

Office of Research Integrity
Assurance Program
1101 Wootton Parkway, Suite 750
Rockville, MD 20852
Phone: 240-453-8400
Fax: 240-276-9574

TO: Small Institution Representative

For small institutions (typically 1 to 10 employees) receiving Public Health Service (PHS) research funds, it may be difficult to conduct an inquiry or investigation into an allegation of research misconduct without real or apparent conflict of interest as required by the PHS Policies on Research Misconduct (42 C.F.R. Part 93). For this reason, small institutions may file a Small Organization Statement with the Office of Research Integrity (ORI) to establish their assurance in lieu of a formal institutional policy. The small institution should file a Small Organization Statement immediately upon notification from ORI or prior to receipt of PHS research funds (see next page and <https://ori.hhs.gov/small-organization-statement>).

By submitting the Small Organization Statement the institution agrees to report all allegations of research misconduct to ORI immediately upon learning of the allegations or evidence of possible research misconduct. ORI will then work with the institution to implement a process consistent with the regulation to handle any allegations of research misconduct at the small institution. This process may involve ORI taking primary responsibility for conducting the inquiry and/or investigation. The institution must also submit an annual report to ORI.

Filing a Small Organization Statement with ORI does not relieve the institution from complying with other provisions of the PHS misconduct regulation (available on the ORI homepage at <https://ori.hhs.gov>). This includes, but is not limited to, the institution's obligation to inform its staff about the statement, to keep a copy of the statement on file, to take necessary immediate or interim administrative actions to handle allegations, to protect the confidentiality of the whistleblower and respondent, and to cooperate with and report to ORI.

Please contact our office if you have any questions.

Sincerely,

Robin Parker
Assurance Program Specialist

Please submit statement on Institutional Letterhead

**Office of Research Integrity
Small Organization Statement
for Handling Allegations of Research Misconduct
Involving Public Health Services Research and Related Activities**

[institution] has incorporated into its policies and procedures the following approach for handling and reporting possible research misconduct and agrees to comply with other provisions of 42 C.F.R. Part 93:

1. Upon becoming aware of an allegation or other evidence of possible research misconduct, the designated misconduct policy and procedures official of **[institution]** will immediately contact the Office of Research Integrity (ORI) at (240) 453-8400, and **[institution]** will submit an annual report to ORI.
2. **[institution]** will work with ORI or other appropriate offices of the Department of Health and Human Services (HHS) to develop and implement a process consistent with the regulation at 42 C.F.R. Part 93 to fully explore the allegation or evidence of misconduct involving PHS support research or research activities. This may entail ORI/HHS taking primary responsibility for conducting the inquiry and/or investigation.
3. **[institution]** will cooperate fully with the ORI/HHS in conducting its oversight and review of possible research misconduct involving PHS supported research or research activities.
4. **[institution]** will inform its employees of their option to report any allegation or evidence of research misconduct directly to ORI rather than to **[institution's]** designated misconduct policies and procedures official.
5. **[institution]** has _____ employees, _____ of whom are involved in PHS research or research activities as defined in 42 C.F.R. Part 93.

Name of Institution:

E-mail Address:

Mailing Address:

Phone:

Fax:

Institutional Official's Name:

Institutional Official's Title:

Institutional Official's Signature:

Date Signed: