

Oakwood University
Policy and Procedures for Addressing Allegations of Research Misconduct
(Compliant with 42 CFR Part 93 – 2024 Revision)

GENERAL POLICIES AND PRINCIPLES:

Oakwood University is committed to holistic development of its faculty staff and students. This development includes grant writing and research. It is the belief and purpose of the University that these endeavors should be undertaken with the utmost care and integrity. To this end the Research Misconduct Committee will establish and oversee policies that ensure integrity in the grant writing and research processes and will undertake the investigation into allegations of misconduct. The Research Misconduct Committee is a university standing committee whose members are appointed by the university's administration. This committee's responsibility includes inquiry into and investigation of any allegation of research misconduct; making recommendations to the respective authorities for adjudication and appeal. The policies and procedures regarding research misconduct at Oakwood University are outlined below.

Oakwood University is responsible for ensuring that these policies and procedures for addressing allegations of research misconduct meet the requirements of the PHS Policies on Research Misconduct (42 CFR Part 93, "the PHS regulation"). The institution will establish and maintain these policies and procedures, inform all institutional members about these policies and procedures, and make these policies and procedures publicly available on the Institution's website as well as in the Faculty Handbook. Oakwood University is committed to following these policies and procedures when responding to allegations of research misconduct.

The Federal Definition of Research Misconduct

Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

SCOPE AND APPLICABILITY

These policies and procedures apply to allegations of research misconduct involving:

1. Applications or proposals for PHS support for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training.
2. PHS-supported biomedical or behavioral research.
3. PHS-supported biomedical or behavioral research training programs

4. PHS-supported activities that are related to biomedical or behavioral research or research training, such as, but not limited to, the operation of tissue and data banks or the dissemination of research information.
5. Research records produced during PHS-supported research, research training, or activities related to that research or research training.
6. Research proposed, performed, reviewed, or reported, as well as any research record generated from that research, regardless of whether an application or proposal for PHS funds resulted in an awarded grant, contract, cooperative agreement, subaward, or other form of PHS support

These policies and procedures apply only to research misconduct occurring within six years of the date HHS or Oakwood University receives an allegation of research misconduct, subject to the following exceptions:

- The six-year time limitation does not apply if the respondent continues or renews any incident of alleged research misconduct that occurred before the six-year period through the use of, republication of, or citation to the portion(s) of the research record alleged to have been fabricated, falsified, or plagiarized, for the potential benefit of the respondent (“subsequent use exception”). For alleged research misconduct that appears subject to this subsequent use exception, but Oakwood University determines is not subject to the exception, the institution will document its determination that the subsequent use exception does not apply and will retain this documentation for the later of seven years after completion of the institutional proceeding or the completion of any HHS proceeding.
- The six-year time limitation also does not apply if ORI or Oakwood University, following consultation with ORI, determines that the alleged research misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public.

These policies and procedures do not supersede or establish an alternative to the PHS regulation or any existing regulations for handling research misconduct involving non-PHS supported research. They do not replace the PHS regulation, and in case of any conflict between this document and 42 CFR Part 93, the PHS regulation will prevail. They are intended to enable Oakwood University to comply with the requirements of the PHS regulation.

Defined Terms

Adjudication: the Vice President for Research and other relevant university officials will examine the inquiry and investigation reports and recommendations, and the rebuttal from the subject. They may choose to accept the reports and recommendations or may differ with detailed explanation in writing for the different path.

Appeals: the subject has the right to appeal the decision if he/she thinks it is biased, or that any member of the inquiry or investigative or adjudicative committees had biased or

malicious intent. The appeal should be in writing and addressed to the Vice President for Research.

Assessment: An assessment's purpose is to determine whether an allegation warrants an inquiry. An assessment is intended to be a review of readily accessible information relevant to the allegation

Complainant. Complainant means an individual who in good faith makes an allegation of research misconduct.

Evidence. Evidence means anything offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact. Evidence includes documents, whether in hard copy or electronic form, information, tangible items, and testimony

Fabrication: making up data or results and recording or reporting them.

Falsification: 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.

Good faith. (a) Good faith as applied to a complainant or witness means having a reasonable belief in the truth of one's allegation or testimony, based on the information known to the complainant or witness at the time. An allegation or cooperation with a research misconduct proceeding is not in good faith if made with knowledge of or reckless disregard for information that would negate the allegation or testimony. (b) Good faith as applied to an institutional or committee member means cooperating with the research misconduct proceeding by impartially carrying out the duties assigned for the purpose of helping an institution meet its responsibilities under 42 CFR Part 93. An institutional or committee member does not act in good faith if their acts or omissions during the research misconduct proceedings are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.

Inquiry. Inquiry means preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures of § 93.307 through § 93.309.

Institution. Institution means any person who applies for or receives PHS support for any activity or program that involves the conduct of biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training. This includes, but is not limited to, colleges and universities, PHS intramural biomedical or behavioral research laboratories, research and development centers, national user facilities, industrial laboratories or other research institutes, research institutions, and independent researchers.

Institutional Deciding Official. Institutional Deciding Official means the institutional official who makes final determinations on allegations of research misconduct and any institutional actions. The same individual cannot serve as the Institutional Deciding Official and the Research Integrity Officer.

Institutional member. Institutional member and members mean an individual (or individuals) who is employed by, is an agent of, or is affiliated by contract or agreement with an institution. Institutional members may include, but are not limited to, officials, tenured and untenured faculty, teaching and support staff, researchers, research coordinators, technicians, postdoctoral and other fellows, students, volunteers, subject

matter experts, consultants, attorneys, or employees or agents of contractors, subcontractors, or sub-awardees.

Institutional record. The institutional record comprises: (a) The records that the institution compiled or generated during the research misconduct proceeding, except records the institution did not consider or rely on. These records include but are not limited to (1) documentation of the assessment as required by § 93.306(c); (2) if an inquiry is conducted, the inquiry report and all records (other than drafts of the report) considered or relied on during the inquiry, including, but not limited to, research records and the transcripts of any transcribed interviews conducted during the inquiry, information the respondent provided to the institution, and the documentation of any decision not to investigate as required by § 93.309(c); (3) if an investigation is conducted, the investigation report and all records (other than drafts of the report) considered or relied on during the investigation, including, but not limited to, research records, the transcripts of each interview conducted pursuant to § 93.310(g), and information the respondent provided to the institution; (4) decision(s) by the Institutional Deciding Official, such as the written decision from the Institutional Deciding Official under § 93.314; (5) the complete record of any institutional appeal consistent with § 93.315; (b) a single index listing all the research records and evidence that the institution compiled during the research misconduct proceeding, except records the institution did not consider or rely on; and (c) a general description of the records that were sequestered but not considered or relied on.

Intentionally. To act intentionally means to act with the aim of carrying out the act.

Inquiry: the misconduct committee will gather information about the allegation to determine if there is evidence of intentional misconduct needing further investigation or the occurrence of an honest error, needing no further investigation.

Investigation: the formal examination of all the records, and evidence of misconduct including interviews with the subject, complainant, and other individuals privy to the alleged misconduct; and determination and recommendation of appropriate action to the Vice President for Research.

Investigation. Investigation means the formal development of a factual record and the examination of that record that meets the criteria and follows the procedures of §§ 93.310 through 93.317.

Knowingly. To act knowingly means to act with awareness of the act.

Plagiarism: the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Preponderance of the evidence. Preponderance of the evidence means proof by evidence that, compared with evidence opposing it, leads to the conclusion that the fact at issue is more likely true than not.

PHS support. PHS support means PHS funding, or applications or proposals for PHS funding, for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training, that may be provided through funding for PHS intramural research; PHS grants, cooperative agreements, or contracts; subawards, contracts, or subcontracts under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements, or contracts.

Recklessly. To act recklessly means to propose, perform, or review research, or report research results, with indifference to a known risk of fabrication, falsification, or plagiarism

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

Research, as used herein, includes all basic, applied, and demonstration research in all fields of science, engineering, and mathematics. This includes, but is not limited to, research in economics, education, linguistics, medicine, psychology, social sciences, statistics, and research involving human subjects or animals.

The research record is the record of data or results that embody the facts resulting from scientific inquiry, and includes, but is not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, and journal articles.

Research Integrity Officer. The Research Integrity Officer (RIO) refers to the institutional official responsible for administering the institution's written policies and procedures for addressing allegations of research misconduct in compliance with 42 CFR Part 93.

Research misconduct. Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.

Research misconduct proceeding. Research misconduct proceeding means any actions related to alleged research misconduct taken under 42 CFR Part 93, including allegation assessments, inquiries, investigations, ORI oversight reviews, and appeals under subpart E of 42 CFR Part 93.

Research record. Research records means the record of data or results that embody the facts resulting from scientific inquiry. Data or results may be in physical or electronic form. Examples of items, materials, or information that may be considered part of the research record include, but are not limited to, research proposals, raw data, processed data, clinical research records, laboratory records, study records, laboratory notebooks, progress reports, manuscripts, abstracts, theses, records of oral presentations, online content, lab meeting reports, and journal articles.

Respondent. Respondent means the individual against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

PROCEDURES FOR ADDRESSING ALLEGATIONS OF RESEARCH MISCONDUCT

Allegation of Misconduct

Upon receiving an allegation of research misconduct, the RIO or another designated institutional official will promptly determine whether the allegation (a) falls within the definition of research misconduct, (b) is within the applicability criteria of 42 CFR Part 93 § 93., and (c) is credible and specific enough to identify and sequester potential evidence.

Assessment

If the RIO or another institutional official determines that the allegation meets these three criteria, they will promptly: (a) document the assessment and (b) initiate an inquiry

and sequester all research records and other evidence. The RIO or other institutional official must document the assessment and retain the assessment documentation securely for seven years after completion of the misconduct proceedings. If the RIO or another institutional official determines that the alleged misconduct does not meet the criteria to proceed to an inquiry, they will write sufficiently detailed documentation to permit a later review by ORI of why Oakwood University did not proceed to an inquiry and securely retain this documentation for seven years.

Convening the Committee and Ensuring Neutrality

Allegations of research misconduct must be presented in written form to the chair of the Research Misconduct Committee (RIO). The Chair shall designate a subcommittee which will include individuals with expertise in the area of the alleged misconduct, to initiate the inquiry process. Oakwood University will ensure that all inquiry committee members understand their commission, keep the identities of respondents, complainants, and witnesses confidential, and conduct the research misconduct proceedings in compliance with the PHS regulation. In lieu of a committee, the institution may task the RIO or another designated institutional official to conduct the inquiry, provided this person utilizes subject matter experts as needed to assist. The subject of the allegation will be notified in writing of the specifics of the allegation and be given adequate time (approximately two weeks) to respond in writing.

INQUIRY: Determining Whether an Investigation Is Warranted

The subcommittee shall proceed to obtain and sequester research records and any other evidentiary material related to the allegation. The inquiry committee, RIO, or other designated institutional official will conduct a preliminary review of the evidence. In the process of fact-finding, the inquiry committee may interview the respondent and/or witnesses. An investigation is warranted if (a) there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct under 42 CFR Part 93 and involves PHS-supported biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training, as provided in § 93.; and (b) preliminary information-gathering and fact-finding from the inquiry indicates that the allegation may have substance. If further investigation is not warranted a written response of the committee findings will be shared with the subject, the complainant and the Provost at Oakwood. The committee will determine the necessity of halting the research or allowing it to continue while the investigation and adjudication is ongoing. If an investigation is warranted, the Chair and the misconduct committee will examine the evidence, schedule independent interviews with the complainant, the subject, and other witnesses. The subject will have the opportunity to rebut the allegations in writing. Once the process is completed, the committee has

determined that intentional research misconduct occurred, and the resultant consequences of this misconduct; the committee will determine the most appropriate response and make a recommendation to the Provost for adjudication.

Documenting the Inquiry

At the conclusion of the inquiry, regardless of whether an investigation is warranted, the inquiry committee, RIO, or other designated institutional official will prepare a written inquiry report. The contents of a complete inquiry report will include:

1. The names, professional aliases, and positions of the respondent and complainant(s).
2. A description of the allegation(s) of research misconduct.
3. Details about the PHS funding, including any grant numbers, grant applications, contracts, and publications listing PHS support.
4. The composition of the inquiry committee, if used, including name(s), position(s), and subject matter expertise.
5. An inventory of sequestered research records and other evidence and description of how sequestration was conducted.
6. Transcripts of interviews, if transcribed.
7. Inquiry timeline and procedural history.
8. Any scientific or forensic analyses conducted.
9. The basis for recommending that the allegation(s) warrant an investigation.
10. The basis on which any allegation(s) do not merit further investigation.
11. Any comments on the inquiry report by the respondent or the complainant(s).
12. Any institutional actions implemented, including internal communications or external communications with journals or funding agencies.
13. Documentation of potential evidence of honest error or difference of opinion.

Oakwood University will complete all aspects of the investigation within 180 days. The institution will conduct the investigation, prepare the draft investigation report for each respondent, and provide the opportunity for respondents to comment. The institution will document the IDO's final decision and transmit the institutional record (including the final investigation report and IDO's decision) to ORI. If the investigation takes more than 180 days to complete, the institution will ask ORI in writing for an extension and document the reasons for exceeding the 180-day period in the investigation report.

Completing the Inquiry

Oakwood University will give the respondent a copy of the draft inquiry report for review and comment. The institution may, but is not required to, provide relevant portions of the report to a complainant for comment.

Oakwood University will notify the respondent of the inquiry's final outcome and provide the respondent with copies of the final inquiry report, the PHS regulation, and these policies and procedures. The institution may, but is not required to, notify a complainant whether the inquiry found that an investigation is warranted. If the institution provides notice to one complainant in a case, it must provide notice, to the extent possible, to all complainants in the case.

Reporting

After an investigative process reports will be submitted to all the relevant agencies; primarily federal funding agencies. If misconduct is of a criminal nature the matter will be transferred to the local agency responsible. It is the responsibility of the adjudicating officer to submit findings of research misconduct to the relevant agencies.

Approved: _____



**Dr. Mbyrukira,
Provost, Oakwood University**