

A QUICK GUIDE TO THE SCIENTIFIC INTEGRITY POLICY AT THE

Centers for Disease Control and Prevention (CDC)



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Table of Contents

1	INTRODUCTION	1
2	SUMMARY	2
3	WHAT DOES THE POLICY GOVERN?	2
4	WHO DOES THE POLICY GOVERN?	5
5	WHAT IS THE PROCESS FOR FILING A COMPLAINT?	6
6	WHAT HAPPENS AFTER A COMPLAINT IS FILED?	7
7	WHAT HAPPENS AFTER THE INVESTIGATION ENDS?	8
8	ADDITIONAL RELEVANT POLICIES AND RESOURCES	9
9	REPRESENTATIVE CASES AND OUTCOMES	9
9	REPRESENTATIVE CASES AND OUTCOMES	9

A Quick Guide to the CDC Scientific Integrity Policy

Scientific integrity principles are indispensable to the missions and the functions of scientific federal agencies in the United States. Conducting sound and unbiased scientific research is essential to maintaining public trust in these agencies. For scientists employed at these agencies, understanding these principles—both how to abide by them, and what to do if they are violated—is a core job function.

Many scientific agencies adopted scientific integrity policies following a 2009 memorandum issued by President Obama, and a subsequent memorandum issued in 2010 by the White House Office of Science and Technology Policy. These policies clarify how individual agencies interpret scientific integrity. In many cases, a policy also describes how a scientist should report a loss of scientific integrity, how the agency will investigate such claims, and the rights of both a complainant and a scientist alleged to have committed a violation.

This guide examines the Centers for Disease Control and Prevention (CDC) scientific integrity policy. The guide is designed to help CDC scientists understand how the policy applies to them, what rights they have under the policy, and how they can avail themselves of these.

The CDC policy could be significantly strengthened to provide clearer enforcement mechanisms, penalties, and rights of appeal. But it is still crucial for agency scientists to know their rights and responsibilities in respect to scientific integrity, as well as the strengths and weaknesses of the policy.

While this guide helps CDC scientists understand the agency's scientific integrity policy, it is not a substitute for legal advice regarding a particular situation. The Climate Science Legal Defense Fund offers free, confidential consultations to scientists with questions about scientific integrity.

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2 SUMMARY

The CDC refers to itself as "the nation's public health agency." Most information about scientific integrity at the CDC is in the <u>CDC Guidance on Scientific Integrity</u> (referred to in this guide as the guidance), which states that the CDC's primary responsibility is providing scientific evidence for developing policies, guidelines, and recommendations (Guidance at 2). According to the CDC, this guidance is designed to support four key areas of scientific integrity: 1) foundations of scientific integrity in government, 2) public communications, 3) use of federal advisory committees, and 4) professional development of government scientists and engineers (Guidance at 1).

The CDC guidance covers traditional research misconduct and includes concepts such as open communication with the public and the professional development of scientists. However, unlike some scientific agencies, the CDC guidance does not address behaviors that can threaten scientific integrity such as political interference, threats, censorship, and suppression.

The CDC doesn't have specific policies or procedures for the filing or the handling of complaints regarding a loss of scientific integrity. There are procedures for dealing with complaints of research misconduct, but these are contained in a separate policy and address only a small portion of what the CDC guidance purports to cover. The CDC appears to have a Research Integrity Officer, but it is not clear based on publicly available information that the CDC has appointed a Scientific Integrity Officer.

The CDC's guidance is dense and not very user-friendly in comparison to the scientific integrity policies of other agencies. Some relevant policies and procedures, such as those that deal with the handling of research misconduct complaints, are located in separate documents. This arrangement places an additional burden on scientists, who must navigate multiple complex documents to fully understand the policies.

3 WHAT DOES THE POLICY GOVERN?

Research Misconduct

The CDC guidance does not have provisions on research misconduct. Instead it refers to policies on research misconduct described in the Code of Federal Regulations (CFR) (Guidance at 4) which defines research misconduct as "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results" (42 CFR § 93.103).

The guidance refers to the <u>CDC Policy for Responding to Allegations of Research Misconduct</u> (referred to in this guide as "the policy on research misconduct" and "policy"), which says employees have an obligation to report research misconduct to the Research Integrity Officer. Employees must also cooperate in the review of allegations as well as any subsequent inquiries and investigations (Guidance at 4). The relevant provisions in the CFR explain that research misconduct does not include honest errors or differences of opinion.

Conflict of Interest

The guidance prohibits CDC employees from having financial conflicts of interests and undertaking actions that create the appearance of ethical or legal violations (Guidance at 4). This section also points to multiple external documents that relate to conflicts of interest or ethical issues, including the <u>Standards of Ethical Conduct for</u> <u>Employees of the Executive Branch</u> and the <u>Confidential Financial Disclosure System Policy</u>.

The CDC guidance mentions conflicts of interest in a few other areas. With regard to authorship and peer review, the guidance states that the existence or appearance of a conflict of interest can compromise the CDC's work, and it requires peer reviewers to provide written assurance that they do not have actual or perceived conflicts of interest (Guidance at 7). The guidance also mentions conflicts of interest in the context of advisory committees, stating that in the case where a committee member's conflict of interest is waived, it will make that waiver available to the public on request (Guidance at 18).

Political Interference

The guidance does not explicitly address political interference with research. In discussing research misconduct, the guidance does say that "in instances when the observed conduct does not fall under the definition of research misconduct but may lead to loss of integrity, actions should still be taken to investigate and prevent such loss of scientific integrity" (Guidance at 4).

This language alludes to the possibility that political interference with research, such as asking researchers to alter their work or censoring research for political reasons, may result in a loss of scientific integrity without meeting the traditional definition of research misconduct. Yet it is vague, and not nearly as comprehensive as the policies of some other agencies that explicitly make political interference with research a violation of scientific integrity.

Threats and Intimidation

The guidance similarly does not explicitly address threatening or intimidating researchers. The language referenced in the section above, which suggests that actions that do not meet the definition of research misconduct can still lead to a loss of scientific integrity, may also potentially be relevant in instances where researchers are threatened or intimidated. However, as discussed in the preceding section, the guidance is vague on this point and leaves researchers with very little clarity as to whether the agency would consider such behaviors violations of scientific integrity.

Use of Science in Agency Decision-Making

The guidance does not address how science should be used in agency decision-making aside from broad language indicating that the CDC must emphasize scientific evidence in developing its policies and similar.

Science Communication

The guidance repeatedly stresses that scientific information should be freely shared (Guidance at 8, 10). This indicates that scientists' ability to communicate their work is an integral part of scientific integrity at the CDC.

Timeliness: The guidance states that the CDC is "committed to the timely release and availability of information to ensure the health of the public" (Guidance at 3).

Press: The guidance contains sections on responding to media inquiries and scientists speaking on their official work without interference, including a broad statement that "CDC employees may, consistent with this policy, speak to members of the press about their work" (Guidance at 15).

However, much of the language is these sections is somewhat constrained. For example, according to the guidance, CDC media relations staff are expected to be honest and accurate, respond promptly to media requests, and promote the free flow of scientific and technical information. Yet the same rights and responsibilities are not extended to CDC scientists. Similarly, the guidance gives speakers at public events the right to conduct media interviews without interference from CDC media relations staff, but it does not extend this right to CDC scientists if they are not presenting at a public event.

The guidance refers to additional CDC polices which may contain relevant information on the communication of scientific information: Clearance of Information Products Disseminated Outside CDC for Public Use and Release of Information to News Media (for media relations staff). Neither appears to be publicly available at the time of this publication.

Social media: The guidance does not address social media use, but the CDC has a separate social media policy.

Testifying before Congress: While the policy does not explicitly state that agency scientists have a right to testify before Congress, that right is protected elsewhere in federal law.

Right of scientists to review and/or correct agency communications: The guidance does not address scientists' right to review or correct agency communications or publications referencing their work or attributing them as authors.

Publishing and lecturing: The CDC recognizes that professional development of its scientists —publishing their work, participating in professional conferences and peer review—is an essential part of maintaining the agency's scientific integrity. As a result, CDC employees and CDC-funded researchers are urged to disseminate their findings and research. CDC researchers are also encouraged to serve as editors for, or on the editorial boards of, professional journals (Guidance at 20-21).

Scientific societies: Membership in professional organizations is encouraged. CDC scientists are allowed to participate in professional or scholarly societies, committees, task forces, and other specialized bodies of professional societies. Most of these activities are considered an extension of an employee's official duties and do not require written approval; however, it may still be prudent for an employee to alert his or her supervisor. Participation beyond ordinary membership (e.g., holding office, committee membership) must be approved in advance by the Ethics Program Activity Office (Guidance at 21-22).

CDC employees are allowed to participate in activities outside the workplace as long as these do not conflict with job duties and do not violate a federal statute or regulation. Employees must obtain approval before

engaging in an outside activity that requires the use of professional qualifications readily identified with CDC employment (Guidance at 22).

Opinion statements: The guidance does not address an employee's right to make public statements of personal opinion. However, research misconduct does not include honest differences of opinion, and federal employees are generally entitled to express personal opinions publicly as long as they make clear that they are not speaking on behalf of the agency.

Hiring Practices

The guidance includes a section on selection of candidates for scientific positions, indicating that this is an important aspect of scientific integrity. Scientific and technical knowledge, credentials, experience, and professional stature should be the basis for hiring decisions with regard to the agency's scientific personnel (Guidance at 6-7). The Office of Personnel Management Group Coverage Qualification Standards for Professional and Scientific Positions is referred to as an external authority.

Federal Advisory Committees

The guidance describes advisory committees as "a key component of CDC's overall strategy to engage the public and stakeholders" (Guidance at 17). According to the guidance, recruiting a diverse and balanced pool of candidates for these committees is an important part of scientific integrity, as is transparency of committee activities. Specific processes are described in the <u>CDC Federal Advisory Committee Management Handbook</u>.

Human and Animal Research Subject Protections

The guidance mentions that the treatment of human and animal research subjects is part of scientific integrity. It says that the CDC has an ethical and legal obligation to "ensure that individuals are protected in all public health research activities it conducts" and "treat animals humanely" (Guidance at 5). The CDC has separate policies for both <u>Human Research Protections</u> and <u>Laboratory Animal Care and Use</u>.

Whistleblower Protections

The guidance states that the CDC is committed to complying with the 2002 Notification and Federal Employee Antidiscrimination and Retaliation Act (No FEAR Act), which requires that federal agencies be accountable for violations of anti-discrimination and whistleblower protection laws. All CDC staff are required to undergo mandatory No FEAR Act training (Guidance at 8). However, the guidance does not provide any additional protections to whistleblowers who come forward beyond what is required by federal law.

4 WHO DOES THE POLICY GOVERN?

The CDC guidance is not clear about who it covers—a significant omission. However, the policy on research misconduct provides some relevant information. That policy covers full-time CDC employees "or person contracted by or affiliated with CDC, any trainee, Personal Services Contractors or Locally Employed Staff in

foreign locations" (Policy § 2, footnotes 3 and 4). A CDC employee scientifically involved in a post-awards arrangement such as a cooperative agreement is also covered by the policy on research misconduct.

While it is not clear whether the CDC would consider these same categories of employees to be bound by its scientific integrity policy, it may provide some insight into how the agency looks at the issue.

5 WHAT IS THE PROCESS FOR FILING A COMPLAINT?

This guide is not a substitute for legal advice about any specific situation. If you are considering filing a scientific integrity complaint, or are the subject of a complaint, please contact the Climate Science Legal Defense Fund or another attorney for advice about your particular circumstances. Nonetheless, we will provide below general information about what the process may entail.

The guidance does not describe procedures for filing a scientific integrity claim or provide details about how these claims will be investigated and addressed. The CDC only offers this kind of structure in a separate policy on research misconduct. That policy and its associated appendices spell out procedures the agency uses to address claims of research misconduct.

It is not clear whether these procedures apply to claims of scientific integrity violations that fall outside research misconduct, such as political interference or censorship. Nonetheless, it is useful to describe the procedures on research misconduct as they provide some information about how the agency would handle such claims. The information in this section, as well as sections 6 and 7, is specific to research misconduct.

Who can make a claim under the policy?

The policy does not specify who is allowed to file a claim of research misconduct.

Where and how can a scientist make a claim?

The Associate Director for Science in that office serves as the CDC Research Integrity Officer (RIO) and is responsible for coordinating investigations of alleged research misconduct (Policy § 3). Someone who believes research misconduct has occurred should file a written allegation with the RIO.

What should a complaint contain?

The policy does not specify what information a claim should contain.

Is there a deadline for filing a complaint?

The policy does not specify whether a complainant is required to bring a claim within a certain timeframe after becoming aware of misconduct.

6 WHAT HAPPENS AFTER A COMPLAINT IS FILED?

Who investigates?

The RIO investigates claims of research misconduct. An investigation includes three separate phases: assessment, inquiry, and investigation.

Assessment

Upon receiving a research misconduct allegation, the RIO must assess whether it is sufficiently credible and specific to warrant further action. The RIO has a brief period—preferably no more than seven days—to conduct this assessment (Policy § 3).

At this stage, the allegation must meet the relevant definition of "research misconduct," which covers fabrication, falsification, or plagiarism (Policy § 3; see also 42 CFR § 93.103). The allegation also needs to meet certain jurisdictional requirements: it must relate to Public Health Service (PHS)-supported biomedical or behavioral research, either intramural or extramural; to applications or proposals for PHS support for such research; to PHS-supported training programs related to such research; or to other PHS-supported activities related to such research (42 CFR § 93.102).

Inquiry

The RIO must conduct an inquiry if all of the above factors are met (Policy § 3). The purpose of the inquiry is to conduct an initial review of the available evidence to determine whether an investigation is warranted. By the time an inquiry starts, the RIO must make a good faith effort to notify the subjects of the complaint in writing and obtain custody of relevant research records and other evidence (Policy, Appendix A § 3(C)).

The RIO is required to appoint an inquiry committee at this stage. The committee should consist of individuals with the scientific expertise necessary to evaluate the evidence and issues involved who do not have personal, professional, or financial conflicts of interest. The respondent (but not the complainant) has a right to be notified of the committee's composition and object within 10 calendar days (Policy, Appendix A § 3(D)).

The inquiry committee interviews the complainant, the subject of the complaint, and relevant witnesses, and also examines relevant research records and materials. The inquiry committee then issues a written report and makes a recommendation as to whether a full investigation is warranted (Policy, Appendix A § 3(F) and (G)). The CDC Chief Science Officer functions as the Deciding Official (DO), and makes the final determination about whether an investigation is warranted. The inquiry and determination must be completed within 60 calendar days absent extenuating circumstances (Policy at § 3).

Investigation

If the DO determines that an investigation is warranted, the investigation must begin within 30 days of making that determination (Policy, Appendix A § 4(A)). This investigation is intended to determine whether and who

committed research misconduct and, if so, how serious the misconduct is. At this stage, the RIO must notify the subject(s) of the complaint, their immediate supervisors, and the immediate supervisors of any relevant witnesses (Policy, Appendix A § 4(B)).

The RIO must appoint an investigation committee and committee chair within 10 days of the beginning of the investigation (Policy, Appendix A § 4(C)). The committee should have at least five members with appropriate expertise and training to evaluate the evidence and issues involved. One member must be a person of similar professional designation as the subject of the complaint.

As with the inquiry committee, a priority is to ensure that the members of the investigation committee have no personal, professional, or financial conflicts of interest. The subject of the complaint, but not the complainant, has the right to object to the committee's proposed membership in writing to the SIO within 10 calendar days of being notified (Policy, Appendix A § 4(D)).

The committee conducts the investigation, which involves: 1) interviewing both the complainant and the subject of the complaint, as well as other available persons with relevant information, and 2) examining research records and evidence (Policy, Appendix A § 4(E)). The investigation must be completed within 120 calendar days absent extenuating circumstances (Policy, Appendix A § 4(I)).

The investigation committee must then prepare an investigation report, which includes a statement of findings for each allegation of research misconduct. Both the complainant and respondent should receive a draft of the report and have 30 calendar days to submit comments. The subject of the complaint, but not the complainant, has the right to see the evidence on which the report is based. (Policy, Appendix A § 4(F) & (G)).

Is the confidentiality of the parties protected?

The RIO is required to limit disclosure of the identity of respondents, complainants, and witnesses to those who need to know. Where legally possible, the RIO must limit the disclosure of any records or evidence from which research subjects might be identified (Policy § 3).

Do the parties have a right to a hearing?

The guidance does not state whether either party has a right to a hearing.

Do the parties have a right to respond to the findings of the investigation?

Both parties have a right to submit comments on the investigation report within 30 days of receiving it. Those comments must be included and considered in the final report (Policy, Appendix A 4(G)).

7 WHAT HAPPENS AFTER THE INVESTIGATION ENDS?

At the end of the investigation, the RIO sends the final investigation report to the DO, who makes a written determination. If the DO's determination varies from the finding of the investigation committee, the DO must

explain the reason for the difference. The DO also has the option to return the report to the investigation committee for further fact-finding or analysis (Policy, Appendix A 4(H)).

Once the DO has reached a final decision, the RIO will notify both parties in writing and determine whether any other parties need to be notified.

If misconduct is found, who decides what the resolution/remedy should be?

The DO determines appropriate agency actions if there is a finding of research misconduct (Policy, Appendix A § 4(H)).

Do the parties have the right to appeal if initial decision is not in their favor?

The person accused of misconduct may appeal the decision by submitting a written request to the RIO within 30 calendar days (Policy, Appendix A § 4(J)). If an appeal is filed, it must be acted upon within 120 days of its filing, unless the RIO finds good cause for an extension. It is not clear from the policy what body considers the merits of such an appeal. The language suggests that it is likely the investigation committee and the RIO, making this a reconsideration rather than an appeal to an independent decision-maker.

What are the penalties for misconduct?

Examples of possible penalties for misconduct may include: 1) withdrawal or correction of pending or published abstracts or papers related to the research misconduct, and 2) other penalties, such as removal from a project, a letter of reprimand, probation, suspension, salary reduction, or initiation of steps leading to possible termination (Policy, Appendix A § 4(H)).

8 ADDITIONAL RELEVANT POLICIES AND RESOURCES

- > CDC Policy for Peer Review of Research and Scientific Programs
- > CDC Policy for Release of Information to News Media (not publicly available)
- > CDC Authorship Policy
- > CDC/ATSDR Policy on Public Health Research and Non-research Data Management and Access
- > CDC Policy on Social Media Use

9 **REPRESENTATIVE CASES AND OUTCOMES**

Unlike some other agencies, the CDC does not appear to make summaries of cases or outcomes publicly available.

The Climate Science Legal Defense Fund produced this guide to help scientists understand their rights under federal agency scientific integrity policies. This guide concerns only U.S. laws, and nothing in it should be construed as legal advice for your individual situation.

CSLDF provides free counsel to scientists with legal questions pertaining to their work. Contact us at **(646) 801-0853** or email **lawyer@csldf.org** to arrange a free and confidential consultation with an attorney.



The Climate Science Legal Defense Fund (CSLDF) works to protect the scientific endeavor by helping defend climate scientists against politically and ideologically motivated attacks. CSLDF is a non-profit organization under section 501(c)(3) of the Internal Revenue Code.

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