Institutional Policies and Procedures for Addressing Research Misconduct Allegations

The U.S. Department of Health and Human Services, Office of Research Integrity (ORI) developed the chart below to assist institutions in understanding the requirements and recommendations for written policies and procedures for addressing research misconduct allegations under 42 C.F.R. Part 93.

ORI's review of your institution's policies and procedures is reflected in the chart. In its review, ORI has determined whether the policies and procedures comply with the requirements of 42 C.F.R. § 93.304 (identified in **BOLD** and by (*)). Your institution must revise its policies and procedures to address any noncompliance identified below, as directed by ORI in [email/letter].

ORI also determined whether the policies and procedures are consistent with certain other provisions of 42 C.F.R. Part 93. ORI suggests that your institution revise its policies and procedures to address any inconsistencies as recommended in the chart below, but it is not required to do so.

This review is not intended to cover all provisions included in 42 C.F.R. Part 93 that apply to institutions. Institutions must comply with all applicable provisions of 42 C.F.R. Part 93 and are encouraged to consult their legal counsel. This review should not be used by institutions or relied on by them as a substitute for familiarity with applicable regulations.

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Regulatory Provisions from 42 C.F.R. Part 93	Review Results	Review Comments
1. Informs institution's research members participating in or otherwise involved with 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)).	The institutional policies and procedures are consistent with this regulatory provision.	There are no comments.

2. Definition of research misconduct is consistent with §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.	The institutional policies and procedures are consistent with this regulatory provision.	There are no comments.
3. Allegation may be presented by any means of communication (written or oral statement or other communication) to an institutional or HHS official (§93.201).	The institutional policies and procedures are consistent with this regulatory provision.	There are no comments.
4. Part 93 generally applies only to research misconduct occurring within six years of the date HHS or an institution receives an allegation (§93.105). The six-year limitation does not apply if the respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, republication or other use for the potential benefit of the respondent of the research record that is alleged to have been fabricated, falsified, or	The institutional policies and procedures are consistent with this regulatory provision.	There are no comments.

plagiarized. The six-year limitation does not apply if ORI or the institution, following consultation with ORI, determines that the alleged misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public.		
5. 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)).	The institutional policies and procedures are consistent with this regulatory provision.	There are no comments.
6. *Notice to the respondent(s), consistent with and within the time limits of this part (§93.304(c)) **§ 93.307 Institutional inquiry.** **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)).** **§ 93.308 Notice of the results of the Inquiry.** **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)).**	The institutional policies and procedures comply with this regulatory provision.	No action is required.

§ 93.310 Institutional investigation. 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)).		
7. *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)).	The institutional policies and procedures comply with this regulatory provision.	No action is required.

8. ***Protocols for handling the research record and evidence, including the requirements of Sec. 93.305 (§93.304(g)).**	The institutional policies and procedures comply with this regulatory provision.	No action is required.
9. *Consistent with Sec. 93.108, protection of the confidentiality of respondents, complainants, and research subjects identifiable from research records or evidence. (§93.304(a)). § 93.108 Confidentiality. (a) Disclosure of the identity of respondents and complainants in research misconduct proceedings is limited, to the extent possible, to those who need to know, consistent with a thorough, competent, objective and fair research misconduct proceeding, and as allowed by law. Provided, however, that: (1) The institution must disclose the identity of respondents and complainants to ORI pursuant to an ORI review of research misconduct proceedings under § 93.403. (2) Under § 93.517(g), HHS administrative hearings must be open to the public. (b) Except as may otherwise be prescribed by applicable law,	The institutional policies and procedures comply with this regulatory provision.	No action is required.

confidentiality must be maintained for any records or evidence from which research subjects might be identified. Disclosure is limited to those who have a need to know to carry out research misconduct proceeding.		
10. *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)).** **<u>** Time Limits</u>** **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**	The institutional policies and procedures do not comply with this provision because there are elements of this provision that have been omitted or not satisfied. Below, unchecked boxes indicate elements of this provision that have been omitted or not satisfied: ☒ Precautions to ensure that there are no unresolved personal, professional, or financial conflicts of interest with the ☐ Complainant, ☒ Respondent, or ☐ Witnesses (§93.304(b)). ☒ Reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practicable by including persons with appropriate scientific expertise who do not have unresolved conflicts of interest as described at (§93.310(f)). ☒ Time limits requirements for conducting research misconduct proceedings as described at 42 C.F.R. Part 93: ☒ Completion of inquiry ☒ Notification to ORI when an investigation is warranted ☒ Initiation of an investigation	The institution is required to revise its written policies and procedures to comply with this regulatory provision [for an example of language that complies with this provision, refer to ORI's Sample Policy and Procedures for Responding to allegations of Research Misconduct, Page 10, Section D; Page 11 Section G; Page 12 Section C (2); Page 13, Section VII. A, and Page 16, Section F: https://ori.hhs.gov/sites/default/files/SamplePolicyandProcedures-5-07.pdf].

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)).**	☒ Completion of all aspects of an investigation.	
11. Purpose of inquiry is to conduct an initial review of evidence to determine whether to conduct an investigation (§93.307(c)).	The institutional policies and procedures are consistent with this regulatory provision.	There are no comments.
12. ***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, 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**	The institutional policies and procedures comply with this regulatory provision.	No action is Required.

evidentiary value of the instruments (§93.305(c)).		
13. Criteria warranting an inquiry §93.307(a)(1) – (3)): An inquiry is warranted if the allegation – (1) Falls within the definition of research misconduct under this part; (2) Is within Sec. 93.102; and (3) Is sufficiently credible and specific so that potential evidence of research misconduct may be identified.	The institutional policies and procedures are consistent with this regulatory provision.	There are no comments.
14. Carry inquiries and investigations through to completion and to pursue diligently all significant issues (§93.316(a)).	The institutional policies and procedures are consistent with this regulatory provision.	There are no comments.
15. Detailed documentation of decision not to investigate (§93.309(c)).	The institutional policies and procedures are consistent with this regulatory provision.	There are no comments.
16. Contents of inquiry report. §93.307(e) Inquiry report. The institution must prepare a written report that meets the requirements of this section and § 93.309. §93.309(a) Within 30 days of finding that an investigation is warranted, the institution must provide ORI with the written finding by the responsible institutional official and a copy of the inquiry report which includes the following information— (1) The name and position of the respondent; (2) A description of the allegations of research misconduct;	The institutional policies and procedures are consistent with this regulatory provision.	There are no comments.

(3) The PHS support, including, for example, grant numbers, grant applications, contracts, and publications listing PHS support; (4) The basis for recommending that the alleged actions warrant an investigation; and (5) Any comments on the report by the respondent or the complainant.		
17. ***Opportunity for the respondent to provide written comments on the institution's inquiry report (§93.304(e)).**	The institutional policies and procedures comply with this regulatory provision.	No action is required.
18. ***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)).**	The institutional policies and procedures comply with this regulatory provision.	No action is required.
19. Criteria warranting an investigation. § 93.307 (d) 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 Part 93 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-	The institutional policies and procedures are consistent with this regulatory provision.	There are no comments.

finding from the inquiry indicates that the allegation may have substance. (§93.307(d) (1-2)).		
20. Notify the ORI Director of the decision to begin an investigation on or before the date the investigation begins and provide an inquiry report that meets the requirements of § 93.307 and § 93.309(§93.310(b)).	The institutional policies and procedures are consistent with this regulatory provision.	There are no comments.
21. ***Written notice to ORI of any decision to open an investigation on or before the date on which the investigation begins (§93.304(d)).**	The institutional policies and procedures comply with this regulatory provision.	No action is required.
22. 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, 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. (§93.310(d)).	The institutional policies and procedures are consistent with this regulatory provision.	There are no comments.
23. 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)).	The institutional policies and procedures are consistent with this regulatory provision.	There are no comments.

24. Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation (§93.310(h)).	The institutional policies and procedures are consistent with this regulatory provision.	There are no comments.
25. ***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)).** **§ 93.318 Notifying ORI of special circumstances.** **At any time during a research misconduct proceeding, as defined in § 93.223, an institution must notify ORI immediately if it has reason to believe that any of the following conditions exist:** **(a) Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.** **(b) HHS resources or interests are threatened.** **(c) Research activities should be suspended.** **(d) There is reasonable indication of possible violations of civil or criminal law.** **(e) Federal action is required to protect the interests of those involved in the research misconduct proceeding.** **(f) The research institution believes the research misconduct proceeding may be made public prematurely so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved.**	The institutional policies and procedures comply with this regulatory provision.	No action is required.

(g) **The research community or public should be informed.**		
26. ***Appropriate interim institutional actions to protect public health, Federal funds and equipment, and the integrity of the PHS-supported research process (§93.304(h)).**	The institutional policies and procedures comply with this regulatory provision.	No action is required.
27. 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)).	The institutional policies and procedures are consistent with this regulatory provision.	There are no comments.
28. Requirements for findings of research misconduct (§93.104) 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.	The institutional policies and procedures are consistent with this regulatory provision.	There are no comments.
29. If unable to complete the investigation within 120 days, the institution must ask ORI for an extension in writing (§93.311(b)).	The institutional policies and procedures are consistent with this regulatory provision.	There are no comments.

30. 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. 93.315 (§93.316(a)).	The institutional policies and procedures are consistent with this regulatory provision.	There are no comments.
31. *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;**	The institutional policies and procedures comply with this regulatory provision.	No action is required.
32. 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	The institutional policies and procedures are consistent with this regulatory provision.	There are no comments.

any, must be submitted within 30 days of the date on which the complainant received the draft investigation report or relevant portions of it.		
33. Investigation report (§93.313) The final institutional investigation report must be in writing and include: (a) *Allegations.* Describe the nature of the allegations of research misconduct. (b) *PHS support.* Describe and document the PHS support, including, for example, any grant numbers, grant applications, contracts, and publications listing PHS support. (c) *Institutional charge.* Describe the specific allegations of research misconduct for consideration in the investigation. (d) *Policies and procedures.* If not already provided to ORI with the inquiry report, include 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	The institutional policies and procedures are consistent with this regulatory provision.	There are no comments.

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.		
34. ***Institutional actions in response to final findings of research misconduct (§93.304(j)).**	The institutional policies and procedures comply with this regulatory provision.	No action is required.

35. ***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)).**	The institutional policies and procedures comply with this regulatory provision.	No action is required.
36. ***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)).**	The institutional policies and procedures comply with this regulatory provision.	No action is required.
37. 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.	The institutional policies and procedures are consistent with this regulatory provision.	There are no comments.
38. ***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**	The institutional policies and procedures comply with this regulatory provision.	No action is required.

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)).		
39. ***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)).**	The institutional policies and procedures comply with this regulatory provision.	No action is required.