Office of Research Integrity

U.S. Department of Health and Human Services

Assurance Program

1101 Wootton Parkway, Suite 240

Rockville, MD 20852

Phone: (240) 453-8407

To: Non-U.S. Institutions

Any institution that applies for or receives U.S. Public Health Service (PHS) support — including grants, cooperative agreements, or contracts or subgrants or subcontracts[[1]](#footnote-2) — to be used for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training, must provide the U.S. Department of Health and Human Services (HHS) with an assurance of compliance with [42 CFR Part 93](https://ori.hhs.gov/sites/default/files/42_cfr_parts_50_and_93_2005.pdf) (the PHS regulation) by establishing and then maintaining an active assurance.[[2]](#footnote-3)

The institution must assure, initially and then annually thereafter, that it:

(1) Has written policies and procedures for addressing allegations of research misconduct, in compliance with the regulation.

(2) Complies with its policies and procedures when responding to allegations of research misconduct.

(3) Complies with all provisions of the regulation[[3]](#footnote-4)

Some non-U.S. institutions have expressed concerns that submitting policies and procedures that are in compliance with all provisions of 42 C.F.R. Part 93 would be contrary to specific laws and regulations in their countries. For these institutions, ORI has provided the document (see following page), *Foreign Institution Statement on Addressing Allegations of Research Misconduct Involving PHS-Funded Research or Activities*.

If you have any questions regarding this statement or your institution’s responsibilities in applying for or receiving PHS funding, please contact: ORI\_Assurance@hhs.gov.

Sincerely,

Robin Parker

Assurance Program Manager

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The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies."

**Foreign Institution Statement on Addressing Allegations of Research Misconduct**

**Involving PHS-Funded Research or Activities**

**[Name of Institution]** has incorporated into its policies and procedures the following approach for addressing allegations of research misconduct when PHS funds are involved.

1. **[Name of Institution]** will designate an official (“Institutional Certifying Official”) to:
* Receive allegations of research misconduct involving PHS funds;
* Develop procedures to enable institutional members or others to make an allegation of research misconduct involving PHS funds; and
* Notify the U.S. Office of Research Integrity (ORI) when an allegation of research misconduct involving PHS funds is received. Phone: (240) 453-8800. E-mail: askORI@hhs.gov.

2. **[Name of Institution]** will work with ORI or another appropriate HHS office to develop and implement a process for responding to research misconduct allegations that is consistent with U.S. Federal regulation,

[42 CFR Part 93](https://ori.hhs.gov/sites/default/files/42_cfr_parts_50_and_93_2005.pdf).

3. **[Name of Institution]**, upon request, will submit reports (in English) to ORI that describe the process the institution followed in conducting the investigation, the evidence on which the conclusions of the investigation are based, and if a finding of research misconduct is made, the administrative actions that are taken against the respondent.

4. **[Name of Institution]** will inform institutional members about who the Institutional Certifying Official is, what that person does, and how to make an allegation of research misconduct involving PHS-supported research. This information also will be posted on the institution’s website.

5. **[Name of Institution]** certifies that this statement will be a permanent amendment to the institution’s policies and procedures for responding to allegations of research misconduct.

6. **[Name of Institution]** will submit the “Annual Report on Possible Research Misconduct” ([Form PHS 6349](https://www.hhs.gov/sites/default/files/phs-6349.pdf)) to ORI by April 30 of each year, via ORI’s secure online submission platform, at: <https://ori.hhs.gov/arprm/>.

Name of Institution: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Institutional Certifying Official’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Institutional Certifying Official’s Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Institutional Certifying Official’s Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E-Mail Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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1. 42 CFR § 93.221 [↑](#footnote-ref-2)
2. 42 CFR § 93.302 [↑](#footnote-ref-3)
3. 42 CFR § 93.301(b) [↑](#footnote-ref-4)