shall be conducted by the CommonSpirit Chief Physician Executive Officer (CPEO). The CPEO shall complete the review and provide a written response to the Respondent within 120 days of receiving the request for review from the RIO. The CMO’s determination is final.

5. Notifications: Upon making a decision relative to Research Misconduct, the Deciding Officer shall notify the Respondent, the Complainant, and RIO of that decision, and may notify others if appropriate. Where Research Misconduct has been found, the Respondent and RIO shall be advised of any corrective or disciplinary action that has been or is being taken. The RIO shall provide the Institutional Record, including any pending and completed corrective or disciplinary actions relating to the Respondent, to any applicable Federal Sponsor, if the agency so requires, in accordance with that agency's requirements.

DEFINITIONS:

Allegation: Disclosure of possible Research Misconduct through any means of communication. The disclosure may be by written or oral statement or other communication to CommonSpirit.

CommonSpirit Employees and Affiliates: employees and workforce of CommonSpirit and its subsidiaries, Medical Staff Members, advanced practice providers, faculty members and individuals in teaching positions, others authorized to provide Research related services at CommonSpirit Facilities, independent contractors of CommonSpirit, its subsidiaries and affiliates, even if no longer employed by or affiliated with CommonSpirit.

CommonSpirit Facilities: any CommonSpirit entity that engages in Research, including hospitals, clinics, outpatient facilities, Dignity Health Medical Foundation, Research Institutes and Centers, Institutional Review Boards (IRBs) and Institutional Animal Care and Use Committees (IACUC).

Complainant: Anyone who makes an Allegation of Research Misconduct. Once the Complaint is made and the necessary information has been provided to the RIO, the Complainant's role in a Research Misconduct proceeding is the same as any other witness.

Complaint: A report of activity that a Complainant believes may constitute Research Misconduct.

Conflict of Interest: When a person participating in the Research Misconduct proceeding has a substantial connection or interest related to the Complainant or Respondent that might bias or otherwise threaten the integrity of the proceeding. This includes, but is not limited to, personal, professional, and financial conflicts of interest.

Deciding Officer: CommonSpirit official who makes final determinations on Allegations of Research Misconduct and any institutional administrative actions. The Deciding Officer may not serve as the Research Integrity Officer (RIO). The CommonSpirit Deciding Officer is the Chief Academic and Scientific Officer.

Discipline: Written censure, reduction in salary, suspension, demotion or dismissal. A finding of Research Misconduct under this Procedure does not constitute discipline.

Evidence: Any document, tangible item, information or testimony offered or obtained during a Research Misconduct Investigation or proceeding that may assist in providing or disproving the Allegation. Evidence includes traditional and electronic documents, databases and other forms of information as well as equipment, slides, samples and computers.

Expert: An individual with subject matter or technical expertise who advises and supports CommonSpirit during Research Misconduct Investigations or proceedings. CommonSpirit representatives are specifically authorized to consult such experts as they believe are needed.

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 Record.

Federal Sponsor: the federal sponsoring agency of the research project, for example, Public Health Service (PHS), National Institute of Health (NIH), National Science Foundation (NSF), Department of Energy (DOE), National Aeronautics and Space Administration (NASA), Department of Defense (DOD) and Food and Drug Administration (FDA).

Good Faith Allegation: An Allegation made with the honest belief that Research Misconduct may have occurred.

Immediate Health Hazard: A condition that exists or has the potential to exist which should be abated or corrected immediately to prevent imminent or ongoing danger of serious damage to human or animal health or the environment.

Inquiry: Preliminary information-gathering and initial fact-finding to determine whether an Allegation or apparent instance of Research Misconduct warrants an Investigation.

Institutional Record: Comprised of: (a) the records that were compiled or generated during the Research Misconduct proceeding, except those records the RIO, Deciding Officer, and/or Institutional Committee did not consider or rely on. These records include, but are not limited to: (1) documentation of the assessment; (2) if an Inquiry is conducted, the Inquiry report and all records (other than drafts of the report) considered or relied on during the Inquiry; (3) if an Investigation is conducted, the Investigation report and all records (other than drafts of the report) considered or relied on during the investigation; (4) the final decision(s) by the Deciding Office; and (5) the complete record of any appeal. (b) a single index listing all the Research Records and Evidence compiled during the research misconduct proceeding, except records the institution did not consider or rely on.

Intentionally: to act with the aim of carrying out the act.

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.

Knowingly: to act with awareness of the act.

Medical Staff: Medical staff members of any CommonSpirit Facility including advanced practice providers who have credentials, practice prerogatives, or similarly granted status.

Notice/Notification: A written communication served in person, sent by mail or its equivalent to the last known street address, facsimile number or e-mail address of the address.

Plagiarism: The appropriation of another person's ideas, processes, results or work without giving appropriate credit. Plagiarism also includes the unattributed verbatim or almost verbatim

copying of sentences and paragraphs from another's work that materially misleads the reader regarding the contribution of the author. It does not include the limited use of identical or nearly identical phrases that describe a commonly used methodology.

Preponderance of the Evidence: Proof by evidence that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.

Remedial Action: Actions necessary to protect research funds. These actions are not disciplinary but are intended to ensure the appropriate expenditure of research funds and to protect the integrity of the research.

Recklessly: to propose, perform, or review research, or report research results, with indifference to a known risk of fabrication, falsification, or plagiarism.

Research: A systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research), including the use of artificial intelligence in relation to any of the foregoing, relating broadly to public health by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, biological causes, functions or effects, diseases, treatments, or related matters to be studied.

Research Integrity Officer (RIO): The institutional official responsible for: (1) assessing Allegations of Research Misconduct to determine if they fall within the definition of Research Misconduct and warrant an Inquiry on the basis that the Allegation is sufficiently credible and specific so that potential evidence of Research Misconduct may be identified; (2) overseeing inquiries and Investigations; and (3) the other responsibilities described in this Procedure. The CommonSpirit Corporate Responsibility System Director of Research Compliance shall be the RIO.

Research Misconduct: Fabrication, Falsification or Plagiarism in proposing, performing or reviewing Research or in reporting Research results. It does not include honest error or differences of opinion.

Research Record: The physical or electronic record of data or results that embody the facts resulting from scientific Inquiry, including but not limited to, research proposals, laboratory records, progress reports, abstracts, theses, oral presentations, internal reports, journal articles and any documents and materials provided to the United States Department of Health and Human Services (DHHS) or the RIO or DO by a Respondent in the course of a Research Misconduct proceeding.

Respondent: The person(s) against whom an Allegation of Research Misconduct is directed or the subject(s) of a preliminary assessment, Inquiry, Investigation or proceeding.
Retaliation: An adverse action taken against a Complainant, witness, or committee member by an institution or one of its members in response to a good faith Allegation of Research Misconduct; or good faith cooperation with a Research Misconduct proceeding.

REFERENCES:

CommonSpirit Health Administrative Policy	Corporate Responsibility A-001, *CommonSpirit Health Standards of Conduct: Our Values in Action Policy and Reference Guide*