SMG 9003.1

FDA STAFF MANUAL GUIDES, VOLUME IV - AGENCY PROGRAM DIRECTIVES

GENERAL OR MULTIDISCIPLINE

POLICY FOR RESPONDING TO ALLEGATIONS OF RESEARCH MISCONDUCT

Effective Date: 04/09/2012

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Appendix A - Research Integrity Officer Responsibilities

1. PURPOSE

The purpose of this Staff Manual Guide (SMG) is to provide the policy and procedures for processing and reviewing allegations of research misconduct levied against a Food and Drug Administration (FDA) employee involved in intramural research or a person who is an agent of, or affiliated by contract or agreement with FDA.

This policy is intended to carry out FDA 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, recording, or reviewing research, or in reporting research results) involving:

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- 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[1] with FDA; and

- FDA supported biomedical or behavioral research, research training or activities related to that research or research training, such as (1) the operation of tissue and data banks and the dissemination of research information, (2) applications or proposals for FDA support for biomedical or behavioral research, research training or activities related to that research or research training, or (3) research records produced in the course of FDA supported research, research training or activities related to that research or research training. This includes any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application or proposal for FDA funds resulted in a grant, contract, cooperative agreement, or other form of FDA support.[2]

This policy and the associated 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 the institution or HHS (Health and Human Services) received the allegation, subject to the subsequent use, health or safety of the public, and grandfather exceptions in 42 CFR § 93.105(b).

2. GENERAL POLICY AND PROCEDURES

A. Responsibility to Report Misconduct

All FDA employees shall report observed, suspected, or apparent research misconduct to the AIRIO. Any FDA official who receives an allegation of research misconduct must report it immediately to the AIRIO. 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 FDA AIRIO 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 AIRIO will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

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

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B. Cooperation with Research Misconduct Proceedings

FDA employees will cooperate with the AIRIO and other FDA officials in the review of allegations and the conduct of inquiries and investigations. Employees, including respondents, are required to cooperate in an official administrative investigation and have an obligation to provide evidence relevant to research misconduct allegations to the AIRIO or other FDA officials.

FDA in responding to allegations of research misconduct will be responsible for ensuring that each person involved in carrying out any part of the research misconduct proceedings do not have unresolved personal, professional, or financial conflicts of interest with the complainant, respondent or witnesses.

C. Confidentiality

The AIRIO shall, as required by 42 CFR § 93.108: limit disclosure of the identity of respondents and complainants, to the extent possible, to those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding, and as allowed by applicable law. However, FDA must disclose the identity of respondents and complainants to HHS's ORI pursuant to an ORI assessment of research misconduct under 42 CFR § 93.402(g) and ORI review of research misconduct proceedings under 42 CFR § 93.403. In addition, an HHS administrative hearing under 42 CFR § 93.517 must be open to the public. Furthermore, except as otherwise prescribed by applicable law, confidentiality must be maintained for any records or evidence from which research subjects may be identified. Disclosure of any records or evidence from which research subjects might be identified will be limited to those who need to know in order to carry out a research misconduct proceeding except as prescribed by applicable law or procedure.

In defending him/herself against an administrative personnel action taken against an employee for scientific misconduct, the employee will be entitled to see all supporting documents and evidence relied upon to propose and decide the action. This includes disclosure of the complainant's identity and all allegations made against the employee. If the adverse action is appealed to the Merit Systems Protection Board (MSPB or an arbitrator), the supporting documents and evidence relied upon must be released to the MSPB or arbitrator. Redacted documents may be submitted as appropriate. The servicing Bethesda Human Resources Center (BHRC) Labor and Employee Relations Specialist (LER) and the Office of General Counsel (OGC) will assist the Agency with this matter

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The AIRIO will use written confidentiality agreements or other mechanisms to ensure that any recipients of confidential information (i.e. those who need to know in order to carry out the research misconduct proceeding) do not make any disclosure of identifying information inconsistent with these policies and/or applicable law. To the extent possible, FDA will provide confidentiality for witnesses when the circumstances indicate that the witnesses may be harassed or otherwise need protection.

Any disclosures of the research misconduct proceeding records, evidence and outcome shall be governed by applicable law and regulations, including the Privacy Act of 1974, 5 U.S.C. 552a, and the routine uses specified in the applicable HHS/FDA Systems of Records Notice related to research misconduct proceedings.

D. Protecting complainants, witnesses, and committee members

FDA employees may not retaliate in any way against complainants, witnesses, or committee members. Employees should immediately report any alleged or apparent retaliation against a complainants, witnesses or committee members to the AIRIO, who shall review the matter and, as necessary, make all reasonable and practical efforts to counter any potential or actual retaliation and protect and restore the position and reputation of the person against whom the retaliation is directed.

E. Protecting the Respondent

As requested and as appropriate, the AIRIO and other FDA 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.[30]

During the research misconduct proceeding, the AIRIO is responsible for ensuring that respondents receive all the notices and opportunities provided for in 42 CFR Part 93 and the policy 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. FDA will permit lawyers to be present at interviews and meetings. However, it will restrict the lawyer's role to advising (as opposed to representing) the respondent. FSLMR and the Collective Bargaining Agreement (CBA) allow BUEs to have a union representative present for these interviews if the employee requests it.

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F. Interim Administrative Actions and Notifying ORI of Special Circumstances

Throughout the research misconduct proceeding, the AIRIO will review the situation to determine if there is any threat of harm to public health, federal funds and equipment, or the integrity of the PHS supported research process. In the event of such a threat, the AIRIO will, in consultation with other institutional officials and ORI, take appropriate interim action to protect against any such threat.[31] 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 AIRIO shall, at any time during a research misconduct proceeding, notify ORI immediately, and when appropriate FDA's OCI, HHS OIG and other law enforcement agencies, if he/she has reason to believe that any of the following conditions exist:[32]

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

3. DEFINITIONS

A. *Agency Intramural Research Integrity Officer* (AIRIO) means the institutional official responsible for: (1) assessing allegations of research misconduct to determine if they fall within the definition of research misconduct, are covered by 42 CFR Part 93, and warrant an inquiry on the basis that the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified; and (2)

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overseeing inquiries and investigations; and (3) the other responsibilities described in this policy.

B. *Allegation* means a disclosure of possible research misconduct through any means of communication. The disclosure may be by written or oral statement or other communication to an FDA or HHS official.[3]

C. *Complainant* means a person who in good faith makes an allegation of research misconduct.[4]

D. *Deciding Official* (DO) means the institutional FDA official who makes final determinations on allegations of research misconduct and any FDA administrative actions. The Deciding Official will not be the same individual as the Agency Intramural Research Integrity Officer and should have no direct prior involvement in the institution's inquiry, investigation, or allegation assessment. A Deciding Official's appointment of an individual to assess allegations of research misconduct, or to serve on an inquiry or investigation committee, is not considered to be direct prior involvement.

E. *Evidence* means any document, tangible item, or testimony offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact.[5]

F. *Good faith* as applied to a complainant or witness, means having a belief in the truth of one's allegation or testimony that a reasonable person in the complainant's or witness's position could have based on the information known to the complainant or witness at the time. An allegation or cooperation with a research misconduct proceeding is not in good faith if it is made with knowing or reckless disregard for information that would negate the allegation or testimony.[6]

G. *HHS* means the United States Department of Health and Human Services.

H. *Inquiry* means preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures of 42 CFR §§ 93.307-93.309.[7]

I. *Institutional member* means a person who is employed by, is an agent of, or is affiliated by contract or agreement with an institution. Institutional members may include, but are not limited to, officials, tenured and untenured faculty, teaching and support staff, researchers, research coordinators, clinical technicians, postdoctoral and other fellows, students, volunteers, agents, and contractors, subcontractors, and subawardees, and their employees.[8]

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J. *Investigation* means the formal development of a factual record and the evaluation of all relevant facts to determine if misconduct occurred and, if so, to determine the responsible person and the seriousness of the misconduct.[9]

K. *Office of Research Integrity* or *ORI* means the office to which the HHS Secretary has delegated responsibility for addressing research integrity and misconduct issues related to PHS supported activities.[10]

L. *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.[11]

M. *Public Health Service* or *PHS* means the unit within HHS that includes the Office of Public Health and Science and the following Operating Divisions: Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and the Substance Abuse and Mental Health Services Administration, and the offices of the Regional Health Administrators.[12]

N. *PHS support* means PHS funding, or applications or proposals therefore, for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training, that may be provided through: PHS grants, cooperative agreements, inter-agency agreements, or contracts or subgrants or subcontracts under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements or contracts.[13]

O. *Records of research misconduct proceedings* means: (1) the research records and evidence secured for the research misconduct proceeding pursuant to this policy and 42 CFR §§ 93.305, 93.307(b), and 93.310(d), except to the extent the Research Integrity Officer determines and documents that those records are not relevant to the proceeding or that the records duplicate other records that have been retained; (2) the documentation of the determination of irrelevant or duplicate records; (3) the inquiry report and final documents (not drafts) produced in the course of preparing that report, including the documentation of any decision not to investigate, as required by 42 CFR § 93.309(c); (4) the investigation report and all records (other than drafts of the report) in support of the report, including the recordings or transcripts of each interview conducted; and (5) the complete record of any appeal within the institution from the finding of research misconduct.[14]

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P. *Research misconduct* means fabrication, falsification, or plagiarism in proposing, performing, recording, or reviewing research, or in reporting research results. *Fabrication* is making up data or results and recording or reporting them. *Falsification* is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record. *Plagiarism* is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. Research misconduct does not include honest error or differences of opinion.[15]

Q. *Research misconduct proceeding* means any actions related to alleged research misconduct that is within 42 CFR Part 93, including but not limited to, allegation assessments, inquiries, investigations, ORI oversight reviews, hearings and administrative appeals.[16]

R. *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, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to HHS or an institutional official by a respondent in the course of the research misconduct proceeding.[17]

S. *Respondent* means the person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.[18]

T. *Retaliation* means an adverse action taken against a complainant, witness, or committee member by FDA or one of its institutional members in response to (1) a good faith allegation of research misconduct; or (2) good faith cooperation with a research misconduct proceeding.[19]

4. RIGHTS AND RESPONSIBILITIES

A. Agency Intramural Research Integrity Officer

The FDA Deciding Official will appoint the AIRIO who will have primary responsibility for implementation of the FDA's policy and procedures on research misconduct. The AIRIO will be an FDA official who is well qualified to administer the procedures and is sensitive to the varied demands made on those who conduct research, those who are accused of research misconduct, those who make good faith allegations of research misconduct, and those who may serve on inquiry and investigation committees.

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A detailed listing of the responsibilities of the AIRIO is set forth in Appendix A. These responsibilities 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 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 notify ORI and other HHS officials of special circumstances, in accordance with Section 4.F. of this policy;
- As necessary, notify FDA's OCI, ORI, and HHS's Office of the Inspector General if there is an appearance of criminal wrongdoing;
- Ensure that administrative actions taken by the FDA 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;
- Sequester research data and evidence pertinent to the allegation of research misconduct in accordance with Section 5.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 3.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 committee; ensure that those committees are properly staffed and that there is expertise appropriate to carry out a thorough and authoritative evaluation of the evidence;

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- 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 FDA 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 agency members;

- In cooperation with other FDA officials, take all reasonable and practical steps to protect or restore the positions and reputations of those alleged to have engaged in research misconduct, but against whom no finding of research misconduct is made;

- Keep the DO and others who need to know generally apprised of the progress of the review of the allegation of research misconduct without directly involving them;

- Notify and make reports to ORI as required by 42 CFR Part 93; and

- Maintain records of the research misconduct proceeding and make them available to ORI in accordance with Section 8.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.[20] As a policy applicable on a case-by-case basis, the FDA 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 calendar days of its initiation); and (2) the draft investigation report or relevant portions of it. If the complainant elects to submit comments on the draft investigation report, the comments must be submitted within 30 calendar days of the date on which the complainant received the draft report. FDA must consider any comments made by the complainant on the draft investigation report and include those comments in the final investigation report.

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C. Respondent

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

- A good faith effort from the AIRIO to notify the respondent in writing at the time of or before beginning an inquiry;[21]

- An opportunity to comment on the inquiry report and have his/her comments attached to the report;[22]

- 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 FDA's policy and procedures on research misconduct;[23]

- 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 calendar 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;[24]

- 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; [25]

- Consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice or bring the counsel or personal advisor to interviews or meetings on the case. FDA will permit lawyers to be present at interviews or meetings. However, it will restrict the lawyer's role to advising (as opposed to representing) the respondent. Under the Federal Service Labor-Management Relations Statute (FSLMRS), bargaining unit employees (BUE) have a right to union representation during investigative interviews conducted by a representative of the Agency.

- 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;[26] 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

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based, and be notified that any comments must be submitted within 30 calendar 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.[27]

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 AIRIO and institutional legal counsel, the Deciding Official may terminate the agency's review of an allegation that has been admitted if FDA's acceptance of the admission and any proposed settlement is approved by ORI.[28]

The settlement agreement should be reviewed by the Bethesda Human Resources Center (BHRC) Labor and Employee Relations Division (LERD).

As provided in 42 CFR § 93.314(a), the respondent shall have the opportunity to request an agency appeal.

D. Deciding Official

The DO will receive the inquiry report and after consulting with the AIRIO, decide whether an investigation is warranted under the criteria in 42 CFR § 93.307(d). Any finding that an investigation is warranted must be made in writing by the DO and must be provided to ORI, together with a copy of the inquiry report meeting the requirements of 42 CFR § 93.309, within 30 calendar days of the finding. If it is found that an investigation is not warranted, the DO and the AIRIO will ensure that detailed documentation of the inquiry is retained for at least 7 years after termination of the inquiry, so that ORI may assess the reasons why the institution decided not to conduct an investigation.[29]

The DO will receive the investigation report and, after consulting with the AIRIO and other appropriate officials, decide the extent to which FDA accepts the findings of the investigation and, if research misconduct is found, decide what, if any, institutional administrative actions are appropriate.

The DO shall ensure that the final investigation report, the findings of the DO and a description of any pending or completed administrative action are provided to ORI, as required by 42 CFR § 93.315. Consistent with 42 CFR §93.102, these procedures do not supersede or establish an alternative to any existing regulations or procedures for handling personnel actions against Federal employees. Therefore, if the DO accepts the findings of research misconduct, and if no appeals are filed challenging the findings of research misconduct, or respondent has

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otherwise exhausted his/her appeal, the DO may refer the matter to the respondent's appropriate supervisor(s) for consideration of appropriate action, which may include an official reprimand, suspension or removal from Federal service. If the respondent is a Federal employee and disciplinary or adverse action is instituted, it must be done in compliance with the policies and laws under which the respondent was appointed and with due regard to any rights the respondent may have under the applicable collective bargaining agreement.

5. CONDUCTING THE ASSESSMENT AND INQUIRY

A. Assessment of Allegations

Upon receiving an allegation of research misconduct, the AIRIO will immediately assess the allegation to determine whether it is sufficiently credible and specific so that potential evidence of research misconduct may be identified, whether it is within the jurisdictional criteria of 42 CFR § 93.102(b), and whether the allegation falls within the definition of research misconduct in this policy and 42 CFR § 93.103.[33] An inquiry must be conducted if these criteria are met.

The assessment period should be brief, preferably concluded within a week. In conducting the assessment, the AIRIO 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 AIRIO 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 AIRIO 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.[34]

C. Notice to Respondent; Sequestration of Research Records

At the time of or before beginning an inquiry, the AIRIO 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

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notified, or the inquiry begins, whichever is earlier, the AIRIO must take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding and 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.[35] The AIRIO may consult with ORI for advice and assistance in this regard.

D. Appointment of the Inquiry Committee

The AIRIO, in consultation with other institutional officials as appropriate, will appoint an inquiry committee and committee chair within 10 calendar days of the initiation of the inquiry or as soon thereafter as practical. The inquiry committee will consist of the appropriate individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry.[36]

AIRIO may notify the respondent of the proposed committee membership to give the respondent an opportunity to object to a proposed member based upon a personal, professional, or financial conflict of interest. The period for submitting objections will be limited to no more than 10 calendar days. The AIRIO will make the final determination of whether a conflict exists.

E. Charge to the Committee and First Meeting

The AIRIO 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;

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- 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 of 42 CFR § 93.102(b); and, (2) the allegation may have substance, based on the committee's review during the inquiry; and

- 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 AIRIO 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 AIRIO will be present or be 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 examine relevant research records and materials. Then the inquiry committee will evaluate the evidence, including the testimony obtained during the inquiry. After consultation with the AIRIO, the committee members will decide whether an investigation is warranted based on the criteria in this policy and 42 CFR § 93.307(d). The scope of the inquiry is not required to and does not normally include deciding whether misconduct definitely occurred, determining definitely who committed the research misconduct, or conducting exhaustive interviews and analyses. However, if a legally sufficient admission of research misconduct is made by the respondent, misconduct may be determined at the inquiry stage if all relevant issues are resolved. In that case, the AIRIO shall promptly consult with ORI to determine the next steps that should be taken. See Section 9.

G. Time for Completion

The inquiry, including preparation of the final inquiry report and the decision of the DO on whether an investigation is warranted, must be completed within 60 calendar days of initiation of the inquiry, unless the AIRIO determines that circumstances clearly warrant a longer period. If the AIRIO approves an extension, the inquiry record must include documentation of the reasons for exceeding the 60-day period,[37] the respondent will be notified of the extension.

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6. THE INQUIRY REPORT

A. Elements of the Inquiry Report

A written inquiry report must be prepared that includes the following information: (1) the name and position of the respondent; (2) a description of the allegations of research misconduct; (3) the FDA support, including, for example, grant numbers, grant applications, contracts and publications listing FDA support; (4) the basis for recommending or not recommending that the allegations warrant an investigation; (5) any comments on the draft report by the respondent or complainant.[38]

A representative from HHS's Office of General Counsel will review the report for legal sufficiency. Modifications should be made as appropriate in consultation with the AIRIO and the inquiry committee.

The inquiry report will include: the names and titles of the committee members and experts who conducted the inquiry; a summary of the inquiry process used; a list of the research records reviewed; summaries of any interviews provided in accordance with the confidentiality section under IV (C) of this policy; and whether any other actions should be taken if an investigation is not recommended.

B. Notification to the Respondent and Opportunity to Comment

The AIRIO will notify the respondent whether the inquiry found an investigation to be warranted, include a copy of the draft inquiry report for comment and include a copy of or refer to 42 CFR Part 93 and FDA's policy and procedures on research misconduct.[39] The respondent's comments must be submitted within 10 calendar days of the date on which he/she received the draft report.

The AIRIO may also notify the complainant whether the inquiry found an investigation to be warranted and provide relevant and appropriate portions of the inquiry report to the complainant for comment. The complainant's comments must be submitted within 10 calendar days of the date on which he/she received the draft report. A confidentiality agreement is a condition for access to the report.

Any comments that are submitted 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 AIRIO.

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C. Institutional Decision and Notification

1. Decision by Deciding Official

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

2. Notification to ORI

   Within 30 calendar days of the DO's decision that an investigation is warranted, the AIRIO will provide ORI with the DO's written decision and a copy of the inquiry report. The AIRIO will also notify those institutional officials who need to know of the DO's decision. The AIRIO must provide the following information to ORI upon request: (1) the FDA's policy 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.[40]

3. Documentation of Decision Not to Investigate

   If the DO decides that an investigation is not warranted, the AIRIO 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.

7. CONDUCTING THE INVESTIGATION

A. Initiation and Purpose

The investigation must begin within 30 calendar days after the determination by the DO that an investigation is warranted.[41] 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

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policy, clinical practice, or public health practice. The findings of the investigation will be set forth in an investigation report.

B. Notifying ORI and Respondent; Sequestration of Research Records

On or before the date on which the investigation begins, the AIRIO must: (1) notify the ORI Director of the decision to begin the investigation and provide ORI a copy of the inquiry report; and (2) notify the respondent in writing of the allegations to be investigated. The AIRIO 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.[42]

The AIRIO will, prior to notifying the respondent of the allegations, take all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the research misconduct proceeding that were not previously sequestered during the inquiry. 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 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.[43]

C. Appointment of the Investigation Committee

The AIRIO, in consultation with other FDA officials as appropriate, will appoint an investigation committee and the committee chair within 10 calendar days of the beginning of the investigation or as soon thereafter as practical. The investigation committee will consist of individuals including appropriate members of the FDA Senior Science Council and others with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the respondent and complainant and conduct the investigation and who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the investigation. Duties of the committee include maintenance of total confidentiality of all allegations, proceedings and deliberations to within the confines of the proceedings/meetings held by the AIRO. Individuals appointed to the investigation committee may also have served on the inquiry committee.

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When necessary to secure the necessary expertise or to avoid conflicts of interest, the AIRIO may select committee members from outside FDA but within HHS.

AIRIO will notify the respondent of the proposed committee membership and give the respondent an opportunity to object to a proposed member based upon a personal, professional, or financial conflict of interest. AIRIO will limit the period for submitting objections to no more than 10 calendar days. The AIRIO will make the final determination of whether a conflict exists.

D. Charge to the Committee and the First Meeting

1. Charge to the Committee

   The AIRIO 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

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- 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 AIRIO 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 policy and 42 CFR Part 93. The AIRIO will be present or available throughout the investigation to advise the committee as needed.

E. Investigation Process

The AIRIO and the investigation committee 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;[44]

- Take reasonable steps to ensure a fair, impartial and unbiased investigation to the maximum extent practical;[45]

- Permit during the investigative process, the respondent to have a lawyer present in an advisory role; FSLMR and the Collective Bargaining Agreement (CBA) allows BUEs to have a union representative present for these interviews if the employee requests it.

- 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;[46] and

- Pursue diligently all significant issues and leads discovered that they determine to be relevant to the investigation, including any evidence of any additional instances of possible research misconduct, and continue the investigation to completion.[47]

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F. Time for Completion

The investigation is to be completed within 120 calendar days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft report for comment to the respondent and on a case-by-case basis to the complainant and sending the final report to ORI. However, if the AIRIO determines that the investigation will not be completed within this 120-day period, he/she will submit to ORI a written request for an extension, setting forth the reasons for the delay. The AIRIO 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.[48]

8. THE INVESTIGATION REPORT

A. Elements of the Investigation Report

The investigation committee and the AIRIO 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 complainant and respondent. (The respondent's C.V. or resume may be included as part of the identification.);

- Describes and documents the FDA support, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing FDA support;

- Describes the specific allegations of research misconduct considered in the investigation;

- Includes FDA's policy and procedures under which the investigation was conducted, unless the policy 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.[49] 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

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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 FDA support; (4) identify whether any publications need correction or retraction; (5) identify the person(s) responsible for the misconduct; and (6) list any current support or known applications or proposals for support that the respondent has pending with non-PHS federal agencies.[50]

B. Comments on the Draft Report and Access to Evidence

1. Respondent

   The AIRIO 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 calendar days from the date he/she received the draft report to submit comments to the AIRIO. The respondent's comments must be included and considered in the final report.[51]

2. Complainant

   As a policy applicable on a case-by-case basis, FDA may provide the complainant a copy of the draft investigation report, or relevant portions of it, for comment. The complainant's comments must be submitted within 30 calendar 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 AIRIO will inform the recipient(s) of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. For example, the AIRIO may require that the recipient(s) sign a confidentiality agreement. (Please refer to Confidentiality Section 4.C.)

C. Decision by Deciding Official

The AIRIO 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 DO, who will determine in writing: (1) whether the FDA accepts the investigation report, its findings, and the recommended agency actions; and (2) the appropriate agency actions in response to the accepted findings of research misconduct. If this

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determination varies from the findings of the investigation committee, the DO will, as part of his/her written determination, explain in detail the basis for rendering a decision different from the findings of the investigation committee. Alternatively, the DO may return the report to the investigation committee with a request for further fact-finding or analysis.

When a final decision on the case has been reached, the AIRIO will normally notify both the respondent and the complainant in writing. If the respondent chooses not to appeal or once the respondent has exhausted his appeal, and after informing ORI, the DO will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case. Any disclosure would be made as allowed by law and in compliance with the Privacy Act. Disclosure will also be in accordance with the Confidentiality provisions under **4. General Policies and Principles**. The AIRIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

D. Appeals

FDA's procedures will provide for an appeal process by the respondent that could result in a reversal or modification of the agency's findings of research misconduct. This process must be completed within 120 calendar days of the filing of the appeal, unless ORI finds good cause for an extension, based upon the agency's written request for an extension that explains the need for the extension. If ORI grants an extension, it may direct the filing of periodic progress reports in accordance with 42 CFR 93.314(c).

Consistent with 42 CFR §93.102, these procedures do not supersede or establish an alternative to any existing regulations or procedures for handling personnel actions against Federal employees. Accordingly, personnel actions must be done in compliance with the policies and laws under which the respondent was appointed and with due regard to any rights the respondent may have under the applicable collective bargaining agreement.

E. Notice to ORI of Institutional Findings and Actions

Unless an extension has been granted, the AIRIO must, within the 120-day period for completing the investigation or the 120-day period for completion of any appeal, submit the following to ORI: (1) a copy of the final investigation report with all attachments and any appeal; (2) a statement of whether the FDA accepts the findings of the investigation

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report or the outcome of the appeal; (3) a statement of whether the agency found misconduct and, if so, who committed the misconduct; and (4) a description of any pending or completed administrative actions against the respondent.[52]

F. Maintaining Records for Review by ORI

The AIRIO must maintain and provide to ORI upon request "records of research misconduct proceedings" as that term is defined by 42 CFR § 93.317. Unless custody has been transferred to HHS or ORI has advised in writing that the records no longer need to be retained, records of research misconduct proceedings must be maintained in a secure manner for 7 years after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation.[53] The AIRIO 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.[54.]

9. COMPLETION OF CASES; REPORTING PREMATURE CLOSURES TO ORI

Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently. The AIRIO must notify ORI in advance if there are plans to close a case at the inquiry, investigation, or appeal stage on the basis that respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except: (1) closing of a case at the inquiry stage on the basis that an investigation is not warranted; or (2) a finding of no misconduct at the investigation stage, which must be reported to ORI, as prescribed in this policy and 42 CFR § 93.315.[55]

10. INSTITUTIONAL ADMINISTRATIVE ACTIONS

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

- Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found;

- The DO initiating the process of removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment;

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- For disciplinary and adverse actions, the DO will consult with the servicing BHRC LER specialist to ensure that the proper procedures are followed when proposing and deciding official disciplinary and adverse actions against employees;

- Restitution of funds to the grantor agency as appropriate; and

- Other action appropriate to the employee's misconduct can be taken by FDA in accordance with the agency's personnel policies.

11. OTHER CONSIDERATIONS

A. Termination or Resignation Prior to Completing Inquiry or Investigation

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

If the respondent, without admitting to the misconduct, elects to resign his/her position after the institution receives an allegation of research misconduct, the assessment of the allegation will proceed, as well as the inquiry and investigation, as appropriate based on the outcome of the preceding steps. If the respondent refuses to participate in the process after resignation, the AIRIO 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.

B. Restoration of the Respondent's Reputation

Following a final finding of no research misconduct, including ORI concurrence where required by 42 CFR Part 93, the AIRIO will, at the request of the respondent and in consultation with the respondent, undertake all reasonable and practical efforts to restore the respondent's reputation.[56] Depending on the particular circumstances and the views of the respondent, the AIRIO should consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in any forum in which the allegation of research misconduct was previously publicized, and expunging all reference to the research misconduct allegation from the respondent's personnel file. Any agency actions to restore the respondent's reputation should first be approved by the DO.

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C. Protection of the Complainant, Witnesses and Committee Members

During the research misconduct proceeding and upon its completion, regardless of whether the FDA or ORI determines that research misconduct occurred, the AIRIO will undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any complainant who made allegations of research misconduct in good faith and of any witnesses and committee members who cooperate in good faith with the research misconduct proceeding.[57] The DO will determine, after consulting with the AIRIO, and with the complainant, witnesses, or committee members, respectively, what steps, if any, are needed to restore their respective positions or reputations or to counter potential or actual retaliation against them. The AIRIO is responsible for implementing any steps the DO approves.

D. Allegations Not Made in Good Faith

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

12. EFFECTIVE DATE

The effective date of this guide is April 9, 2012.

13. Document History – SMG 9003.1, Policy for Responding to Allegations of Research Misconduct

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	03/13/2012	N/a	Executive Secretary, FDA Management Council	Janet Woodcock, Chair, FDA Management Council

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ATTACHMENT A

Agency Intramural Research Integrity Officer Responsibilities

I. General

The AIRIO has lead responsibility for ensuring that FDA:

- Takes all reasonable and practical steps to foster a research environment that promotes the responsible conduct of research, research training, and activities related to that research or research training, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct.

- Has a written policy and procedures for responding to allegations of research misconduct and reporting information about that response to ORI, as required by 42 CFR Part 93.

- Complies with its written policy and procedures and the requirements of 42 CFR Part 93.

- Informs agency employees who are subject to 42 CFR Part 93 about its research misconduct policy and procedures and its commitment to compliance with the policy and procedures.

- Takes appropriate interim action during a research misconduct proceeding to protect public health, federal funds and equipment, and the integrity of the FDA supported research process.

- As necessary, notifies FDA's OCI and/or HHS's OIG if there is an appearance of criminal wrongdoing.

II. Notice and Reporting to ORI and Cooperation with ORI

The AIRIO has lead responsibility for ensuring that FDA:

- Notifies ORI immediately and when appropriate FDA's OCI, HHS OIG and other law enforcement agencies if, at any time during the research misconduct proceeding, it has reason to believe that health or safety of the public is at risk, HHS resources or interests are threatened, research activities should be suspended, there is 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 institution believes that the research misconduct proceeding may be made public prematurely, or the research community or the public should be informed.

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- Provides ORI with the written finding by the responsible FDA official that an investigation is warranted and a copy of the inquiry report, within 30 days of the date on which the finding is made.

- Notifies ORI of the decision to begin an investigation on or before the date the investigation begins.

- Within 120 calendar days of beginning an investigation, or such additional days as may be granted by ORI (or upon completion of any appeal made available by FDA) provides ORI with the investigation report, a statement of whether the agency accepts the investigation's findings, a statement of whether the agency found research misconduct and, if so, who committed it, and a description of any pending or completed administrative actions against the respondent.

- Seeks advance ORI approval if FDA plans to close a case at the inquiry, investigation, or appeal stage on the basis that the respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except the closing of a case at the inquiry stage on the basis that an investigation is not warranted or a finding of no misconduct at the investigation stage.

- Cooperates fully with ORI during its oversight review and any subsequent administrative hearings or appeals, including providing all research records and evidence under the agency's control, custody, or possession and access to all persons within its authority necessary to develop a complete record of relevant evidence.

III. Research Misconduct Proceeding

A. General

The AIRIO is responsible for:

- Promptly taking all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner.

- Taking all reasonable and practical steps to ensure the cooperation of respondents and other agency members with research misconduct proceedings, including, but not limited to their providing information, research records and evidence.

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- Providing confidentiality to those involved in the research misconduct proceeding as required by 42 CFR 93.108, other applicable law, and FDA policy.

- Determining whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional or financial conflict of interest and taking appropriate action, including recusal, to ensure that no person with such a conflict is involved in the research misconduct proceeding.

- Keeping the Deciding Official (DO) and others who need to know apprised of the progress of the review of the allegation of research misconduct.

- In cooperation with other agency officials, taking all reasonable and practical steps to protect or restore the positions and reputations of good faith complainants, witnesses, and committee members and to counter potential or actual retaliation against them by respondents or other agency members.

- Making all reasonable and practical efforts, if requested and as appropriate, 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.

- Assisting the DO in implementing his/her decision to take administrative action against any complainant, witness, or committee member determined by the DO not to have acted in good faith.

- Maintaining records of the research misconduct proceeding, as defined in 42 CFR 93.317, in a secure manner for 7 years after completion of the proceeding, or the completion of any ORI proceeding involving the allegation of research misconduct, whichever is later, unless custody of the records has been transferred to ORI or ORI has advised that the records no longer need to be retained.

- Ensuring that administrative actions taken by FDA and ORI are enforced and taking appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards, of those actions.

B. Allegation Receipt and Assessment

The AIRIO is responsible for:

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- Consulting confidentially with persons uncertain about whether to submit an allegation of research misconduct.

- Receiving allegations of research misconduct.

- Assessing each allegation of research misconduct to determine if an inquiry is warranted because the allegation falls within the definition of research misconduct, is within the jurisdictional criteria of 42 CFR 93.102(b), and is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

C. Inquiry

The AIRIO is responsible for:

- Initiating the inquiry process if it is determined that an inquiry is warranted.

- At the time of, or before beginning the inquiry, making a good faith effort to notify the respondent in writing, if the respondent is known.

- On or before the date on which the respondent is notified, or the inquiry begins, whichever is earlier, taking all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding, inventorying the records and evidence and sequestering 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 the instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.

- Appointing an inquiry committee and committee chair as soon after the initiation of the inquiry as is practical.

- Preparing a charge for the inquiry committee in accordance with the agency's policy and procedures.

- Convening the first meeting of the inquiry committee and at that meeting briefing the committee on the allegations, the charge to the committee, and the appropriate procedures for conducting the inquiry, including the need for confidentiality and for developing a plan for the inquiry, and assisting the committee with organizational and other issues that may arise.

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- Providing the inquiry committee with needed logistical support, e.g., expert advice, including forensic analysis of evidence, and clerical support, including arranging witness interviews and recording or transcribing those interviews.

- Being available or present throughout the inquiry to advise the committee as needed and consulting with the committee prior to its decision on whether to recommend that an investigation is warranted on the basis of the criteria in the agency's policy and procedures and 42 CFR 93.307(d).

- Determining whether circumstances clearly warrant a period longer than 60 calendar days to complete the inquiry (including preparation of the final inquiry report and the decision of the DO on whether an investigation is warranted), approving an extension if warranted, and documenting the reasons for exceeding the 60-day period in the record of the research misconduct proceeding.

- Assisting the inquiry committee in preparing a draft inquiry report, sending the respondent and the complainant a copy of the draft report for comment within a time period that permits the inquiry to be completed within the allotted time, taking appropriate action to protect the confidentiality of the draft report, receiving any comments from the respondent and the complainant, and ensuring that the comments are attached to the final inquiry report.

- Receiving the final inquiry report from the inquiry committee and forwarding it, together with any comments the AIRIO may wish to make, to the DO who will determine in writing whether an investigation is warranted.

- Within 30 calendar days of a DO decision that an investigation is warranted, providing ORI with the written finding and a copy of the inquiry report and notifying those agency officials who need to know of the decision.

- Notifying the respondent and the complainant whether the inquiry found an investigation to be warranted and including in the notice copies of or a reference to 42 CFR Part 93 and FDA's research misconduct policy and procedures.

- Providing to ORI, upon request, FDA's policy and procedures under which the inquiry was conducted, the research records and evidence reviewed, transcripts or recordings of any interviews, copies of all relevant documents, and the charges to be considered in the investigation.

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- If the DO decides that an investigation is not warranted, securing and maintaining 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.

D. Investigation

The AIRIO is responsible for:

- Initiating the investigation within 30 calendar days after the determination by the DO that an investigation is warranted.

- On or before the date on which the investigation begins: (1) notifying ORI of the decision to begin the investigation and providing ORI a copy of the inquiry report; and (2) notifying the respondent in writing of the allegations to be investigated.

- Prior to notifying respondent of the allegations, taking all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the research misconduct proceeding that were not previously sequestered during the inquiry.

- In consultation with other FDA officials as appropriate, appointing an investigation committee and committee chair as soon after the initiation of the investigation as is practical.

- Preparing a charge for the investigation committee in accordance with FDA's policy and procedures.

- Convening the first meeting of the investigation committee and at that meeting: (1) briefing the committee on the charge, the inquiry report and the procedures and standards for the conduct of the investigation, including the need for confidentiality and developing a specific plan for the investigation; and (2) providing committee members a copy of FDA's policy and procedures and 42 CFR Part 93.

- Providing the investigation committee with needed logistical support, e.g., expert advice, including forensic analysis of evidence, and clerical support, including arranging interviews with witnesses and recording or transcribing those interviews.

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- Being available or present throughout the investigation to advise the committee as needed.

- On behalf of FDA, the AIRIO is responsible for each of the following steps and for ensuring that the investigation committee: (1) uses diligent efforts to conduct an investigation that includes an examination of all research records and evidence relevant to reaching a decision on the merits of the allegations and that is otherwise thorough and sufficiently documented; (2) takes reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical; (3) interviews 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 records or transcribes each interview, provides the recording or transcript to the interviewee for correction, and includes the recording or transcript in the record of the research misconduct proceeding; and (4) pursues 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 continues the investigation to completion.

- Upon determining that the investigation cannot be completed within 120 calendar days of its initiation (including providing the draft report for comment and sending the final report with any comments to ORI), submitting a request to ORI for an extension of the 120-day period that includes a statement of the reasons for the extension. If the extension is granted, the AIRIO will file periodic progress reports with ORI.

- Assisting the investigation committee in preparing a draft investigation report that meets the requirements of 42 CFR Part 93 and FDA's policy and procedures, sending the respondent and complainant a copy of the draft report for his/her comment within 30 calendar days of receipt, taking appropriate action to protect the confidentiality of the draft report, receiving any comments from the respondent and complainant and ensuring that the comments are included and considered in the final investigation report.

- Transmitting the draft investigation report to agency counsel for a review of its legal sufficiency.

- Assisting the investigation committee in finalizing the draft investigation report and receiving the final report from the committee.

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- Transmitting the final investigation report to the DO and: (1) if the DO determines that further fact-finding or analysis is needed, receiving the report back from the DO for that purpose; (2) if the DO determines whether or not to accept the report, its findings and the recommended agency actions, transmitting to ORI within the time period for completing the investigation, a copy of the final investigation report with all attachments, a statement of whether FDA accepts the findings of the report, a statement of whether FDA found research misconduct, and if so, who committed it, and a description of any pending or completed administrative actions against the respondent; or (3) if FDA provides for an appeal by the respondent that could result in a modification or reversal of the DO's finding of research misconduct, ensuring that the appeal is completed within 120 calendar days of its filing, or seeking an extension from ORI in writing (with an explanation of the need for the extension) and, upon completion of the appeal, transmitting to ORI a copy of the investigation report with all attachments, a copy of the appeal proceedings, a statement of whether FDA accepts the findings of the appeal proceeding, a statement of whether FDA found research misconduct, and if so, who committed it, and a description of any pending or completed administrative actions against the respondent.

- When a final decision on the case is reached, the AIRIO will normally notify both the respondent and the complainant in writing and will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of involved journals, collaborators of the respondent, or other relevant parties should be notified of the outcome of the case.

- Maintaining and providing to ORI upon request all relevant research records and records of the agency's research misconduct proceeding, including the results of all interviews and the transcripts or recordings of those interviews.

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REFERENCES

[1] 42 CFR § 93.214
[2] 42 CFR § 93.102
[3] 42 CFR § 93.201
[4] 42 CFR § 93.203
[5] 42 CFR § 93.208
[6] 42 CFR § 93.210
[7] 42 CFR § 93.212
[8] 42 CFR § 93.214
[9] 42 CFR § 93.215
[10] 42 CFR § 93.217
[11] 42 CFR § 93.219
[12] 42 CFR § 93.220
[13] 42 CFR § 93.221
[14] 42 CFR § 93.224
[15] 42 CFR § 93.103
[16] 42 CFR § 93.223
[17] 42 CFR § 93.224
[18] 42 CFR § 93.225
[19] 42 CFR § 93.226
[20] 42 CFR § 93.310(g)
[21] 42 CFR §§ 93.304(c), 93.307(b)
[22] 42 CFR §§ 93.304(e), 93.307(f)
[23] 42 CFR § 308(a)
[24] 42 CFR § 310(c)
[25] 42 CFR § 310(g)
[26] 42 CFR § 310(g)
[27] 42 CFR §§ 93.304(f), 93.312(a)
[28] 42 CFR § 93.316
[29] CFR § 93.309(c)
[30] 42 CFR § 93.304(k)
[31] 42 CFR § 93.304(h)
[32] 42 CFR § 93.318
[33] 42 CFR § 93.307(a)
[34] 42 CFR § 93.307(c)
[35] 42 CFR §§ 93.305, 93.307(b)
[36] 42 CFR § 93.304(b)
[37] 42 CFR § 93.307(g)
[38] 42 CFR § 93.309(a)
[39] 42 CFR § 93.308(a)
[40] 42 CFR § 93.309(a) and (b)
[41] 42 CFR § 93.310(a)
[42] 42 CFR § 93.310(b) and (c)
[43] 42 CFR § 93.310(d)
[44] 42 CFR § 93.310(e)
[45] 42 CFR § 93.310(f)
[46] 42 CFR § 93.310(g)
[47] 42 CFR § 93.310(h)
[48] 42 CFR § 93.311
[49] 42 CFR § 93.313
[50] 42 CFR § 93.313(f)
[51] 42 CFR §§ 93.312(a), 313(g)
[52] 42 CFR § 93.315
[53] 42 CFR § 93.317(b)
[54] 42 CFR §§ 93.300(g), 93.403(b) and (d)
[55] 42 CFR § 93.316(a)
[56] 42 CFR § 93.304(k)
[57] 42 CFR § 93.304(l)