Research Foundation for Mental Hygiene, Inc.

Policies and Procedures for Responding to Allegations of Research Misconduct

Contents

A. INTRODUCTION

Public trust in science and medicine depends on the integrity of the research enterprise. The Research Foundation for Mental Hygiene, Inc. (RFMH) is committed to the highest ethical standards in the design, review, conduct and reporting of research.

RFMH takes seriously all allegations of misconduct, and believes that the procedures for the inquiry, investigation and adjudication of any misconduct should be clear for all parties involved. RFMH is also cognizant of the need for protections and fair treatment for the complainant, the respondent and all witnesses involved in any misconduct proceeding. This Policy is designed to address both of these issues.

Definitions of certain key terms used in this Policy are provided in Section B below.

This statement of policy and procedures is intended to carry out RFMH's responsibilities under the Public Health Service (PHS) Policies on Research Misconduct, 42 C.F.R. § 93 and the Federal Policy on Research Misconduct of the Office of Science and Technology.

This Policy applies to all research proposed (including applications for funding), performed, reviewed or reported, or any research record generated from that research when:

1. The Respondent(s) is an individual(s) who, at the time of the alleged research misconduct, was acting in his/her capacity as an employee or agent of RFMH, or affiliated by contract or agreement with RFMH (this individual(s) may be an employee of OMH, OPWDD or OASAS); and/or,

2. The research is funded through RFMH, whether or not federally funded.

The provisions of this Policy and Procedures do not apply to authorship or collaboration disputes and apply only to allegations of research misconduct that occurred within six years of the date that RFMH or HHS received the allegation, except: (1) when the Respondent continues or renews any incident of alleged Research Misconduct that occurred before the six-year limitation through the citation, republication or other use for the potential benefit of the Respondent of the research record that is alleged to have been fabricated, falsified, or plagiarized; or (2) if the federal Office of Research Integrity (ORI) or RFMH (following consultation with ORI when related to Department of Health and Human Services (DHHS) funding) determine that the alleged misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public. The six-year limitation in this Policy is not intended to limit any other RFMH Policies and Procedures.

Persons conducting an inquiry or investigation should be aware that the Respondent may be employed by the State of New York, an Academic Affiliate or other employer. These employees, particularly those represented by a union, may enjoy certain due process protections during the course of an inquiry or investigation that may lead to disciplinary action. Consideration should be given to the need to consult with the administrative or human resources director of the facility or other entity employing the Respondent either before an inquiry is conducted or when an investigation is commenced depending upon the specific circumstances.

Inquiries and Investigations can be stressful for all concerned, and Respondents, Complainants, or others may wish to seek outside counseling and/or the support of a trusted advisor.

B. DEFINITIONS

"Complainant": means a person who in good faith makes an allegation of Research Misconduct.

"Fabrication": means making up data or results and recording or reporting them.

"Falsification": means the manipulation of 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": as applied to a Complainant, Respondent or Witness, means having a belief in the truth of one's allegation or testimony that a reasonable person in the Complainant's, Respondent's or Witness's position could have, based on the information known to the Complainant, Respondent or Witness at the time. An Allegation or cooperation with a Research Misconduct proceeding is not in good faith if made with knowing or reckless disregard for information that would negate the Allegation or testimony. Good faith as applied to a member of the Inquiry or Investigation Committee or a Research Integrity Committee member includes cooperating with the Research Misconduct proceeding by carrying out the duties assigned impartially for the purpose of helping RFMH meet its responsibilities under this Policy. A member of the Inquiry, Investigation, or Research Integrity Committee does not act in good faith if his/her acts or omissions are dishonest or influenced by personal, professional or financial conflicts of interest with those involved in the Research Misconduct proceeding.

"Inquiry Committee": means an Inquiry Committee of three or more persons appointed by a Research Integrity Committee for the purpose of conducting an initial inquiry into an allegation of Research Misconduct.

"Investigation Committee": means an Investigation Committee of three or more persons appointed by a Research Integrity Committee for the purpose of conducting an Investigation into an allegation of Research Misconduct.

"Person": means any individual, corporation, partnership, institution, association, unit of government, or legal entity, however organized.

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

"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.

"Research": means a systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research), or specific knowledge (applied research) 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 Committee (RIC)": means a standing committee, comprised of three or more appropriately qualified members, that is responsible for the implementation of the policies and procedures under this Policy. The Directors of NYSPI, NKI and IBR will each appoint a Research Integrity Committee to be responsible for allegations relating to research conducted at their Institute. The Managing Director of RFMH will appoint a Research Integrity Committee to be responsible for allegations relating to all other RFMH locations. The RIC shall consult with appropriate experts, including legal counsel, as necessary to carry out its functions.

"Research Misconduct" means any Fabrication, Falsification or Plagiarism in proposing, performing or reviewing research or reporting Research results. Research Misconduct does not include honest error or differences of opinion. In addition, this Policy does not cover authorship or collaboration disputes unless they involve Plagiarism and applies only to allegations of research misconduct that occurred within six years of the date RFMH or DHHS received the allegation, subject to the subsequent use, health or safety of the public and the grandfather exceptions in 42 CFR § 93.105(b).

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

"Respondent": means the person against whom an allegation of research misconduct is directed or who is the subject of research misconduct proceeding.

"Witness": means any individual who testifies or provides information with regard to an Allegation or whose Research Record is used as evidence during the course of a Research Misconduct proceeding.

C. COMPLIANCE WITH LAWS, REGULATIONS AND POLICIES

The administrative procedures to be followed by RFMH pursuant to this Policy are, in all cases, subject to the requirements of law. RFMH will comply with all applicable federal and state laws, regulations and policies with respect to Research Misconduct.

D. AGENCY SPECIFIC REQUIREMENTS

To the extent that any research that is subject to allegations of Research Misconduct was supported by, or is proposed to be supported by any federal agency whose policies are inconsistent with the terms of this Policy the terms of the applicable agency Policy shall apply to the administrative polices described herein. Additional agency requirements may be included as Attachments to this Policy, as amended from time to time.

E. MAKING AN ALLEGATION

1. Any individual who has questions with respect to possible Research Misconduct or who is considering making an allegation of Research Misconduct may meet privately with the Chair of

the applicable Research Integrity Committee or, if that person is not available, with another member of the Research Integrity Committee for advice or to discuss such questions.

2. RFMH encourages reasonable efforts to be made to resolve issues of alleged Research Misconduct prior to the commencement of formal administrative procedures pursuant to this Policy. If an individual believes that there are grounds for making an allegation of Research Misconduct, such individual may initially notify the Chair of the applicable Research Integrity Committee who will use his or her good faith efforts to resolve such individual's concerns informally. The administrative procedures described in this Policy (other than the safeguards described in Sections M.1, M.2, M.3, M.4, M.5 and M.6 below) shall not be applicable to any such informal process.

3. In the event that the concerns of any individual are not resolved informally to the satisfaction of such individual, such individual may make a formal allegation of Research Misconduct (an "Allegation"). Allegations should be made in writing and delivered to the Chair of the applicable Research Integrity Committee. In the event that an allegation is made orally or by other means of communication it shall be documented by the Institution or RFMH official receiving the allegation and delivered to the Chair of the RIC or may be documented by the Chair of the RIC.

4. An allegation of Research Misconduct may have profound implications for the Complainant, the Respondent and any Witness in a Research Misconduct proceeding and any individual making an allegation of Research Misconduct should take great care in documenting the basis of any charge.

5. Determination that a Research Misconduct Process is Warranted: Promptly (generally within one week) after receipt of an allegation of research misconduct the Research Integrity Committee ("RIC") shall determine whether the allegation, (i) meets the definition of Research Misconduct, (ii) the allegation is sufficiently credible and specific so that the potential evidence of research misconduct may be identified, and (iii) the allegation falls within the scope of this Policy (see Introduction on page two).

6. When an allegation involves more than one RFMH component the involved Institute Directors and Managing Director may assign responsibility to a single RIC, establish a joint RIC or take similar actions to provide for a single review process. Similarly, if a potential conflict of interest makes it inappropriate for a particular RIC to oversee a Research Misconduct process the Institute Director, Managing Director or Governance Committee of the Board of Directors, as appropriate, may appoint an ad hoc RIC to oversee the process. When an allegation relates to activities falling under this Policy and under the Policy of another Institution, the Institute Director and Managing Director may enter into an agreement with that Institution to conduct a joint inquiry and/or investigation process or to have RFMH or the other Institution rely, in whole or in part, on the inquiry and/or investigation conducted by the other. The agreement shall ensure that safeguards and protections consistent with those in this Policy are applied.

F. RESPONSE TO AN ALLEGATION; PREREQUISITES FOR FINDING OF RESEARCH MISCONDUCT

1. A response to an Allegation shall consist of three phases:

   a. Inquiry: the gathering of preliminary information and fact-finding to assess whether such Allegation has substance and if so, whether an Investigation is warranted (an "Inquiry");

   b. Investigation: the formal development of a factual record with respect to such Allegation and the examination and evaluation of such 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 (an "Investigation"); and

   c. Adjudication: the formal procedure for reviewing and evaluating the evidentiary record and report of an Investigation and for determining whether to agree with the recommended findings and to impose appropriate corrective actions (an "Adjudication").

2. A finding of Research Misconduct requires the satisfaction of all of the following prerequisites:

   a. there has been a significant departure from accepted practices in the relevant research community;

   b. the Research Misconduct has been committed intentionally, knowingly or recklessly; and

   c. the Allegation is proven by a Preponderance of the Evidence.

3. It is expected that the Complainant, the Respondent and any other person involved in the administrative procedures described in this Policy will act in good faith in participating in such procedures, including maintaining confidentiality and cooperating with the conduct of an Inquiry and/or Investigation.

G. 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 RFMH's responsibilities under 42 C.F.R. § 93 for PHS funded research.

If the Respondent, without admitting to the misconduct, elects to resign his or her position after RFMH receives an allegation of research misconduct, the assessment of the allegation will proceed, as well as the Inquiry or Investigation, as appropriate based on the outcome of the preceding steps. If the Respondent refuses to participate in the process after resignation or termination, the RIC, 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.

H. ADMISSION OF RESEARCH MISCONDUCT

The Respondent should be given the opportunity to admit that Research Misconduct occurred and that he/she committed the research misconduct. With the advice of the RIC and/or other institutional officials, the Facility Director and Managing Director may terminate the review of an allegation that has been admitted. When the research is PHS funded, acceptance of the admission and any proposed settlement must be approved by the federal Office of Research Integrity.

I. THE INQUIRY PHASE

1. Upon receipt of an allegation and determination that a Research Misconduct process is warranted (see E 5 above) the Research Integrity Committee shall send written confirmation of receipt of the allegation to the Complainant and notify (i) the Respondent, (ii) Managing Director of RFMH, and (iii) the Director of Institute/Facility of the filing of the Allegation.

2. The Research Integrity Committee shall select three or more persons (the "Inquiry Committee") to assess the Allegation and shall appoint one of these persons as the Chair of the Inquiry Committee. In selecting the Inquiry Committee the Research Integrity Committee should consider appointing a person who holds a similar level/type of position as the Complainant and/or the Respondent. For example, if the Respondent is a technician, consideration should be given to including as a member a person who is also a technician. The Inquiry Committee must consist of individuals who do not have unresolved personal, professional or financial conflicts of interest with those involved in the Inquiry and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues relating to the Allegation, interview the principals and key witnesses and conduct the Inquiry. Consideration should be given to the need to include a member from outside the Institute to provide expertise and/or to promote confidence that the decisions of the committee are fair and unbiased. No member of the Research Integrity Committee shall be appointed to the Inquiry Committee.

3. If the Inquiry subsequently identifies additional Respondents, the Research Integrity Committee shall so notify them in writing.

4. Sequestration of Research Records: On or before the date on which a Respondent is notified of the filing of an Allegation against him/her and at any other time during the Research Misconduct proceeding when additional records or evidence are discovered, the Research Integrity Committee shall promptly take all reasonable and practical steps to obtain custody of all of the Research Record and evidence needed to conduct the Research Misconduct proceeding, inventory the Research Record and evidence, and sequester them in a secure manner, except that where the Research Record or evidence encompasses 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.

5. The Research Integrity Committee shall prepare a written Charge for the Inquiry Committee which shall contain the elements included in the attached template (Attachment 3). One or more

members of the Research Integrity Committee shall meet with the Inquiry Committee at its first meeting to review the charge, discuss the allegations and any related issues that were identified during the initial assessment of the Allegation, review appropriate procedures for conducting the Inquiry, assist the Inquiry Committee with organizing plans for the Inquiry and address any questions raised by the Inquiry Committee. The Research Integrity Committee shall be available throughout the Inquiry to advise the Inquiry Committee as needed.

6. The Inquiry Committee shall review such evidence and interview such persons as may be necessary to make an assessment of whether the Allegation has substance and whether an Investigation is warranted.

7. The safeguards described in Section M below shall be provided to the Complainant, the Respondent, any Witness and any Inquiry Committee member, as applicable, during the Inquiry.

8. Upon completion of the Inquiry, the Inquiry Committee shall provide the Respondent with a draft written report (the "Inquiry Report") of their findings and recommendation as to whether or not there is sufficient evidence to undertake an Investigation and a copy of the recording or transcript of the Respondent's own testimony. The Respondent may comment in writing within 10 days of receipt, including providing any corrections to the recording or transcript. The Inquiry Committee shall also provide the Complainant with copies of those portions of the Inquiry Report relevant to the Complainant and a copy of the recording or transcript of the Complainant's own testimony. The Complainant may comment in writing within 10 days of receipt, including providing any corrections to the recording or transcript of the Complainant's testimony.

9. Following the review by the Inquiry Committee of any written comments on the draft Inquiry Report provided by the Respondent or the Complainant, the Inquiry Committee shall provide the Research Integrity Committee with a final Inquiry Report. The report shall be signed by each member of the Inquiry Committee and provided in hard copy or as a locked pdf or in similar secure format.

10. The Research Integrity Committee may accept or reject the recommendation of the Inquiry Committee and shall promptly provide the Respondent and the Director of the Facility and Managing Director of RFMH with written notification of its decision, indicating in such notification the principal reasons for such decision and a copy of the final Inquiry Report.

11. In general, an Inquiry should be completed within 60 days of its initiation, provided that the Research Integrity Committee may approve one or more reasonable extensions to the extent deemed necessary or appropriate.

12. If the Research Integrity Committee recommends that an Investigation is not warranted the records of the Inquiry shall be secured and maintained for a period of seven (7) years.

J. THE INVESTIGATION PHASE

1. If, at the conclusion of an Inquiry, the Research Integrity Committee determines that an Investigation is warranted, the Research Integrity Committee shall so notify, in addition to the persons listed in Section I.10 above, the Office of Research Integrity if PHS funded research is

involved. Notification to other federal and non federal sponsors shall be made in accordance with applicable regulations, sponsor policies and contracts.

2. The Research Integrity Committee shall appoint an Investigation Committee (the "Investigation Committee") to conduct the Investigation. The Investigation Committee shall consist of at least three members, none of whom is a member of the Research Integrity Committee with respect to the Allegation relating to such Investigation and at least one of whom is an expert in the area of research that is the subject of such Investigation. Membership of the Investigation Committee shall include persons who have expertise pertinent to the matter and who will carry out the Investigation thoroughly, fairly and promptly. The committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the Investigation. The Research Integrity Committee should consider appointing a person who holds a similar level/type of position as the Complainant and/or the Respondent. For example, if the Respondent is a technician, consideration should be given to including as a member a person who is also a technician. The Research Integrity Committee may appoint a person who is not affiliated with RFMH to the Investigation Committee if such person has the requisite expertise. Consideration should be given to the need to include a member from outside the Institute to provide expertise and/or to promote confidence that the decisions of the committee are fair and unbiased. The Research Integrity Committee shall select one of the members of the Investigation Committee to be the Chair of the Investigation Committee.

3. The Research Integrity Committee shall prepare a written charge for the Investigation Committee which shall contain the elements included in the attached template (Attachment 4). One or more members of the Research Integrity Committee shall meet with the Investigation Committee at its first meeting to review the charge, discuss the allegations, appropriate procedures for conducting the Investigation, assist the Investigation Committee with organizing plans for the Investigation and address any questions raised by the Investigation Committee. The Research Integrity Committee shall be available throughout the Investigation to advise the Investigation Committee as needed.

4. The Investigation Committee shall:

    a. use diligent efforts to ensure that the Investigation is thorough and sufficiently documented and includes the examination of all Research records and evidence relevant to reaching a decision on the merits of the Allegation;

    b. take reasonable steps to ensure an impartial and unbiased Investigation to the maximum extent practicable;

    c. interview the Complainant, the Respondent and any other available person who has been reasonably identified as having information regarding any relevant aspects of the Investigation. If any of these individuals are not available for interview after reasonable attempts have been made to contact them or if the Complainant does not wish to participate further in the process, the RIC may permit the Investigation to continue without such interview;

    d. provide the Complainant, the Respondent and the Witnesses with a copy of the recording or transcript of their own interview and the opportunity to correct such recording or transcript, if necessary and

e. pursue diligently all significant issues and leads discovered that are relevant to the Investigation.

5. The safeguards described in Section M below shall be provided to the Complainant, the Respondent, any Witness and any member of the Investigation Committee, as applicable, during an Investigation.

6. Upon completion of the Investigation, the Investigation Committee shall provide the Respondent with (a) a draft written report (the "Investigation Report") of its findings and recommendations as to whether or not a finding of Research Misconduct should be made and, may include recommendations for corrective actions that would be appropriate under the circumstances and (b) a copy of, or supervised access to, the evidence on which the Investigation Report is based. The Respondent may comment on the draft report provided that any such comments must be made to the Investigation Committee within 30 days of receipt of the draft. The Investigation Committee may, in its sole discretion, provide the Complainant with copies of those portions of the draft Investigation Report that are relevant to the Complainant. If the Complainant is provided with material the Complainant may comment on those portions of the draft Investigation Report, provided that any such comments must be given to the Investigation Committee in writing within 30 days of receiving such draft.

7. Following the review by the Investigation Committee of any written comments on the draft Investigation Report provided by the Respondent or the Complainant, the Investigation Committee shall provide the Research Integrity Committee with a final Investigation Report (using the template in Attachment 5) which shall include as an attachment the written comments, if any, of the Respondent.

8. The Research Integrity Committee may accept, reject or modify the recommendations of the Investigation Committee and shall add such corrective actions as it deems appropriate. The Research Integrity Committee shall promptly provide the Respondent with written notification of its decision, indicating in such notification the principal reasons for such decision. At the sole discretion of the Research Integrity Committee, notice of the final decision may, but is not required to be, provided to the Complainant.

9. In general, an Investigation should be completed within 120 days of its initiation, provided that the Research Integrity Committee may approve one or more reasonable extensions to the extent deemed necessary or appropriate.

K. THE ADJUDICATION PHASE

1. If the Research Integrity Committee accepts the Investigation Committee's recommendation that a finding of Research Misconduct should be made, the Institute Director or Managing Director, as applicable, shall review the reports of the Investigation Committee and the Research Integrity Committee. The Institute Director or Managing Director, as applicable, may accept, reject or modify the recommendations of the Research Integrity Committee and shall promptly provide the Respondent, with written notification of his/her decision, indicating in such notification the principal reasons for such decision. A recommendation by the Research Integrity Committee will be rejected or modified by the Institute Director or Managing Director only if the recommendation is found to be clearly erroneous, or arbitrary and capricious, or the process by which it was obtained was not in substantial compliance with these policies and procedures.

   At the sole discretion of the Institute Director or Managing Director as the case may be, the Complainant may, but is not required to be, notified of the final determination.

2. The safeguards described in Section M below shall be provided to the Complainant, the Respondent, any Witness and any member of the Investigation Committee, as applicable, during Adjudication.

3. In general, Adjudication should be completed within 60 days of its initiation, provided that the Institute Director or Managing Director as applicable may approve one or more reasonable extensions to the extent deemed necessary or appropriate.

L. APPEAL

1. A Respondent shall have the right, within 30 days after his/her receipt of the notification that the Adjudication Phase has been completed and is closed to file a written appeal with the RFMH Board of Directors with regard to the finding of Research Misconduct and/or the corrective actions imposed. The appeal must be addressed to the Board of Directors and RECEIVED at the main office of RFMH, 150 Broadway, Suite 301, Menands, NY 12204 within 30 days of receipt of the notice of adjudication.

2. During the Appeal the Respondent shall have the right to obtain the assistance of counsel or non-lawyer personal advisor (at Respondent's expense) to assist in the preparation of the written appeal documents.

3. All correspondence from RFMH to the Respondent shall be sent to the Respondent directly. If requested in writing by the Respondent, copies of correspondence may, but are not required to be, sent to the legal counsel or personal advisor.

4. Following the decision of the Institute Director or Managing Director the record upon which the appeal will be considered is closed and the Respondent does not have the right to submit additional information or materials.

5. The Governance Committee shall select three persons to review the appeal on behalf of the Board of Directors and may affirm the decision of the Institute Director or Managing Director or recommend to the Board of Directors that the decision be overturned or modified. The three persons shall include members of the Governance Committee and/or other appropriately qualified persons chosen by the Governance Committee to hear the appeal and must consist of persons who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the Research Misconduct Investigation. The decision of the Governance Committee or Board of Directors shall be final in all respects with respect to RFMH, and the Respondent shall have no further right of appeal.

6. In the course of reviewing an appeal, the Governance Committee may submit question(s) to the RIC. The RIC shall respond by providing copies of documents or other evidence already in the closed record of the Investigation that are relevant to the question asked. The Respondent shall then be given the opportunity to identify additional documents or other evidence from the closed record which directly respond to the question(s) raised.

7. In reviewing an appeal the decision of the Institute Director or Managing Director, as the case may be, will be overturned or modified by the Governance Committee or the Board of Directors only if the decision is found to be clearly erroneous, or arbitrary and capricious, or the process by which it was obtained was not in substantial compliance with these policies and procedures..

8. The Governance Committee of the Board of Directors shall promptly provide the Respondent, the Institute Director or Managing Director and the Funding Agency with written notification of the decision, indicating in such notification the principal reasons for such decision. At the sole discretion of the Governance Committee, the Complainant may but is not required to be notified of the final determination.

9. In general, an appeal should be completed within 30 days of its filing with the Board of Directors, provided that the Governance Committee or President of the Board of Directors may approve one or more reasonable extensions to the extent deemed necessary or appropriate.

10. At the completion of the Appeal phase, or following the Adjudication phase if no appeal is submitted, a final determination that Research Misconduct has occurred will be reported to the direct sponsors of the research, if any.

M. SAFEGUARDS

1. **Confidentiality:** To the extent possible consistent with a fair and thorough investigation and as allowed by law, knowledge about the identity of a Complainant, a Respondent and any Witnesses shall be limited to those persons identified in this Policy and others who need to know and all written materials and information with respect to any proceedings shall be kept confidential. To the extent allowed by law, any information obtained during the scientific misconduct proceeding that might identify the subjects of research shall be maintained securely and confidentially and shall not be disclosed, except to those who need to know in order to carry out the research misconduct proceeding.

2. **Conflicts of Interest:** The Research Integrity Committee shall take reasonable steps to ensure that all individuals responsible for carrying out any part of the administrative procedures

described in this Policy do not have unresolved personal, professional or financial conflicts of interest with the Complainant, Respondent or any Witness.

3. **Safeguards for a Complainant:** In addition to any other safeguards provided for in this Policy, the following safeguards shall be provided to a Complainant:

    a. If an Allegation has been made by a Complainant in good faith, RFMH shall ensure that:

        (i) the Complainant is treated fairly and reasonably;
        (ii) all reasonable and practical efforts are made to protect the Complainant from potential or actual retaliation;
        (iii) the procedures described in this Policy are fair and objective; and
        (iv) diligent efforts are made to protect or restore the position and reputation of the Complainant.

        However, in the event that the Research Integrity Committee determines that a Complainant has made an Allegation for malicious reasons, or was otherwise not acting in good faith in making such Allegation, the Committee shall recommend that appropriate actions up to and including dismissal if the person is an RFMH employee, or exclusion from conducting research funded through RFMH, be taken against such Complainant.

    b. During an Inquiry, the Complainant shall have the right to meet with the Inquiry Committee.

    c. During an Investigation, the Complainant shall have the right to:

        (i) identify persons who have information regarding any relevant aspects of the Investigation to be interviewed by the Investigation Committee;
        (ii) reasonable notice of the timing of the meeting with the Investigation Committee;
        (iii) be accompanied by counsel or a non-lawyer personal advisor (at Complainant's expense); and
        (iv) obtain a copy of a transcript of his/her own testimony, if any, and to correct such transcript, if necessary.

4. **Safeguards for a Respondent:** In addition to any other safeguards provided for in this Policy, the following safeguards shall be provided to a Respondent:

    a. A Respondent is assumed not to have committed Research Misconduct unless and until a finding of such has been made in accordance with this Policy and should be protected from penalty and public knowledge of any accusation until judged culpable. The Respondent in turn shall cooperate with the administrative procedures described in this Policy, including by providing information, research records and evidence to RFMH representatives referred to herein when so requested.

    b. RFMH shall not impede the ability of a Respondent to continue to do his/her work, and shall ensure that other disciplinary or adverse action not be taken, during the period of any Inquiry or Investigation unless the Institute Director or Managing Director

determines that there are compelling reasons to suspend the Respondent's work or take such action during all or a portion of such period.

c. During an Inquiry, the Respondent shall have the right to:

(i) meet with the Inquiry Committee;
(ii) have reasonable access to the data and other evidence supporting the Allegation;
(iii) respond to the Allegation orally and in writing; and
(iv) provide written comments on the Inquiry report as described further in Section I.8 above.

d. During an Investigation, the Respondent shall have the right to:

(i) appear before the Investigation Committee to present testimony on his/her behalf;
(ii) reasonable notice of the meeting;
(iii) identify persons who have any information regarding any relevant aspects of the Investigation to be interviewed by the Investigation Committee;
(iv) be accompanied by counsel or non-lawyer personal advisor (at Respondent's expense);
(v) obtain a copy of a transcript of his/her own testimony, if any, and to correct such transcript, if necessary, and
(vi) provide written comments on the investigation report as described further in section J.6 above.

e. During an appeal, the Respondent shall have the right to review the final Investigation Report and to obtain the assistance of counsel or non-lawyer personal advisor (at Respondent's expense) to assist in the preparation of the written appeal documents.

f. RFMH shall take all reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputation of any Respondent against whom no finding of Research Misconduct is made.

5. **Safeguards for Witnesses.**

If a Witness has cooperated with a Research Misconduct proceeding in good faith, RFMH shall ensure that:

a. all reasonable and practical efforts are made to protect such Witness from potential or actual retaliation; and

b. diligent efforts are made to protect or restore the position and reputation of such Witness.

6. **Safeguards for Research Integrity Committee, Inquiry Committee and Investigation Committee Members.**

   RFMH shall ensure that:

   a. all reasonable and practical efforts are made to protect members of the Research Integrity Committee, Inquiry Committee and Investigation Committee from potential or actual retaliation; and

   b. diligent efforts are made to protect or restore the position and reputation of such members.

N. CORRECTIVE ACTIONS AND PENALTIES

The purpose of the procedures described in this Policy is remedial. The corrective actions with respect to any finding of Research Misconduct shall be commensurate with the seriousness of the Research Misconduct, including, without limitation, the degree to which the Research Misconduct was knowing, intentional or reckless; was an isolated event or part of a pattern; or had significant impact on the Research Record, research subjects, other researchers, RFMH, other institutions or the public. Corrective actions and penalties: may include limitations on or exclusion from the ability to seek funding for research through RFMH, may affect RFMH employment up to and including termination, may involve withdrawal or correction of pending or published abstracts and papers emanating from the research where Research Misconduct was found, may involve removal from a research project, training requirements, increased supervision, monitoring of future work, and any other actions and penalties deemed appropriate by RFMH.

O. NOTIFICATION TO FUNDING AGENCY AND OTHERS

In addition to the notices provided for in Sections J, K and L above and in Attachments 1 (PHS funded research) and 2 (NSF funded research), the Research Integrity Committee may recommend to the Institute Director or Managing Director, during the course of any phase of the administrative procedures provided for in this Policy, that a report be made to a sponsor or other entity, such as law enforcement, if any of the circumstances listed below occur. The Institute Director and Managing Director shall consider the recommendation of the RIC and other information made available to them and make such notifications when deemed appropriate.

a. if public health or safety is at risk;

b. if the resources or interests of such Funding Agency are threatened;

c. if research activities should be suspended;

d. if there is reasonable indication of possible violations of civil or criminal law;

e. if federal action is requested to protect the interests of those involved in the investigation;

f. if the Research Integrity Committee believes that the administrative processes may be made public prematurely, so that appropriate steps may be taken to safeguard evidence and protect the rights of those involved; or

g. if the research community or the public should be informed.

Before a report is made to a non-federal sponsor, an appropriate confidentiality agreement shall be entered into between RFMH and the sponsor

Upon the completion of the administrative procedures provided for in this Policy, if there has been a finding of Research Misconduct, notification of such will be given to journals and societies to which erroneous, inaccurate or fraudulent papers or abstracts have been submitted, and to past and present collaborating investigators and other institutions and research agencies with which the Respondent is or was previously affiliated to the extent deemed appropriate by the Research Integrity Committee.

P. RECORD RETENTION

All records of the research misconduct proceeding shall be maintained for seven (7) years following completion of the proceeding or any ORI or HHS proceeding under Subparts D and E of 42 C.F.R. § 93, whichever is later, unless RFMH has transferred custody of the records and evidence to HHS, or ORI has advised RFMH that the records no longer need to be retained. Records for non PHS funded research shall be kept for seven (7) years, unless a longer period is specified in an agreement with the sponsor or sponsor policy.

Attachment 1: Terms Applicable to Research Funded by the Public Health Service of the U.S. Department of Health and Human Services

This Attachment sets forth additional provisions from the Public Health Service ("PHS") Policies on Research Misconduct (the "PHS Policies") of the Department of Health and Human Services applicable to Allegations of Research Misconduct involving PHS Research.

A. DEFINITIONS

For purposes of this Attachment, the following terms have the meanings set forth below:

"PHS Research": (i) Applications or proposals for PHS support for biomedical or behavioral extramural or intramural research, research training or activities related to that research or research training, such as the operation of tissue and data banks and the dissemination of research information; (ii) PHS supported biomedical or behavioral extramural or intramural research; (iii) PHS supported biomedical or behavioral extramural or intramural research training programs; (iv) PHS supported extramural or intramural activities that are related to biomedical or behavioral research or research training, such as the operation of tissue and data banks or the dissemination of research information; and (v) Plagiarism of research records produced in the course of PHS supported research, research training or activities related to that research or research training.

B. THE INQUIRY PHASE

The Inquiry Report must include the following information:

1. the name and position of the Respondent;

2. a description of the Allegation;

3. the PHS support, including grant numbers, grant applications, contracts and publications listing PHS support;

4. the basis for recommending that the alleged actions warrant an Investigation; and

5. any written comments on the Inquiry Report by the Respondent or the Complainant.

C. THE INVESTIGATION PHASE

An Investigation must be initiated within 30 days after the Research Integrity Committee's determination that an Investigation is warranted. On or before the date on which the investigation begins Research Integrity Committee shall provide ORI with the written finding that an investigation is warranted and a copy of the Inquiry Report.

The final Investigation Report must include the following information:

1. a description of the nature of the Allegations;

2. a description of the PHS support, including, for example, any grant numbers, grant application, contracts and publications listing PHS support;

3. a description of the specific Allegations of Research Misconduct for consideration in the Investigation;

4. if not already provided with the Inquiry Report, copies of this Policy;

5. identification and summary of the research records and evidence reviewed, identification of any evidence taken into custody but not reviewed, and a description of any relevant records and evidence not taken into custody with an explanation of why they were not taken into custody; and

6. for each separate Allegation identified during the Investigation, a finding as to whether Research Misconduct did or did not occur and if so:

    (i) a statement whether the Research Misconduct was Falsification, Fabrication or Plagiarism, and if it was intentional, knowing, or in reckless disregard;
    (ii) a summary of the facts and the analysis which support the conclusion and the merits of any reasonable explanation by the Respondent;
    (iii) a description of the specific PHS support;
    (iv) an indication of whether any publications need correction or retraction;
    (v) identification of the person(s) responsible for the Research Misconduct;
    (vi) a description of any current support or known applications or proposals for support that the Respondent has pending with non-PHS federal agencies; and
    (vii) any written comments made by the Respondent or the Complainant on the draft Investigation Report.

At the conclusion of the investigation RFMH will provide ORI with (a) a copy of the Final Investigation Report, including any appeals, (b) a statement of whether RFMH accepts the findings in the report and (c) a description of any pending or completed administrative actions against the Respondent(s).

The Investigation must be completed within 120 days, including conducting the investigation, repairing the report of findings, providing the draft report for comment and sending the final report to ORI. However, if RFMH determines that the investigation will not be completed within this 120 day period, he/she will submit a written request for an extension to ORI setting forth the reasons for the delay.

D. RECORD RETENTION

All records of the research misconduct proceeding will be maintained for 7 years following completion of the proceeding or any ORI or HHS proceeding under Subparts D and E of 42 C.F.R. § 93, whichever is later, unless RFMH has transferred custody of the records and evidence to HHS, or ORI has advised RFMH that the records no longer need to be retained.

E. INTERIM PROTECTIVE ACTIONS

At any time during a research misconduct proceeding, RFMH shall take appropriate interim actions to protect public health, federal funds and equipment, and the integrity of the PHS supported research process. The necessary actions will vary according to the circumstances of each case, but examples of actions that may be necessary include delaying the publication of research results, providing for closer supervision of one or more researchers, requiring approvals for actions relating to the research that did not previously require approval, auditing pertinent records, or taking steps to contact other institutions that may be affected by an allegation of research misconduct.

At any time during a research misconduct proceeding, RFMH shall notify ORI immediately if there is reason to believe that any of the following conditions exist:

1. Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.

2. HHS resources or interests are threatened.

3. Research activities should be suspended.

4. There is a reasonable indication of violations of civil or criminal law.

5. Federal action is required to protect the interests of those involved in the research misconduct proceeding.

6. RFMH determines that the research misconduct proceeding may be made public prematurely, so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved.

7. RFMH believes the research community or public should be informed.

Attachment 2: Terms Applicable to Research Funded by the National Science Foundation (NSF)

Allegations of Research Misconduct involving NSF funded research or applications for NSF funding shall also comply with the requirements of 45 CFR 689, including its reporting requirements.

Attachment 3: Template for Charge to the Inquiry Committee

(Content areas must be included in actual Charge)

To: Members of the Inquiry Committee (NAMES)

From: Research Integrity Committee (NAMES)

Subject: Allegation of Possible Research Misconduct

Date:

CONFIDENTIAL

Attached is documentation of the allegation of Research Misconduct and a copy of the RFMH Policies and Procedures for Responding to Allegations of Research Misconduct.

Name of Complainant(s):
Name of Respondent(s):
Study Title(s) with IRB/IACUC number(s) and grant number(s) if applicable:

In response to this allegation and any related issues identified during the initial assessment of the allegation the Research Integrity Committee is appointing an Inquiry Committee, comprised of NAMES OF INQUIRY COMMITTEE MEMBERS to review documentation, and to conduct such interviews as it deems necessary (at a minimum, the Respondent (if available), but typically also the Complainant and key witnesses) in order to make recommendations and determinations and provide a report to the Research Integrity Committee on its findings.

1. The Inquiry shall be completed within 45 days unless the Research Integrity Committee approves and documents the reasons behind its decision to grant an extension of time. *Note: the process of conducting an Inquiry, preparing the final report and reaching a decision on whether an Investigation is warranted should be completed within 60 days unless the Research Integrity Committee determines and documents the reasons for granting an extension.*

2. In addition to the issues raised by the Complainant the Inquiry Committee should address the following related issues that were identified by the Research Integrity Committee during its initial assessment of the allegation: SPECIFY

3. The purpose of the Inquiry is to conduct an initial review of the evidence, including, when necessary, 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.

4. An Investigation will be warranted if: (a) there is a reasonable basis for concluding that the allegation falls within the definition of Research Misconduct, and (b) the allegation may have substance, based upon the Inquiry Committee's review during the Inquiry.

5. You are responsible for preparing a written report of your findings and providing that report to the Research Integrity Committee. The report shall include the following:

    a. The name and position of the Respondent.

    b. A description of the allegations of Research Misconduct.

    c. A summary of the inquiry process used, including identification of records reviewed, summaries of persons interviewed.

    d. A listing of all research projects known to be involved including grant numbers, grant applications, contracts, publications and, when applicable, the associated IRB and/or IACUC numbers.

    e. The basis for recommending or not recommending that the allegations warrant an Investigation.

    f. Recommendations for other actions that might be appropriate if an Investigation is not recommended.

    g. Any comments on the draft report by the Complainant or the Respondent. The Respondent must be provided with a copy of your draft report and be provided a reasonable opportunity to review and provide written comments.

6. You must: (a) 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 (b) 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 Research Integrity Committee is available to you to offer guidance and arrange consultation with legal counsel if required.

cc: Institute/Facility Director
Managing Director

Attachment 4: Template for Charge to the Investigation Committee

(Content areas must be included in actual Charge)

To: Members of the Investigation Committee (NAMES)

From: Research Integrity Committee (NAMES)

Subject: Allegation of Possible Research Misconduct

Date:

CONFIDENTIAL

Based upon the findings of an Inquiry Committee a determination has been made that an Investigation of possible Research Misconduct is necessary. You are being appointed to carry out an investigation into the following allegations and related issues identified during the Inquiry and any related issues that arise during the course of your Investigation: DESCRIBE

A copy of the Inquiry Report and a copy of the RFMH Policies and Procedures for Responding to Allegations of Research Misconduct are attached.

The Investigation Committee shall 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 Research Misconduct and who was responsible.

In order to determine that Research Misconduct was committed you must find that a preponderance of the evidence establishes that:

a. Research Misconduct occurred (the Respondent has the burden of proving by a preponderance of the evidence any affirmative defenses raised);
b. The Research Misconduct is a significant departure from accepted practices of the relevant research community; and
c. The Respondent committed the Research Misconduct intentionally, knowingly or recklessly.

The Investigation Committee shall:

1. use diligent efforts to ensure that the Investigation is thorough and sufficiently documented and includes the examination of all Research records and evidence relevant to reaching a decision on the merits of the Allegation;
2. take reasonable steps to ensure an impartial and unbiased Investigation to the maximum extent practicable;

3. interview the Complainant, the Respondent 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;
4. pursue diligently all significant issues and leads discovered that are relevant to the Investigation;
5. 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
6. 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.

Preparation and Submission of Investigation Report:

Upon completion of the Investigation, the Investigation Committee shall provide the Respondent with (a) a draft written report (the "Investigation Report") of your findings and recommendations as to whether or not a finding of Research Misconduct should be made and, may include recommendations for corrective actions that would be appropriate under the circumstances and (b) a copy of, or supervised access to, the evidence on which the Investigation Report is based. The Investigation Committee shall also provide the Complainant with copies of those portions of the draft Investigation Report that are relevant to the Complainant. The Respondent and the Complainant may comment on the draft Investigation Report, provided that any such comments must be given to the Investigation Committee in writing within 30 days of receiving such draft.

Following the review by the Investigation Committee of any comments on the draft Investigation Report provided by the Respondent or the Complainant, the Investigation Committee shall provide the Research Integrity Committee with a final Investigation Report which shall be in the form of the attached Template for Investigation Report.

The Investigation Report shall include the following:

1. A description of the nature of the allegation of Research Misconduct, including identification of the Respondent.
2. A listing of all research projects known to be involved including grant numbers, grant applications, contracts, publications and, when applicable, the associated IRB and or IACUC numbers.
3. Identifies and summarizes the research records and evidence reviewed and identifies any evidence taken into custody but not reviewed.
4. Includes a statement of findings for each allegation of Research.

For each finding of Research Misconduct identified during the Investigation the Investigation Report 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 the 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 research support, including any PHS funding;
4. Identify whether any publications need correction or retraction;
5. Identify the person(s) responsible for the misconduct; and
6. List any current grant or contract support or known applications pending for support.

Your Investigation, including submission of your report to the Research Integrity Committee should be completed within 120 days of its initiation, except that the Research Integrity Committee may approve one or more reasonable extensions to the extent deemed necessary or appropriate.

The Research Integrity Committee is available to you to offer guidance and arrange consultation with legal counsel if required. Assistance can also be provided in arranging outside experts to consult with the Investigation Committee.

cc: Institute/Facility Director
Managing Director

Attachment 5: Template for Investigation Committee Report

RFMH TEMPLATE FOR INVESTIGATION REPORT

NOTE: Material in italics is either guidance or identifies what information needs to be inserted by the Investigation Committee. All italicized text should be deleted from the final report.

*The report should have the word "**CONFIDENTIAL**" included on each page of the report.*

Contents

I. Introduction

This Report documents the review and conclusions of the Investigation Committee (the "Committee") appointed to investigate allegations of Research Misconduct against *(insert number)* individual(s) at *(insert name of facility).*

The members of the Committee were appointed by the Research Integrity Committee on (*insert date*). The members of the Committee are:

> *Insert the names, degrees, title, and institutional affiliation of each member of the Committee.*
>
> *Drop a footnote naming any individual who acted as a staff member to the Committee and state that they staffed the Committee.*

None of the Committee members had any conflicts of interest that would have precluded their participation. The Committee conducted this Investigation pursuant to the Research Foundation for Mental Hygiene, Inc. Policies and Procedures for Responding to Allegations of Research Misconduct ("Research Misconduct Policy"). The Research Misconduct Policy is attached as Exhibit 1.

II. Background

A. Location

Describe and name the Lab, Department, program or other context within which the Research Misconduct is alleged to have occurred.

B. Complainant

Identify the Complainant. In the case of an anonymous Allegation, an Institutional Official may assume the role of Complainant for purposes of the Research Misconduct Investigation.

C. Respondent(s)

Identify the Respondent(s) and the nature of their affiliation with RFMH and the Department of Mental Hygiene, e.g. Respondent is a state employee, Research Scientist III at the x Institute in y Department and is a co- Investigator on the grant supporting the research.

D. Allegation

Identify the date on which the Allegation was made and to whom the Allegation was made. If the Allegation was not made directly to the Research Integrity Committee (RIC) specify when it was provided to the RIC.

The Allegation is attached as Exhibit 2. The Allegation consists of *describe the nature and format of the Allegation, e.g., a letter and a CD containing copies of supporting documents.*

Describe the substance of the Allegation.

E. Research Projects and Funding

Provide a listing of all research projects known to be involved and, for each, include the grant number(s), Principal Investigator(s), any pending grant applications, contracts, publications and, when applicable, the associated IRB and/or IACUC numbers.

F. Sequestration of Research Records

Describe the process used by the RIC, Inquiry Committee and Investigation Committee to identify, sequester and secure relevant records and other evidence. Describe the method used to inventory and track records and other evidence, including transcripts and/or recordings of interviews. Summarize the items sequestered and, if appropriate, attach a log of documents and other evidence to this report as Exhibit 3.

III. The Investigation

A. Charge to the Investigation Committee

State the Charge to the Investigation Committee and attach the Charge document as Exhibit 4.

Reference the findings of the Inquiry Committee and attach the Inquiry Committee Report as Exhibit 5.

B. Process of the Investigation

Identify the steps taken in the Investigation, including review of the Inquiry Report, records and other evidence reviewed, interviews conducted. Also identify any evidence that was taken into custody but not reviewed.

C. Review

The Committee's review is summarized below:

Provide a detailed summary of the review of materials.

D. Findings

*For **each** Allegation of Research Misconduct that the Committee was charged to review, including those identified during the Investigation, the Committee shall state whether or not the Committee determines that Research Misconduct occurred and, for any findings of Research Misconduct:*

1. Identify whether the Research Misconduct was falsification, fabrication, or plagiarism, identify the person(s) responsible, and for each whether it was committed intentionally, knowingly, or recklessly; and

2. Summarize the facts and the analysis that support the conclusions and consider the merits of any reasonable explanation by the Respondent, including any effort by the 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. Provide references to the documents and other evidence, including transcripts and/or recordings of interviews used to reach the conclusions; and

3. Identify the specific research grant or contract support and any known applications pending for such support, and identify the sponsor; and

4. Identify whether any publications need correction or retraction; and

5. Recommend other corrective actions to address the actual and/or reasonably foreseeable consequences of the Research Misconduct.

IV. Respondent(s) Response to the Report

The Respondent(s) was/were provided with a copy of the above, including the attachments, and an opportunity to review the evidence on which this report is based. The Respondent(s) was/were provided 30 days to submit written response(s) which is attached as Exhibit 6.

V. Response of the Committee

The Committee reviewed the response*(s)* of the Respondent*(s)*. *Address the relevant issues raised by the Respondent(s). If any Findings are revised, provide the restated Finding(s), including any revisions to the recommended corrective actions.*

VI. Conclusion

Based on its Investigation, and in accordance with the Research Misconduct Policy, the Committee concludes *concisely summarize the broad findings.*

VII. Signatures of the Committee Members

(Insert Date)

_____
Insert Committee member name

_____
Insert Committee member name

_____
Insert Committee member name

_____
Insert Committee member name

_____
Insert Committee member name

VIII. List of Exhibits