



# **GUIDANCE**

*for*

Public Health Service Policies on Research Misconduct

42 CFR Part 93 (2024)

## **Subsequent Use Exception**

U.S. Department of Health and Human Services

Office of the Assistant Secretary for Health

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Public Health Service Policies on Research Misconduct  
42 CFR Part 93 Guidance on Subsequent Use Exception  
**Contains Nonbinding Recommendations**

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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 the subsequent use exception 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 continues to include a “subsequent use” exception to the general six-year time limitation for applicability of Part 93. However, the updated regulation clarifies when the subsequent use exception applies and includes a documentation requirement.<sup>1</sup> For research misconduct that appears subject to the subsequent use exception, institutions must consider applicability of the exception on an allegation-by-allegation basis. This guidance addresses institutions’ responsibilities regarding the subsequent use exception.

## Subsequent Use in Research Misconduct Proceedings

Institutions must follow 42 CFR Part 93 and address alleged research misconduct occurring within six years of the date an institution or HHS receives the allegation. Alleged research misconduct that occurred before the six-year window is generally not subject to 42 CFR Part 93.<sup>2</sup>

However, if the alleged research misconduct occurred before the six-year window, but the respondent has continued or renewed the alleged research misconduct by using, republishing, or citing to the portion(s) of the research record alleged to have been fabricated, falsified, or plagiarized for the respondent’s potential benefit within the six-year window, then the alleged misconduct falls under the subsequent use exception.

Under the 2005 version of 42 CFR Part 93, institutions may consider a respondent’s use, republication, or citation to any part of the research record alleged to have been fabricated, falsified, or plagiarized.<sup>3</sup> Under the revised regulation, however, institutions may only consider the respondent’s use, republication, or citation of the specific portion(s) of the research record alleged to have been fabricated, falsified, or plagiarized. Thus, the revised regulation narrows the scope of the subsequent use exception. For example, under the revised regulation, if an institution receives an allegation of research misconduct about Figure A in a paper published outside of the six-year window and this respondent uses Figure B from the paper in a grant application within the six-year window, the subsequent use exception would not apply to Figure A, as the specific portion of the research record alleged to have been fabricated, falsified, or plagiarized was not used by the respondent for their potential benefit.

In addition, the updated regulation clarifies that, for research misconduct that appears subject to the subsequent use exception, institutions are responsible for determining whether the exception applies. In practical terms, upon receipt of research misconduct allegations that fall outside of the six-year time limitation, the institution must examine each allegation to determine whether the subsequent use

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<sup>1</sup> 42 CFR § 93.104.

<sup>2</sup> Although institutions may address allegations outside the six-year time limitation, consistent with their institutional policies, 42 CFR Part 93 only requires institutions to address allegations received within the six-year time limitation (unless the subsequent use or health and safety exceptions apply).

<sup>3</sup> 42 CFR § 93.105(b)(1) (2005).

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exception applies. ORI recommends that institutions document their determination as part of their assessment documentation.<sup>4</sup>

In making this determination, the institution will need to assess whether, during the six years before HHS or an institution received the allegation, the respondent used, republished, or cited the portion of the research record alleged to have been fabricated, falsified, or plagiarized, for the respondent's potential benefit. If so, the exception applies. The research record may include, but is not limited to, source data, processed data, text, journal articles, funding proposals, or data repositories. The revised regulation specifies that this exception applies when the respondent uses, republishes, or cites to the portion(s) of the research record that is alleged to have been fabricated, falsified, or plagiarized in submitted or published manuscripts, submitted PHS grant applications, progress reports submitted to PHS funding components, posters, presentations, or other research records within six years of when the allegations were received by HHS or an institution.<sup>5</sup> Examples of when the exception does not apply include, but are not limited to: when the usage was not for the respondent's potential benefit, or when the citation did not involve the relevant portion of the research record.

For research misconduct that initially appears subject to the subsequent use exception, but the institution determines the exception does not apply, the institution must retain documentation of its determination.<sup>6</sup>

ORI understands that concerns, uncertainties, and other issues occasionally emerge in the context of institutional management of research misconduct allegations. The institution's Research Integrity Officer (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 the subsequent use exception, please reach out to ORI at any time for guidance by calling (240) 453-8800 or emailing [AskORI@hhs.gov](mailto:AskORI@hhs.gov).

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<sup>4</sup> §§ 93.306(c)(2)(i) and 93.306(b)(3).

<sup>5</sup> § 93.104(b)(1)(i).

<sup>6</sup> §§ 93.104(b)(1)(ii) and 93.318.

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

### § 93.104 Time limitations.

(a) *Six-year limitation.* This part applies only to research misconduct occurring within six years of the date HHS or an institution receives an allegation of research misconduct.

(b) *Exceptions to the six-year limitation.* Paragraph (a) of this section does not apply in the following instances:

(1) *Subsequent use exception.* The respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the use of, republication of, or citation to the portion(s) of the research record (e.g., processed data, journal articles, funding proposals, data repositories) alleged to have been fabricated, falsified, or plagiarized, for the potential benefit of the respondent.

(i) When the respondent uses, republishes, or cites to the portion(s) of the research record that is alleged to have been fabricated, falsified, or plagiarized, in submitted or published manuscripts, submitted PHS grant applications, progress reports submitted to PHS funding components, posters, presentations, or other research records within six years of when the allegations were received by HHS or an institution, this exception applies.

(ii) For research misconduct that appears subject to the subsequent use exception, institutions must document their determination that the subsequent use exception does not apply. Such documentation must be retained in accordance with § 93.318.

(2) *Exception for the health or safety of the public.* If ORI or the institution, following consultation with ORI, determines that the alleged research misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public, this exception applies.

### § 93.306 Institutional assessment.

(a) *Purpose.* An assessment's purpose is to determine whether an allegation warrants an inquiry.

(b) *Conducting the institutional assessment.* Upon receiving an allegation of research misconduct, the RIO or another designated institutional official must promptly assess the allegation to determine whether the allegation:

(1) Falls within the definition of research misconduct under this part;

(2) Is within the applicability criteria of § 93.102; and

(3) Is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

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(c) *Assessment results.*

(1) An inquiry must be conducted if the allegation meets the three assessment criteria in paragraph (b) of this section.

(2) If the RIO or another designated institutional official determines that requirements for an inquiry are met, they must:

(i) Document the assessment; and

(ii) Promptly sequester all research records and other evidence, consistent with § 93.305(a), and promptly initiate the inquiry.

(3) If the RIO or another designated institutional official determines that requirements for an inquiry are not met, they must keep sufficiently detailed documentation of the assessment to permit a later review by ORI of the reasons why the institution did not conduct an inquiry. Such documentation must be retained in accordance with § 93.318.

## § 93.318 Retention and custody of the institutional record and all sequestered evidence.

(a) *Maintenance of institutional record and all sequestered evidence.* An institution must maintain the institutional record and all sequestered evidence including physical objects (regardless of whether the evidence is part of the institutional record) in a secure manner for seven years after completion of the proceeding or the completion of any HHS proceeding involving the research misconduct allegation under subparts D and E of this part, whichever is later, unless custody has been transferred to HHS under paragraph (b) of this section or ORI advises otherwise in writing.

(b) *Provision for HHS custody.* On request, institutions must transfer custody, or provide copies, to HHS of the institutional record or any component of the institutional record and any sequestered evidence (regardless of whether the evidence is included in the institutional record) for ORI to conduct its oversight review, develop the administrative record, or present the administrative record in any proceeding under subparts D and E of this part.

## Pertinent Sections of 42 CFR Part 93 (2005)

### § 93.105 Time limitations.

(a) *Six-year limitation.* This part applies only to research misconduct occurring within six years of the date HHS or an institution receives an allegation of research misconduct.

(b) *Exceptions to the six-year limitation.* Paragraph (a) of this section does not apply in the following instances:

(1) *Subsequent use exception.* The respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, republication or

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other use for the potential benefit of the respondent of the research record that is alleged to have been fabricated, falsified, or plagiarized.

(2) *Health or safety of the public exception.* If ORI or the institution, following consultation with ORI, determines that the alleged misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public.

(3) *“Grandfather” exception.* If HHS or an institution received the allegation of research misconduct before the effective date of this part.