



STATE OF CONNECTICUT
Department of Mental Health & Addiction Services



Commissioner's Policy Statement and Implementing Procedures

SUBJECT:	Policy on Misconduct in Research
P & P NUMBER:	Chapter 8.3
APPROVED:	Miriam Delphin-Rittmon, Commissioner Date: 10/15/2015
EFFECTIVE DATE:	October 15, 2015 <i>Miriam Delphin-Rittmon</i>
REVISED:	6/1/2011, replaced Commissioner's Policy Statement No. 75 02/28/97
REFERENCES:	Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93
FORMS AND ATTACHMENTS:	

STATEMENT OF PURPOSE: The purpose of this policy is to outline expectations regarding the reporting of suspected research misconduct, as well as the manner in which reported research misconduct is investigated and acted upon; in order to maintain the integrity of research and to foster a climate conducive to such scientific integrity; and in order to comply with federal regulations regarding research misconduct.

POLICY: The Department of Mental Health & Addiction Services (DMHAS) is committed to fulfilling its responsibilities under the Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93. This policy applies to allegations of research misconduct (fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results) as outlined at 42 CFR 93.103 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 this institution, and whose conduct is not subject to review by another institution; and
- Received federal funding for research activities at the DMHAS, or state funding for research activities, including support for biomedical or behavioral research, research training or activities related to that research or research training; (2) Submitted applications or proposals for support of biomedical or behavioral research, research training or activities related to

that research or research training involving the DMHAS, or (3) Produced research records, research training or activities related to that research or research training in the DMHAS facilities. This includes any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application or proposal resulted in a grant, contract, cooperative agreement, or other form of support.

This policy does not apply to authorship or collaboration disputes and applies only to allegations of research misconduct that occurred within six years of the date the institution received the allegation, subject to the subsequent use, health or safety of the public, and grandfather exceptions in 42 CFR § 93.105(b).

Definitions:

Terms used have the same meaning as given them in the Public Health Service Policies on Research Misconduct, 42 CFR Part 93.

I. GENERAL POLICIES AND PRINCIPLES:

A. Appointment of Research Integrity Officer

The Research Integrity Officer is appointed by the Commissioner of the DMHAS and will have primary responsibility for implementation of the institution's policies and procedures on research misconduct.

B. Responsibility to Report Misconduct

All institutional members will report observed, suspected, or apparent research misconduct to the RIO. 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 to discuss the suspected research misconduct informally, which may include discussing it 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.

At any time, an institutional member may have confidential discussions and consultations about concerns of possible misconduct with the RIO and will be counseled about appropriate procedures for reporting allegations.

C. 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.

D. 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.

E. Protecting Complainants, Witnesses, and Committee Members

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.

F. 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 institution. Respondents may consult with legal counsel or a non-lawyer 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.

G. Interim Administrative Actions

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 federally supported research process. In the event of such a threat, the RIO will, in consultation with other institutional officials and, if federally funded, the Office of Research Integrity (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;
- The DMHAS or federal 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 federal action may be necessary to safeguard evidence and protect the rights of those involved; or
- The research community or public should be informed.

II. RIGHTS AND RESPONSIBILITIES

A. Research Integrity Officer

These responsibilities of the RIO include the following duties related to research misconduct proceedings:

- Consult confidentially with persons uncertain about whether to submit an allegation of research misconduct;
- Receive allegations of research misconduct;
- Assess each allegation of research misconduct in accordance with Section V.A of this policy to determine whether it falls within the definition of research misconduct and warrants an inquiry;
- As necessary, take interim action and when research involved federal funding, notify ORI of special circumstances, in accordance with Section III.G of this policy;
- Sequester research data and evidence pertinent to the allegation of research misconduct in accordance with Section V.C. of this policy and maintain it securely in accordance with this policy and applicable law and regulation;

- Provide confidentiality to those involved in the research misconduct proceeding as required by 42 CFR § 93.108, other applicable law, and institutional policy;
- Notify the respondent and provide opportunities for him/her to review/comment/respond to allegations, evidence, and committee reports in accordance with Section IV.C of this policy;
- Inform respondents, complainants, and witnesses of the procedural steps in the research misconduct proceeding;
- Appoint the chair and members of the inquiry and investigation committees, ensure that those committees are properly staffed and that there is expertise appropriate to carry out a thorough and authoritative evaluation of the evidence;
- Determine whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional, or financial conflict of interest and take appropriate action, including recusal, to ensure that no person with such conflict is involved in the research misconduct proceeding;
- In cooperation with other institutional officials, take all reasonable and practical steps to protect or restore the positions and reputations of good faith complainants, witnesses, and committee members and counter potential or actual retaliation against them by respondents or other institutional members;
- Keep the Commissioner and others who need to know apprised of the progress of the review of the allegation of research misconduct;
- Notify and make reports to ORI as required by 42 CFR Part 93;
- Ensure that administrative actions taken by the institution and ORI are enforced and take appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards of those actions; and
- Maintain records of the research misconduct proceeding and make them available to ORI in accordance with Section VIII.F of this policy.

B. Complainant

The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the inquiry and investigation. As a matter of good practice, the complainant should be interviewed at the inquiry stage and given the transcript or recording of the interview for correction. The complainant must be interviewed during an investigation, and be given the transcript or recording of the

interview for correction. When deemed appropriate, DMHAS may provide to the complainant for comment: (1) relevant portions of the inquiry report (within a timeframe that permits the inquiry to be completed within 60 days of its initiation); and (2) the draft investigation report or relevant portions of it. The institution must require that comments on the draft investigation report be submitted within 30 days of the date on which the complainant received the draft report. The institution must consider any comments made by the complainant on the draft investigation report and include those comments in the final investigation report.

C. Respondent

The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry and investigation. The respondent is entitled to:

- A good faith effort from the RIO to notify the respondent in writing at the time of or before beginning an inquiry;
- An opportunity to comment on the inquiry report and have his/her comments attached to the report;
- Be notified of the outcome of the inquiry, and receive a copy of the inquiry report that includes a copy of, or refers to 42 CFR Part 93 and the DMHAS policies and procedures on research misconduct;
- Be notified in writing of the allegations to be investigated within a reasonable time after the determination that an investigation is warranted, but before the investigation begins (within 30 days after the institution decides to begin an investigation), and be notified in writing of any new allegations, not addressed in the inquiry or in the initial notice of investigation, within a reasonable time after the determination to pursue those allegations;
- Be interviewed during the investigation, have the opportunity to correct the recording or transcript, and have the corrected recording or transcript included in the record of the investigation;
- Have interviewed during the investigation any witness who has been reasonably identified by the respondent as having information on relevant aspects of the investigation, have the recording or transcript provided to the witness for correction, and have the corrected recording or transcript included in the record of investigation; and
- Receive a copy of the draft investigation report and, concurrently, a copy of, or supervised access to the evidence on which the report is based, and be notified that any comments must be submitted within 30 days of the date on which the copy was received and that the comments will be considered by the institution and addressed in the final report.

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 RIO and/or other institutional officials, the Commissioner may terminate the institution's review of an allegation that has been admitted, if the institution's acceptance of the admission and any proposed settlement is approved by ORI.

D. Commissioner

As the deciding official, the Commissioner will receive the inquiry report and after consulting with the RIO and/or other institutional officials, decide whether DMHAS has jurisdiction in relation to the alleged research misconduct and whether an investigation is warranted under the criteria in 42 CFR § 93.307(d) as follows:

- There is a reasonable basis for concluding that the allegation falls within the definition of research misconduct;
- Preliminary information-gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance.

Any finding that an investigation is warranted must be made in writing by the Commissioner and where federal funding is involved, must be provided to ORI, together with a copy of the inquiry report meeting the requirements of 42 CFR § 93.309, within 30 days of the finding. If it is found that an investigation is not warranted, the Commissioner and the RIO will ensure that detailed documentation of the inquiry is retained for at least 7 years after termination of the inquiry, in case ORI or other affected agencies need to review the decision.

The Commissioner will receive the investigation report and, after consulting with the RIO and/or other institutional officials, decide the extent to which DMHAS accepts the findings of the investigation and, if research misconduct is found, decide what, if any, institutional administrative actions are appropriate. If the research was federally funded, the Commissioner shall ensure that the final investigation report, the findings of the Commissioner and a description of any pending or completed administrative actions are provided to ORI, as required by 42 CFR § 93.315.

III. CONDUCTING THE ASSESSMENT AND INQUIRY

A. 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 outlined in Section I.B of this policy and whether the allegation falls within the definition of research misconduct in 42 CFR § 93.103. Unless the respondent is covered under a different institution's research misconduct policy, an inquiry must be conducted if these criteria are met. If the

respondent is covered under a different institution's research policy, the RIO must report the allegation to that institution.

The assessment period should be brief, preferably 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, as provided in paragraph C of this section.

B. 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.

C. 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.

D. Appointment of the Inquiry Committee

The RIO, in consultation with other institutional officials as appropriate, will 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 at least one individual 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.

E. 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 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 as outlined in Section I.B of this policy 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.

F. 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. 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, if the research in question was federally funded, the institution shall promptly consult with ORI to determine the next steps that should be taken.

G. Time for Completion

The inquiry, including preparation of the final inquiry report and the decision of the

Commissioner 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.

IV THE INQUIRY REPORT

A. Elements of the Inquiry Report

A written inquiry report must be prepared that conforms to 42 CFR 93.309 and includes the following information:

- The name and position of the respondent;
- A description of the allegations of research misconduct;
- State or federal support, including, for example, grant numbers, grant applications, contracts and publications listing support;
- The basis for recommending or not recommending that the allegations warrant an investigation;
- Any comments on the draft report by the respondent or complainant.

Institutional counsel should 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 also include:

- Names and titles of the committee members and experts who conducted the inquiry;
- Summary of the inquiry process used;
- List of the research records reviewed;
- Summaries of any interviews; and
- Whether any other actions should be taken if an investigation is not recommended.

B. 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 business days following completion of the report, and include a copy of or refer to 42 CFR Part 93 and the DMHAS policy and procedures on research misconduct. When deemed appropriate the RIO may notify the complainant whether the inquiry found an investigation to be warranted and provide relevant portions of the inquiry report to the complainant for comment within 10 business days. A confidentiality agreement should be a condition for access to the report.

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.

C. Institutional Decision and Notification

1. Decision by Commissioner

The RIO will transmit the final inquiry report and any comments to the Commissioner, who will determine in writing whether an investigation is warranted. The inquiry is completed when the Commissioner makes this determination.

2. Notification to ORI

For federally funded research, the RIO will provide ORI with the Commissioner's written decision and a copy of the inquiry report within 30 calendar days of the decision that an investigation is warranted. The RIO will also notify those institutional officials who need to know of the Commissioner'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.

3. Documentation of Decision Not to Investigate

If the Commissioner decides that an investigation is not warranted, the RIO shall secure and maintain for 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 HHS personnel upon request.

V. CONDUCTING THE INVESTIGATION

A. Initiation and Purpose

The investigation must begin within 30 calendar days after the determination by the Commissioner 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.

B. Notifying ORI and Respondent; Sequestration of Research Records

Where the research involved is federally funded, 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, on or before the date on which the investigation begins. 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 investigation 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 institution'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.

C. 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. When necessary to secure the necessary expertise or to avoid conflicts of interest, the RIO may select committee members from outside the institution.

The RIO will notify the respondent of the proposed committee membership in order to give the respondent an opportunity to object to a proposed member based upon a personal, professional, or financial conflict of interest. Any objection by the respondent must be submitted in writing within 10 calendar days. The RIO, in consultation with other institutional officials as appropriate, will make the final determination as to whether a conflict exists.

D. Charge to the Committee and the First Meeting

1. 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;
- Informs the committee that it must conduct the investigation as prescribed in paragraph E of this section;
- 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.

2. 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.

E. 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, and continue the investigation to completion.

F. 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, where appropriate. However, if the RIO determines that the investigation will not be completed within this 120-day period and the research is federally funded, 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.

VI. THE INVESTIGATION REPORT

A. 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 of research misconduct, including identification of the respondent;
- Describes and documents federal support, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing federal support;
- Describes the specific allegations 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 federal support; (4) identify whether any publications need correction or retraction; (5) identify the person(s) responsible for the misconduct; and (6) list any current federal support or known applications or proposals for support that the respondent has pending with federal agencies.

B. Comments on the Draft Report and Access to Evidence

1. 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.

2. Complainant

When deemed appropriate the RIO may provide the complainant a copy of the draft investigation report, or relevant portions of it, for comment. If this option is employed, 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. See 42 CFR §§ 93.312(b) and 93.313(g).

3. Confidentiality

In distributing the draft report, or portions thereof, to the respondent and complainant 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. For example, the RIO may require that the recipient sign a confidentiality agreement.

C. Decision by Commissioner

The RIO will assist the investigation committee in finalizing the draft investigation report, including ensuring that the respondent's and complainant's comments are included and considered, and transmit the final investigation report to the Commissioner, who will determine in writing: (1) whether the institution 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 Commissioner 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 Commissioner 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 Commissioner 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.

VII. RECONSIDERATION OF INVESTIGATION COMMITTEE FINDINGS

A. Where the investigation committee determines that misconduct has occurred, the respondent may request a reconsideration of such findings; and the following procedures will be followed:

B. Respondent

- Within 10 calendar days of issuance of the investigation report, forward a written request for reconsideration to the RIO;
- Outline the rationale for requesting a reconsideration of findings, including any additional supporting information.

C. RIO

- Within 10 calendar days of receipt, forward acknowledgement of receipt to respondent and notify the Commissioner and the investigation committee of the request for reconsideration;
- Within 30 calendar days convene a meeting of the investigation committee to review the request and original investigation report, and to develop a

specific plan to proceed based upon the information provided in the request for reconsideration;

D. Investigation Committee and RIO

- Ensure that the reconsideration process is thorough and includes evaluation of any additional records or evidence presented by the respondent;
- As deemed warranted by the investigation committee, interview the respondent and any other available person who reasonably appears to have information relevant to the request for reconsideration;
- Based upon information obtained during the reconsideration process, recommend either upholding, overturning or modifying the original findings;
- Complete a written reconsideration report within the 120 day period for completing the investigation, unless an extension is deemed necessary; in which case ORI approval will be sought for such extension where necessary.

E. Decision by Commissioner

- The RIO will transmit the investigation committee's written recommendation to the Commissioner, who will determine, in writing, whether the DMHAS will accept the recommendations of the committee. If the decision varies from the committee's recommendations, the Commissioner will provide a written explanation for reaching a different decision.
- When the Commissioner has reached a final reconsideration decision, the RIO will notify the respondent in writing of the decision. Where a decision has been reversed, the RIO will normally notify the complainant.

F. 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 where the research involved federal funding:

- A copy of the final investigation report with all attachments and any appeal;
- A statement of whether the DMHAS accepts the findings of the investigation report or the outcome of the appeal;
- A statement of whether the DMHAS found misconduct and, if so, who committed the misconduct; and

- A description of any pending or completed administrative actions against the respondent.

VIII 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 federal agencies 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 institution’s handling of such an allegation.