

§ 93.103

PHS funds resulted in a grant, contract, cooperative agreement, or other form of PHS support.

(c) This part does not supersede or establish an alternative to any existing regulations or procedures for handling fiscal improprieties, the ethical treatment of human or animal subjects, criminal matters, personnel actions against Federal employees, or actions taken under the HHS debarment and suspension regulations at 45 CFR part 76 and 48 CFR subparts 9.4 and 309.4.

(d) This part does not prohibit or otherwise limit how institutions handle allegations of misconduct that do not fall within this part's definition of research misconduct or that do not involve PHS support.

§ 93.103 Research misconduct.

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

(a) Fabrication is making up data or results and recording or reporting them.

(b) 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.

(c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

(d) Research misconduct does not include honest error or differences of opinion.

§ 93.104 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 Time limitations.

(a) *Six-year limitation.* This part applies only to research misconduct occurring within six years of the date

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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 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.

§ 93.106 Evidentiary standards.

The following evidentiary standards apply to findings made under this part.

(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. The destruction, absence of, or respondent's failure to provide research records adequately 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, knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain the records but did not do so, or maintained the records and failed to produce them in a timely manner and that the respondent's conduct constitutes a significant departure from accepted practices of the relevant research community.

(2) The respondent has the burden of going forward with and the burden of proving, by a preponderance of the evidence, any and all affirmative defenses raised. In determining whether HHS or the institution has carried the burden