



# **GUIDANCE**

*for*

Public Health Service Policies on Research Misconduct

42 CFR Part 93 (2024)

## **State of Mind**

U.S. Department of Health and Human Services

Office of the Assistant Secretary for Health

Office of Research Integrity (ORI)

2026

Public Health Service Policies on Research Misconduct  
42 CFR Part 93 Guidance on State of Mind  
**Contains Nonbinding Recommendations**

## Table of Contents

Overview .....	3
Determining a Respondent’s State of Mind .....	3
General Guidance .....	3
Intentional and Knowing Misconduct .....	4
Reckless Misconduct .....	4
Additional Guidance.....	4
Pertinent Sections of 42 CFR Part 93 (2024) .....	6
§ 93.103 Requirements for findings of research misconduct.....	6
§ 93.105 Evidentiary standards. ....	6
§ 93.221 Intentionally.....	6
§ 93.223 Knowingly.....	6
§ 93.231 Recklessly.....	7
§ 93.234 Research misconduct.....	7

This guidance document is provided by the Office of Research Integrity (ORI) to assist entities that apply for or receive Public Health Service (PHS) funding for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training. It addresses the topic of determining a respondent’s state of mind according to the revised Public Health Service Policies on Research Misconduct regulation at 42 CFR Part 93 (2024). This guidance document does not create or confer rights for or on any person and does not operate to bind ORI, the Department of Health and Human Services, or the public. It also does not guarantee that ORI will find an institution compliant with 42 CFR Part 93. In case of any conflict between this document and 42 CFR Part 93, the regulation will prevail.

Date of Issuance: May 2026

## Overview

In September 2024, the Department of Health and Human Services (HHS) updated its Public Health Service Policies on Research Misconduct regulation ([42 CFR Part 93](#)). The updated regulation continues to require that, for a finding of research misconduct, there be a significant departure from the accepted practices of the relevant research community, the misconduct be committed intentionally, knowingly, or recklessly, and the allegation be proven by a preponderance of the evidence.<sup>1</sup>

Accordingly, institutions must determine the state of mind of the respondent when evaluating if the evidence supports a finding of research misconduct.

The terms “intentionally,” “knowingly,” and “recklessly” were not defined in the 2005 regulation. To provide clarity and ensure uniform application in the research community, the updated regulation includes the following definitions:

- Intentionally: To act intentionally means to act with the aim of carrying out the act.<sup>2</sup>
- Knowingly: To act knowingly means to act with awareness of the act.<sup>3</sup>
- Recklessly: To act recklessly means to propose, perform, or review research, or report research results, with indifference to a known risk of fabrication, falsification, or plagiarism.<sup>4</sup>

## Determining a Respondent’s State of Mind

### General Guidance

Determining whether the respondent acted intentionally, knowingly, or recklessly is often one of the most challenging issues faced by committee members, research integrity officers (RIOs), and institutional officials as they evaluate research misconduct allegations. Under 42 CFR Part 93, an institution may determine that a respondent acted both intentionally and knowingly. However, if an institution determines that a respondent acted recklessly, the institution cannot also determine that the respondent acted knowingly or intentionally.

Different evidentiary sources may help establish a respondent’s state of mind (intentional, knowing, or reckless). Contemporaneous email correspondence; computer hard drives and metadata (committee members may compare versions of manuscripts or grant applications and relevant figures or images); interviews with complainants, respondents, and witnesses; and written responses to inquiry and investigation reports may shed light on the state of mind of the respondent.

---

<sup>1</sup> 42 CFR Part §§ 93.103 and 93.105.

<sup>2</sup> § 93.221.

<sup>3</sup> § 93.223.

<sup>4</sup> § 93.231.

## Intentional and Knowing Misconduct

Evidence demonstrating any of the following may support a determination that a respondent acted intentionally and knowingly:

- Figure or image manipulation, which are affirmative acts,
- Falsifications that all support a given hypothesis,
- Motive, e.g., acting in response to referee comments,
- A number and pattern of falsifications that could not have occurred without intentional and knowing conduct,
- Falsification that could not have occurred without intentional and knowing conduct, and/or
- A combination of the above.

## Reckless Misconduct

Evidence demonstrating all three of the following may support a determination that a respondent acted recklessly:

- The respondent proposed, performed, or reviewed research, or reported research results,
- The respondent knew of a risk of fabrication, falsification, or plagiarism, and
- The respondent acted with indifference to that risk.

Evidence that a respondent departed from accepted research practices alone is not sufficient to establish a reckless state of mind. Similarly, it is not sufficient to demonstrate that a respondent should have taken a certain level of care, unless the respondent knew there was a risk of fabrication, falsification, or plagiarism under the particular circumstances.

## Additional Guidance

Under 42 CFR Part 93, “[r]esearch misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.”<sup>5</sup> If an institution determines that a respondent’s actions were honest error or reflected a difference of opinion, the institution would not need to further consider the respondent’s state of mind.<sup>6</sup>

RIOs and committee members may also find it helpful to consult institutional legal counsel when evaluating a respondent’s state of mind and determining whether a preponderance of the evidence supports a finding of research misconduct.

ORI understands that concerns, uncertainties, and other issues occasionally emerge in the context of institutional management of research misconduct allegations. The institution’s RIO and other relevant institutional personnel are encouraged to contact ORI for technical assistance and/or attend a RIO Boot Camp, which ORI sponsors on a periodic basis. For more information on determining a respondent’s

---

<sup>5</sup> § 93.234.

<sup>6</sup> See ORI Guidance on Honest Error <https://ori.hhs.gov/guidance-documents>.

Public Health Service Policies on Research Misconduct  
42 CFR Part 93 Guidance on State of Mind  
**Contains Nonbinding Recommendations**

state of mind please reach out to ORI at any time for guidance by calling (240) 453-8800 or emailing [AskORI@hhs.gov](mailto:AskORI@hhs.gov).

## Pertinent Sections of 42 CFR Part 93 (2024)

### § 93.103 Requirements for findings of research misconduct.

A finding of research misconduct made under this part requires that:

- (a) There be a significant departure from accepted practices of the relevant research community;
- and
- (b) The misconduct be committed intentionally, knowingly, or recklessly; and
  - (c) The allegation be proven by a preponderance of the evidence.

### § 93.105 Evidentiary standards.

(a) *Standard of proof.* An institutional or HHS finding of research misconduct must be proved by a preponderance of the evidence.

(b) *Burden of proof.*

(1) The institution or HHS has the burden of proof for making a finding of research misconduct. A respondent's destruction of research records documenting the questioned research is evidence of research misconduct where the institution or HHS establishes by a preponderance of the evidence that the respondent intentionally or knowingly destroyed records after being informed of the research misconduct allegations. A respondent's failure to provide research records documenting the questioned research is evidence of research misconduct where the respondent claims to possess the records but refuses to provide them upon request.

(2) The respondent has the burden of going forward with and proving, by a preponderance of the evidence, all affirmative defenses raised. In determining whether HHS or the institution has carried the burden of proof imposed by this part, the finder of fact shall give due consideration to admissible, credible evidence of honest error or difference of opinion presented by the respondent.

(3) The respondent has the burden of going forward with and proving, by a preponderance of the evidence, any mitigating factors relevant to a decision to impose administrative actions after a research misconduct proceeding.

### § 93.221 Intentionally.

To act intentionally means to act with the aim of carrying out the act.

### § 93.223 Knowingly.

To act knowingly means to act with awareness of the act.

Public Health Service Policies on Research Misconduct  
42 CFR Part 93 Guidance on State of Mind  
**Contains Nonbinding Recommendations**

### § 93.231 Recklessly.

To act recklessly means to propose, perform, or review research, or report research results, with indifference to a known risk of fabrication, falsification, or plagiarism.

### § 93.234 Research misconduct.

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.