



**Office of Research Integrity
Small Institution Statement
for Handling Allegations of Research Misconduct
Under 42 CFR Part 93**



For small institutions (typically 1 to 50 institutional members) applying for or receiving Public Health Service (PHS) research funds, it may be difficult to conduct an inquiry or investigation into an allegation of research misconduct as required by the PHS Policies on Research Misconduct (42 CFR Part 93) without real or perceived conflicts of interest. A small institution is defined in this regulation as:

§ 93.240 Small institution. Small institution means an institution that may be too small to conduct an inquiry or investigation into an allegation of research misconduct as required by this part without actual or apparent conflicts of interest.

Small institutions may file this Small Institution Statement with the Office of Research Integrity (ORI) in lieu of the written policies and procedures required by 42 CFR §§ 93.300(a), 93.301, and 93.304 when completing the Research Integrity Assurance Establishment form and when filing the Research Integrity Assurance and Annual Report on Possible Research Misconduct. Consistent with § 93.303, ORI will notify institutions whether their use of the Small Institution Statement is approved.

Filing a Small Institution Statement with ORI does not relieve the institution from complying with any other provisions of [42 CFR Part 93](#). The regulation states that by submitting a Small Institution Statement, the institution agrees to report all allegations of research misconduct to ORI. ORI or another appropriate HHS office will work with the institution to develop and/or advise on an administrative process for handling allegations of research misconduct consistent with 42 CFR Part 93. The regulation also states that if a small institution has or believes it has a conflict of interest during any phase of a research misconduct proceeding, the small institution may contact ORI for guidance.

All institutions, including small institutions, that apply for or receive PHS support for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training with PHS funding, are required to file the Research Integrity Assurance and Annual Report on Possible Research Misconduct form with ORI. The annual report will contain information on the institution's compliance with 42 CFR Part 93 with respect to allegations of research misconduct. The Institutional Certifying Official is responsible for certifying the content of this report and for ensuring the report is submitted as required. Along with its annual report, an institution must send ORI such other information as ORI may request on the institution's research misconduct proceedings covered by Part 93 and the institution's compliance with Part 93. **ORI has released guidance on small institutions, which can be found at ori.hhs.gov/guidance-documents.**

Name of Institution:

E-mail Address:

Mailing Address:

Phone:

(Note: Your institution may substitute this information by completing this statement on your institutional letterhead)

Do you believe your institution qualifies as a small institution, as defined in 42 CFR Part 93? A small institution is too small to conduct an inquiry or investigation into an allegation of research misconduct as required by 42 CFR Part 93 without actual or apparent conflicts of interest.

Yes No

If yes, complete the remainder of this statement.

[Institution Name] has ___ (number of) institutional members per 42 CFR § 93.219.

[Institution Name] certifies that it will comply with 42 CFR Part 93. Small institutions are exempt from the requirement to have written policies and procedures per 42 CFR §§ 93.300(a), 93.301, and 93.304 but otherwise must comply with 42 CFR Part 93. **[Institution Name]** further certifies that:

1. Upon becoming aware of any allegation of research misconduct or other evidence of possible research misconduct, the designated institutional official of **[Institution Name]** will immediately contact ORI at AskORI@hhs.gov or (240) 453-8800.
2. **[Institution Name]** will work with ORI or other appropriate HHS offices to develop and implement a process consistent with 42 CFR Part 93 to address allegation(s) of research misconduct.
3. **[Institution Name]** will cooperate with ORI/HHS during any research misconduct proceeding or compliance review under 42 CFR Part 93.
4. **[Institution Name]** will inform its institutional members of their option to report any allegation of research misconduct or evidence of research misconduct directly to ORI rather than to **[institution's]** designated institutional official.
5. **[Institution Name]** will submit an annual report (known as the Research Integrity Assurance and Annual Report on Possible Research Misconduct form) to ORI.

Institutional Certifying Official's Name:

Institutional Certifying Official's Title:

Institutional Certifying Official's Signature:

Date: