Outline for an Inquiry/Investigation Report for ORI[1]

The following annotated outline may be useful in preparing the Inquiry/Investigation Report required by the Office of Research Integrity (ORI), under the U.S. Public Health Service (PHS) regulations at 42 C.F.R. Part 93, except when special factors may suggest a different approach (if applicable, please contact ORI).

I. Background

A. Include sufficient background information to ensure a full understanding of the issues that concern PHS under its definition of research misconduct.[2] This section should detail the facts leading to the institutional inquiry, including a description of the research at issue, the individuals involved in the alleged misconduct, the role of the complainant, and any associated public health issues. All relevant dates, including the date the institution received the allegations, should be included.

II. Allegations

A. List all of 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 should be cited. The allegations identified in this section will form the structure or context in which the subsequent analysis and findings are presented.

III. PHS Support

A. For each allegation of research misconduct under the PHS definition, identify the PHS support for the research at issue or the report (e.g., publication) or the grant application containing the alleged falsification, fabrication, or plagiarism. In addition, identify any current support or known applications or proposals for support that the respondent has pending with non-PHS federal agencies, per § 93.313(f)(6).

[1]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.

[2]42 C.F.R. § 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.

B. If the alleged research misconduct occurred more than six years before the date the institution received the initial allegation of research misconduct, identify any exceptions to the six-year limitation under 42 C.F.R. § 93.105(b), including respondent's subsequent use, if any, that meets the requirements of § 93.105(b)(1).

IV. Institutional Inquiry: Process and Recommendations

A. Summarize the earlier inquiry process, including the composition of the inquiry committee (including names, degrees, departmental affiliation, and expertise), date of appointment, and the charge to the committee. List the individuals interviewed, the evidence sequestered, the evidence reviewed at the inquiry stage, and the measures taken to ensure its security; the policies and procedures used (or a citation to the pertinent section of the institution's policies and procedures); and any other factors that may have influenced the proceedings (non-responsive or cooperative respondent, complainant, or witnesses; difficultly in sequestering or examining evidence; institutional procedural issues, etc.).

B. Describe in detail how evidence, including electronic evidence such as hard drives, was sequestered. Please see "Submitting Electronic Records to ORI" for helpful information about sequestration.

V. Institutional Inquiry/Investigation: Analysis (for each allegation)

A. <u>Background</u>

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

B. <u>Analysis</u>

i. The analysis of each allegation should take into account all of 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 allegation. The source of each statement, claim, or other evidence should be cited (e.g., computer laptop, desktop, external hard drive, or server, including file folder names and locations; laboratory notebook with page numbers and dates; clinical research documentation and dates; relevant manuscripts or grant applications; emails; transcripts of interviews; etc.).

ii. Any use of additional expert analysis outside of the inquiry/investigation committee should be noted (subject matter expert or consultant). The forensic, statistical, or special analysis of the physical evidence, such as similarity of features or background in contested figures, should be noted and included with attachments.

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

iv. Summarize each argument that the respondent raised in his or her defense against the research misconduct allegation, including any comments on the draft investigation report, and cite the source of each argument. Address each of the respondent's arguments and explain whether any reasonable argument has merit, and if not, explain why not. Any inconsistencies in the respondent's various arguments should be noted. Identify and consider any comments made by the complainant on the draft investigation report.

v. The analysis should be consistent with the terms of PHS definition of research misconduct. Describe any evidence that shows that the respondent knowingly, intentionally, or recklessly engaged in the alleged falsification, fabrication, plagiarism.[3]

vi. Similarly, describe the evidence supporting the possibility that honest error or differences of scientific opinion occurred with respect to the issue. The determination of whether the alleged misconduct is intentional, knowing, or reckless, including consideration of evidence of honest error or difference of opinion, should be made at the investigation stage, following a complete review of the evidence.

C. Conclusions

i. For an Inquiry:

a. Describe whether the inquiry committee recommended that an investigation was warranted, namely, a reasonable basis for concluding that the allegation falls within the definition of research misconduct and involves PHS-supported research, and preliminary information-gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance. If the committee concluded that the evidence is insufficient to warrant an investigation, explain why.

[3]42 C.F.R. § 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.

ii. For an Investigation: Findings of Research Misconduct or No Research Misconduct

a. Concisely state the investigation committee's finding for each identified allegation. For each allegation, the investigation report must state whether or not the committee found research misconduct, using the PHS definition, and must identify the evidence that supports that conclusion.

b. A finding of research misconduct under the PHS regulation must be supported by a preponderance of the evidence. Institutions may have their own standard of proof under their research misconduct policies and procedures, which may be higher than preponderance of the evidence. In such cases, institutional officials must examine the evidence and report to ORI what their conclusions are under a preponderance of the evidence standard.

c. If the investigation finds research misconduct for one or more allegations, the report must identify the type of misconduct for each allegation (fabrication, falsification, or plagiarism). The report must indicate the extent and seriousness of the fabrication, falsification, or plagiarism, including its effect on research findings, publications, grants, human or animal research subjects, and the laboratory or project in which the research misconduct occurred.

d. If additional respondents are identified, the institution must make a separate determination of the respondents' culpability for each allegation. The specific individual who committed the misconduct must be identified. The report must state whether the misconduct was committed intentionally, knowingly, or recklessly, and if so, summarize the evidence that the research misconduct was committed intentionally, knowingly, or recklessly.

e. The report should identify the relevant research community, articulate the accepted practices in the relevant research community, and state how any research misconduct found was a significant departure from these accepted practices at the time the misconduct occurred.

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

iii. Misconduct under the Institution's Policies

a. 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 allegation that the investigation

committee determines to be research misconduct solely under the institution's own definition must be identified as such. These findings are not subject to ORI's jurisdiction if ORI agrees that they do not meet the PHS definition of research misconduct.

iv. If the institution plans to close a case at the inquiry (or investigation) stage on the basis that the respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, the institution must notify ORI in advance. ORI will conduct an oversight review to determine the adequacy and completeness of the admission, and if the institution should continue with its research misconduct proceedings or closure of the case.

VI. Institutional Administrative Actions.

A. The institution must describe any pending or completed administrative actions against the respondent. The institution also must identify any published research reports or other sources of scientific information (such as data bases) that should be retracted or corrected and should take steps to ensure that appropriate officials who can effect these corrections or retractions are notified.

VII. Attachments

A. Copies of all significant documentary evidence that is referenced in the report must be appended to the report, if possible (relevant notebook pages or other research records, relevant committee or expert analyses of data, transcripts or summaries of all interviews, 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."[4] Identify any sequestered evidence that was not reviewed by the investigation committee, if applicable.

B. In the attachments, it is useful to identify 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.

[4]Please refer to the document "Submitting Electronic Records to ORI" for more detail and explanation regarding submitting records to ORI electronically.