CHECKLIST: Policies and Procedures for Handling Research Misconduct Allegations

This checklist is used by the U.S. Department of Health and Human Services, Office of Research Integrity (ORI) and is intended only to provide general information regarding ORI's review of institutional policies.

This is not an exhaustive list. Institutions, as defined in 42 C.F.R. § 93.213, are required to comply with 42 C.F.R. Part 93 in its entirety. Individuals responsible for drafting their institutional policies and procedures should consult their legal counsel to ensure compliance with 42 C.F.R. Part 93. This checklist should not be used by institutions or relied on by them as a substitute for familiarity with the Federal laws and regulations applicable to research misconduct, including 42 U.S.C. 289b and 42 C.F.R. Part 93. 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. This document is subject to change without notice.

Regulatory Requirements	**Notes (e.g. Page/Section)**
1. Informs institution's research members participating in or otherwise involved in PHS-supported biomedical or behavioral research, research training or activities related to that research or research training, including those applying for support from any PHS funding component, about its policies and procedures for responding to allegations of research misconduct, and the institution's commitment to compliance with the policies and procedures (§93.302(a)(2)(i)).	
2. Institutional contact information, if any, for reporting possible research misconduct. (Not required by the regulation).	
3. Definition of research misconduct is consistent with §93.103 ☐ Fabrication ☐ Falsification ☐ Plagiarism ☐ Does not include honest error or differences of opinion ☐ Research misconduct means fabrication, falsification, or plagiarism in proposing,	

performing, or reviewing research, or in reporting research results.	
4. Allegation may be presented by any means of communication to an institutional or HHS official (§93.201).	
5. Six-year limitation on allegations from the date HHS or an institution receives an allegation, and exceptions to the six-year limitation (§93.105).	
6. The institution must take all reasonable and practical steps to ensure the cooperation of respondents and other institutional members with research misconduct proceedings, including, but not limited to, their providing information, research records, and evidence (§93.300(f)).	
7. Notice to the respondent(s), consistent with and within the time limits of this part (§93.304(c)) ☐ At the time of or before beginning an inquiry, an institution must make a good faith effort to notify in writing the presumed respondent, if any (§93.307(b)) ☐ If the inquiry subsequently identifies additional respondents, the institution must notify them (§93.307(b)) ☐ The institution must notify the respondent whether the inquiry found that an investigation is warranted. The notice must include a copy of the inquiry report and include a copy of or refer to this part and the institution's policies and procedures adopted under its assurance. (§93.308(a)) ☐ Notify the respondent in writing of the allegations within a reasonable amount of time after determining that an investigation is warranted, but before	

the investigation begins. The institution must give the respondent written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the inquiry or in the initial notice of investigation (§93.310(c)).	
8. Either before or when the institution notifies the respondent of the allegation, inquiry or investigation, promptly take all reasonable and practical steps to obtain custody of all the 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; (§93.305(a), §93.307(b)).	
9. Protocols for handling the research record and evidence, including the requirements of Sec. 93.305 (§93.304(g)).	
10. Consistent with Sec. 93.108, protection of the confidentiality of ☐ Respondents, ☐ Complainants, and ☐ Research subjects identifiable from research records or evidence (§93.304(a)).	
11. A thorough, competent, objective, and fair response* to allegations of research misconduct consistent with and within the time limits** of 42 C.F.R. Part 93, including precautions to ensure that individuals	

responsible for carrying out any part of the research misconduct proceeding do not have unresolved personal, professional, or financial conflicts of interest with the ☐ Complainant, ☐ Respondent, or ☐ Witnesses (§93.304(b)). *****<u>Ensuring a fair investigation</u> ☐ Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practicable, including participation of persons with appropriate scientific expertise who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry or investigation (§93.310(f)). ** Time Limits ☐ The institution must complete the inquiry within 60 calendar days of its initiation unless circumstances clearly warrant a longer period. 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 (§93.307(g)) ☐ Within 30 days of finding that an investigation is warranted, provide ORI with the written finding by the responsible institutional official and a copy of the inquiry report (§93.309(a)) ☐ Begin the investigation within 30 days after determining that an investigation is warranted (§93.310(a)) ☐ An institution must complete all aspects of an investigation within 120 days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft report for comment in accordance with Sec. 93.312, and sending the final report to ORI under Sec. 93.315. (§93.311(a)).	

12. Purpose of inquiry is to conduct an initial review of evidence to determine whether to conduct an investigation (§93.307(c)).	
13. Undertake all reasonable and practical efforts to take custody of additional research records and evidence that is discovered during the course of a research misconduct proceeding (§93.305(c)).	
14. Criteria warranting an inquiry (§93.307(a)(1) - (3)) ☐ Falls within the definition of research misconduct under 42 C.F.R. Part 93, ☐ Is within Sec. 93.102, and ☐ Is sufficiently credible and specific so that potential evidence of research misconduct may be identified.	
15. Carry inquiries and investigations through to completion and to pursue diligently all significant issues (§93.316(a)).	
16. Documentation of decision not to investigate (§93.309(c)).	
17. Contents of inquiry report (§93.307(e), §93.309(a)) ☐ The name and position of the respondent. ☐ A description of the allegations of research misconduct. ☐ The PHS support, including, for example, grant numbers, grant applications, contracts, and publications listing PHS support ☐ The basis for recommending that the alleged actions warrant an investigation; and	

☐ Any comments on the report by the respondent or the complainant.	
18. Opportunity for the respondent to provide written comments on the institution's inquiry report (§93.304(e)).	
19. Retention of records of research misconduct proceedings, as defined by 42 C.F.R. Part 93, including the inquiry report and final documents produced in the course of preparing inquiry report (§93.317(a)(3), §93.317(b)).	
20. Criteria warranting an investigation. An investigation is warranted if there is— ☐ (1) A reasonable basis for concluding that the allegation falls within the definition of research misconduct under this part and involves PHS supported biomedical or behavioral research, research training or activities related to that research or research training, as provided in § 93.102; and ☐ (2) Preliminary information-gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance. (§93.307(d) (1-2)).	
21. Notify ORI on or before date investigation begins (§93.310(b)).	
22. Written notice to ORI of any decision to open an investigation on or before the date on which the investigation begins (§93.304(d)).	
23. To the extent they have not already done so at the allegation or inquiry stages, 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)).	
24. Conduct required interviews that are transcribed or recorded, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of the investigation (§93.310(g)).	
25. Pursue leads. Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation (§93.310(h)).	
26. Notice to ORI under Sec. 93.318 and notice of any facts that may be relevant to protect public health, Federal funds and equipment, and the integrity of the PHS-supported research process (§93.304(i)).	
27. Appropriate interim institutional actions to protect public health, Federal funds and equipment, and the integrity of the PHS-supported research process (§93.304(h)).	
28. Documentation. Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of the allegations (§93.310(e)).	
29. Requirements for findings of research misconduct (§93.104) ☐ Significant departure from accepted practices of the relevant research community, and ☐ Misconduct committed intentionally, knowingly, or recklessly, and ☐ Proven by a preponderance of evidence.	

30. If unable to complete the investigation within 120 days, the institution must ask ORI for an extension in writing (§93.311(b)).	
31. Notify ORI in advance if the institution 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 under Sec. 93.515 (§93.316(a)).	
32. Respondent comments (§93.304(f)) ☐ Opportunity for the respondent to provide written comments on the draft report of the investigation, and ☐ Provisions for the institutional investigation committee to consider and address the comments before issuing the final report.	
33. Opportunity to comment on the investigation report (§ 93.312): a. ☐ The institution must give the respondent a copy of the draft investigation report and, concurrently, a copy of, or supervised access to, the evidence on which the report is based. The comments of the respondent on the draft report, if any, must be submitted within 30 days of the date on which the respondent received the draft investigation report. b. ☐ The institution may provide the complainant a copy of the draft investigation report or relevant portions of that report. The comments of the	

complainant, if any, must be submitted within 30 days of the date on which the complainant received the draft investigation report or relevant portions of it.	
34. Investigation report, including (§93.313): a. ☐ Describe the nature of the allegations of research misconduct b. ☐ Describe and document the PHS support (e.g., grant numbers, grant applications, contracts, and publications listing PHS support) c. ☐ Institutional charge (e.g., description of the specific allegations of research misconduct for consideration in the investigation) d. ☐ If not already provided to ORI with the inquiry report, copy of the institutional policies and procedures under which the investigation was conducted e. ☐ Research records and evidence. Identify and summarize the research records and evidence reviewed, and identify any evidence taken into custody but not reviewed f. ☐ Statement of findings. For each separate allegation of research misconduct identified during the investigation, provide a finding as to whether research misconduct did or did not occur, and if so-- 1. ☐ Identify whether the research misconduct was falsification, fabrication, or plagiarism, and if it was intentional, knowing, or in reckless disregard 2. ☐ Summarize the facts and the analysis which support the conclusion and consider the merits of any reasonable explanation by the respondent 3. ☐ Identify the specific PHS support. 4. ☐ Identify whether any publications need correction or retraction	

5. ☐ Identify the person(s) responsible for the misconduct; and 6. ☐ List any current support or known applications or proposals for support that the respondent has pending with non-PHS Federal agencies g. ☐ Comments. Include and consider any comments made by the respondent and complainant on the draft investigation report h. ☐ Maintain and provide records. 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.	
35. Institutional actions in response to final findings of research misconduct (§93.304(j)).	
36. All reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputation of persons alleged to have engaged in research misconduct but against whom no finding of research misconduct is made (§93.304(k)).	
37. All reasonable and practical efforts to protect or restore the position and reputation of any complainant, witness, or committee member and to counter potential or actual retaliation against these complainants, witnesses, and committee members (§93.304(l)).	
38. The institution must give ORI the following (§93.315): a. ☐ Investigation Report. Include a copy of the report, all attachments, and any appeals b. ☐ Final institutional action. State whether the institution found research	

misconduct, and if so, who committed the misconduct c. ☐ Findings. State whether the institution accepts the investigation's findings. d. ☐ Institutional administrative actions. Describe any pending or completed administrative actions against the respondent.	
39. Full and continuing cooperation with ORI during its oversight review under Subpart D of 42 C.F.R. Part 93 or any subsequent administrative hearings or appeals under Subpart E of 42 C.F.R. Part 93. This includes providing all research records and evidence under the institution's control, custody, or possession and access to all persons within its authority necessary to develop a complete record of relevant evidence (§93.304(m)).	
40. Unless custody has been transferred to HHS under 42 C.F.R. Sec. 93.317(c), or ORI has advised the institution in writing that it no longer needs to retain the records, maintain records of research misconduct proceedings in a secure manner for 7 years after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation under 42 C.F.R. Part 93, Subparts D and E, whichever is later (§93.317(b)).	