

Office of Research Integrity
Assurance Program
1101 Wootton Parkway, Suite 750
Rockville, MD 20852
Phone: 301-443-5300
Fax: 301-594-0042

TO: Small Organizations

The Office of Research Integrity (ORI) has received numerous calls from small businesses and sole proprietorships indicating that they have so few employees (typically 1 to 10 persons) that they cannot conduct a review, inquiry, or investigation without apparent or real conflicts of interest, as is required by their Assurance and the PHS Regulations at 42 CFR Part 50, Subpart A. Thus, the ORI has prepared the attached "Statement for Small Organizations," and if your organization wishes to use the Statement, please submit it on your organization's letterhead.

This small organization policy requires an institution to report to the ORI all allegations of research misconduct involving PHS support immediately upon learning of such allegations or evidence of possible misconduct. The ORI or another appropriate office in the Department of Health and Human Services (HHS) would then work with your organization to develop and implement a process consistent with the regulations at 42 CFR Part 50, Subpart A, to fully explore the allegation or evidence of misconduct in research. This may entail the HHS taking primary responsibility for conducting the inquiry and/or investigation.

In addition, your organization would still be required to comply with the other requirements of the regulations, including the organization's obligations to inform its staff about this policy; to keep a copy of this policy on file; to take immediate or interim administrative actions on allegations, as necessary; and to protect the confidentiality of the whistleblower and respondent and to cooperate with and make reports to the ORI.

Please contact our office if you have any questions.

Sincerely,

Douglas S. Brown
Assurance Program Manager

**Statement on Dealing with Allegations of Research Misconduct
Under Public Health Service Research-related Activities**

[name of organization] has incorporated into its policies and procedures for dealing with and reporting possible research misconduct the following approach:

1. Upon becoming aware of an allegation or other evidence of possible research misconduct, the designated misconduct policy and procedures official of **[name of organization]** will immediately contact the Office of Research Integrity (ORI) at 301-443-5330.
2. **[name of organization]** will then work with the ORI or other appropriate offices of the Department of Health and Human Services (HHS) to develop and implement a process consistent with the regulations at 42 CFR Part 50, Subpart A, to fully explore the allegation or evidence of misconduct in research. This may entail the HHS taking primary responsibility for conducting the inquiry and/or investigation.
3. **[name of organization]** will cooperate fully with the ORI/HHS and, as appropriate, with any cognizant parties in exploring the facts of the situation.
4. **[name of organization]** will inform all employees that they have the option of reporting any allegation or evidence of research misconduct directly to the ORI rather than to the designated misconduct policy and procedures official of **[name of organization]**.
5. **[name of organization]** has _____ employees.

Name of Organization: _____
Address: _____

Phone: _____
Business Official's Name: _____
Business Official's Title: _____
Business Official's Signature: _____
Date Signed: _____