I. Purpose

Maintaining high ethical standards in the conduct of scientific research is essential to the discovery of new knowledge and to establishing public trust. The Stanley Manne Children's Research Institute (Manne Research Institute) promotes the responsible conduct of research in a manner fully compliant with all applicable regulations and deals promptly with allegations or evidence of research misconduct. This policy outlines the process for the handling allegations of research misconduct (fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results) involving a person who, at the time of the alleged research misconduct, was employed by, was an agent of, or was affiliated by contract or agreement with the Manne Research Institute, and

(1) Public Health Service (PHS) supported biomedical or behavioral research, research training, or activities related to that research or research training,
(2) applications or proposals for PHS support for biomedical or behavioral research, research training, or activities related to that research or research training, or
(3) plagiarism of research records produced in the course of PHS supported research, research training or activities related to that research or research training. This includes any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application or proposal for PHS funds resulted in a grant, contract, cooperative agreement, or other form of PHS support.

II. Definitions

Abuse of Confidentiality means the use of ideas and preliminary data gained from (i) access to information not otherwise available through the opportunity for editorial review of manuscripts submitted to journals, and (ii) the opportunity for peer review of proposals being considered for funding by agency panels or by internal Committees such as the Institutional Review Board, the Institutional Animal Care and Use Committee, or the Radiation Safety Committee.

Allegation is a disclosure of possible research misconduct through any means of communication.

Complainant is the person(s) who in *Good Faith* makes an *Allegation* of *Research Misconduct* or *reports alleged Noncompliance*.

Conflict of Interest and commitment refers to a divergence between an individual's interests and his/her professional obligations to the Manne Research Institute, such that an independent observer might reasonably question whether the person's action were determined by considerations other than the best interests of the Manne Research Institute.

Deciding Officer (DO) is the President and Chief Research Officer (CRO) of the Stanley Manne Children's Research Institute. The DO will be notified by the RIO of all inquiries and Investigations and their outcomes. The DO represents the Manne Research Institute when it is determined that present or former research personnel are the subject of complaints or Investigations that involve outside institutions. In the event of a determination of research misconduct, the President and CRO may invoke sanctions according to established procedures of the Manne Research Institute.

Director, Office of Research Integrity & Compliance (ORIC) reports to the Chief Operating Officer (COO) of the Stanley Manne Children's Research Institute. The Director of ORIC oversees matters related to research integrity and provides guidance and oversight to the research compliance committees, including but not limited to: the Institutional Review Board (IRB), the Institutional Biosafety Committee (IBC), and the Radiation Safety Committee. The Director works closely with the Legal Department and the Corporate Compliance Office. The Director is responsible for guiding and monitoring research compliance activities, maintaining a current knowledge of laws and regulatory requirements, and developing a system whereby related information and updates are disseminated throughout the organization to ensure the Institution is addressing research integrity and research compliance issues. The Director has authority to review all documents and other information that are relevant to research compliance activities.

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.

Fabrication is making up data or results and recording or reporting them.

Falsification is 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.

Good Faith Allegation refers to an allegation made with the honest belief that research misconduct may have occurred based on the information known to the Complainant or witness at the time. An allegation is not in good faith if made with knowing or reckless disregard for willful ignorance of the facts that would disprove the allegation.

Inquiry refers to the initial process for determining whether an allegation or apparent instance of research misconduct has substance and warrants an Investigation.

Investigation refers to the formal examination and evaluation of all relevant facts to determine, based on a preponderance of evidence, whether research misconduct has occurred and, if so, to determine the responsible person and the nature and seriousness of the research misconduct.

Investigator refers to any individual who is engaged in the design, conduct or reporting of research.

Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

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

Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Research Integrity Officer (RIO) is the Chief Operating Officer (COO) of the Stanley Manne Children's Research Institute. The RIO is responsible for 1) assessing allegations of research misconduct to determine if they fall within the definition of research misconduct under 42 CFR 93 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) other responsibilities as described om this policy. The RIO is also responsible for making timely reports to the relevant external agencies, as required, and for appropriately maintaining documentation of all research misconduct proceedings.

Research Misconduct is *fabrication*, *falsification*, or *plagiarism* in proposing, performing, or reviewing research, or in reporting research results. It also includes *abuse of confidentiality*. Research misconduct does not include honest error or honest differences of opinion.

Research Misconduct Proceeding means any action related to alleged research misconduct, including but is not limited to, allegation assessments, inquires, Investigations, The U.S. Department of Health and Human Services Office of Research Integrity (ORI) oversight reviews, hearings, and administrative appeals.

Research Record is the record of data or results that embody the facts resulting from scientific Inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to PHS or an institutional official by a Respondent in the course of the research misconduct proceeding.

Respondent is the person(s) against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding. The Respondent is responsible for maintaining confidentiality and cooperating with the conduct of an Inquiry and Investigation.

Retaliation means an adverse action taken against a Complainant, witness, or Committee member by an institution or one of its members in response to (a) a good faith allegation of research misconduct; or (b) good faith cooperation with a research misconduct proceeding.

III. Policy Statements

A. Responsibility to Report Research Misconduct

An environment of open and candid communications is fostered at the Manne Research Institute. All employees have a duty to report any conduct that is unlawful or unethical, including suspected research misconduct. All institutional members should report observed, suspected, or apparent research misconduct to their supervisor, the RIO, the Director of ORIC, the Corporate Compliance Office, or Leadership. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may meet with or contact the RIO at 773.755.6310 to discuss informally, anonymously, and/or hypothetically. If the circumstances described by the individual do not meet the definition of research misconduct, the RIO will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

To encourage personnel to report knowledge or suspicion of illegal or unethical acts, they may also phone the Compliance office at 312.227.4679 or leave a message at 312.227.5288. The voicemail is checked daily by the Corporate Compliance Office.

In addition, an anonymous hotline is available: 1.800.273.8452. An outside service will ask for detailed information about reported concerns. The report will be reviewed with the caller for accuracy and is then forwarded to the Corporate Compliance Office within twenty-four (24) hours of receipt. Callers wishing to remain anonymous will receive an ID number to be used so they can call back to report more details or receive a follow-up response. This hotline is available twenty-four (24) hours a day, seven (7) days a week.

Any allegations of research misconduct will be taken seriously, examined, and addressed promptly to minimize potential harm. Review, as outlined in the procedures, will be conducted in a manner to ensure confidentiality, fairness, and prompt action to protect all involved and the integrity of the research.

B. Cooperation with Research Misconduct Proceedings

Institutional members will cooperate with the RIO and other institutional officials in the review of allegations and the conduct of inquiries and Investigations. Institutional

members, including Respondents, have an obligation to provide evidence relevant to research misconduct allegations to the RIO or other institutional officials.

C. Confidentiality

The RIO shall, as required by 42 CFR 93.108: (1) limit disclosure of the identity of Respondents and Complainants to those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding; and (2) except as otherwise prescribed by law, limit the disclosure of any records or evidence from which research subjects might be identified to those who need to know in order to carry out a research misconduct proceeding. The RIO should use written confidentiality agreements or other mechanisms to ensure that the recipient does not make any further disclosure of identifying information.

D. Protecting Complainants, witnesses, and Committee members

The Manne Research Institute will protect, to the fullest extent permitted by law, the identity of personnel who desires to remain anonymous. Institutional members may not retaliate in any way against Complainants, witnesses, or Committee members. Institutional members should immediately report any alleged or apparent retaliation against Complainants, witnesses or Committee members to the RIO, who shall review the matter and, as necessary, make all reasonable and practical efforts to counter any potential or actual retaliation and protect and restore the position and reputation of the person against whom the retaliation is directed.

E. Protecting the Respondent

As requested and as appropriate, the RIO and other institutional officials shall make all reasonable and practical efforts to protect or restore the reputation of persons alleged to have engaged in research misconduct, but against whom no finding of research misconduct is made.

During the research misconduct proceeding, the RIO is responsible for ensuring that Respondents receive all the notices and opportunities provided for in 42 CFR Part 93 and the policies and procedures of the Manne Research Institute. Respondents may consult with legal counsel or personal adviser (who is not a principal or witness in the case) to seek advice and may bring the counsel or personal adviser to interviews or meetings on the case.

F. Interim Administrative Actions and Notifying ORI of Special Circumstances

Throughout the research misconduct proceeding, the RIO will review the situation to determine if there is any threat of harm to public health, federal funds and equipment, or the integrity of the PHS supported research process. In the event of such a threat, the RIO will, in consultation with other Institutional officials and ORI, take appropriate interim action to protect against any such threat. Interim action might include additional monitoring of the research process and the handling of federal funds and equipment, reassignment of personnel or of the responsibility for the handling of federal funds and equipment, additional review of research data and results or delaying publication. The RIO shall, at any time during a research misconduct proceeding, notify ORI immediately if he/she has reason to believe that any of the following conditions exist:

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

IV. Procedures

A. Conducting the Assessment and Inquiry

1. Assessment of Allegations

Upon receiving an allegation of research misconduct, the RIO will immediately assess the allegation to determine whether it is sufficiently credible and specific so that potential evidence of research misconduct may be identified, whether it is within the jurisdictional criteria of 42 CFR 93.102(b), and whether the allegation falls within the definition of research misconduct in 42 CFR 93.103. An Inquiry must be conducted if these criteria are met. The assessment should be concluded within a week. In conducting the assessment, the RIO need not interview the Complainant, Respondent, or other witnesses, or gather data beyond any that may have been submitted with the allegation, except as necessary to determine whether the allegation is sufficiently credible and

specific so that potential evidence of research misconduct may be identified. The RIO shall, on or before the date on which the Respondent is notified of the allegation, obtain custody of, inventory, and sequester all research records and evidence needed to conduct the research misconduct proceeding.

2. Initiation and Purpose of the Inquiry

   If the RIO determines that the criteria for an Inquiry are met, he or she will immediately initiate the Inquiry process. The purpose of the Inquiry is to conduct an initial review of the available evidence to determine whether to conduct an Investigation. An Inquiry does not require a full review of all the evidence related to the allegation.

3. Notice to Respondent; Sequestration of Research Records

   At the time of or before beginning an Inquiry, the RIO must make a good faith effort to notify the Respondent in writing, if the Respondent is known. If the Inquiry subsequently identifies additional Respondents, they must be notified in writing. On or before the date on which the Respondent is notified, or the Inquiry begins, whichever is earlier, the RIO must take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments. The RIO may consult with ORI for advice and assistance in this regard.

4. Appointment of the Inquiry Committee

   The RIO, in consultation with other institutional officials as appropriate, may appoint an Inquiry Committee and Committee Chair as soon after the initiation of the Inquiry as is practical. The Inquiry Committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the Inquiry and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the Inquiry.

5. Charge to the Committee and First Meeting

   The RIO will prepare a charge for the Inquiry Committee that:

   - Sets forth the time for completion of the Inquiry;
   - Describes the allegations and any related issues identified during the allegation assessment;
   - States that the purpose of the Inquiry is to conduct an initial review of the evidence, including the testimony of the Respondent, Complainant and key witnesses, to determine whether an Investigation is warranted, not to determine whether research misconduct definitely occurred or who was responsible;
   - States that an Investigation is warranted if the Inquiry Committee determines: (1) there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct and is within the jurisdictional criteria of 42 CFR 93.102(b); and, (2) the allegation may have substance, based on the Committee's review during the Inquiry.
   - Informs the Inquiry Committee that they are responsible for preparing or directing the preparation of a written report of the Inquiry that meets the requirements of this policy and 42 CFR 93.309(a).

   At the Committee's first meeting, the RIO will review the charge with the Committee, discuss the allegations, any related issues, and the appropriate procedures for conducting the Inquiry, assist the Committee with organizing plans for the Inquiry, and answer any questions raised by the Committee. The RIO will be present or available throughout the Inquiry to advise the Committee as needed.

6. Inquiry Process

   The Inquiry Committee will normally interview the Complainant, the Respondent, and key witnesses as well as examining relevant research records and materials. Then the Inquiry Committee will evaluate the evidence, including the testimony obtained during the Inquiry. Those interviewed at the Inquiry stage will be given the transcript or recording of the interview for correction.

   After consultation with the RIO, the Committee members will decide whether an Investigation is warranted based on the criteria in this policy and 42 CFR 93.307(d). The scope of the Inquiry is not required to and does not normally include deciding whether misconduct definitely occurred, determining definitely who committed the research

misconduct or conducting exhaustive interviews and analyses. However, if a legally sufficient admission of research misconduct is made by the Respondent, misconduct may be determined at the Inquiry stage if all relevant issues are resolved. In that case, the RIO shall promptly consult with ORI to determine the next steps that should be taken.

7. Time for Completion

The Inquiry, including preparation of the final Inquiry Report and the decision of the DO on whether an Investigation is warranted, must be completed within 60 calendar days of initiation of the Inquiry, unless the RIO determines that circumstances clearly warrant a longer period. If the RIO approves an extension, the Inquiry record must include documentation of the reasons for exceeding the 60-day period. The Respondent will be notified of the extension.

B. The Inquiry Report

1. Elements of the Inquiry Report

A written Inquiry Report must be prepared that includes the following information: (1) the name and position of the Respondent; (2) a description of the allegations of research misconduct; (3) the PHS support, including, for example, grant numbers, grant applications, contracts and publications listing PHS support; (4) the basis for recommending or not recommending that the allegations warrant an Investigation; (5) any comments on the draft report by the Respondent or Complainant.

Institutional counsel will review the report for legal sufficiency. Modifications should be made as appropriate in consultation with the RIO and the Inquiry Committee. The Inquiry Report should include: the names and titles of the Committee members and experts who conducted the Inquiry; a summary of the Inquiry process used; a list of the research records reviewed; summaries of any interviews; and whether any other actions should be taken if an Investigation is not recommended.

2. Notification to the Respondent and Opportunity to Comment

The RIO shall notify the Respondent whether the Inquiry found an Investigation to be warranted, include a copy of the draft Inquiry Report for comment within 10 days, and include a copy of or refer to 42 CFR Part 93 and the Manne Research Institute's policies and procedures on research misconduct.

Any comments that are submitted by the Respondent or Complainant will be attached to the final Inquiry Report. Based on the comments, the Inquiry Committee may revise the draft report as appropriate and prepare it in final form. The Committee will deliver the final report to the RIO.

3. Institutional Decision and Notification

   a. Decision by Deciding Official

      The RIO will transmit the final Inquiry Report and any comments to the DO, who will determine in writing whether an Investigation is warranted. The Inquiry is completed when the DO makes this determination.

   b. Notification to ORI

      Within 30 calendar days of the DO's decision that an Investigation is warranted, the RIO will provide ORI with the DO's written decision and a copy of the Inquiry Report. The RIO will also notify those Institutional officials who need to know of the DO's decision. The RIO must provide the following information to ORI upon request: (1) the institutional policies and procedures under which the Inquiry was conducted; (2) the research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and (3) the charges to be considered in the Investigation.

   c. Notification to National Institutes of Health (NIH)

      When a recipient institution finds, learns, or suspects that falsified, fabricated, or plagiarized information has affected the integrity of NIH-supported research, including but not limited to, applications for funding and progress reports, or published research or research products supported by NIH funds, NIH has a need to know this information, and the Manne Research Institute must immediately provide information on the affected research to the NIH Office of Extramural Research – Research Integrity (OER-RI), in a manner consistent with the ORI confidentiality regulations, 42 CFR 93.108.

   d. Documentation of Decision Not to Investigate

      If the DO decides that an Investigation is not warranted, the RIO shall secure and

maintain for seven (7) years after the termination of the Inquiry sufficiently detailed documentation of the Inquiry to permit a later assessment by ORI of the reasons why an Investigation was not conducted. These documents must be provided to ORI or other authorized PHS personnel upon request.

C. Conducting the Investigation

1. Initiation and Purpose

The Investigation must begin within 30 calendar days after the determination by the DO that an Investigation is warranted. The purpose of the Investigation is to develop a factual record by exploring the allegations in detail and examining the evidence in depth, leading to recommended findings on whether research misconduct has been committed, by whom, and to what extent. The Investigation will also determine whether there are additional instances of possible research misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged research misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice. Under 42 CFR 93.313 the findings of the Investigation must be set forth in an Investigation Report.

2. Notifying ORI and Respondent; Sequestration of Research Records

On or before the date on which the Investigation begins, the RIO must: (1) notify the ORI Director of the decision to begin the Investigation and provide ORI a copy of the Inquiry Report; and (2) notify the Respondent in writing of the allegations to be investigated. The RIO must also give the Respondent written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the Inquiry or in the initial notice of the Investigation.

The RIO will, prior to notifying Respondent of the allegations, take all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the research misconduct proceeding that were not previously sequestered during the Inquiry. The need for additional sequestration of records for the Investigation may occur for any number of reasons, including the Manne Research Institute's decision to investigate additional allegations not considered during the Inquiry stage or the identification of records during the Inquiry process that had not

been previously secured. The procedures to be followed for sequestration during the Investigation are the same procedures that apply during the Inquiry.

3. Appointment of the Investigation Committee

The RIO, in consultation with other institutional officials as appropriate, will appoint an Investigation Committee and the Committee Chair as soon after the beginning of the Investigation as is practical. The Investigation Committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the Investigation and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the Respondent and Complainant, and conduct the Investigation. Individuals appointed to the Investigation Committee may also have served on the Inquiry Committee.

4. Charge to the Committee and the First Meeting

a. Charge to the Committee

The RIO will define the subject matter of the Investigation in a written charge to the Committee that:

- Describes the allegations and related issues identified during the Inquiry;
- Identifies the Respondent;
- Defines research misconduct;
- Informs the Committee that it must evaluate the evidence and testimony to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, the type and extent of it and who was responsible;
- Informs the Committee that in order to determine that the Respondent committed research misconduct it must find that a preponderance of the evidence establishes that: (1) research misconduct, as defined in this policy, occurred (Respondent has the burden of proving by a preponderance of the evidence any affirmative defenses raised, including honest error or a difference of opinion); (2) the research misconduct is a significant departure from accepted practices of the relevant research community; and (3) the Respondent committed the research misconduct intentionally, knowingly, or recklessly; and
- Informs the Committee that it must prepare or direct the preparation of a written Investigation Report that meets the requirements of this policy and 42 CFR 93.313.

b. First Meeting

The RIO will convene the first meeting of the Investigation Committee to review the charge, the Inquiry Report, and the prescribed procedures and standards for the conduct of the Investigation, including the necessity for confidentiality and for developing a specific Investigation plan. The Investigation Committee will be provided with a copy of this statement of policy and procedures and 42 CFR Part 93. The RIO will be present or available throughout the Investigation to advise the Committee as needed.

5. Investigation Process

The Investigation Committee and the RIO must:

- Use diligent efforts to ensure that the Investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of each allegation;
- Take reasonable steps to ensure an impartial and unbiased Investigation to the maximum extent practical;
- Interview each Respondent, Complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the Investigation, including witnesses identified by the Respondent, and record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of the Investigation; and
- Pursue diligently all significant issues and leads discovered that are determined relevant to the Investigation, including any evidence of any additional instances of possible research misconduct (i.e., review of previous/other research efforts of the affected personnel), and continue the Investigation to completion.

During the formal Investigation, every reasonable effort will be made to protect the identity of the Respondent and the Complainant. The Respondent will normally be entitled to know the identity of all witnesses, if any, called before the Investigation Committee. Cases that depend solely upon the observations or statements of the Complainant may be unable to proceed without the involvement of that individual, or the ability to review may be severely limited. In cases that can rely on documentary evidence only, the Complainant may remain uninvolved without compromising the Investigation.

6. Time for Completion

The Investigation is to be completed within 120 days of beginning it, including conducting the Investigation, preparing the report of findings, providing the draft report for comment and sending the final report to ORI. However, if the RIO determines that the Investigation will not be completed within this 120-day period, he/she will submit to ORI a written request for an extension, setting forth the reasons for the delay. The RIO will ensure that periodic progress reports are filed with ORI, if ORI grants the request for an extension and directs the filing of such reports.

D. The Investigation Report

Appropriate interim actions, prior to the draft, review, and finalization of the Investigation Report may be taken at the request of the Committee to protect public health, federal funds and equipment, and the integrity of the federally supported research process.

1. Elements of the Investigation Report

The Investigation Committee and the RIO are responsible for preparing a written draft report of the Investigation that:

- Describes the nature of the allegation(s) of research misconduct, including identification of the Respondent (including a CV or resume);
- Describes and documents the PHS support, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing PHS support;
- Describes the specific allegation(s) of research misconduct considered in the Investigation;
- Includes the institutional policies and procedures under which the Investigation was conducted, unless those policies and procedures were provided to ORI previously;
- Identifies and summarizes the research records and evidence reviewed and identifies any evidence taken into custody but not reviewed; and
- Includes a statement of findings for each allegation of research misconduct identified during the Investigation. Each statement of findings must: (1) identify whether the research misconduct was falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly; (2)

summarize the facts and the analysis that support the conclusion and consider the merits of any reasonable explanation by the Respondent, including any effort by Respondent to establish by a preponderance of the evidence that he or she did not engage in research misconduct because of honest error or a difference of opinion; (3) identify the specific PHS support; (4) identify whether any publications need correction or retraction; (5) identify the person(s) responsible for the misconduct; and (6) list any current support or known applications or proposals for support that the Respondent has pending with non-PHS federal agencies.

2. Comments on the Draft Report and Access to Evidence

   a. Respondent

   The RIO must give the Respondent a copy of the draft Investigation Report for comment and, concurrently, a copy of, or supervised access to the evidence on which the report is based. The Respondent will be allowed 30 days from the date he/she received the draft report to submit comments to the RIO. The Respondent's comments must be included and considered in the final report.

   b. Complainant

   On a case-by-case basis, the Complainant may be provided a copy of the draft Investigation Report, or relevant portions of it, for comment. The Complainant's comments must be submitted within 30 days of the date on which he/she received the draft report and the comments must be included and considered in the final report (42 CFR 93.312(b) and 93.313(g)).

   c. Confidentiality

   In distributing the draft report, or portions thereof, to the Respondent (and Complainant, if applicable), the RIO will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality (i.e., sign a confidentiality agreement).

3. Decision by Deciding Official

The RIO will assist the Investigation Committee in finalizing the draft Investigation

Report, including ensuring that the Respondent's (and, if applicable, Complainant's comments are included and considered, and transmit the final Investigation Report to the DO, who will determine in writing: (1) whether the Manne Research Institute accepts the Investigation Report, its findings, and the recommended Institutional actions; and (2) the appropriate Institutional actions in response to the accepted findings of research misconduct. If this determination varies from the findings of the Investigation Committee, the DO will, as part of his/her written determination, explain in detail the basis for rendering a decision different from the findings of the Investigation Committee. Alternatively, the DO may return the report to the Investigation Committee with a request for further fact-finding or analysis.

When a final decision on the case has been reached, the RIO will normally notify both the Respondent and the Complainant in writing. After informing ORI, the DO will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the Respondent in the work, or other relevant parties should be notified of the outcome of the case. The RIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

4. Notice to ORI of Institutional Findings and Actions

Unless an extension has been granted, the RIO must, within the 120-day period for completing the Investigation, submit the following to ORI: (1) a copy of the final Investigation Report with all attachments; (2) a statement of whether the Manne Research Institute accepts the findings of the Investigation Report; (3) a statement of whether the Manne Research Institute found misconduct and, if so, who committed the misconduct; and (4) a description of any pending or completed administrative actions against the Respondent.

5. Maintaining Records for Review by ORI

The RIO must maintain and provide to ORI upon request "records of research misconduct proceedings" as that term is defined by 42 CFR 93.317. Unless custody has been transferred to HHS or ORI has advised in writing that the records no longer need to be retained, records of research misconduct proceedings must be maintained in a secure manner for 7 years after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation. The RIO is also responsible for providing any information, documentation, research records, evidence or clarification requested by ORI to carry out its review of an allegation of research

misconduct or of the Manne Research Institute's handling of such an allegation.

E. Completion of Cases; Reporting Premature Closures to ORI

Generally, all Inquiries and Investigations will be carried through to completion and all significant issues will be pursued diligently. The RIO must notify ORI in advance if there are plans to close a case at the Inquiry, Investigation, or appeal stage on the basis that Respondent has admitted guilt, a settlement with the Respondent has been reached, or for any other reason, except: (1) closing of a case at the Inquiry stage on the basis that an Investigation is not warranted; or (2) a finding of no misconduct at the Investigation stage, which must be reported to ORI, as prescribed in this policy and 42 CFR 93.315.

F. Institutional Administrative Actions

If the DO determines that research misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consultation with the RIO. The administrative actions may include:

- Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found;
- Removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment;
- Restitution of funds to the grantor agency as appropriate; and
- Other action appropriate to the research misconduct.

G. Other Considerations

1. Termination or Resignation Prior to Completing Inquiry or Investigation

   The termination of the Respondent's Institutional employment, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the research misconduct proceeding or otherwise limit any of the Manne Research Institute's responsibilities under 42 CFR Part 93.

   If the Respondent, without admitting to the misconduct, elects to resign his or her position after the Manne Research Institute receives an allegation of research misconduct, the assessment of the allegation will proceed, as well as the Inquiry and Investigation, as appropriate based on the outcome of the preceding steps. If the

Respondent refuses to participate in the process after resignation, the RIO and any Inquiry or Investigation Committee will use their best efforts to reach a conclusion concerning the allegations, noting in the report the Respondent's failure to cooperate and its effect on the evidence.

2. Restoration of the Respondent's Reputation

   Following a final finding of no research misconduct, including ORI concurrence where required by 42 CFR Part 93, the RIO must, at the request of the Respondent, undertake all reasonable and practical efforts to restore the Respondent's reputation. Depending on the particular circumstances and the views of the Respondent, the RIO should consider notifying those individuals aware of or involved in the Investigation of the final outcome, publicizing the final outcome in any forum in which the allegation of research misconduct was previously publicized, and expunging all reference to the research misconduct allegation from the Respondent's personnel file. Any actions of the Manne Research Institute to restore the Respondent's reputation should first be approved by the DO.

3. Protection of the Complainant, Witnesses and Committee Members

   During the research misconduct proceeding and upon its completion, regardless of whether the Manne Research Institute or ORI determines that research misconduct occurred, the RIO must undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any Complainant who made allegations of research misconduct in good faith and of any witnesses and Committee members who cooperate in good faith with the research misconduct proceeding. The DO will determine, after consulting with the RIO, and with the Complainant, witnesses, or Committee members, respectively, what steps, if any, are needed to restore their respective positions or reputations or to counter potential or actual retaliation against them. The RIO is responsible for implementing any steps the DO approves.

4. Allegations Not Made in Good Faith

   If relevant, the DO will determine whether the Complainant's allegations of research misconduct were made in good faith, or whether a witness or Committee member acted in good faith. If the DO determines that there was an absence of good faith he/she will determine whether any administrative action should be taken against the person who failed to act in good faith.

V. Cross References/Related Regulations/Policies
42 CFR 93
Administrative Policy: "Code of Conduct"

Date Reviewed/Revised: 03/26/19