Policy and Procedure: Research Integrity and Misconduct Policy
Type: Administrative (ADM) / RWJBH Research Office
Applicable To: Newark Beth Israel Medical Center, Inc. Children's Hospital of New Jersey, Barnabas Health Medical Group, P.C., Robert Wood Johnson Physician Enterprise, P.C., RWJBH Corporate Services, Inc., Children's Specialized Hospital, Robert Wood Johnson University Hospital Rahway, Robert Wood Johnson University Hospital, Inc. dba Robert Wood Johnson University Hospital Somerset, Robert Wood Johnson University Hospital, Inc., Trinitas Regional Medical Center, RWJBarnabas Health Behavioral Health Center, Jersey City Medical Center, Inc., Robert Wood Johnson University Hospital Hamilton, Robert Wood Johnson Health Network, Monmouth Medical Center, Inc., Clara Maass Medical Center, Community Medical Center, Inc., Cooperman Barnabas Medical Center, Inc., Monmouth Medical Center, Inc. dba Monmouth Medical Center Southern Campus
Procedure owner: RWJBH Research Office
Effective date: January 1, 2026
Approved by: Office of General Counsel, RWJBH Research Office

PURPOSE:
The purpose of this Policy is to establish a system-wide framework for the fair, consistent, and appropriate handling of Allegations of Research Misconduct and other serious research integrity concerns within RWJBarnabas Health System (RWJBH) in accordance with applicable law. This Policy implements the requirements of 42 CFR Part 93 for Allegations of Research Misconduct involving research supported by the Public Health Service (PHS). RWJBH may, in its sole discretion, apply this Policy as a framework for addressing other allegations of research misconduct or research integrity that are not subject to 42 CFR Part 93, and for referring such matters to other institutional policies or processes, as appropriate.

POLICY STATEMENT:
RWJBH is committed to the responsible conduct of research and to maintaining the integrity of the research record. Allegations of Research Misconduct, as defined under 42 CFR Part 93, will be reviewed in a thorough, objective, and fair manner, consistent with applicable regulatory requirements. Where Research Misconduct is substantiated, RWJBH will take appropriate corrective action and will fulfill all administrative requirements, including reporting obligations and cooperate with the Office of Research Integrity (ORI) and other regulatory authorities, as required by applicable law.

APPLICABLE LAW:
This Policy supplements applicable law and does not replace it. Applicable law supersedes any conflicting provisions of the Policy. For allegations of Research Misconduct received on or after January 1, 2026, RWJBH shall apply the revised Public Health Service Policies on Research Misconduct at 42 CFR Part 93 (2024). For allegations of Research Misconduct received before January 1, 2026, RWJBH shall apply the 2005 version of 42 CFR Part 93, unless RWJBH and the Respondent elect in writing to apply the revised regulation, consistent with 42 CFR 93.75.

RWJBH shall maintain active research integrity assurances as required under 42 CFR Part 93 and shall designate an Institutional Certifying Official or designee responsible for required certifications and submissions to the ORI.

SCOPE AND APPLICABILITY:

This Policy applies to all individuals involved in research conducted at any RWJBH facility, research training, and research related activities conducted under RWJBH oversight, including proposals for PHS support, whether or not an award is made. This Policy applies to individuals only to the extent RWJBH has responsibility for research integrity oversight for the research at issue.

DISCLOSURE OF POLICY:

The current version of the Policy is publicly available on the RWJBH Internet website. Individuals involved in research under RWJBH oversight must review this Policy and any updates.

DEFINITIONS:

A. *Accepted Practices of the Relevant Research Community* means the norms and standards recognized by the relevant research community as appropriate and responsible methods and practices for conducting, reporting, and reviewing research.
B. *Allegation* means a disclosure of possible research misconduct, whether made by written or oral statement or other communication to an institutional official.
C. *Assessment* means an evaluation of an Allegation to determine whether it is credible and specific, falls within the definition of Research Misconduct and not other forms of non-compliance, and presents sufficient evidence to warrant further Inquiry.
D. *Complainant* means a person who, in Good Faith, makes an Allegation of Research Misconduct.
E. *Evidence* means any document, tangible item, or testimony offered or obtained during a Research Misconduct Proceeding that tends to prove or disprove the existence of an alleged fact.
D. *Fabrication* means making up data or results, and recording or reporting them.
E. *Falsification* means 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.
F. *Good Faith* means having a reasonable belief in the truth of an allegation or testimony, or cooperating honestly and objectively in a Research Misconduct Proceeding.
G. *Individuals involved in research under RWJBH oversight* means individuals involved in the design, conduct, operations, review, or reporting of research conducted under RWJBH oversight, including employees, Institutional Review Board members, medical staff members, agents, contractors, subcontractors, subawardees, trainees, students, and volunteers.
H. *Inquiry* means preliminary information-gathering and preliminary fact-finding conducted to determine whether an Investigation is warranted.
I. *Institution* means RWJBH, including all owned, operated, or affiliated RWJBH facility hospitals, medical centers, physician practices, and other RWJBH entities conducting or supporting research under RWJBH governance or oversight.
J. *Institutional Certifying Official* (*ICO*) means the RWJBH institutional official responsible for certifying and submitting to ORI the institution's research integrity assurances and annual reports.
K. *Institutional Deciding* Official (IDO) means the RWJBH institutional official responsible for making the final institutional determination in a Research Misconduct Proceeding.
L. *Institutional Record* means all records compiled or generated by RWJBH or its designee during a Research
M. *Misconduct Proceeding*, that RWJBH considered or relied on, including Assessment documentation, Inquiry and Investigation Reports and supporting records, interview recordings and transcripts, information provided by the Respondent, the recommendations of the RIO, the final written determination of the IDO and the complete record of any appeal or review within the Institution. Records sequestered but not relied on are not part of the Institutional Record but shall be separately maintained and described.
N. *Intentionally* means acting with the conscious objective to engage in the conduct in question.
O. *Investigation* means the formal development of a factual record and the examination of that record leading to a decision regarding whether Research Misconduct occurred, and, if so, who committed the misconduct and what actions are appropriate.
P. *Knowingly* means acting with awareness that the conduct is of the nature described or that the circumstances exist.
Q. *Office of Research Integrity (ORI)* means the office within the U.S. Department of Health and Human Services (HHS) to which the Secretary has delegated responsibility for addressing research integrity and misconduct issues related to Public Health Services (PHS) supported activities.
R. *Plagiarism* means the appropriation of another person's ideas, processes, results, or words without giving

appropriate credit. Plagiarism does not include the limited use of identical or nearly identical phrases that describe a commonly used methodology, self-plagiarism, or authorship or credit disputes.
S. *Preponderance of the evidence* means proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.
T. *Public Health Service (PHS)* means the U.S. Department of Health and Human Services funding components whose research activities are subject to 42 CFR Part 93.
U. *Recklessly* means acting with conscious disregard of a substantial and unjustifiable risk that the conduct will result in a significant departure from accepted practices of the relevant research community.
V. *Research Integrity Officer (RIO)* means the institutional official appointed by the IDO to be responsible for assessing Allegations of Research Misconduct; determining whether such Allegations fall within the definition of Research Misconduct, under 42 CFR Part 93, and warrant an Inquiry; overseeing Inquiries and Investigations; and performing other responsibilities described in this Policy.
W. *Research Misconduct* means Fabrication, Falsification, or Plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research Misconduct does not include honest error or differences of opinion, consistent with 42 CFR 93.103.
X. *Research Misconduct Proceeding* means any actions related to alleged Research Misconduct including but not limited to, Assessments, Inquiries, Investigations, sponsor or agency oversight reviews, hearings and administrative appeals.
Y. *Research Record* means the record of data or results that embody the facts resulting from scientific inquiry, in any form or medium, including but not limited to, research proposals, laboratory records, progress reports, abstracts, theses, presentations, internal reports, journal articles, and any documents and materials provided to an institutional official.
Z. *Respondent* means the person against whom an Allegation of Research Misconduct is directed or who is the subject of a Research Misconduct Proceeding.
AA. *Retaliation* means an adverse action taken against a complainant, witness, or committee member by RWJBH or its designee in response to a Good Faith Allegation of Research Misconduct; or Good Faith cooperation with a Research Misconduct Proceeding.

INSTITUTIONAL ROLES AND RESPONSIBILITIES:

RWJBH addresses allegations of Research Misconduct through a structured five-stage process as described in this Policy. The Institutional Deciding Official (IDO) is responsible for making the final determination in a Research Misconduct Proceeding. RWJBH designates the RWJBH President and Chief Executive Officer (or designee) as the IDO.

The IDO shall appoint the Executive Vice President and Chief Medical and Quality Officer, or another senior institutional official with appropriate authority and experience, to serve as the Research Integrity Officer (RIO). The RIO is responsible for overseeing the Research Misconduct Proceedings under this Policy. If the RIO has a conflict with any Allegation, the RIO shall inform the IDO, who shall appoint an alternate RIO to handle the Allegation.

The IDO and RIO should consult with the Chief Legal Officer or designee, as appropriate, throughout the Research Misconduct Proceeding.

The RWJBarnabas Health President and Chief Executive Officer, or a designee, shall also designate an Institutional Certifying Official (ICO), who shall be a senior institutional official with appropriate authority to certify institutional compliance and submit required research-integrity assurances.

PROTECTING COMPLAINANTS AND RESPONDENTS:

RWJBH will not tolerate retaliation against any individual who in good faith reports or participates in a Research Misconduct Proceeding including Complainants, witnesses, and committee members. RWJBH will protect the confidentiality of Research Misconduct Proceedings to the extent possible, consistent with a fair and objective proceeding, and as required by applicable law. During the pendency of a Research Misconduct Proceeding, disclosure of the identity of the Complainant, Respondent, witnesses, and other individuals involved shall be limited to those with a need to know.

RWJBH cannot guarantee the anonymity of the Complainant or other participants, particularly where

disclosure is necessary to afford the Respondent reasonable and sufficient information to respond to the Allegations or as otherwise required by law. Permissible disclosures are limited to those necessary carry out the Research Misconduct Proceeding and the Office of Research Integrity (ORI). Individuals with a need to know may include journals, editors, publishers, co-authors and collaborating institutions as determined by the RIO in consultation with the Chief Legal Officer or designee. This limitation on disclosure applies during the pendency of the Research Misconduct Proceeding and does not apply after RWJBH has made a final institutional determination.

In cases where a Research Misconduct Proceeding concludes with no finding of Research Misconduct against a Respondent, RWJBH shall take all reasonable and practical steps, if requested and as appropriate, to protect or restore the professional reputation of the Respondent.

STAGE I: MAKING AN ALLEGATION:

Purpose. The purpose of Stage I is to provide a mechanism for individuals to report concerns regarding potential Research Misconduct or other research integrity issues and to ensure that such concerns are promptly directed to the RIO for initial consideration.

Procedure. Any individual may report an Allegation or concern regarding potential Research Misconduct or research integrity issues, either in writing or orally ("Complainant"). Individuals involved in research under RWJBH oversight have an obligation to report suspected Research Misconduct.

Reports may be made to the RIO, RWJBH Research Office, Local or Corporate Compliance, the Office of General Counsel, or to a supervisor or manager, and may also be submitted anonymously through the Corporate Compliance Helpline. Reports received through any reporting channel shall be promptly referred to RIO for Assessment in accordance with this Policy. The RIO may consult confidentially with any person who requests guidance and is uncertain about whether a concern should be reported or whether the conduct at issue may constitute Research Misconduct.

To the extent known, the Complainant should provide the following when making a report:

- The name of the RWJBH research study involved;
- The name(s) of the individual(s) involved in the alleged conduct ("Respondent")
- The date or time frame of the alleged conduct;
- A description of the conduct at issue, including what the Complainant believes may constitute Research Misconduct;
- A statement of how the Complainant became aware of the concern;
- Any other relevant information, including known conflicts or other interests; and
- If known, whether the research is supported by the Public Health Service (PHS) or other federal sponsor, including any grant/award number.

Outcome. All Allegations and concerns received under Stage I shall proceed to Stage II (Assessment) for preliminary evaluation and determination of next steps.

STAGE II: ASSESSMENT:

Purpose. The purpose of an Assessment is to conduct a preliminary evaluation of an Allegation to determine whether it is credible and specific, falls within the definition of Research Misconduct, and warrants further review through an Inquiry or referral to other appropriate institutional processes.

Procedure. The Assessment is a limited, threshold review of readily available information. The RIO shall review the Allegation and any materials submitted with it. The Assessment does not involve full fact-finding, interviews, or adjudication on the merits. The RIO may consult with appropriate institutional officers, including the Chief Legal Officer or designee, as necessary. When allegations involve research conducted at multiple RWJBH facilities or in collaboration with other institutions, one institution shall be designated as the lead institution if a joint Research Misconduct Proceeding is conducted.

Part 93 Applicability Determination. As part of the Assessment, the RIO shall determine and document as part of the Institutional Record:

- whether the Allegation involves research subject to 42 CFR Part 93 (i.e., PHS-supported research, a PHS funding application, or PHS-related research/training activity).
- whether the Allegation is governed by the 2005 version of 42 CFR Part 93 or the revised 2024 regulation, based on the date the Allegation was received; and
- whether the Allegation falls within the six-year limitation period including whether an exception applies (42 CFR 93.104); and
- whether the Allegation is sufficiently credible and specific such that potential evidence of Research Misconduct may be identified.

Timeframe. The Assessment period should conclude within ten (10) business days.

Safeguards. In assessing any Allegation, the RIO shall, as appropriate:

- Sequester research data and evidence pertinent to the Allegations, before or at the time of Respondent notification, and maintain sequestered materials in a secure location;
- Confirm that individuals involved in handling an Allegation are free from unresolved personal, professional, or financial conflict of interest and take appropriate action, including recusal, to ensure an impartial proceeding; and
- Inform the IRB Chair of record if the RIO identifies undue risk or actual harm to research participants or violation of human subject protection requirements.

Outcomes. The Assessment shall result in one of the following:

1. Inquiry required – Part 93 pathway.
If the Assessment indicates potential Research Misconduct and 42 CFR Part 93 applies, an Inquiry shall be initiated under this Policy.

2. Inquiry permitted – Non-Part-93 Research Misconduct.
If the Assessment indicates potential Research Misconduct that is not subject to 42 CFR Part 93 (including Research Misconduct in non-PHS-supported research), RWJBH may, in its discretion, initiate an Inquiry using a substantially similar process. ORI reporting and other Part-93-specific requirements do not apply.

3. Referral – Other research integrity or compliance issues.
If the matter does not constitute Research Misconduct but involves other research integrity, regulatory, or professional conduct concerns, the RIO shall refer the matter to the appropriate institutional office or process (e.g., Compliance, Office of General Counsel, Human Resources, Medical Staff Bylaws, IRB) and document the referral and rationale in the file.

4. Closure without Inquiry.
If the Assessment does not present sufficient information to warrant further review, the RIO shall close the matter with documentation

5. Parallel actions permitted.
Research Misconduct and other non-compliance are not mutually exclusive; referrals may occur in parallel with an Inquiry when appropriate.

Documentation. The RIO shall maintain an Assessment file as part of the Institutional Record. The Assessment file shall include the Allegation and any materials submitted with it, any documents reviewed during the Assessment, and a written Assessment summary documenting the allegation, the Part 93 applicability determination, and the resulting disposition. The RIO may consult with appropriate institutional offices, including Legal Affairs or Compliance, as warranted by the circumstances. Assessment documentation shall be retained as part of the Institutional Record even when an inquiry is not opened and maintained for the period required under the Record Retention section of this Policy and to permit potential review by the Office of Research Integrity.

STAGE III. INQUIRY:

Purpose. The purpose of an Inquiry is to determine whether an Investigation is warranted. An Investigation is warranted if there is a reasonable basis for concluding that the Allegation falls within the definition of Research Misconduct and may have substance based on the preliminary information gathered during the Assessment.

Procedure. In conducting an Inquiry, the RIO shall:

- Notify the Respondent in writing that an Inquiry has been initiated on or before the date the Inquiry begins;
- Inform Respondents, Complainants, and witnesses of the procedural steps in Inquiry;
- Notify additional Respondents identified during the Inquiry in writing; and
- Take interim action as necessary to protect research participants, preserve research records, or address other immediate risks, and consult with the Chief Legal Officer or designee, regarding and required notification to the IRB Chair, sponsoring agency or the ORI.

Review of Allegations. The RIO shall review evidence related to the Allegation to determine whether an Investigation is warranted. An actual finding of Research Misconduct, including any determination of whether alleged misconduct was intentional, knowing, or reckless, may not be made at the Inquiry stage.

Inquiry Report. The RIO shall prepare the Inquiry Report in accordance with Appendix A (Research Misconduct Inquiry Report). In preparing the Inquiry Report the RIO may consult with Legal Affairs, Compliance, or other appropriate institutional officials.

Timeframe. The RIO shall conclude the Inquiry within ninety (90) days of initiation. If additional time is needed, the RIO shall document the reasons for the delay in writing and include that documentation in the Inquiry Report.

Notice. The RIO shall notify the Respondent(s) of the Inquiry outcome and provide an opportunity to respond within a reasonable timeframe. Notice shall include a copy of the Inquiry Report, this Policy and a reference to 42 CFR Part 93, when applicable. RWJBH may, but is not required to, provide relevant portions of the report to a Complainant for comment. If notice is provided to one complainant in a case, it must be provided, to the extent possible, to all complainants in the case.

ORI Submission. For studies subject to 42 CFR Part 93, within 30 days of determining that an Investigation is warranted, the RIO, in consultation with the Chief Legal Officer or designee shall submit a copy of the Inquiry Report to ORI.

Outcome. Based on the Inquiry, the matter shall result in one of the following:

1. Investigation required – Part 93 pathway. If the Inquiry indicates that an Investigation is warranted and 42 CFR Part 93 applies, the matter shall proceed to Stage IV in accordance with Part 93.

2. Investigation permitted – Non-Part-93 Research Misconduct. If the Inquiry indicates that an Investigation is warranted but 42 CFR Part 93 does not apply, RJWBH may, in its discretion, proceed to Stage IV using a substantially similar process.

3. Closure without Investigation. If the Inquiry does not warrant an Investigation, the matter shall be closed with appropriate documentation.

Documentation. The RIO shall retain the Inquiry Report and all supporting documentation as part of the Institutional Record, including in cases where the Inquiry concludes without an Investigation.

STAGE IV. INVESTIGATION AND FINAL DETERMINATION:

Purpose. The purpose of the Investigation and Final Determination is to conduct a thorough and objective examination of the evidence relating to an Allegation of Research Misconduct, determine whether Research Misconduct occurred, and make a final institutional determination. Where the

Allegation involves Research Misconduct subject to 42 CFR Part 93, the Investigation shall be conducted in accordance with Part 93. Where the Allegation involves Research Misconduct that is not subject to Part 93, RWJBH may conduct a substantially similar Investigation, and the ORI reporting and other Part-93-specific requirements do not apply.

Initiation and Notice. Within thirty (30) calendar days of determining that an Investigation is warranted, the RIO shall notify the Respondent(s) in writing of the Allegation(s) to be investigated. If new Allegations are identified during the Investigation, the RIO shall provide written notice within a reasonable timeframe. For studies subject to 42 CFR Part 93, the RIO shall notify the ORI in consultation with the Chief Legal Officer or designee, on or before the Investigation begins.

Investigation Oversight and Conduct. The Investigation may be conducted by the RIO, or when the RIO determines that the nature, complexity, or subject matter of the Allegations warrants, by an ad hoc panel ("Panel") appointed by the RIO. In making this determination, the RIO may consult with the Chief Legal Officer or designee, as appropriate. When a Panel is convened, it shall be organized and function in accordance with the Panel Formation Policy, attached as Appendix B. The Investigation shall be conducted in accordance with this Policy and applicable law and shall include a thorough, objective, and fair examination of the relevant evidence, interviews as appropriate.

Interviews and Evidence. All interviews of witnesses, Respondent(s), and Complainant(s) must be recorded and transcribed. Each interviewee shall have an opportunity to review and correct the transcript of their own interview. Recordings and transcripts shall be included in the Institutional Record. The Respondent shall not be present during interviews of other witnesses but shall receive copies of all interview transcripts.

Burden of Proof and Evaluation Factors. A finding of Research Misconduct requires that it be established by a preponderance of the evidence that:

(1) there was a significant departure from accepted practices of the relevant research community;
(2) the departure was committed intentionally, knowingly, or recklessly; and
(3) the allegation is supported by a preponderance of the evidence.

RWJBH bears the burden of proof. The Respondent bears the burden of proof for any affirmative defenses and mitigating factors.

In evaluating the evidence, the following factors may be considered, including but not limited to:

- harm or potential harm to research subjects;
- issues related to research data acquisition, management, sharing or ownership
- whether the Respondent destroyed research records after being informed of the Allegation or claimed to possess relevant research records but refused to provide them upon request;
- conflict among investigators, trainees, clinical research coordinators or any other persons involved in the research; and
- publication-related issues (e.g., authorship, attributions, acknowledgments, citations or accuracy).

Draft Investigation Report. Upon completion of the Investigation, the RIO or, if applicable, the Panel, shall prepare a draft Investigation Report in accordance with Appendix C, addressing each Allegation separately and setting forth its findings and recommendations. Where there are multiple Respondents, the Panel shall prepare a separate draft Investigation Report for each Respondent.

Respondent Comment. The RIO shall provide the Respondent(s) with a copy of the draft Investigation Report, together with a copy of, or supervised access to, the evidence on which the report is based. The Respondent(s) shall be notified that that their written comments must be submitted within thirty (30) days of receipt of the draft report. Any timely comments shall be included and considered as part of the final Investigation Report.

Final Investigation Report. The RIO, or, if applicable, the Panel shall issue a final Investigation Report.

The final Investigation Report shall include the elements identified in Appendix C and shall become part of the Institutional Record.

RIO Report to the IDO. Upon completion of the Investigation, the RIO shall transmit the Investigation Report to the IDO, together with any recommended remedial measures. In recommending remedial measures the RIO may consider, the nature and level of misconduct, the pattern of conduct, and the level of harm or potential harm to research subjects.

The RIO may recommend any or all of the following remedial measures as appropriate:

- Warning: issuance of a written warning to Respondent;
- Monitoring: appointment of a monitor to oversee the research and/or the Respondent, with reporting obligations as determined by the RIO;
- Suspension: suspension of the study, the Respondent's research activities, and/or employment (in coordination with Human Resources and subject to applicable employment agreements);
- Termination: Termination of Respondent research privileges and/or employment; and
- Reporting: notification to sponsors, regulatory agencies, and/or medical staff, as applicable.

The RIO's recommendations to the IDO shall become part of the Institutional Record.

Final Determination. The IDO, in consultation with the Chief Legal Officer or designee, shall make the final determination in writing based solely on the Institutional Record. The IDO may also request additional analyses from the RIO within fifteen (15) days of the RIO's recommendation and may consult with other institutional officials including, Human Resources and Compliance . The IDO shall provide written notice of the final determination to the Respondent, the RIO and the Chief Legal Officer or designee. The written determination shall inform the Respondent of their right to Appeal pursuant to Stage V. of this Policy. For studies subject to 42 CFR Part 93, the final determination shall reference 42 CFR Part 93 and this Policy. The written final determination is part of the Institutional Record.

Transmittal to ORI. For studies subject to 42 CFR Part 93, following the IDO final determination, the RIO, in consultation with the Chief Legal Officer or designee shall transmit the complete Institutional Record to ORI. If the Respondent files an appeal pursuant to Stage V., transmittal of the Institutional Record shall be coordinated with the completion of the appeal.

Timeframes. For studies subject to 42 CFR Part 93, the entire Stage IV. process must be concluded within one hundred and eighty days (180) of its initiation, including the final determination by the IDO and transmitting the Institutional Record to ORI. If the Investigation cannot be concluded in 180 days, then the RIO, in consultation with the Chief Legal Officer or designee, shall request an extension in writing from the ORI. For all other studies, the Investigation shall be concluded within one hundred eighty (180) days unless circumstances warrant otherwise.

Outcome. Unless appealed pursuant to Stage V., the determination issued under this Policy constitutes RWJBH's final institutional determination. Nothing in this Policy limits RWJBH's ability to take or consider actions under other applicable institutional policies, procedures, or authorities, including the Medical Staff Bylaws, employment policies, or contractual arrangements, as applicable.

Documentation. The Institutional Record for Stage IV. shall include the Assessment file and summary , the Inquiry Report, the draft Investigation Report, the Respondent's comments on the draft Investigation Report, the final Investigation Report, the RIO's recommendation to the IDO, all interview recordings and transcripts, and the IDO written final determination. The Institutional Record shall be retained in accordance with the Record Retention section of this policy.

STAGE V. RESPONDENT APPEALS:

Following a final determination by the IDO, the Respondent shall have thirty (30) days to submit a written appeal to IDO or designee. The appeal shall be limited to: (a) material procedural error that affected the outcome; (b) newly discovered evidence not reasonably available during the investigation; or (c) the sanction imposed. The appeal shall not constitute a new investigation. The appeal official shall review only the grounds identified in the appeal and may affirm, modify or reverse the determination or remand the matter to the RIO

for further proceedings. The appeal official shall issue a written decision within thirty (30) days. The decision of the appeal official is final and constitutes RWJBH's final institutional determination. Nothing in this policy limits RWJBH's ability to take action under other applicable institutional policies or authorities.

For studies subject to 42 CFR Part 93, if an appeal is filed, the RIO shall promptly notify ORI. Transmittal of the Institutional Record to ORI shall be coordinated with the completion of the appeal.

OTHER REQUIRED REPORTING

General. RWJBH shall comply with any reporting obligations to the ORI, sponsors, clinical research organizations (CRO), and/or the U.S. Food and Drug Administration (FDA) and other bodies, as applicable. The RIO shall consult with the Chief Legal Officer or designee before performing any external reporting.

Interim Reporting- Special Circumstances. During any Research Misconduct Proceeding, the RIO shall assess whether any of the following exists:

- a risk to health or safety of the public, including an immediate need to protect human or animal subjects
- an issue sensitive to the general public;
- a need to protect or preserve HHS's resources or interests;
- a need to suspend research;
- a need to take immediate steps to protect a Complainant, Respondent or any other RWJBH personnel;
- a likelihood of public disclosure;
- potential criminal conduct; or
- any other matter involving significant public interest.

If any such circumstances are identified, the RIO shall promptly report them to the IDO. For studies subject to 42 CFR Part 93, the RIO, after consultation with the Chief Legal Officer or designee, shall communicate such matters to ORI at any time during the Research Misconduct Proceeding, as required by regulation. In addition, if at any time a Research Misconduct Proceeding reveals an immediate risk to the health or safety of human or animal subjects, the RIO shall promptly notify the RWJBH 's IRB Chair.

Early Closure Based on Admission or Settlement. For studies subject to 42 CFR Part 93, the RIO, in consultation with the Chief Legal Officer or designee, shall notify the ORI in advance if RWJBH intends to close a proceeding at the assessment, inquiry, investigation, or appeal stage based on a Respondent's admission or a settlement.

Any admission of Research Misconduct must be set forth in a written, signed statement by the Respondent that:

- specifies the fabrication, falsification, and/or plagiarism that occurred;
- identifies the affected Research Records; and
- satisfies all elements required for a finding of research misconduct under 42 CFR 93.103, consistent with 42 CFR 93.317.

Applicable Reporting. The RIO shall consider whether there may be any reporting obligations to the sponsor, the FDA, NIH, and/or local RWJBH medical staff, as applicable and shall inform the IDO accordingly.

RECORD RETENTION

The RIO shall maintain the complete Institutional Record of each Research Misconduct Proceeding. The Institutional Record shall include, as applicable:

- All research records and evidence compiled or generated during the proceeding;
- A single index of all such records; and
- A general description of any Research Records that were sequestered but not relied upon.

The Institutional Record and all sequestered evidence shall be retained for seven (7) years after completion of the institutional proceeding or any HHS proceeding, whichever is later, unless custody is transferred to

HHS.

4. Related Documents:

Document Type	Document Name
Related Documents:	Office of Research Integrity (ORI): https://ori.hhs.gov
Regulatory References:	42 CFR Part 93 — Public Health Service Policies on Research Misconduct (2024 Final Rule, effective January 1, 2026) 42 CFR Part 93 — Public Health Service Policies on Research Misconduct (2005)

APPENDIX A

ELEMENTS OF A RESEARCH MISCONDUCT INQUIRY REPORT

(1) The names, professional aliases, and positions of the Respondent and Complainant;

(2) A description of the allegation(s) of Research Misconduct;

(3) If PHS support, including, for example, grant numbers, grant applications, contracts, and publications listing PHS support;

(4) The composition of the inquiry committee, if used, including name(s), position(s), and subject matter expertise;

(5) Inventory of sequestered research records and other evidence and description of how sequestration was conducted;

(6) Transcripts of any transcribed interviews;

(7) Timeline and procedural history;

(8) Any scientific or forensic analyses conducted;

(9) The basis for recommending that the allegation(s) warrant an investigation;

(10) The basis on which any allegation(s) do not merit an investigation;

(11) Any comments on the inquiry report by the Respondent or the Complainant; and

(12) Any institutional actions implemented, including communications with journals or funding agencies.

APPENDIX B

RESEARCH INTEGRITY PANEL - CREATION, GOVERNANCE, AND DUTIES

Appointment and Composition
Panel members shall be selected based on appropriate scientific, clinical, or other relevant expertise necessary to evaluate the Allegations and Evidence at issue. Panel members may be selected from within or outside RWJBH, as appropriate to ensure expertise, impartiality, and independence.

Impartiality and Conflicts of Interest
Individuals with unresolved personal, professional, or financial conflicts of interest related to the matter shall not serve on the Panel. Prior to appointment, Panel members shall be screened for conflicts of interest and bias. The Respondent shall be notified of proposed Panel membership and afforded an opportunity to submit written objections for cause. The RIO shall evaluate any timely objections and take appropriate action, including recusal or replacement of Panel members, as warranted.

Role of the RIO
The RIO shall provide administrative and procedural support to the Panel and ensure that the Investigation is conducted in accordance with this Policy. The RIO shall not direct or influence the Panel's factual findings or conclusions.

Confidentiality
Anyone involved in the research misconduct proceedings, including all Panel members, shall maintain the confidentiality of the Research Misconduct Proceeding in accordance with this Policy and applicable law.

APPENDIX C
RESEARCH MISCONDUCT INVESTIGATION REPORT

A final investigation report for each Respondent must be in writing and include:

(a) Description of the nature of the allegation(s) of research misconduct, including any additional allegation(s) addressed during the Research Misconduct Proceeding.

(b) Description and documentation of the PHS support, including, for example, any grant numbers, grant applications, contracts, and publications listing PHS support.

(c) Description of the specific allegation(s) of research misconduct for consideration in the investigation of the respondent.

(d) Composition of investigation committee, including name(s), position(s), and subject matter expertise.

(e) Inventory of sequestered research records and other evidence, except records the institution did not consider or rely on; and a description of how any sequestration was conducted during the investigation. This inventory must include manuscripts and funding proposals that were considered or relied on during the investigation.

(f) Transcripts of all interviews conducted, as described in § 93.310(g).

(g) Identification of the specific published papers, manuscripts submitted but not accepted for publication (including online publication), PHS funding applications, progress reports, presentations, posters, or other research records that allegedly contained the falsified, fabricated, or plagiarized material.

(h) Any scientific or forensic analyses conducted.

(i) If not already provided to ORI, the institutional policies and procedures under which the investigation was conducted.

(j) Any comments made by the respondent and complainant on the draft investigation report and the investigation committee's consideration of those comments.

(k) A statement for each separate allegation of whether the investigation committee recommends a finding of research misconduct.

(1) If the investigation committee recommends a finding of research misconduct for an allegation, the investigation report must, for that allegation:

(i) Identify the individual(s) who committed the research misconduct.

(ii) Indicate whether the research misconduct was falsification, fabrication, and/or plagiarism.

(iii) Indicate whether the research misconduct was committed intentionally, knowingly, or recklessly.

(iv) State whether the other requirements for a finding of research misconduct, as described in § 93.103, have been met.

(v) Summarize the facts and the analysis which support the conclusion and consider the merits of any explanation by the respondent.

(vi) Identify the specific PHS support, if any.

(vii) Identify whether any publications need correction or retraction.

(2) If the investigation committee does not recommend a finding of research misconduct for an allegation, the investigation report must provide a detailed rationale.

(3) List of any current support or known applications or proposals for support that the respondent has pending with PHS and non-PHS Federal agencies.