RESEARCH INTEGRITY

Policy Number:	**LEG-120**
Issued Date:	**April 2026**
Initiating Organization:	**Legal Office**
Applicability:	**All Employees**

Policy Statement

ORAU upholds the highest standards of scientific rigor in research. ORAU fosters an environment that promotes research integrity and the responsible conduct of research; discourages research misconduct; identifies potential and actual conflicts of interest in research ("COIR"); and deals promptly with allegations or evidence of possible research misconduct.

Policy Rationale

The purpose of this policy is to support ORAU's pursuit of research opportunities by establishing the process to identify researcher and institutional conflicts of interest and misconduct in research as required by federal regulations, state laws, or contract.

Policy Requirements

This policy does not supersede or establish an alternative to the Public Health Services ("PHS") regulation or any existing regulations for handling research misconduct involving non-PHS supported research. The policy does not replace the PHS regulation, and in case of any conflict between this document and 42 CFR Part 93, Public Health Service Policies on Research Misconduct, the PHS regulation will prevail. They are intended to enable ORAU to comply with the requirements of the PHS regulation.

This policy and the attachments 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.

This policy and procedures apply only to research misconduct occurring within six years of the date Health and Human Services (HHS) or ORAU 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 ORAU's Research Integrity Committee determines is not subject to the exception, ORAU 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 ORAU's proceeding or the completion of any HHS proceeding.
- The six-year time limitation also does not apply if the PHS Office of Research Integrity ("ORI") or ORAU, 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.

Financial interests of ORAU researchers must be identified, disclosed, and reviewed to prevent potential COIR that reasonably appear to affect ORAU's processes for the design, conduct, reporting, review, or oversight of research.

Substantiated allegations of misconduct in research or unreported COIR will result in corrective action up to and including termination.

Responsibilities

See Attachment 3, Research Integrity Handbook, for ORAU's institutional responsibilities.

A. Complaintant

1. Brings research misconduct allegations directly to the attention of ORAU or an HHS official through any means of communication.
2. Makes allegations in good faith as having a reasonable belief in the truth of one's allegation or testimony, based on the information known to the complainant at the time.

B. Complaint Respondent

Maintains all records documenting the questioned research and produces them upon request.

C. Witness

1. Provides information for review during research misconduct proceedings.
2. Cooperates with the research misconduct proceedings in good faith and has a reasonable belief in the truth of their witness statements, based on the information known to them at the time.

D. Employee

1. Reports immediately any actual or potential conflict of interest and/or allegations of unethical research conduct to the Chief Research and University Partnerships Officer (CRUPO) or the Chief Legal and Risk Officer (CLRO).
2. Cooperates with any inquiry and/or investigation.

E. Researcher

1. Self-identifies to the CRUPO as a researcher when responsible for the design, conduct, or reporting of research or educational activities that are funded or proposed triennially.
2. Completes CITI Responsible Conduct in Research Training triennially.
3. Completes annually the Conflict of Interest in Research Screening Questionnaire (Attachment 1) [leg120a1.docx] (.docx) .
4. Discloses to the CLRO and manager any actual or potential conflicts of interest including those created by the interests of the researcher's family.
5. Does not accept or offer monetary or other items of value to influence contract awards or research outcomes.
6. Presents accurate credentials (training, list of publications, previous research grants, etc.) when pursuing new research contracts, publication, participation in professional society affairs, etc.
7. Performs within the confines of their training/knowledge during research activities or when reviewing others' research.

8. Keeps their research confidential during the conduct of research, except as is necessary for collaboration or consultation with others and only with express permission of their sponsors, employer, applicable government agencies, etc.
9. Reports findings completely, accurately, and honestly.
10. Lists accurate references used in their publications.
11. Assumes an appropriate position in the author list based on their contribution and only allows their names to be used on publications where significant contributions were made.

F. Manager

1. Identifies risk of conflict of interest for all research activities under his/her authority.
2. Reviews and signs the Conflict of Interest in Research Screening Questionnaire (Attachment 1) [leg120a1.docx] (.docx) submitted by researcher(s), and completes the administrative review and recommendations section of Attachment 1, if necessary.
3. Reports immediately all allegations or other evidence of possible research misconduct or conflict of interest in research to the CLRO.
4. Assigns, as requested, necessary personnel for the inquiry of any alleged research misconduct.

G. Research Integrity Committee Member

1. Acts in good faith to cooperate with the research misconduct proceedings by impartially carrying out their assigned duties.
2. Has relevant scientific expertise and is free of real or perceived conflicts of interest with any of the parties involved in the misconduct proceedings.
3. Determines whether an investigation is warranted and documents the decision in an inquiry report.
4. Participates in recorded interviews of each respondent, complaintant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent(s).
5. Determines whether the respondent(s) engaged in research misconduct and documents the decision in the investigation report.

H. Chief Research and University Partnerships Officer (CRUPO)

1. Serves as the Research Integrity Officer (RIO) and leads the Research Integrity Committee.
2. Consults with the CLRO to promptly assess the allegation to determine whether the allegation:
   (a) is within the definition of research misconduct under the PHS regulation

   (b) is within the applicability criteria of the regulation at § 93.102, and

(c) is sufficiently credible and specific so that potential evidence of research misconduct may be identified. Keeps sufficiently detailed documentation of the assessment to permit a later review by ORI of the reasons.

3. Provides the Legal Office (LO) an annual list of employees that serve as researchers.
4. Serves as ORAU representative to the agency funding research.
5. Reports misconduct or conflict of interest in accordance with the guidelines of the funding source.
6. Appoints member of the research team to serve on the Research Integrity Committee.
7. Provides response to Department of Health and Human Services, Public Health Service annual report on possible research misconduct.
8. Advises the president of all actions initiated to resolve an alleged misconduct.

I. Director, ORISE

Adjudicates findings of research misconduct as required by the ORISE contract.

J. Chief Human Resources Officer (CHRO)

1. Refers immediately allegations of research misconduct or conflict of interest in research on the part of employees to the CLRO for inquiry.
2. Protects, to the maximum extent possible, the privacy of those who report apparent misconduct and the affected individual(s).

K. Chief Legal and Risk Officer (CLRO)

1. Provides records pertaining to conflict of interest to the funding agency as required.
2. Collects and reviews the ORAU Conflict of Interest in Research Screening Questionnaires (Attachment 1) [leg120a1.docx] (.docx) from researchers annually.
3. Maintains the completed forms for at least three years.
4. Leads the Research Integrity Committee.
5. Serves as a Research Integrity Committee member.

I. President and Chief Executive Officer (CEO)

1. Serves as the Institutional Deciding Official (IDO) and makes the final determination of research misconduct findings.
2. Documents the determination in a written decision that includes whether research misconduct occurred, and if so, what kind and who committed it, and a description of the relevant actions ORAU has taken or will take.

3. Serves as appeal authority for all conditions or restrictions that may be imposed for identified conflicts of interest.

Cancellation

This policy cancels and supersedes LEG-120 dated June 2020.

References

1. 42 C.F.R., Part 93, Public Health Service Policies on Research Misconduct
2. 42 C.F.R § 50.604, Public Health, Department of Health and Human Services
3. 10 C.F.R., Part 733, Allegation of Research Misconduct
4. HR-900, Corrective Action [../hr/hr900.html]
5. RES-100, Research Policy [../research/res100.html]

Addendums

1. ORISE Contract Requirements [leg120ad1.html]

Attachments

1. ORAU Conflict of Interest in Research Screening Questionnaire [leg120a1.docx] (.docx)
2. Research Misconduct Proceedings Handbook [leg120a3.pdf] (.pdf)
3. Definitions [definitions.html]
4. Policy Changes [leg120changes.html]

ORISE ADDENDUM 1

RESEARCH INTEGRITY

ORISE CONTRACT REQUIREMENTS	
Policy Number:	**LEG-120**
Issued Date:	**April 2026**
Initiating Organization:	**Legal Office**
Applicability:	**Employees who Conduct Research**

For research conducted under the ORISE contract, ORAU will comply with DEAR 952.235-71 and any relevant clauses of the ORISE contract. This includes responsibility for maintaining the integrity of research performed pursuant to the ORISE contract including the prevention, detection, and remediation of research misconduct.

The Research Integrity Committee will conduct inquiries, investigations, and adjudication of allegations of research misconduct in accordance with its established procedures and the requirements of the ORISE contract.

ORAU **RESEARCH INTEGRITY**	Policy Number:	**LEG-120**
	DRAFT Date:	**FEB 2020**
	Initiating Organization:	**General Counsel's office**
CONFLICT OF INTEREST IN RESEARCH SCREENING QUESTIONNAIRE	Applicability:	**All Employees**

The researcher will notify the General Counsel's office immediately when changes must be made to information contained on the screening questionnaire. Please refer to Attachment 2 of LEG-120, Research Integrity, for the definition of a conflict of interest in research and other relevant terms.

Name	Position/Title	Organizational Unit

Do you currently conduct research or do you anticipate making application for funding that may support research, including ORAU-Directed Research and Development (ODRD), during the next twelve months?

☐**Yes** ☐**No**

If you answer "Yes," please complete Parts I and II. If "No," proceed to Part II.

PART I SCREENING QUESTIONNAIRE

1. Do you have a consulting or other financial relationship with an external sponsor/donor of your research? ☐**Yes** ☐**No**

2. Do you have a managerial role or a significant financial interest in a company in a field of your research or a company that does business with ORAU? ☐**Yes** ☐**No**

3. Do you have non-ORAU professional or income-producing activities?
   ☐**Yes** ☐**No**

4. Do you, your spouse, or dependent children have any other relationships, commitments, or activities that might, in your good faith judgement, present or appear to present a conflict of interest? Such relationships may include financial or fiduciary interests or uncompensated activities.
   ☐**Yes** ☐**No**

If you answer "no" to all questions in Part I, complete Part II and submit to your manager. If you answer "yes" to any questions in Part I, complete Parts II and III and submit to your manager for review.

PART II AFFIRMATION

In submitting this form, I affirm that the above information is true, and I have read ORAU Policy LEG-120, Research Integrity.

_____
Employee Signature

_____
Manager's Signature

_____
General Counsel's Signature

PART III FINANCIAL DISCLOSURE

1. Do you have a consulting or other financial relationship with a sponsor/donor of your current ORAU-based research or other programs? ☐**Yes** ☐**No**

Nature of Activities	Company/Organization	Days Spent During Previous Year	Estimated Days to be Spent In Current Year

Attach additional sheets as necessary

2. Do you have a managerial role or a significant financial interest in a company in a field of your research or a company that does business with ORAU? ☐**Yes** ☐**No**

Nature of Activities	Company/Organization	Days Spent During Previous Year	Estimated Days to be Spent In Current Year

Attach additional sheets as necessary

"Significant financial interest" means anything of monetary value, including, but not limited to, salary or other payments for services; equity interests; and intellectual property rights.

3. Do you have non-ORAU professional or income-producing activities?
☐**Yes** ☐**No**

Nature of Activities	Company/Organization	Days Spent During Previous Year	Estimated Days to be Spent In Current Year

Attach additional sheets as necessary

_____

Signature

_____

Printed Name

PART IV ADMINISTRATIVE REVIEW AND RECOMMENDATIONS

Manager

Based on the activity reported, and to the best of my knowledge and in my judgement:

☐ No conflict of interest exists.

☐ A conflict of interest may exist but does not appear to be significant

☐ A significant conflict of interest is believed to exist and the following actions are recommended:

Signature

Printed Name

General Counsel and Chief Research Officer

Based on the activity reported, and to the best of my knowledge and in my judgement:

☐ No conflict of interest exists.

☐ A conflict of interest may exist but does not appear to be significant

☐ A significant conflict of interest is believed to exist and the following actions should be taken.

Signature

Printed Name

ORAU **RESEARCH INTEGRITY**	Policy Number:	**LEG-120**
	Issued Date:	**April 2026**
	Initiating Organization:	**Legal Office (LO)**
RESEARCH MISCONDUCT PROCEEDINGS HANDBOOK	Applicability:	**All Employees**

ORAU'S GENERAL RESPONSIBILITIES

1. To the extent possible, ORAU will limit disclosure of the identity of complaint respondents, complainants, and witnesses while conducting the research misconduct proceedings to those who need to know, inform all institutional members about these policies and procedures, and make these policies and procedures publicly available. This limitation on disclosure no longer applies once ORAU has made a final determination of research misconduct findings.
2. ORAU will respond to each allegation of research misconduct under 42 CFR Part 93 in a thorough, competent, objective, and fair manner.
3. ORAU will take all reasonable and practical steps to ensure the cooperation of complaint respondents and other institutional members with research misconduct proceedings, including, but not limited to, providing information, research records, and other evidence.
4. ORAU agrees to cooperate with the Office of Research Integrity (ORI) during any research misconduct proceeding or compliance review, including addressing deficiencies or additional allegations in the institutional record if directed by ORI and to assist in administering and enforcing any HHS administrative actions imposed on institutional members.
5. ORAU may also take steps to manage published data or acknowledge that data may be unreliable.

ORAU'S RESPONSIBILITIES DURING AND AFTER A RESEARCH MISCONDUCT PROCEEDING

1. Except as may otherwise be prescribed by applicable law, ORAU will maintain confidentiality for any records or evidence from which research subjects might be identified and will limit disclosure to those who need to know to carry out a research misconduct proceeding.
2. Before or at the time of notifying the complaint respondent of the allegation(s) and whenever additional items become known or relevant, ORAU will promptly take all reasonable and practical steps to obtain all research records and other evidence and sequester them securely.
3. ORAU will ensure that the institutional record contains all required elements, i.e., research records that were compiled and considered during the proceedings, assessment documentation, and inquiry and/or investigation reports.
4. Upon completion of the inquiry, ORAU will provide ORI with the complete inquiry report and add it to the institutional record.
5. ORAU will maintain the institutional record and all sequestered research records and other evidence in a secure manner for seven years after completion of ORAU and/or HHS proceeding.
6. ORAU will provide information related to the alleged research misconduct and proceedings to ORI upon request and transfer custody or provide copies of the institutional record or any component of it and any sequestered evidence to HHS, regardless of whether the evidence is included in the institutional record. Additionally, ORAU will promptly notify ORI of any special circumstances that may arise.
7. Disclosure of the identity of complaint respondents, complainants, and witnesses while ORAU is conducting the research misconduct proceedings is limited to those who need to know, which ORAU will determine consistent with a thorough, competent, objective, and fair research

misconduct proceeding, and as allowed by law. Those who need to know may include institutional review boards, journals, editors, publishers, co-authors, and collaborating institutions.

ORAU'S RESPONSIBILITIES TO THE COMPLAINANT(S)

1. ORAU will provide confidentiality consistent with 42 CFR Part 93 for all complainants in a research misconduct proceeding.
2. ORAU will take precautions to ensure that individuals responsible for carrying out any part of the research misconduct proceeding do not have potential, perceived, or actual personal, professional, or financial conflicts of interest with the complainant(s).
3. ORAU agrees to take all reasonable and practical steps to protect the positions and reputations of complainants and to protect these individuals from retaliation by complaint respondents and/or other institutional members.
4. If ORAU chooses to notify one complainant of the inquiry results in a case, all complainants will be notified by ORAU, to the extent possible.

ORAU'S RESPONSIBILITIES TO THE COMPLAINT RESPONDENT(S)

1. ORAU will provide confidentiality consistent with 42 CFR Part 93 to all complaint respondents in a research misconduct proceeding.
2. ORAU will make a good-faith effort to notify the complaint respondent(s) in writing of the allegations being made against them.
3. ORAU will take 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 complaint respondent. ORAU is responsible for giving the complaint respondent(s) copies of or supervised access to the sequestered research records.
4. ORAU will notify the complaint respondent whether the inquiry found that an investigation is warranted, provide the complaint respondent an opportunity to review and comment on the inquiry report, and attach their comments to the inquiry report.
5. If an investigation is commenced, ORAU must notify the complaint respondent, give written notice of any additional allegations raised against them not previously addressed by the inquiry report, and allow the complaint respondent(s) an opportunity to review the witness transcripts.
6. ORAU will give the complaint respondent(s) an opportunity to read and comment on the draft investigation report and any information or allegations added to the institutional record.
7. ORAU will give due consideration to admissible, credible evidence of honest error or difference of opinion presented by the complaint respondent.
8. ORAU will bear the burden of proof, by a preponderance of the evidence, for making a finding of research misconduct.
9. ORAU will make all reasonable, practical efforts, if requested and appropriate, to protect or restore the reputation of complaint respondents against whom no finding of research misconduct is made.

ORAU'S RESPONSIBILITIES TO RESEARCH INTEGRITY COMMITTEE MEMBERS

1. ORAU will ensure that the Research Integrity Committee conducts research misconduct proceedings in compliance with the PHS regulation.
2. ORAU will take all reasonable and practical steps to protect the positions and reputations of good-faith committee members and to protect these individuals from retaliation.

ORAU'S RESPONSIBILITIES TO THE WITNESS[ES]

1. ORAU will provide confidentiality consistent with 42 CFR Part 93 for all witnesses.
2. ORAU will take precautions to ensure that individuals responsible for carrying out any part of the proceedings do not have unresolved personal, professional, or financial conflicts of interest with the witnesses.
3. ORAU will take all reasonable and practical steps to protect the positions and reputations of witnesses and to protect these individuals from retaliation.

RESEARCH INTEGRITY COMMITTEE PROCEEDINGS

1. Committee members or anyone acting on behalf of ORAU will conduct research misconduct proceedings consistent with the PHS regulation.
2. The Committee considers complaint respondent and/or complainant comments on the inquiry/investigation report(s) and document that consideration in the investigation report.
3. An investigation into multiple complaint respondents may convene with the same investigation committee members or anyone acting on behalf of ORAU, but there will be separate investigation reports and separate research misconduct determinations for each complaint respondent. Committee members may serve for more than one investigation, in cases with multiple complaint respondents. Committee members may also serve for both the inquiry and the investigation.
4. The complaint respondent has the burden of going forward with and proving, by a preponderance of evidence, affirmative defenses raised.
5. The complaint respondent's destruction of research records documenting the questioned research is evidence of research misconduct where a preponderance of evidence establishes that the complaint respondent intentionally or knowingly destroyed records after being informed of the research misconduct allegations.
6. The complaint respondent's failure to provide research records documenting the questioned research is evidence of research misconduct where the complaint respondent claims to possess the records but refuses to provide them upon request.

PROCEDURES FOR ADDRESSING ALLEGATIONS OF RESEARCH MISCONDUCT ASSESSMENT

A. <u>ASSESSMENT</u>

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.

1. 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 § 93.102;
    c. is credible and specific enough to identify and sequester potential evidence.
2. 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.

3. 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.
4. 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 ORAU did not proceed to an inquiry and securely retain this documentation for seven years.

B. <u>INQUIRY</u>:

An inquiry's purpose is to conduct an initial review of the evidence to determine whether an allegation warrants an investigation. An inquiry does not require a full review of all related evidence.

1. An inquiry is warranted if the allegation
   a. falls within the definition of research misconduct under 42 CFR Part 93,
   b. is within the applicability criteria of § 93.102, and
   c. is sufficiently credible and specific so that potential evidence of research misconduct may be identified.
2. ORAU will complete the inquiry within 90 days of initiating it unless circumstances warrant a longer period, in which it will sufficiently document the reasons for exceeding the time limit in the inquiry report.

Sequestering Evidence And Notifying the Complaint Respondent

1. Before or at the time of notifying the complaint respondent(s), ORAU will obtain the original or substantially equivalent copies of all research records and other evidence that are pertinent to the proceeding, inventory these materials, sequester the materials in a secure manner, and retain them for seven years.
2. ORAU has a duty to obtain inventory and securely sequester evidence that extends to whenever additional items become known or relevant to the inquiry or investigation.
3. At the time of or before beginning the inquiry, ORAU will make a good-faith effort to notify the presumed complaint respondent(s), in writing, that an allegation(s) of research misconduct has been raised against them, the relevant research records have been sequestered, and an inquiry will be conducted to decide whether to proceed with an investigation.
4. If additional allegations are raised, ORAU will notify the complaint respondent(s) in writing.
5. When appropriate, ORAU will give the complaint respondent(s) copies of, or reasonable supervised access to, the sequestered materials.
6. If additional complaint respondents are identified, ORAU will provide written notification to the new complaint respondent(s). All additional complaint respondents will be given the same rights and opportunities as the initial complaint respondent. Only allegations specific to a particular complaint respondent will be included in the notification to that complaint respondent.

Convening The Committee And Ensuring Neutrality

1. ORAU will ensure that all inquiry committee members understand their commission, keep the identities of complaint respondents, complainants, and witnesses confidential, and conduct the research misconduct proceedings in compliance with the PHS regulation.

2. In lieu of a committee, ORAU may task the CRO/RIO or another designated institutional official to conduct the inquiry, provided this person utilizes subject matter experts as needed to assist in the inquiry.

Determining Whether An Investigation Is Warranted

1. The inquiry committee, CRO/RIO, or other designated institutional official will conduct a preliminary review of the evidence.
2. In the process of fact-finding, the inquiry committee may interview the complaint respondent and/or witnesses.
3. 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 § 93.102; and (b) preliminary information gathering and fact-finding from the inquiry indicates that the allegation may have substance.
4. The inquiry committee will not determine if research misconduct occurred, nor assess whether the alleged misconduct was intentional, knowing, or reckless; such a determination is not made until the case proceeds to an investigation.

Documenting The Inquiry

At the conclusion of the inquiry, regardless of whether an investigation is warranted, the inquiry committee, CRO/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 complaint 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 complaint 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.

Completing The Inquiry

1. ORAU will give the complaint respondent a copy of the draft inquiry report for review and comment.
2. ORAU may, but is not required to, provide relevant portions of the report to a complainant for comment.

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

Investigation Is Not Warranted

If the inquiry committee, CRO/RIO, or other designated institutional official determines that an investigation is not warranted, ORAU will keep sufficiently detailed documentation to permit a later review by ORI of why ORAU did not proceed to an investigation, store these records in a secure manner for at least seven years after the termination of the inquiry, and provide them to ORI upon request.

Investigation Is Warranted

1. If the inquiry committee, CRO/RIO, or other designated institutional official determines that an investigation is warranted, ORAU must: (a) within a reasonable amount of time after this decision, provide written notice to the complaint respondent(s) of the decision to conduct an investigation of the alleged misconduct, including any allegations of research misconduct not addressed during the inquiry; and (b) within 30 days of determining that an investigation is warranted, provide ORI with a copy of the inquiry report.
2. On a case-by-case basis, ORAU may choose to notify the complainant that there will be an investigation of the alleged misconduct but is required to take the same notification action for all complainants in cases where there is more than one complainant.

C. INVESTIGATION

The purpose of an investigation is to formally develop a factual record, pursue leads, examine the record, and recommend finding(s) to the CEO/IDO, who will make the final decision, based on a preponderance of evidence, on each allegation and any institutional actions.

1. As part of its investigation, ORAU will pursue diligently all significant issues and relevant leads, including any evidence of additional instances of possible research misconduct, and continue the investigation to completion.
2. Within 30 days after deciding an investigation is warranted, ORAU will notify ORI of the decision to investigate and begin the investigation.

Notifying The Complaint Respondent And Sequestering Evidence

1. ORAU will notify the complaint respondent(s) of the allegation(s) within 30 days of determining that an investigation is warranted and before the investigation begins.
2. If any additional complaint respondent(s) are identified during the investigation, ORAU will notify them of the allegation(s) and provide them an opportunity to respond consistent with the PHS regulation.

3. If ORAU identifies additional complaint respondents during the investigation, it may choose to either conduct a separate inquiry or add the new complaint respondent(s) to the ongoing investigation.
4. ORAU will obtain the original or substantially equivalent copies of all research records and other evidence, inventory these materials, sequester them in a secure manner, and retain them for seven years after its proceeding or any HHS proceeding, whichever is later.

Convening An Investigation Committee

1. After vetting investigation committee members for conflicts of interest and appropriate scientific expertise, ORAU will convene the committee and ensure that the members understand their responsibility to conduct the research misconduct proceedings in compliance with the PHS regulation.
2. The investigation committee will conduct interviews, pursue leads, and examine all research records and other evidence relevant to reaching a decision on the merits of the allegation(s).
3. ORAU will use diligent efforts to ensure that the investigation is thorough, sufficiently documented, and impartial and unbiased to the maximum extent practicable.
4. ORAU will notify the complaint respondent in writing of any additional allegations raised against them during the investigation.

Conducting Interviews

1. ORAU will interview each complaint respondent, complainant(s), and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the complaint respondent.
2. ORAU will number all relevant exhibits and refer to any exhibits shown to the interviewee during the interview by that number.
3. ORAU will record and transcribe interviews during the investigation and make the transcripts available to the interviewee for correction.
4. ORAU will include the transcript(s) with any corrections and exhibits in the institutional record of the investigation.
5. The complaint respondent will not be present during the witnesses' interviews, but ORAU will provide the complaint respondent with a transcript of each interview, with redactions as appropriate to maintain confidentiality.

Documenting The Investigation

1. ORAU will complete all aspects of the investigation within 180 days.
2. ORAU will conduct the investigation, prepare the draft investigation report for each complaint respondent, and provide the opportunity for complaint respondents to comment.
3. ORAU will document the CEO/IDO's final decision and transmit the institutional record (including the final investigation report and CEO/IDO's decision) to ORI.
4. If the investigation takes more than 180 days to complete; ORAU will ask ORI in writing for an extension and document the reasons for exceeding the 180-day period in the investigation report.
5. The investigation report for each complaint respondent will include:
   a. Description of the nature of the allegation(s) of research misconduct, including any additional allegation(s) addressed during the research misconduct proceeding.

b. Description and documentation of the PHS support, including any grant numbers, grant applications, contracts, and publications listing PHS support. This documentation includes known applications or proposals for support that the complaint respondent has pending with PHS and non-PHS Federal agencies.
c. Description of the specific allegation(s) of research misconduct for consideration in the investigation of the complaint respondent.
d. Composition of investigation committee, including name(s), position(s), and subject matter expertise.
e. Inventory of sequestered research records and other evidence, except records ORAU did not consider or rely on. This inventory will include manuscripts and funding proposals that were considered or relied on during the investigation. The inventory will also include a description of how any sequestration was conducted during the investigation.
f. Transcripts of all interviews conducted.
g. Identification of the specific published papers, manuscripts submitted but not accepted for publication (including online publication), PHS funding applications, progress reports, presentations, posters, or other research records that contain the allegedly falsified, fabricated, or plagiarized material.
h. Any scientific or forensic analyses conducted.
i. A copy of these policies and procedures.
j. Any comments made by the complaint respondent and complainant(s) on the draft investigation report and the committee's consideration of those comments.
k. A statement for each separate allegation of whether the committee recommends a finding of research misconduct.

6. If the committee recommends a finding of research misconduct for an allegation, the investigation report will present a finding for each allegation. These findings will
   a. identify the individual(s) who committed the research misconduct;
   b. indicate whether the misconduct was falsification, fabrication, and/or plagiarism;
   c. indicate whether the misconduct was committed intentionally, knowingly, or recklessly;
   d. identify any significant departure from the accepted practices of the relevant research community and that the allegation was proven by a preponderance of the evidence;
   e. summarize the facts and analysis supporting the conclusion and consider the merits of any explanation by the complaint respondent;
   f. identify the specific PHS support; and
   g. state whether any publications need correction or retraction.
7. If the investigation committee does not recommend a finding of research misconduct for an allegation, the investigation report will provide a detailed rationale for its conclusion.
8. The investigation committee should also provide a list of any current support or known applications or proposals for support that the complaint respondent has pending with PHS and non-PHS Federal agencies.

Completing The Investigation

1. ORAU will give the complaint respondent a copy of the draft investigation report and, concurrently, a copy of, or supervised access to, the research records and other evidence that the investigation committee considered or relied on.
2. The complaint respondent will submit any comments on the draft report to ORAU within 30 days of receiving the draft investigation report.

3. If ORAU chooses to share a copy of the draft investigation report or relevant portions of it with the complainant(s) for comment, the complainant's comments will be submitted within 30 days of the date on which they received the report.
4. ORAU will add any comments received to the investigation report.

CEO/IDO Review Of The Investigation Report

The CEO/IDO will review the investigation report and make a final written determination of whether ORAU found research misconduct and, if so, who committed the misconduct. In this statement, the CEO/IDO will include a description of relevant institutional actions taken or to be taken.

Creating And Transmitting The Institutional Record

1. After the CEO/IDO has made a final determination of research misconduct findings, ORAU will add the CEO/IDO's written decision to the investigation report and organize the institutional record in a logical manner.
2. The institutional record consists of the records that were compiled or generated during the research misconduct proceeding, except records ORAU did not rely on.
3. These records include documentation of the assessment, a single index listing all research records and evidence, the inquiry report and investigation report, and all records considered or relied on during the investigation.
4. The institutional record also includes the CEO/IDO's final decision and any information the complaint respondent provided to ORAU.
5. The institutional record must also include a general description of the records that were sequestered but not considered or relied on.
6. If the complaint respondent filed an appeal, the complete record of any institutional appeal also becomes part of the institutional record.
7. ORAU will wait until the appeal is concluded to transmit the institutional record to ORI.
8. After the CEO/IDO has made a final written determination, and any institutional appeal is complete, ORAU must transmit the institutional record to ORI.

Other Procedures And Special Circumstances, Multiple Institutions, And Multiple Complaint Respondents

1. If the alleged research misconduct involves multiple institutions, ORAU may work closely with the other affected institutions to determine whether a joint research misconduct proceeding will be conducted.
2. If so, the cooperating institutions will choose an institution to serve as the lead institution. In a joint research misconduct proceeding, the lead institution will obtain research records and other evidence pertinent to the proceeding, including witness testimony, from the other relevant institutions.
3. By mutual agreement, the joint research misconduct proceeding may include committee members from the institutions involved.
4. The determination of whether further inquiry and/or investigation is warranted, whether research misconduct occurred, and the institutional actions to be taken may be made by the institutions jointly or tasked to the lead institution.

5. If the alleged research misconduct involves multiple complaint respondents, ORAU may either conduct a separate inquiry for each new complaint respondent or add them to the ongoing proceedings.
6. ORAU must give additional complaint respondent(s) notice of and an opportunity to respond to the allegations.

Complaint Respondent Admissions

1. ORAU will promptly notify ORI in advance if at any point during the proceedings (including the assessment, inquiry, investigation, or appeal stage) it plans to close a research misconduct case because the complaint respondent has admitted to committing research misconduct or a settlement with the complaint respondent has been reached.
2. If the complaint respondent admits to research misconduct, ORAU will not close the case until providing ORI with the complaint respondent's signed, written admission.
3. The admission must state the specific fabrication, falsification, or plagiarism that occurred, which research records were affected, and that it constituted a significant departure from accepted practices of the relevant research community.
4. ORAU must not close the case until giving ORI a written statement confirming the complaint respondent's culpability and explaining how ORAU determined that the complaint respondent's admission fully addresses the scope of the misconduct.

Other Special Circumstances

At any time during the misconduct proceedings, ORAU will immediately notify ORI if any of the following circumstances arise:

1. Health or safety of the public is at risk, including an immediate need to protect human or animal 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. HHS may need to take appropriate steps to safeguard evidence and protect the rights of those involved.

D. RECORDS RETENTION

ORAU will maintain the institutional record and all sequestered evidence, including physical objects (regardless of whether the evidence is part of the institutional record), in a secure manner for seven years after the completion of the proceeding or the completion of any HHS proceeding, whichever is later, unless custody has been transferred to HHS.

ORAU LEGAL POLICIES	Policy Number:	LEG-120
	Issued Date:	July 2026
	Initiating Organization:	Legal Office
DEFINITIONS	Applicability:	All Employees

1) **Agency:** includes federal executive departments and agencies, as defined in 5 U.S.C. §552(f), as well as independent regulatory commissions and government corporations, as defined in 31 U.S.C. 9101(1).

2) **Any person**: a broad term that encompasses individuals (including foreign citizens), partnerships, corporations, associations, and foreign or domestic governments.

3) **Appropriated Funds:** funds that are available within a prescribed amount to an operating agency for the purpose of making allotments and incurring obligations; for the purpose of this policy, does not include profit or award fee from a covered federal action

4) **Conflict of Interest (COI):** a potential or actual conflict of interest exists when a significant financial interest could or reasonably appear to affect the design, conduct, or reporting of research or educational activities.

5) **Corroborative evidence**: evidence that gives support to the truth or factual accuracy of something

6) **Credible evidence:** evidence that will not necessarily prove the existence of a fact or the truth of an allegation, but evidence that is trustworthy enough to be submitted to the Office of Inspector General in support of an allegation

7) **Director:** leadership level that consists of assistant program directors, department directors, program directors, and technical directors.

8) **Executive:** chief officers, vice presidents, and president.

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

10) **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.

11) **Federal Contract**: an acquisition contract awarded by a federal agency, including those subject to the Federal Acquisition Regulations (FAR), and any other acquisition contract for real or personal property or services not subject to the FAR.

12) **Findings of Research Misconduct:** requires that there be a significant departure from accepted practices of the relevant research community; and the misconduct be committed intentionally, or knowingly, or recklessly; and the allegation be proven by a preponderance of evidence.

13) **Formal Inquiry**: an investigation into or an examination of an event or other matter of public

concern conducted by a government entity; the subject matter of a formal inquiry may include but is not limited to compliance, efficiency of procedures and processes, misconduct, waste, fraud, or criminal activity; for the purposes of this policy, any request for information from a government oversight agency or an office of an inspector general is considered a formal inquiry

14) **Inquiry:** information gathering and initial fact-finding to determine whether an allegation or apparent instance of misconduct warrants an investigation.

15) **Institutional Review:** a review of an investigator's financial disclosure by appropriate ORAU authorities to determine whether a significant financial interest directly and significantly affects the design, conduct, or reporting of research or educational activities.

16) **Investigation**: the formal examination and evaluation of all relevant facts to determine if misconduct has occurred.

17) **Manager:** leadership level that consists of group managers, section managers, directors, and executives.

18) **Misconduct or Misconduct in Research:** fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community in proposing, performing, or reviewing research, or in reporting research results. It does not include honest error or differences in interpretations or judgments of data.

19) **Nonemployee:** individual members of the ORAU Board of Directors or the Council of Sponsoring Institutions, if participating in contract or grant work funded through ORAU.

20) **Person**: includes any individual, corporation, company, association, authority, firm, partnership, society, State, and local government, regardless of whether such entity is operated for profit or not

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

22) **Reasonable Belief**: based on what a reasonable person in a similar situation would believe, evidence that is available for review, and business judgement.

23) **Record**: any information that would practically and legally be deemed an agency record when maintained or controlled by an agency. A record may be presented in any format, including that which is maintained or created electronically. Not all records held by ORAU are federal records reachable by the FOIA law. Various records held by ORAU are private corporate records, the disclosure of which is considered on a case-by-case basis.

24) **Research**: a systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research, for purposes of this policy, whether or not the activities are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. A systematic investigation, study, exploration, examination or experimentation into a subject to establish facts, reach new

conclusions, or contribute to the body of knowledge. Customer reports, published conference proceedings, invited presentations, trade journal articles, and peer reviewed publications count as sponsor and public dissemination of research results and can be indicative of project-based research activity and impact.

25) **Researcher**: the principal investigator, co-principal investigators, and any other person at or associated with ORAU who is responsible for the design, conduct or reporting of research or educational activities funded or proposed for funding.

26) **Significant Financial Interest:** anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights).

    The term does not include:

    - Salary, royalties, or other remuneration from ORAU
    - Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities
    - Income from service on advisory committees or review panels for public or nonprofit entities
    - Financial interests in business enterprises or entities if the value of such interests does not exceed $10,000 and does not represent more than a five percent ownership interest for any one enterprise or entity when aggregated for the employee/nonemployee and the employee's/nonemployee's spouse and dependent children.
    - Salary, royalties or other payments that when aggregated for the employee/nonemployee and the employee's/nonemployee's spouse and dependent children over the next twelve months, are not expected to exceed $10,000.