

Supplementary Guidance and Procedures for Allegations Subject to 42 CFR Part 93

Public Health Service (PHS) Policies on Research Misconduct, <u>42 CFR Part 93</u>, applies to all research misconduct proceedings that pertain to PHS supported research or applications for PHS research support. This document contains additional guidance and procedures for such proceedings and is supplementary to the UF Policy on Research Integrity, found on the <u>UF Policy Hub</u>.

For the purposes of this supplementary guidance, *Research Misconduct* means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results in PHS supported research or applications for PHS research support. Research misconduct does not include honest error or differences of opinion.

Exigent Or Special Circumstances

Procedural Step	PHS Citation
 Upon receipt of a new allegation, and thereafter as new circumstances arise, UF Research Integrity Officer (RIO) will promptly notify the Office of Research Integrity (ORI) if UF has reason to believe that any of the following conditions exist: Health or safety of the public is at risk, including an immediate need to protect human or animal subjects; PHS or other sponsor or institutional resources or interests are threatened; Research activities should be suspended; There is reasonable indication of possible violations of civil or criminal law; Federal action is required to protect the interests of those involved in the research misconduct proceeding; The research misconduct proceeding may be made public prematurely; or The research community or public should be informed. 	§93.304(i) §93.304(h) §93.318
 In cases of exigent circumstances, UF must take appropriate interim institutional actions to protect public health, Federal funds and equipment, and the integrity of the PHS-supported research process. Interim actions may include: Additional monitoring of the research process and the handling of federal funds and equipment; Reassignment of personnel or of the responsibility for the handling of federal funds and equipment; Additional review of research data and results; Delay of publication of research results; or Other actions as deemed appropriate by UF. 	

Inquiry Stage

Procedural Step	PHS Citation
Either before or when the institution notifies Respondent of the allegation, inquiry or investigation, RIO will promptly take all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments	§93.307 (a); §93.307 (b)
RIO must provide written notice of inquiry and a copy of the Research Integrity Policy and Regulation 1.0101 to Respondent.	§ 93.307 (b)
If, at any time during the inquiry or subsequent investigation, the RIO identifies additional respondents, RIO must notify them in accordance with the UF Policy on Research Integrity.	
RIO will engage in preliminary information gathering and preliminary fact-finding. The institution must complete the inquiry within 60 calendar days of its initiation unless circumstances clearly warrant a longer period.	§93.307(g)
If the inquiry takes longer than 60 days to complete, the inquiry record must include documentation of the reasons for exceeding the 60-day period.	
RIO will prepare an inquiry report that includes name and position of Respondent; a description of the allegation; the basis for concluding whether an investigation is warranted; and a description of any extramural support for the research at issue (e.g., the proposal, grant or contract number, or publications that cite such support). RIO will send the draft inquiry report to Respondent; providing Respondent with 10 calendar days to review and comment. Any comments will become part of the inquiry report.	§ 93.307 (e) § 93.307 (f)
RIO will submit Inquiry Report to UF Deciding Official (DO). DO will accept or reject the report in writing within 10 calendar days of receipt. Within 30 days of finding that an investigation is warranted, UF will provide ORI with the written finding official and a copy of the inquiry report and begin the investigation.	§93.309(a) §93.310(b)

Investigation Stage

Procedural Step	PHS Citation
DO will send a copy of the final inquiry report and notice of investigation letter to Respondent. The notice should advise Respondent that they may select an advisor of their choice to be present when interviewed by the committee.	§93.310(c) §93.308(a)
Throughout the investigation, and to the extent they have not already done so at the allegation or inquiry stages, RIO will take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding.	§93.310(d)
RIO will appoint a non-conflicted investigation committee of at least three faculty members from the relevant scientific community. UF will complete all aspects of the investigation within 120 days of beginning it, including conducting the investigation, preparing the report of findings, and providing the draft report to Respondent for comment. If the investigation cannot be completed within 120 days, UF will request an extension from ORI.	§93.310 (a) §93.311(a) §93.311(b)
Once impaneled, the committee will review all evidence, pursue all leads relevant to the investigation, and if needed, determine if potential instances of research misconduct extend beyond the initial allegation. The Committee must also interview the Complainant, Respondent, and any other available person reasonably identified by the Committee as having information about any relevant aspect of the investigation. Each interview must be recorded and transcribed. Interviewees will have the opportunity to review the transcription and provide comments. The recording, transcript and any interview comments will become part of the investigative record.	§93.310 (g) §93.310(h)
 Committee must prepare an investigation report, which must: Describe the nature of the allegations of research misconduct; Describe and document the PHS support (e.g., grant numbers, grant applications, contracts, and publications listing PHS support); Include the institutional charge (e.g., description of the specific allegations of research misconduct for consideration in the investigation); Include a copy of the institutional policies and procedures under which the investigation was conducted, if not already provided to ORI with the inquiry report; Identify and summarize the research records and evidence reviewed, and identify any evidence taken into custody but not reviewed; For each separate allegation of research misconduct, provide a finding as to whether research misconduct did or did not occur, and if sooldentify whether the research misconduct was falsification, fabrication, or plagiarism, and if it was intentional, knowing, or in reckless disregard 	§93.313

 Summarize the facts and the analysis which support the conclusion and consider the merits of any reasonable explanation by the respondent Identify the specific PHS support Identify whether any publications need correction or retraction Identify the person(s) responsible for the misconduct; and List any current support or known applications or proposals for support that the respondent has pending with non-PHS Federal agencies; Include and consider any comments made by the respondent draft investigation report. 	
UF will maintain, and provide to ORI upon request, all relevant research records, and records of the institution's research misconduct proceeding, including results of all interviews and the transcripts or recordings of such interviews.	§93.313
Respondent will be provided with a copy of the draft investigation report and supporting evidence. Respondent will have the opportunity to provide comments on the draft investigation report and must provide them to the committee within 30 days of receipt of the draft report. The Committee must review Respondent's comments, consider any comments, and include them in the final report.	§93.312
Once complete, the Committee will send the final report to DO who will review Committee's final investigation report and determine in writing whether to accept the report, return the report to the Committee and request further fact-finding or analysis, or reject the findings of the committee. If DO reaches a different finding than the Committee, DO must explain the basis in writing	§93.315
UF will notify Respondent and ORI of the investigation outcome and will provide a copy of investigation report and DO's acceptance/rejection of Committee's findings.	§93.313 §93.315
UF will notify ORI in advance if UF plans to close a case at the inquiry, investigation, or appeal stage on the basis that the respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except the closing of a case at the inquiry stage on the basis that an investigation is not warranted or a finding of no misconduct at the investigation stage, which must be reported to ORI.	§93.515 §93.316(a)