

Outline for an Inquiry/Investigation Report for ORI

The following annotated outline may prove useful in preparing the Inquiry/Investigation Report required by the Office of Research Integrity (ORI), under the PHS regulation, except when special factors may suggest a different approach.

1. Background

Include sufficient background information to ensure a full understanding of the issues that concern the PHS under its definition of research misconduct.* This section should detail the facts leading to the institutional inquiry, including a description of the research at issue, the persons involved in the alleged misconduct, the role of the complainant, and any associated public health issues. All relevant dates should be included.

2. Allegations

List all the allegations of research misconduct raised by the complainant and any additional research misconduct allegations that arose during the inquiry/investigation. The source and basis for each allegation or issue should be cited except to the extent that the confidentiality of a complainant requesting anonymity is compromised or where the identity of the source is irrelevant or unnecessary. The allegations identified in this section will form the structure or context in which the subsequent analysis and findings are presented.

3. PHS Support

For each allegation of research misconduct under the PHS definition, identify the PHS support for the research or report (e.g., publication) at issue or the application containing the falsification/fabrication or plagiarism.

4. Institutional Inquiry: Process and Recommendations

Summarize the earlier inquiry process, including the composition of the committee (names, degrees, departmental affiliation, and expertise), and the charge to the committee. List the persons interviewed, the evidence secured and reviewed and the measures taken to ensure its security, the policies and procedures used (or citation to the pertinent section of the institution's policies and procedures), and any other factors that may have influenced the proceedings.

* Sec. 93.103: Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. (a) Fabrication is making up data or results and recording or reporting them. (b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record. (c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. (d) Research misconduct does not include honest error or differences of opinion.

5. Institutional Inquiry/Investigation: Analysis

For each allegation:

Background

Describe the particular matter (e.g., experiment or component of a clinical protocol) in which the alleged misconduct occurred and why and how the issue came to be under investigation.

Analysis

The analysis should take into account all the relevant statements, claims (e.g., a claim of a significant positive result in an experiment), rebuttals, documents, and other evidence, including circumstantial evidence, related to the issue. The source of each statement, claim, or other evidence should be cited (e.g., laboratory notebook with page and date, medical chart documents and dates, relevant manuscripts, transcripts of interview, etc.).

Any use of additional expert analysis should be noted (forensic, statistical, or special analysis of the physical evidence, such as similarity of features or background in contested figures).

Summarize or quote relevant statements, including rebuttals, made by the complainant, respondent, and other pertinent witnesses and reference/cite the appropriate sources. It should describe the relative weight given to the various witnesses and pieces of evidence, noting inconsistencies, credibility, and persuasiveness.

Summarize each argument that the respondent raised in his or her defense against the scientific misconduct allegation and cite the source of each argument. Any inconsistencies among the respondent's various arguments should be noted.

The analysis should be consistent with the terms of PHS definition of research misconduct. Explain why the act(s) of misconduct constitute a significant departure from accepted practices of the relevant research community. Describe any evidence that shows that the respondent acted with intent, that is, any evidence that the respondent knowingly, intentionally, or recklessly engaged in the alleged falsification, fabrication, plagiarism.**

** Sec. 93.104 Requirements for findings of research misconduct. A finding of research misconduct made under this part requires that -- (a) There be a significant departure from accepted practices of the relevant research community; and (b) The misconduct be committed intentionally, knowingly, or recklessly; and (c) The allegation be proven by a preponderance of the evidence.

Similarly, describe the evidence supporting the possibility that honest error or differences of scientific opinion occurred with respect to the issue.

Conclusions

a. For an Inquiry:

Did the inquiry find sufficient evidence of possible scientific misconduct to warrant an investigation? If not, explain why the evidence is insufficient.

b. For an Investigation: Findings of Misconduct or No Misconduct

Concisely state the investigation committee's finding for each identified issue. The investigation report should make separate findings as to whether or not each issue constitutes research misconduct, using the PHS definition and requirements for findings of research misconduct

A finding of research misconduct should be supported by a preponderance of the evidence. Institutions may have their own standard of proof under their research misconduct policies and procedures, one that may be higher than preponderance of the evidence. In such cases, ORI has requested that institutional officials reexamine the evidence and report to ORI what their conclusions would have been under a preponderance of the evidence standard.

If the investigation finds research misconduct on one or more issues, the report should identify the type of misconduct for each issue (fabrication, falsification, or plagiarism). The report should indicate the extent and seriousness of the fabrication, falsification, or plagiarism, including its effect on research findings, publications, research subjects, and the laboratory or project in which the research misconduct occurred.

The institutional report should confirm that any research misconduct found was a significant departure from accepted practices of the relevant research community at the time the misconduct occurred and that the research misconduct was committed intentionally, knowingly, or recklessly.

Publications, standards of the institution or relevant professional societies, State and Federal regulations, expert opinion, can be described and cited as the basis for the accepted research community practice.

c. **Misconduct under the Institution's Policies**

The investigation committee may determine that an action that does not constitute research misconduct under the PHS definition is, nevertheless, research misconduct under the institution's own definition (e.g., clinical protocol deviations or other violations of human subjects protection; documented animal welfare concerns; substandard data management practices; or deficient mentoring of trainees). Any issue that the investigation committee determines to be scientific misconduct solely under the institution's own definition should be identified as such. These findings are not subject to ORI's jurisdiction if ORI agrees that they do not meet the PHS definition or jurisdictional basis.

6. **Recommended Institutional Actions**

Based on its findings, the investigation committee or official should recommend administrative actions that it believes the institution should take consistent with its policies and procedures, including appropriate actions against the respondent, such as a letter of reprimand, special supervision, probation, termination, etc. The institution should also identify any published research reports or other sources of scientific information (such as data bases) that should be retracted or corrected and take steps to ensure that appropriate officials who can effect these corrections or retractions are notified.

Attachments

Copies of all significant documentary evidence that is referenced in the report should be appended to the report, if possible (relevant notebook pages or other research records, relevant committee or expert analyses of data, transcripts or summary of each interview, respondent and complainant responses to the draft report(s), manuscripts, publications or other documents, including grant progress reports and applications, etc.). Include a "List of Attachments."

It is useful to identify in such attachments the allegedly false statements, misrepresentations in figures or parts of figures, areas of plagiarism, etc. on a copy of the page or section of the questioned document (e.g., a page from a research notebook). For alleged plagiarism, a side-by-side comparison with the original data or text that is alleged to have been plagiarized is helpful.