The Centers for Disease Control and Prevention (CDC)[1] has reissued the **"Responding to Allegations of Research Misconduct"** policy

1. **Reason for Reissuance:** To update CDC's policy "Investigating Scientific Misconduct (CDC-GA-2002-08)" in response to newly issued federal regulation and additional guidance from the Office of Research Integrity (ORI).

2. **Summary of Policy:**
   The purpose of this policy is to provide guidance for responding to allegations of research misconduct at CDC. Revisions include updates to the terminology, definitions, and scope of to align CDC policy with 42 CFR Part 93 and guidance from ORI. Notably, the term "research misconduct" replaces "scientific misconduct." Research misconduct refers to fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. The revised policy is limited to misconduct that occurs within 6 years of allegation and provides a robust description each OPDIV responsibility.

3. **Related Issuances:** PHS Policies on Research Misconduct, 42 CFR Part 93 (May 17, 2005) Whistleblower Guidelines. HHS Office of Research Integrity, last updated June 20, 2007; Responsible Conduct of Research Integrity (RCR) HHS Office of Research Integrity, last updated November 29, 2005

4. **Responsible Officials:** Office of the Chief Science Officer (OSCO)

5. **Material Superseded:** CDC-GA-2002-08: Investigating Scientific Misconduct.

6. **Recertification:** This document is scheduled for recertification on or before the last working day of July 2014.

7. **Points of Contact:** Blanca Torres, Policy Specialist, Management Analysis and Services Office (MASO), 404 498 1502

To go directly to the policy, click on the link below or enter the following URL into the location line of your browser.

https://cdc.sharepoint.com/sites/SBI/CDCOperationalDocuments/CDC-SA-2002-01.pdf

s/Carlton Duncan
Deputy Chief Operating Officer

Distribution: All CDC/ATSDR Staff

[1] Note: References to CDC also apply to the Agency for Toxic Substances and Disease Registry (ATSDR).

CATEGORY – Science Administration
CDC -SA-2002-01
Date of Issue: 9/29/00 UPDATED: 10/23/02 7/28/09[1]
Proponent: Associate Director for Science, Office of the Director, CDC
Material Superseded: Formerly CDC-GA-2002-08

# RESPONDING TO ALLEGATIONS OF RESEARCH MISCONDUCT

**Sections:**



**Appendix**



**Exhibit**



## 1. PURPOSE/BACKGROUND

The Centers for Disease Control and Prevention (CDC or agency)[2] seeks to uphold high standards of intellectual honesty in the formulation, conduct, and reporting of scientific research. CDC's portfolio of policies and procedures uphold the agency's core values of "accountability, respect and integrity". Allegations of misconduct that prove to be untrue, even if they were made in good faith, can damage careers and have an adverse effect on research.

The purpose of this policy is to provide guidance for responding to allegations of research misconduct at CDC. The policy is intended to carry out CDC's responsibilities under the Public Health Service (PHS) Policies on Research Misconduct, Title 42, Code of Federal Regulations (CFR) Part 93 (May 17, 2005). For the purposes of this policy the terms research and research misconduct are defined below:

- Research is defined by 42 CFR § 93.222 as "a systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) relating broadly to public health by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, biological causes, functions or effects, diseases, treatments, or related matters to be studied."

[1] Updated to reflect current policy format.
[2] References to CDC also apply to the Agency for Toxic Substances and Disease Registry (ATSDR).

- Research Misconduct refers to fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

## 2. SCOPE

This policy applies to allegations of research misconduct involving:

- intramural research conducted, or proposed to be conducted, in CDC facilities by any person[3];

- intramural research conducted or proposed to be conducted by a CDC employee[4] as part of their official CDC duties or CDC training activity in any facility.

Extramural institutions and CDC will refer allegations of research misconduct involving extramural research to the HHS Office of Research Integrity (ORI) for assessment and possible inquiry and investigation.

## 3. POLICY

The following are principal tenets of this important policy:

- Responding to allegations of research misconduct consists of three separate, but related, steps: assessment, inquiry, and investigation.

- The Office of the Chief Science Officer (OCSO) shall be responsible for the oversight of investigations of allegations of scientific research misconduct.

- The Associate Director for Science (ADS), in OCSO, shall serve as the agency's Research Integrity Officer (RIO) and shall be responsible for coordinating the investigation process concerning the alleged intramural research misconduct.

- An allegation of research misconduct must be submitted in writing (paper or email) by a complainant to the RIO in order to be acted upon pursuant to this policy.

- If questions arise about whether an incident falls within the definition of research misconduct, individuals may discuss the incident with the RIO informally, using

[3] For the purposes of this policy, a CDC employee scientifically involved in post-awards (e.g., cooperative agreement) will also be considered to be conducting "intramural research," and the procedures in this policy will apply. As needed or applicable, the RIO will seek guidance from ORI to facilitate and coordinate parallel inquiries or overlapping investigations involving CDC and a non-CDC institution.

[4] For the purposes of this policy, CDC employees are defined as any full-time employee (FTE) or person contracted by or affiliated with CDC, any trainee, Personal Services Contractors or Locally Employed Staff in foreign locations. Also for the purposes of this policy, contractors are held to the same standard of conduct as FTEs although their hiring mechanism differs. Should a contractor fail to cooperate with the procedures outlined in this policy, the RIO will notify the Procurement and Grants Office (PGO) for assistance. If there is an allegation of research misconduct against a contractor and after an investigation, CDC makes a finding of research misconduct against said contractor, the PGO would be notified.

anonymous or hypothetical terms. If, following such discussion, the individual believes that the incident falls within the definition of research misconduct, then the individual should submit the allegation in writing to the RIO.

- Upon receiving a written allegation of research misconduct, the RIO will assess the allegation. The assessment period should be brief, preferably concluded within seven calendar days.

- If the allegation is sufficiently credible and specific and falls within the jurisdictional criteria of 42 CFR § 93.102(b), and the definition of research misconduct in 42 CFR § 93.103, then an inquiry must be conducted.

- The RIO shall: (1) limit disclosure of the identity of respondents, complainants, and witnesses to those who need to know; and (2) except as otherwise prescribed by law, limit the disclosure of any records or evidence from which research subjects might be identified. The RIO, at his/her discretion may elect to establish ad hoc confidentiality agreements or other mechanisms to ensure unnecessary disclosure does not occur. Members of the Inquiry Committee should not have any unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry. All Inquiry Committee members must sign a statement indicating that no personal, professional or financial conflicts of interest exist with respect to the respondent, complainant, or the case in question.

- On or before the date on which the respondent is notified, or the inquiry begins, whichever is earlier, the RIO must take reasonable and practical steps to obtain custody of the research records and evidence needed to conduct the research misconduct proceedings. These records and evidence must be inventoried and securely stored as per 42 CFR 93.317.[5]

- The RIO shall appoint an inquiry committee and committee chair within seven calendar days after the conclusion of the assessment period. The inquiry committee 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.

- Based on the inquiry, the agency's Deciding Official (DO) makes the final determination concerning whether an investigation is warranted. The inquiry, including preparation of the final report and the DO determination must be completed within 60 calendar days, unless extenuating circumstances (e.g., illness, other emergencies) clearly warrant a longer period. The respondent is permitted to review and comment on the final report.

If warranted, the RIO will appoint an investigation committee and the committee chair within 10 days of the beginning of the investigation. Investigation Committee members should not have any unresolved personal, professional, or financial conflicts of interest with those involved with the investigation. All Investigation Committee members must

[5] See additional information in references G,H and I in policy “Responding to Allegations of Research Misconduct”

sign a statement indicating that no personal, professional or financial conflicts of interest exist with respect to the respondent, complainant, or the case in question.

- The investigation is to be completed within 120 calendar days, including submission of the final report to ORI unless there are extenuating circumstances (e.g., illness, other emergency) and the RIO proposes a new timeline.

- CDC's Chief Science Officer (CSO) functions as the agency's Deciding Official (DO) and is the final approval for the finding for the Agency. The DO determines 1) whether the agency accepts the investigation report and findings and 2) appropriate agency actions in response.

- The respondent may appeal the decision by submitting a written request to the RIO within 30 calendar days.

- Records of the research misconduct proceeding, as defined in 42 CFR 93.317, are to be stored in a secure manner for seven years after completion of the proceeding, or the completion of such a proceeding, 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. All records in CDC custody will be secured in accordance with standard federal regulations 36 CFR Part 1220.

- The procedures outlined in Appendix A, "Procedures" are an integral part of the policy and must be adhered to.

- As appropriate, the RIO and other agency officials shall make reasonable and practical efforts to protect or restore the reputation of persons alleged to have engaged in research misconduct (known as the respondent in an inquiry), but against whom no finding of research misconduct is made.

- Throughout these proceedings, the RIO shall periodically determine if any threat of harm exists to public health, federal funds and equipment, or the integrity of the PHS supported research process. If a threat is identified, the RIO shall, in consultation with other agency officials and ORI, take appropriate interim action to protect against such threat.

## 4. RESPONSIBILITIES

### A. The Agency's Deciding Official (DO)

Shall be responsible for 1) reviewing final investigation reports, the recommended findings for reports and Appeals and the recommended agency responses, and 2) making final decisions on appeals

### B. The Agency's Research Integrity Officer (RIO)

Shall make reasonable and practical efforts to protect the position and reputation of respondent, complainants, witnesses, and committee members, during the research misconduct proceeding and upon its completion, regardless of the outcome. Any alleged or apparent retaliation against these individuals should be immediately reported to the RIO for review. As necessary, the RIO will make reasonable and

practical efforts to counter any potential or actual retaliation.[6] The RIO's full scope of responsibilities is further described in Appendix B.

**C. Inquiry and Investigation Committee Members**
Shall be responsible for maintaining confidentiality of all oral and written information; and reporting promptly any perceived conflict of interest and threat of harm to public health, federal funds and equipment, the integrity of the PHS supported research process or retaliation to anyone involved in the process.

**D. All CDC Employees**
Shall be responsible for reporting observed, suspected, or apparent research misconduct to the agency's Research Integrity Officer (RIO) as well as maintain confidentiality if involved in any part of the process. They are required to cooperate with the RIO in the review of allegations and the conduct of inquiries and investigations. They also must provide relevant evidence to the RIO as requested.

## 5. REFERENCES

Policies on Research Misconduct, 42 CFR Part 93: http://ori.dhhs.gov/documents/FR_Doc_05-9643.shtml Public Health Service (PHS), last updated May 17, 2005.

Whistleblower Guidelines: http://ori.dhhs.gov/misconduct/whistleblowers.shtml HHS Office of Research Integrity, last updated June 20, 2007.

Responsible Conduct of Research (RCR): http://ori.dhhs.gov/policies/RCR_Policy.shtml HHS Office of Research Integrity, last updated November 29, 2005.

Records Management Policy: https://cdc.sharepoint.com/sites/SBI/CDCOperationalDocuments/CDC-GA-2005-07.pdf CDC, last updated February 2008.

Management of Electronic Records Policy: http://aops-mas-iis.od.cdc.gov/Policy/Doc/policy523.pdf. CDC, last updated February 2008.

Policy on Record Keeping Procedures For Managing E-mails and Attachments that Qualify as Federal Records: http://aops-mas-iis.od.cdc.gov/Policy/Doc/policy238.htm. CDC, last updated October 2005.

Federal Records General Provisions, 36 CFR 1220: http://edocket.access.gpo.gov/cfr_2007/julqtr/pdf/36cfr1220.1.pdf Code of Federal Regulations, as amended on 5/13/02.

Disposition of Federal Records, 36 CFR 1228: http://www.access.gpo.gov/nara/cfr/waisidx_07/36cfr1228_07.html Code of Federal Regulations, as amended on 12/17/2007.

[6] No Fear Act available at URL: http://www.hhs.gov/eeo/no_fear_act_of_2001.html

## 6. DEFINITIONS

**Allegation** means a disclosure of possible research misconduct through any means of communication. The disclosure should consist of a written statement to a CDC or HHS official.

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

**Deciding Official (DO)** means the agency official who makes final determinations on allegations of research misconduct and any agency administrative actions. At CDC, the CDC Chief Science Officer serves in this role.

**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.

**Extramural research** means research funded by grants or cooperative agreements that are awarded by CDC to outside institutions. Outside institutions use CDC funding to pay for research projects and resources, including the salaries of extramural scientists employed by such institutions; thus, scientists/staff conducting extramural research are not federal employees.

**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.

Good faith as applied to a committee member means cooperating with the purpose of helping an institution meet its responsibilities under 42 CFR Part 93. A committee member does not act in good faith if his/her acts or omissions on the committee are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.

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

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

**Intramural research** means research supported by CDC and conducted by CDC staff (employees, contractors, visiting scientists, fellows, and students) in its own facilities or its components. Research programs are typically the mission-related research agenda or portfolio for the coordinating center (CC), coordinating office (CO), or national center

(NC)[7]. Research studies include projects undertaken by CDC scientists that involve research findings intended for dissemination and that are not funded through assistance (grant or cooperative agreement) or acquisition (contract).

**Investigation** means the formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation for a finding of research misconduct which may include a recommendation for other appropriate actions, including administrative actions.

**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.

**Preponderance of the evidence** means proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is probably more true than not (see Appendix A, item L).

**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.

**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, or contracts or subgrants or subcontracts under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements or contracts.

**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) , 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.

**Research** is defined by 42 CFR § 93.222 as “a systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) relating broadly to

[7] For ease of reference within policy documents, “center” will refer collectively to CDC’s national centers, institute, and the Agency for Toxic Substances and Disease Registry (an independent Health and Human Services agency that is led by the CDC director and for which CDC provides administrative services).

public health by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, biological causes, functions or effects, diseases, treatments, or related matters to be studied."

**Research Integrity Officer (RIO)** 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) overseeing inquiries and investigations; and (3) the other responsibilities described in this policy. At CDC, the CDC Associate Director for Science serves in this role.

**Research misconduct** means fabrication, falsification, or plagiarism in proposing, performing, 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.

**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.

**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.

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

**Retaliation** means an adverse action taken against a complainant, witness, or committee member by the respondent or CDC in response to (1) a good faith allegation of research misconduct; or (2) good faith cooperation with a research misconduct proceeding.

## 7. ABBREVIATIONS AND ACRONYMS

**ADS** - Associate Director for Science
**CC/CO/NC** – coordinating center/coordinating office/national center
**CSO** – Chief Science Officer
**DO** – Agency Deciding Official
**OCSO** – Office of Chief Science Officer
**ORI** – Office of Research Integrity
**RIO** – Research Integrity Officer