GUIDANCE

for

Public Health Service Policies on Research Misconduct

42 CFR Part 93 (2024)

Admissions

U.S. Department of Health and Human Services
Office of the Assistant Secretary for Health
Office of Research Integrity (ORI)
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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 admissions 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.

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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 requires institutions to promptly notify ORI in advance if the institution plans to close a research misconduct proceeding at the assessment, inquiry, investigation, or appeal stage on the basis that the respondent has admitted to committing research misconduct or a settlement with the respondent has been reached.[1] This notification must include both the respondent's written, signed admission statement and the institution's written statement describing how it determined that the scope of the misconduct was fully addressed by respondent's admission and confirmed the respondent's culpability.[2]

The Respondent's Admission Statement

The respondent's written, signed admission statement must meet all the elements required for a research misconduct finding under 42 CFR Part § 93.103.[3] This means that, for each specific allegation of research misconduct the respondent admits to having committed, the statement must:

- describe the type of research misconduct – falsification, fabrication and/or plagiarism;
- identify the affected research records (e.g., the specific published papers, manuscripts, PHS funding applications, progress reports, presentations, posters, or other research records that contain the original material that was falsified, fabricated, and/or plagiarized and the compromised data)[4];
- explain whether the research misconduct was conducted knowingly, intentionally, and/or recklessly; and
- acknowledge that respondent's actions were a significant departure from accepted practices of the relevant research community.

It is also advisable for the admission statement to include a description of how the misconduct was committed, which may include image relabel and reuse, data omission, fabrication, or other types of research misconduct and identify specific actions taken (e.g., splicing, rotation, or cropping).

An institution can provide information and guidance to assist the respondent in drafting the document, such as admission requirements stipulated above and in 42 CFR Part 93. It is recommended that the respondent write the admission. The admission statement does not have to be a long document, but it must contain the required elements.

Because the respondent, via the written statement, is admitting to the allegation(s) of research misconduct, the statement should not allude to honest error, difference of opinion, or mitigating factors,

[1] 42 CFR § 93.317(a).
[2] § 93.317(b).
[3] § 93.317(b).
[4] § 93.236; *See* ORI guidance on Research Records at https://ori.hhs.gov/guidance-documents.

such as a lack of knowledge, training, instrument failure, or other reasons.[5] Research misconduct is defined as "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting result results. Research misconduct does not include honest error or differences of opinion."[6]

The Institution's Statement on the Respondent's Admission

The respondent's admission statement must be accompanied by the institution's written statement describing how the institution determined that the scope of the misconduct was fully addressed by the respondent's written admission and why the admission confirms the respondent's culpability.[7] Both statements should be supported by the institutional record, which should establish the pertinent details of the case, including who committed the research misconduct, the type of research misconduct, how the research misconduct occurred, the level of intent, the research records affected, etc.

Carrying Proceedings through Completion

ORI expects institutions to carry inquiries and investigations through to completion and to pursue diligently all significant issues and credible allegations of research misconduct.[8] Research Integrity Officers (RIOs) and other institutional officials in charge of proceedings should not allow an early admission on the part of the respondent to limit the scope of an inquiry or investigation. The institution should carefully examine the scope of the allegations and consult with ORI before accepting a respondent's admission as sufficient reason to curtail the proceedings.[9]

In some instances, a respondent may admit to some, but not all of, the allegations. When complications like this arise, institutions are encouraged to seek advice through ORI's Rapid Response for Technical Assistance program.

If an institution plans to close a research misconduct proceeding at any stage on the basis that the respondent has admitted to committing research misconduct, ORI must be notified in advance.[10] ORI will consult with the institution and may conduct an oversight review of the institution's handling of the case and take additional actions, including approval or conditional approval of the institution's closure of the case, directing the institution to complete its process, or directing the institution to address deficiencies in the institutional record.[11]

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[5] If the respondent wishes to assert that the alleged fabrication, falsification, or plagiarism resulted from honest error or a difference in opinion, the respondent can include such assertions in their written responses to inquiry and investigation reports.
[6] § 93.234.
[7] § 93.317(b).
[8] § 93.317(a).
[9] § 93.317(c); *See* ORI guidance on Pursuing Leads at https://ori.hhs.gov/guidance-documents.
[10] § 93.317(b).
[11] § 93.317(c).

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 admissions, please reach out to ORI at any time for guidance by calling (240) 453-8800 or emailing AskORI@hhs.gov.

Pertinent Sections of 42 CFR Part 93 (2024)

§ 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.

§ 93.236 Research record.

Research record means the record of data or results that embody the facts resulting from scientific inquiry. Data or results may be in physical or electronic form. Examples of items, materials, or information that may be considered part of the research record include, but are not limited to, research proposals, raw data, processed data, clinical research records, laboratory records, study records, laboratory notebooks, progress reports, manuscripts, abstracts, theses, records of oral presentations, online content, lab meeting reports, and journal articles.

§ 93.317 Completing the research misconduct process.

(a) ORI expects institutions to carry inquiries and investigations through to completion and to pursue diligently all significant issues and credible allegations of research misconduct. Institutions must notify ORI in advance if the institution plans to close a research misconduct proceeding at the assessment, inquiry, investigation, or appeal stage on the basis that the respondent has admitted to committing research misconduct or a settlement with the respondent has been reached.

(b) A respondent's admission of research misconduct must be made in writing and signed by the respondent. An admission must specify the falsification, fabrication, and/or plagiarism that occurred and which research records were affected. The admission statement must meet all elements required for a research misconduct finding under § 93.103 and must be provided to ORI before the institution closes its research misconduct proceeding. The institution must also provide a statement to ORI describing how it determined that the scope of the misconduct was fully addressed by the admission and confirmed the respondent's culpability.

(c) After consulting with the institution on its basis for closing a case under paragraph (a) of this section, ORI may conduct an oversight review of the institution's handling of the case and take appropriate action including:

(1) Approving or conditionally approving closure of the case;

(2) Directing the institution to complete its process;

(3) Directing the institution to address deficiencies in the institutional record;

(4) Referring the matter for further investigation by HHS; or

(5) Taking a compliance action.