Jaeb Center for Health Research

Standard Operating Procedure:

HRPP 605:

Research Misconduct

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Version History

Version	Author	Approver	Effective Date	Revision Description
1.0	Lesley Zajac	N/A	31 Oct 2008	Initial development of procedure
2.0	Lesley Zajac	N/A	01 Jan 2012	Added notification of OHRP into procedures
2.1	Jennifer Neal-Jimenez	N/A	28 Jan 2016	Clarified job title of person responsible for reporting
2.2	Jeannie Perkins; Jasmine Conner; Kirra Meserve	Jeannie Perkins	19 Jan 2018	Formatting; added version history, added required training; added definition of research misconduct
3.0	Jeannie Perkins; Kirra Meserve; Jonathan Sibayan; Zachary Duff; Adam Glassman; Roy Beck	Jeannie Perkins	13 Aug 2019	Revised all processes and procedures for clarity and provided template reports and notifications
3.1	Jeannie Perkins	Jeannie Perkins	10 Nov 2020	Defined PHS; other minor edits
3.2	Jennifer Caetano	Jeannie Perkins	12 Sep 2021	Updated links
3.3	Zachary Duff	Jeannie Perkins	01 Jul 2022	Updated to disseminate for 3-year training requirement; other minor edits.

Contents

1. Overview

This standard operating procedure (SOP) describes how the Jaeb Center for Health Research (JCHR) intends to meet the requirements of the federal regulations on Research Misconduct in accordance with the JCHR HRPP/IRB Policy 2017.12/14 – Research Misconduct. All terms and definitions herein are consistent with those used in 42 CFR 93, Public Health Service Policies on Research Misconduct.

Each institution that applies for or receives funding or support from the federal government for research or other related activities must identify, manage and report research misconduct allegations under such research related activities. The main responsibility for the receipt, inquiry, investigation and reporting of allegations of research misconduct (herein referred to as "proceedings") falls to the JCHR Director of the Human Research Protection Program (HRPP). Once JCHR has made the determination to conduct an investigation, a copy of the official inquiry report must be sent to the JCHR Institutional Review Board (IRB) Office, the Office of Research Integrity (ORI), and/or other funders as applicable. The JCHR IRB members will determine if IRB coverage will be suspended or terminated for any JCHR investigators or clinical sites/site investigators in cases where the JCHR IRB is providing coverage for clinical sites. The Director of the HRPP will ensure reporting (as required) of any suspension or termination of research activities to the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) as applicable. In addition, other funders may have specific reporting requirements. Further, in accordance with the Reliance Agreements established with local IRBs, the JCHR IRB may also need to report to the local IRBs.

For individuals not employed by JCHR (independent contractors) or for institutions other than JCHR that do not have a formally designated institutional official responsible for overseeing research misconduct inquiries and investigations, JCHR may take on that responsibility or utilize the services of a consortium or other qualified persons to fulfil the obligations of 42 CFR 93.306, and in accordance with established JCHR policies and procedures. The consortium will be a group of qualified persons that will conduct the research misconduct proceedings herein on behalf of JCHR.

2. Scope

The JCHR employees who are required to read and sign-off on this SOP:

- All JCHR Staff
- JCHR IRB Members (documented with a training memo)

3. Research Misconduct

In accordance with JCHR's Research Misconduct policy, and per 42 CFR 93.103, "Research Misconduct" means:
Any fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results:

1. Fabrication is making up data or results and recording or reporting them
2. 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
3. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

NOTE: Research misconduct does not include honest error or differences of opinion.

In order to be a *finding of research misconduct* as described above, the following must have been demonstrated as identified during the inspection of the allegation:

1. There was a significant departure from accepted practices for the relevant research community;
2. The misconduct was committed intentionally, knowingly, or recklessly; *and*
3. The allegation can be proven by a preponderance of the evidence.

4. Allegations of Research Misconduct

While 42 CFR 93 specifically applies to research misconduct relating to federally supported research related activities, JCHR expects the reporting of and inquiry into research misconduct allegations about any JCHR employee or activity. The allegation should be sent directly to the Director of the HRPP, preferably in writing, as soon as misconduct is suspected. In the event that the allegation is against the Director of the HRPP or against his/her employee(s), the Chief Financial Officer (CFO) will follow this SOP as described, and manage the process as indicated for the Director of the HRPP to avoid conflict. The allegation shall contain the following:

1. Who the specific party is believed to be involved in the misconduct
2. What instance/issue/document is believed to be involved in the misconduct
3. The dates surrounding the misconduct
4. The specific project/protocol(s) involved, if applicable
5. The details/descriptions of the misconduct/why is it believed that misconduct has occurred
6. Any supporting documentation
7. Contact information for the reporting party making the allegation

The individual(s) making an allegation do not have to be certain that an instance meets the definition of research misconduct in order to report an allegation. If the individual(s) even suspect(s) in good faith that there might be misconduct, then an allegation should be made so that JCHR can make an inquiry.

The individual(s) making the allegation will not be penalized or retaliated against by JCHR for making an allegation in good faith. Consistent with JCHR's Whistleblower Policy, "any director, officer, or employee who has, in good faith, reported a concern of a violation will not be subject to retaliation by JCHR or any of its employees. By definition, retaliation includes intimidation, harassment, discrimination, blacklisting, or any other adverse employment (future or present) consequences. Moreover, any director, officer, or employee that retaliates against a reporter will be subject to disciplinary action up to and including termination of employment."

To the extent allowed by law, the identities of the party being evaluated for research misconduct ("respondent") and the individual(s) making the allegation will be maintained securely and confidentially. The Director of the HRPP shall ensure that there is not disclosure of any identifying information by the investigating consortium, except on a need to know basis (as required to conduct the proceeding and as required by federal agencies, IRBs, and/or other supporting funders).

5. Inquiries into Research Misconduct Allegations

The Director of the HRPP must first determine if an inquiry is justified by confirming that an allegation meets all of the following:

1. The allegation meets the definition of research misconduct (defined above)
2. The suspected misconduct involves either Public Health Service (PHS) supported research, applications for PHS research support, or research records specified in 42 CFR Section 93.102(b) (or involves another activity that requires an inquiry in accordance with JCHR standards or funder requirements)
3. The allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

If it is determined that the criteria are met and JCHR will move forward with an inquiry, the Director of the HRPP shall notify the respondent in writing that an inquiry is being made (see Notice of Inquiry into Research Misconduct Letter Template {LINK}). The letter, which may be in the form of an email, should be sent as soon as it is practical to do so, understanding that evidence may need to be obtained prior to notification being sent to reduce the likelihood that evidence would be destroyed deliberately, in error, or as permitted during the natural course of record retention processes.

The Director of the HRPP will evaluate the information provided and will determine if there is enough information to warrant an inquiry into research misconduct. The Director of the HRPP will appoint a Consortium to conduct the Inquiry. The Inquiry shall be completed with a report to the Director of the HRPP within fifty-two (52) calendar days of initiation, as documented on a Research Misconduct Inquiry Report {LINK}. If the inquiry takes longer than sixty (60) days to complete, then the Director of the HRPP shall include documentation of the reasons for the delay in the inquiry record.

When the Director of the HRPP notifies the respondent(s) of the results of the inquiry, he/she shall attach copies of the inquiry report and this Research Misconduct SOP. This notification shall inform the respondent(s) of the determination to investigate (or not) as described in the Inquiry Determination Letter Template {LINK}, which may be in the form of an email. The respondent(s) will have seven (7) calendar days to respond to the letter. If it is determined that an investigation is warranted, then the Director of the HRPP must submit the Research Misconduct Inquiry Report to ORI (and other funders as required), including any responses from the respondent(s) about the report, within thirty (30) calendar days of the determination.

6. Investigations of Research Misconduct

If the inquiry results in a determination that an investigation is warranted, then the investigation shall begin within thirty (30) calendar days of that determination, and will be conducted by a consortium of qualified individuals appointed by the Director of the HRPP. JCHR shall use its best efforts to complete the investigation within one hundred twenty (120) calendar days of the date on which it began, including conducting the investigation, preparing the report of findings, providing the draft report to the respondent for comment, and sending the final report to ORI. If more time is needed, JCHR can submit a request for an extension to ORI in writing. The Research Misconduct Investigation Report Template {LINK} will be used.

As part of the investigation, the consortium shall schedule interview(s) with the respondent(s), witnesses or others as needed, providing advance notice of at least seven (7) calendar days prior to the interviews so that the respondent(s) may prepare and arrange for the attendance of legal counsel, if the respondent wishes. Note: Due to the sixty (60) days permitted for the development and review of the draft report, the time for the actual investigation may be limited to sixty (60) days. Interviews will be recorded or transcribed and filed with the misconduct records, along with any additional documentation, meeting minutes or other records as required. Audio recording and/or transcripts of the interviews shall be provided to the interviewee(s) for review and correction. Corrections and comments must be provided within seven (7) calendar days of receipt by the interviewee.

Once the consortium prepares the final draft Research Misconduct Investigation Report, it will be provided to the respondent(s) for comment within thirty (30) days of creation via the Research Misconduct Investigation Determination Letter template {LINK}. This letter may be in email format. The respondent(s) shall also have a copy of, or supervised access to, the evidence on which the report is based. The respondent(s) must submit any comments regarding the report within thirty (30) days. JCHR shall ensure that these comments are included and considered in the final investigation report submitted to ORI as an attachment to the Research Misconduct Investigation Report.

JCHR shall maintain and provide to ORI, upon request, all relevant research records and records of our research misconduct proceeding, including results of all interviews and the transcripts or recordings of such interviews.

7. General Considerations

7.1 Obtaining Evidence

To make determinations regarding the need to inquire, investigate and report, the necessary steps will be taken throughout the proceedings, within reason, to obtain all evidence and records (or certified copies and equivalent data such as a report in lieu of raw data), herein referred to as "records." Additional records may be requested or developed during the conduct of the proceedings such as newly identified evidence, recordings of interviews, minutes of misconduct meetings, etc. All records obtained as part of the proceedings will be tracked using the Research Misconduct Records Inventory Tracker {LINK}, and will be archived in a secure, limited access folder specific to research misconduct investigations. JCHR shall maintain all records of the research misconduct proceedings for seven (7) years after completion of the proceedings, or any ORI or Department of Health and Human Services (HHS) proceedings, whichever is later, unless JCHR has transferred custody of the records and evidence to HHS, or ORI has advised JCHR that it no longer needs to retain the records.

JCHR's efforts to obtain the necessary records may require the support of additional persons. Only individuals who do not have a potential conflict with the person(s) making the complaint, the respondent, or any anticipated witnesses shall be selected (e.g., in the consortium). Each person will attest to a lack of conflict by signing the Inquiry Disclosure and Confidentiality Form (see Template {LINK}). The form also requires that the person attest to their understanding of the confidential nature of the inquiry and subsequent investigation (proceedings) as applicable.

7.2 Ensuring Confidentiality

JCHR shall protect the confidentiality of all persons and records involved in the proceedings (e.g., the person making the allegation, the respondent, the persons involved in conducting the inquiry and/or investigation, any identifying subject information in records, etc.). All identifying subject information shall be redacted in the misconduct records except where it is necessary to support proceedings. Identities shall be limited to those who need to know to conduct the proceedings, to fulfil reporting requirements, and as permitted by law. However, JCHR must disclose the identities of the person(s) making the complaint and the respondent to the ORI if an investigation will be conducted, and if a hearing is required, HHS hearings are open to the public and confidentiality cannot be guaranteed.

7.3 Protective Measures

The Director of the HRPP will work with the JCHR director responsible for grants administration, Executive Leadership and the JCHR IRB to determine any measures that need to be taken throughout the proceedings to protect federal funds, public health, equipment, human subjects, and/or research integrity. Such actions may include immediately freezing access to data and removing access to files and folders.

During the proceedings, the Director of the HRPP must notify ORI (and other funders as required) immediately if JCHR has reason to believe that any of the following special circumstances exist:

1. Health or safety of the public is at risk, including an immediate need to protect human subjects.
2. HHS resources or interests are threatened.
3. Research activities should be suspended.
4. There is reasonable indication of possible violations of civil or criminal law.
5. Federal action is required to protect the interests of those involved in the research misconduct proceeding.

6. 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.
7. The research community or public should be informed.

7.4 Ensuring a Fair Research Misconduct Proceeding

Part of ensuring fair proceedings is the requirement of the burden of proof as required through a preponderance of evidence. Per 42 CFR 93.106(b): "(1) The institution or HHS has the burden of proof for making a finding of research misconduct. The destruction, absence of, or respondent's failure to provide research records adequately documenting the questioned research is evidence of research misconduct where the institution or HHS establishes by a preponderance of the evidence that the respondent intentionally, knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain the records but did not do so, or maintained the records and failed to produce them in a timely manner and that the respondent's conduct constitutes a significant departure from accepted practices of the relevant research community. (2) The respondent has the burden of going forward with and the burden of proving, by a preponderance of the evidence, any and all affirmative defenses raised. In determining whether HHS or the institution has carried the burden of proof imposed by this part, the finder of fact shall give due consideration to admissible, credible evidence of honest error or difference of opinion presented by the respondent. (3) The respondent has the burden of going forward with and proving by a preponderance of the evidence any mitigating factors that are relevant to a decision to impose administrative actions following a research misconduct proceeding."

Further, to ensure fair proceedings as described herein, JCHR shall:

1. Use diligent efforts to ensure that the investigation is thorough, sufficiently documented, and includes examination of all research records and evidence relevant to reaching a decision on the merits of the allegations;
2. Provide respondent(s) sufficient opportunity to review, respond to, and include comments in reports;
3. Record or transcribe each interview, and provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of investigation;
4. Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of additional instances of possible research misconduct, and continue the investigation to completion;
5. Comply with any additional actions requested by ORI or other agencies;
6. Comply with the requirements for conducting an investigation in 42 CFR 93; and
7. Take all other reasonable steps to ensure an impartial and unbiased research misconduct proceeding to the maximum extent practicable.

7.5 Other Notifications

In addition to submitting the final Research Misconduct Investigation Report to ORI, the report may also be included in submissions to others, such as:

- JCHR Institutional Review Board (IRB)
- Office for Human Research Protections (OHRP)
- Food and Drug Administration (FDA)
- Other agencies and funders as applicable
- Local IRBs (in accordance with the terms of the Reliance Agreement)

7.6 Restoring Reputations

JCHR shall undertake all reasonable, practical, and appropriate efforts to protect and restore the reputation of all persons involved in the aggregation, inquiry or investigation of research misconduct, and of the person(s) alleged to have engaged in research misconduct, but against whom no finding of research misconduct was made.