



Science Advancement & Outreach  
A DIVISION OF PETA

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October 27, 2022

Office of the Secretary  
Department of Health and Human Services  
Via e-mail: [OASH-ORI-Public-Comments@hhs.gov](mailto:OASH-ORI-Public-Comments@hhs.gov)  
Re: Regulations RFI

To whom it may concern:

As the Office of Research Integrity (ORI) is aware, a number of high-profile cases involving misconduct by federally funded investigators have been recently publicized, including the devastating [possibility](#) that a 2006 study of Alzheimer’s disease in rats may have misled the scientific and patient communities for more than a decade, resulting in millions of wasted research dollars.

ORI recently published the results of several investigations into National Institutes of Health (NIH)-funded researchers at the [University of California–Los Angeles](#), [University of California–Berkeley](#), [University of Wisconsin–Madison](#), and [Albert Einstein College of Medicine](#) who were determined to have “intentionally, knowingly, and/or recklessly falsified” data in scientific publications and/or federal grant applications that involved the use of animals. The recent ORI reports also included documented [misconduct](#) from Deepak Kaushal, director of one of the nation’s seven multimillion-dollar national primate research centers and the current recipient of more than \$7.5 million in NIH grant funds. Currently, the penalties for misconduct do not prohibit the investigators from continuing to receive federal research funds, and many of these investigators continue to conduct their work with taxpayer money.

Presently, there is no mechanism that ensures that individuals charged with reviewing grant applications are aware of misconduct or Public Health Service (PHS) Policy violations committed by applicants or their home institutions. This lack of transparency impacts reviewers’ ability to make informed judgments based on a comprehensive set of facts pertaining to the application. The current grant review system enables individuals who have engaged in research misconduct to continue receiving federal funds, potentially producing additional compromised and misleading results. This practice not only rewards investigators for problematic work but also erodes the public’s trust in science.

Additionally, misconduct involving vulnerable human subjects and non-human animals should garner additional scrutiny from ORI. Research with non-consenting animals or human participants who are unable to provide full consent, or who have been otherwise identified vulnerable (pregnant women and fetuses, minors, prisoners, persons with diminished mental capacity, and those who are educationally or economically disadvantaged) deserve the highest level of protections. Any respondents found guilty of misconduct while conducting research with these populations should be barred from research using these populations in the future.

Government funding for research is an honor that should be preserved for scientists who have demonstrated integrity; it should be denied to those who disregard PHS requirements and federal laws and regulations, particularly when that disregard exploits vulnerable individuals.

**Therefore, when revising [42 CFR part 93](#), the following sections should be changed:**

**[§ 93.105\(b\) Exceptions to the six-year limitation.](#)**

A subpart (4) should be added to this section:

(4) *Vulnerable subjects exception.* If the alleged misconduct involved research undertaken using vulnerable human participants (pregnant people, fetuses and neonates, minors, incarcerated persons, individuals with mental disabilities, and educationally or economically disadvantaged persons) or non-human animals.

**[§ 93.108 Confidentiality.](#)**

A subpart (a)(3) should be added to this section:

(3) If misconduct is established, the identity of the respondents must be revealed in federal grant applications as well as to institutional human subjects and animal use review boards, where applicable.

**[§ 93.318 Notifying ORI of special circumstances.](#)**

A subpart (h) should be added to this section:

(h) The alleged misconduct involved research undertaken using vulnerable human participants (as defined above) or non-human animals.

**[§ 93.401 Interaction with other offices and interim actions.](#)**

Subpart (c) should be changed to read:

(c) The information provided will be disclosed as part of the peer review and advisory committee review processes and may be used by the Secretary in making decisions about the award or continuation of funding.

**[§ 93.407 HHS administrative actions.](#)**

An additional subpart (d) should be added to this section:

In connection with findings of research misconduct that involved studies using vulnerable human participants (as defined above) or non-human animals, respondents will be barred from using vulnerable human subjects or non-human animals under PHS-supported research.

Sincerely,



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