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General Policies and Principles

UNE is committed to upholding the highest standards of scientific rigor in research.[1] The University is committed to fostering an environment that promotes research integrity and the responsible conduct of research, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct.[2]

All institutional members are expected to conduct research with honesty, rigor, and transparency. Each institutional member is responsible for contributing to an organizational culture that establishes, maintains, and promotes research integrity and the responsible conduct of research.

UNE strives to reduce the risk of research misconduct, support all good-faith efforts to report suspected misconduct, promptly and thoroughly address all allegations of research misconduct, and seek to rectify the scientific record and/or restore researchers' reputations, as appropriate.

Research misconduct is contrary to the interests of UNE, the health and safety of the public, the integrity of research, and the conservation of public funds. Both UNE and all of its faculty, students, and research partners have an affirmative duty to protect those funds from misuse by ensuring the integrity of all research conducted on behalf of UNE.[3]

UNE 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. UNE is committed to following these policies and procedures when responding to allegations of research misconduct.[4]

For definitions of terms used in this section and elsewhere, see the Definitions section.

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.[5]
2. PHS-supported biomedical or behavioral research.[6]
3. PHS-supported biomedical or behavioral research training programs.[7]
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.[8]
5. Research records produced during PHS-supported research, research training, or activities related to that research or research training.[9]
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.[10]

7. Research, research training, or related activities conducted under the auspices of UNE regardless of funding source, including projects supported by non-PHS funding agencies, state agencies, foundations, industry sponsors, private donors, or conducted without external funding.
8. Research records, data, materials, or other documentation generated in the course of any research, research training, or related activities conducted under the responsibility of UNE, regardless of whether the activity is supported by PHS funds.

For research activities not supported by PHS funds, UNE will apply the same internal procedures, definitions, and standards for reviewing allegations of research misconduct; however, reporting to the U.S. Office of Research Integrity (ORI) is not required. Reporting obligations for non-PHS supported research will be limited to the applicable sponsor, regulatory body, or others as required by institutional policies.

These policies and procedures apply only to research misconduct occurring within six years of the date[11] HHS or UNE 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").[12] For alleged research misconduct that appears subject to this subsequent use exception, but UNE 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.[13]
- The six-year time limitation also does not apply if ORI or UNE, 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.[14]

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.[15] 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 UNE to comply with the requirements of the PHS regulation and to assist UNE in enforcing its commitment to research integrity even when the PHS regulation is not applicable.

Definitions

Accepted practices of the relevant research community. This term means those practices established by 42 CFR Part 93 and by PHS funding components, as well as commonly accepted professional codes or norms within the overarching community of researchers and institutions that apply for and receive PHS

awards.[16]

Administrative record. The administrative record comprises: the institutional record; any information provided by the respondent to ORI, including but not limited to the transcript of any virtual or in-person meetings under § 93.403(b) between the respondent and ORI, and correspondence between the respondent and ORI; any additional information provided to ORI while the case is pending before ORI; and any analysis or additional information generated or obtained by ORI. Any analysis or additional information generated or obtained by ORI will also be made available to the respondent.[17]

Allegation. This term is a disclosure of possible research misconduct through any means of communication and brought directly to the attention of an institutional or HHS official.[18]

Assessment. Assessment means a consideration of whether an allegation of research misconduct appears to fall within the definition of research misconduct; appears to involve PHS-supported biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training; and is sufficiently credible and specific so that potential evidence of research misconduct may be identified. The assessment only involves the review of readily accessible information relevant to the allegation.[19]

Complainant. Complainant means an individual who in good faith makes an allegation of research misconduct.[20]

Designated institutional official. An individual to whom the Research Integrity Officer (RIO) may delegate certain responsibilities permitted under federal research misconduct regulations (42 CFR Part 93). When delegated, the designated institutional official may conduct the assessment of an allegation to determine whether it falls within the definition of research misconduct and warrants an inquiry, and may also conduct or coordinate the inquiry phase, including securing research records, reviewing evidence, conducting interviews, and preparing required summaries or documentation. The designated institutional official may additionally assist the RIO with implementing interim measures and performing other procedural or administrative tasks associated with managing a research misconduct proceeding. The designated institutional official does not serve as the Institutional Deciding Official, does not make findings of research misconduct, and does not issue the institution's final determination.

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 from any source, tangible items, and testimony.[21]

Fabrication. Fabrication means making up data or results and recording or reporting them.[22]

Falsification. Falsification means 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.[23]

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.[24]

HHS (U.S. Department of Health and Human Services). The federal agency responsible for protecting the health of all Americans and providing essential human services. In the context of research misconduct, HHS oversees the federal Office of Research Integrity (ORI), which monitors investigations of research misconduct involving Public Health Service (PHS)-funded research.

Inquiry. Inquiry means preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures of § 93.307 through § 93.309.[25]

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.[26]

Institutional Deciding Official (IDO). 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.[27] The UNE Institutional Deciding Official is Gwendolyn Mahon, Ph.D.

Institutional member. Institutional member and members means 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, or attorneys, or employees or agents of contractors, subcontractors, or sub-awardees.[28]

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.[29]

Intentionally. To act intentionally means to act with the aim of carrying out the act.[30]

Interview Summary (or Interview Summaries). A written, summarized account prepared by the inquiry committee, Research Integrity Officer (RIO), or other designated institutional official of the key points, observations, and information obtained during an interview conducted during the research misconduct inquiry phase. Unlike a transcript, an interview summary is not a verbatim record. It highlights relevant facts, statements, and evidence, and may include clarifying notes or context to assist in the evaluation of the case. Interview summaries are considered confidential records and are used in preparing reports, supporting findings, or facilitating internal review.

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.[31]

Knowingly. To act knowingly means to act with awareness of the act.[32]

Office of Research Integrity (ORI). The federal office established by Public Health Service Act section 493 (42 U.S.C. 289b) and to which the HHS Secretary has delegated responsibility for addressing research integrity and misconduct issues related to PHS-supported activities.

Plagiarism. Plagiarism means the appropriation of another person's ideas, processes, results, or words, without giving appropriate credit. (a) Plagiarism includes the unattributed verbatim or nearly verbatim copying of sentences and paragraphs from another's work that materially misleads the reader regarding the contributions of the author. It does not include the limited use of identical or nearly identical phrases that describe a commonly used methodology. (b) Plagiarism does not include self-plagiarism or authorship or credit disputes, including disputes among former collaborators who participated jointly in the development or conduct of a research project. Self-plagiarism and authorship disputes do not meet the definition of research misconduct.[33]

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.[34]

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.[35]

The PHS comprises all Agency Divisions of Health and Human Services including:

- Administration for Children and Families (ACF)
- Administration on Aging (AoA)
- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control and Prevention (CDC)
- Centers for Medicare & Medicaid Services (CMS)
- Federal Occupational Health (FOH)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (HIS)
- National Institutes of Health (NIH)
- Substance Abuse and Mental Health Services Administration (SAMHSA)
- Public Health Service Commissioned Corps.

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.[36]

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.[37] The UNE Research Integrity Officer is Karen Houseknecht, Ph.D.

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.[38] Research misconduct may be committed directly or through the use or assistance of other persons, entities, or tools, including artificial intelligence (AI), when such conduct results in fabrication, falsification, or plagiarism as defined in this policy.

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.[39]

Research record. Research record 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.[40]

Respondent. Respondent means the individual against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.[41]

Retaliation. Retaliation means an adverse action taken against a complainant, witness, or committee member by an institution or one of its members in response to (a) a good faith allegation of research

misconduct or (b) good faith cooperation with a research misconduct proceeding.[42]

Suspension and Debarment Official. Suspension and Debarment Official or SDO means the HHS official authorized to impose suspension and debarment, which are the actions that Federal agencies take to disqualify persons deemed not presently responsible from doing business with the Federal Government.[44]

Transcript. A complete, verbatim written record of statements, questions, and responses made during an interview, or hearing conducted as part of a research misconduct inquiry or investigation. Transcripts may be produced by a certified court reporter, stenographer, or through an audio recording subsequently transcribed. A transcript is required only for the research misconduct investigation phase, where formal findings and potential reporting to federal agencies or appeals may occur. During the research misconduct inquiry phase, a verbatim transcript is typically not required, and a written interview summary is sufficient to document relevant information. Transcripts are considered confidential records.

Roles, Rights, and Responsibilities

Institution

UNE's General Responsibilities

To the extent possible, the institution will limit disclosure of the identity of 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.[45] This limitation on disclosure no longer applies once the institution has made a final determination of research misconduct findings.[46] The institution will respond to each allegation of research misconduct under 42 CFR Part 93 in a thorough, competent, objective, and fair manner.[47] The institution will take all reasonable and practical steps to ensure the cooperation of respondents and other institutional members with research misconduct proceedings, including, but not limited to, their providing information, research records, and other evidence.[48] The institution agrees to cooperate with 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.[49] The institution may also take steps to manage published data or acknowledge that data may be unreliable.[50]

UNE's Responsibilities During and After a Research Misconduct Proceeding

Except as may otherwise be prescribed by applicable law, the institution 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.[51] Before or at the time of notifying the respondent of the allegation(s) and whenever additional items become known or relevant,

the institution will promptly take all reasonable and practical steps to obtain all research records and other evidence and sequester them securely.[52] The institution 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. Upon completion of the inquiry, the institution will provide ORI with the complete inquiry report and add it to the institutional record.[53] The institution will maintain the institutional record and all sequestered research records and other evidence in a secure manner for seven years after completion of the institutional and/or HHS proceeding.[54]

The institution 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.[55] Additionally, the institution will promptly notify ORI of any special circumstances that may arise.[56]

Disclosure of the identity of respondents, complainants, and witnesses while the institution is conducting the research misconduct proceedings is limited to those who need to know, which the institution 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.[57]

UNE's Responsibilities to the Complainant(s)

The institution will provide confidentiality consistent with 42 CFR Part 93 for all complainants in a research misconduct proceeding. The institution will also 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).[58] The institution agrees to take all reasonable and practical steps to protect the positions and reputations of complainants and to protect these individuals from retaliation by respondents and/or other institutional members.[59] If UNE chooses to notify one complainant of the inquiry results in a case, all complainants will be notified by the institution, to the extent possible.[60]

UNE's Responsibilities to the Respondent(s)

As with complainants, the institution will provide confidentiality consistent with 42 CFR Part 93 to all respondents in a research misconduct proceeding. The institution will make a good-faith effort to notify the respondent(s) in writing of the allegations being made against them. [61] The institution 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 respondent.[62] The institution is responsible for giving the respondent(s) copies of or supervised access to the sequestered research records.[63] The institution will notify the respondent whether the inquiry found that an investigation is warranted, provide the respondent an opportunity to review and comment on the inquiry report, and attach their comments to the inquiry report.[64] If an investigation is commenced, the institution must notify the respondent, give written notice of any additional allegations raised against

them not previously addressed by the inquiry report, and allow the respondent(s) an opportunity to review the witness transcripts. [65] The institution will give the respondent(s) an opportunity to read and comment on the draft investigation report and any information or allegations added to the institutional record.[66] The institution will give due consideration to admissible, credible evidence of honest error or difference of opinion presented by the respondent.[67]

The institution will bear the burden of proof, by a preponderance of the evidence, for making a finding of research misconduct.[68] The institution will make all reasonable, practical efforts, if requested and as appropriate, to protect or restore the reputation of respondents against whom no finding of research misconduct is made.[69]

UNE's Responsibilities to Committee Members

The institution will ensure that a committee, consortium, or person acting on the institution's behalf conducts research misconduct proceedings in compliance with the PHS regulation. The institution 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.[70]

UNE's Responsibilities to the Witness[es]

The institution will provide confidentiality consistent with 42 CFR Part 93 for all witnesses. The institutions 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.[71] The institutions will also take all reasonable and practical steps to protect the positions and reputations of witnesses and to protect these individuals from retaliation.[72]

Research Integrity Officer

The Research Integrity Officer (RIO) is the institutional official responsible for administering UNE's written policies and procedures for addressing allegations of research misconduct in compliance with the PHS regulation.[73] The same individual will not serve as both the Institutional Deciding Official and the RIO.[74] The institution may choose to have the RIO or another designated institutional official conduct the inquiry in lieu of a committee, and, if needed, this individual may utilize one or more subject matter experts to assist them in the inquiry.[75]

Upon receiving an allegation of research misconduct, the RIO or another designated institutional official will 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.[76]

If the RIO or another designated institutional official determines that the requirements for an inquiry are met, they shall document the assessment, promptly sequester all research records and other evidence per the PHS regulation, and promptly initiate the inquiry.[77] The RIO ensures that staff support is available for scheduling interviews, sequestering records, and preparing the institutional record. The

RIO also coordinates with General Counsel on legal issues and with Human Resources on personnel matters.

If the RIO or another designated institutional official determines that requirements for an inquiry are not met, they will keep sufficiently detailed documentation of the assessment to permit a later review by ORI of the reasons why UNE did not conduct an inquiry.[78] The institution will keep this documentation and related records in a secure manner for seven years and provide them to ORI upon request.[79]

Complainant

The complainant is the person who in good faith makes an allegation of research misconduct.[80] The complainant brings research misconduct allegations directly to the attention of an institutional or HHS official through any means of communication.

The complainant will make allegations in good faith, as it is defined in the PHS regulation, 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.[81]

Respondent

The respondent is the individual against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.[82] The respondent has the burden of going forward with and proving, by a preponderance of evidence, affirmative defenses raised.[83] The respondent's destruction of research records documenting the questioned research is evidence of research misconduct where a preponderance of evidence establishes that the respondent intentionally or knowingly destroyed records after being informed of the research misconduct allegations.[84] The respondent's failure to provide research records documenting the questioned research is evidence of research misconduct where the respondent claims to possess the records but refuses to provide them upon request.[85]

The respondent will not be present during the witnesses' interviews but will be provided a transcript of the interview after it takes place.[86] The respondent will have opportunities to (a) view and commenton the inquiry report, (b) view and comment on the investigation report, and (c) submit any comments on the draft investigation report to UNE within 30 days of receiving it.[87]

If admitting to research misconduct, the respondent will sign a written statement specifying the affected research records and confirming the misconduct was falsification, fabrication, and/or plagiarism; committed intentionally, knowingly, or recklessly; and a significant departure from accepted practices of the relevant research community.[88]

Committee and Consortium Members

Committee members (and consortium members where applicable) are experts who act in good faith to cooperate with the research misconduct proceedings by impartially carrying out their assigned duties for

the purpose of helping UNE meet its responsibilities under 42 CFR Part 93.[89] Committee and consortium members will have relevant scientific expertise and be free of real or perceived conflicts of interest with any of the involved parties.[90]

Committee or consortium members or anyone acting on behalf of UNE will conduct research misconduct proceedings consistent with the PHS regulation. They will determine whether an investigation is warranted, documenting the decision in an inquiry report.[91] During an investigation, committee or consortium members participate in recorded interviews of each respondent, complainant, 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).[92] They will also determine whether or not the respondent(s) engaged in research misconduct and document the decision in the investigation report.[93] They consider respondent and/or complainant comments on the inquiry/investigation report(s) and document that consideration in the investigation report.[94]

An investigation into multiple respondents may convene with the same investigation committee or consortium members or anyone acting on behalf of UNE, but there will be separate investigation reports and separate research misconduct determinations for each respondent.[95] Committee or consortium members may serve for more than one investigation, in cases with multiple respondents.[96] Committee members may also serve for both the inquiry and the investigation.

Witnesses

Witnesses are people whom UNE has reasonably identified as having information regarding any relevant aspects of the investigation. Witnesses provide information for review during research misconduct proceedings. Witnesses will cooperate with the research misconduct proceedings in good faith and have a reasonable belief in the truth of their testimony, based on the information known to them at the time.[97]

Institutional Deciding Official

The Institutional Deciding Official (IDO) makes the final determination of research misconduct findings.[98] The IDO cannot serve as the RIO.[99] The IDO documents their 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 UNE has taken or will take.[100] In making the final determination and prior to issuing a written decision, the IDO consults with General Counsel regarding legal issues, compliance considerations, and potential institutional risk. The IDO's written decision becomes part of the institutional record.[101]

Office of Research Integrity & Compliance

The UNE Office of Research Integrity & Compliance is responsible for maintaining the case-tracking system and docket numbers, storing all physical and digital records of research misconduct cases, and ensuring that all records are retained for at least seven years in accordance with institutional and federal requirements.

General Counsel

General Counsel provides guidance to the Research Integrity Officer, Institutional Deciding Official, inquiry and investigation committee members, and other institutional leadership involved in research misconduct proceedings. General Counsel advises on due process, notification language, record retention and sequestering, confidentiality, and interactions with external parties (e.g., sponsors or regulatory agencies). General Counsel also reviews draft reports and final decisions for compliance with federal regulations and institutional policy, and for potential institutional risk.

Human Resources

Human Resources coordinates interim administrative actions affecting employees involved in research misconduct cases, ensures implementation of anti-retaliation protections, and provides guidance on employee rights and responsibilities in accordance with institutional policies.

Information Technology Services (ITS)

Information Technology Services (ITS) provides technical support to ensure the security, integrity, and accessibility of electronic records and communications related to research misconduct proceedings. ITS is responsible for implementing role-based access controls to limit data access to authorized personnel, preserving and securing electronic research records and communications, supporting secure storage and retrieval of case materials, and assist with electronic evidence collection of forensic analysis as requested by the Research Integrity Officer or another designated institutional official. ITS actions are strictly technical and supportive. ITS does not make determinations regarding findings, recommendations, or sanctions.

Procedures for Addressing Allegations of Research Misconduct

Reporting Channels

Allegations of research misconduct may be submitted by any person, also referred to as the complainant, through the following official channels:

- Direct report to the RIO, any Dean, Department Chair, or the Director of Research Integrity & Compliance.
- Send an e-mail to the UNE Office of Research & Innovation mailbox (ori@une.edu)
- Call the UNE Compliance Hotline at (866) 587-6636
  (this method must be used if the complainant wishes to remain anonymous)

All personnel receiving an allegation must forward it to the RIO promptly, and typically within three (3) business days. The RIO will acknowledge receipt of the allegation promptly, and typically within five (5) business days, inform the complainant (if known) of confidentiality protections, and outline the next

steps in the process. The Office of Research Integrity & Compliance will assign a case number, record intake details, and documents all actions chronologically in the case management system.

Per UNE policy, it is a violation for any individual to engage in retaliatory acts against a complainant or against anyone who assists in, or participates in, a proceeding or investigation related to an allegation. Any person, including the complainant, should promptly report any suspected or apparent retaliation to Human Resources.

Assessment

An assessment's purpose is to determine whether an allegation warrants an inquiry.[102] An assessment is intended to be a review of readily accessible information relevant to the allegation.[103]

The assessment will typically be completed within ten (10) business days of receipt of the allegation, unless an extension is justified in writing by the RIO or another designated institutional official. During the assessment, the RIO or another designated institutional official may conduct limited fact-checks using readily accessible materials, and may consult with General Counsel as needed. No notice is provided to the respondent during the assessment phase.

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, and (c) is credible and specific enough to identify and sequester potential evidence.[104]

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.[105] 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.[106] 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 UNE did not proceed to an inquiry and securely retain this documentation for seven years.[107] If an inquiry is not opened, the RIO or another designated institutional official will place this documentation in secure storage and notify the complainant, if known, that the assessment is complete and that an inquiry will not be initiated.

Inquiry

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.[108] An inquiry's purpose is to conduct an initial review of the evidence to determine whether an allegation warrants an investigation.[109] An inquiry does not require a full review of all related evidence.[110] UNE will complete the inquiry within 90 days of initiating it unless circumstances warrant a longer period. If the inquiry is not completed within 90 days, the inquiry report will document the reasons for exceeding the 90-day period.[111]

Sequestering Evidence and Notifying the Respondent

Before or at the time of notifying the respondent(s), UNE 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.[112] The institution 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.[113]

In carrying out these responsibilities, the RIO or another designated institutional official will identify all relevant data systems, devices, research locations, and laboratory spaces potentially containing research records or evidence. Digital records will be preserved through forensic imaging or comparable methods that maintain integrity and adhere to chain-of-custody standards. Physical materials will be inventoried, labeled, and documented in a standardized evidence log. All sequestered evidence, whether digital or physical, will be stored in controlled-access environments, with access restricted to authorized personnel only.

At the time of or before beginning the inquiry, UNE will make a good-faith effort to notify the presumed 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.[114] If additional allegations are raised, the institution will notify the respondent(s) in writing.[115] When appropriate, the institution will give the respondent(s) copies of, or reasonable supervised access to, the sequestered materials.[116]

If additional respondents are identified, UNE will provide written notification to the new respondent(s).[117] All additional respondents will be given the same rights and opportunities as the initial respondent.[118] Only allegations specific to a particular respondent will be included in the notification to that respondent.[119]

Convening the Committee and Ensuring Neutrality

UNE 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 in the inquiry.[120]

Inquiry committees will typically consist of three (3) members, including at least one subject matter expert with relevant scientific or scholarly expertise. Committee members are appointed by the RIO and will be screened for real or apparent conflicts of interest to ensure neutrality and objectivity. If appropriate internal expertise is unavailable, the RIO may retain external subject matter experts to serve on the committee or to provide specialized consultation. All committee members and any internal or external experts engaged in the inquiry must sign a confidentiality agreement prior to accessing materials or participating in committee deliberations.

A majority of the members must be present to conduct business. The determination of whether an

investigation is warranted will be made by majority vote of the committee. Only members without conflicts of interest or unresolved bias concerns may participate in deliberations or voting.

Interview Procedures

The purpose of interviews during the inquiry phase is to gather information and clarify facts relevant to the allegation of research misconduct. Interviews are conducted to support the determination of whether the allegation warrants an investigation. Depending on the inquiry structure used, interviews may be conducted by a majority of the inquiry committee, the RIO, or another designated institutional official.

Scheduling and Conducting Interviews:

- The inquiry committee, the RIO, or other designated institutional official schedules interviews with the respondent(s), complainant(s), and any relevant witnesses in a timely manner.
- The person or persons conducting the inquiry may order and number interviews in their best judgment, although it is usually preferable to conduct witness and complainant interviews before the respondent interview, allowing the inquiry committee, the RIO, or other designated institutional official to review and assess initial factual information prior to speaking with the respondent.
- The respondent will be given an opportunity to participate in an interview before the inquiry committee, the RIO, or other designated institutional official reaches a determination on whether an investigation is warranted.
- The respondent will be advised that they are entitled to consult with an attorney of their choice, and at their expense, or an advisor of their choice as long as that advisor is not a witness or UNE personnel involved in or likely to be involved in the research misconduct inquiry and investigation process. The attorney or advisor may be present during an interview or meetings in an advisory capacity but may not disrupt the process or interfere with the interview and may not address substantive matters during the interview.
- The respondent may identify potential witnesses for the inquiry; however, the inquiry committee, the RIO, or other designated institutional official will determine whether proposed witnesses possess information relevant to the inquiry scope.
- Interviews will be conducted in a private and neutral setting to protect confidentiality and minimize potential retaliation. Reasonable accommodations will be provided as needed.
- Individuals being interviewed are informed of the purpose of the interview y and their responsibility to provide accurate information.
- The inquiry committee, the RIO, or other designated institutional official may consult with General Counsel or Human Resources prior to or during the interview if questions of law, policy, or personnel actions arise.

Documentation:

- The inquiry committee, the RIO, or other designated institutional official prepares written summaries of all interviews, which include the date, time, participants, and a factual account of the discussion.
- Interview summaries will be prepared promptly, typically within ten (10) business days of the interview, and finalized as soon as practicable.
- Interviews conducted during the inquiry phase are typically not audio-recorded. The inquiry committee, the RIO, or other designated institutional official may authorize audio recording when necessary to ensure accuracy.
- Interview summaries are maintained in the institutional case file in secure storage. Originals or recordings of interviews are treated as confidential research records and handled in accordance with the institution's sequestering procedures.

Confidentiality and Non-Retaliation:

- All participants in interviews are instructed to maintain confidentiality regarding the content and existence of the interview, except as required for the inquiry.
- The institution prohibits retaliation against any individual who participates in, provides information to, or assists with the inquiry. Any suspected retaliation must be promptly reported to Human Resources.

Use of Subject Matter Experts:

- Subject matter experts assisting in the inquiry may attend interviews if their expertise is necessary to understand the information being provided.
- All experts must sign a confidentiality agreement prior to participating in interview.

Follow-Up:

- If new information arises during an interview that affects the scope of the inquiry, the inquiry committee, the RIO, or other designated institutional official may schedule additional interviews or request supplemental documentation.
- Interviews are conducted and completed in a timely manner, typically within the overall timeframe established for the inquiry phase.

Determining Whether an Investigation Is Warranted

The inquiry committee, RIO, or other designated institutional official will conduct a preliminary review of the evidence.[121] In the process of fact-finding, the inquiry committee may interview the respondent and/or witnesses.[122] 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.[123]

Note: The criteria described above reflects federal requirements for PHS-supported research under 42 CFR Part 93. UNE applies the same criteria and procedures for determining whether an investigation is warranted for non-PHS-funded or unfunded research, unless otherwise required by applicable law or sponsor policy.

The inquiry committee, RIO, or other designated institutional official 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.[124]

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. If transcripts do not exist, the draft inquiry report will include written summaries of interviews.
   Note: Transcripts or written summaries of interviews included in the draft inquiry report may be redacted to protect the identities of complainants or witnesses, or to mitigate legitimate concerns about retaliation. Redactions will not remove factual content necessary for the respondent to meaningfully review and comment on the draft report. The rationale for any redactions will be documented in the institutional record.
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.[125]
13. Documentation of potential evidence of honest error or difference of opinion.[126]

Completing the Inquiry

UNE will give the respondent a copy of the draft inquiry report for review and comment.[127] The institution may, but is not required to, provide relevant portions of the report to a complainant for comment.[128]

- Draft Report to Complainant: The institution may provide relevant portions of the draft inquiry report to the complainant(s) for review and comment. Any portions provided will be redacted as necessary to protect confidentiality of other individuals and to prevent retaliation. Complainants will be informed that their feedback should focus on factual accuracy or missing information, not on the outcome or conclusions of the inquiry.
- Legal Review: The inquiry committee, the RIO, or other designated institutional official may consult with General Counsel prior to releasing the draft investigation report to ensure legal sufficiency, proper confidentiality protections, adequate redaction of sensitive information, and compliance with institutional policies and applicable laws.
- Time to Respond: Respondents and complainants (if provided the draft) will be given ten (10) business days to submit written comments.
- Reviewing Feedback: The inquiry committee, the RIO, or other designated institutional official will review all feedback submitted. Relevant clarifications, corrections, or additional factual information will be incorporated into the final inquiry report, and a summary of the feedback and how it was addressed will be included in the institutional record.

UNE 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.[129] The institution may, but is not required to, notify a complainant whether the inquiry found that an investigation is warranted.[130] 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.[131]

If an Investigation Is Not Warranted:

If the inquiry committee, RIO, or other designated institutional official determines that an investigation is not warranted, UNE will keep sufficiently detailed documentation to permit a later review by ORI of why the institution 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. [132]

If an Investigation is Warranted:

If the inquiry committee, RIO, or other designated institutional official determines that an investigation is warranted, UNE must: (a) within a reasonable amount of time after this decision, provide written notice to the respondent(s) of the decision to conduct an investigation of the alleged misconduct, including any allegations of research misconduct not addressed during the inquiry;[133] and within 30 days of determining that an investigation is warranted, provide ORI with a copy of the inquiry report.[134]

On a case-by-case basis, UNE 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.[135]

Investigation

The purpose of an investigation is to formally develop a factual record, pursue leads, examine the record, and recommend finding(s) to the IDO, who will make the final decision, based on a preponderance of evidence, on each allegation and any institutional actions.[136] As part of its investigation, the institution 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.[137] Within 30 days after deciding an investigation is warranted, UNE will notify ORI of the decision to investigate and begin the investigation.[138]

Notifying the Respondent and Sequestering Evidence

UNE will notify the respondent(s) of the allegation(s) within 30 days of determining that an investigation is warranted and before the investigation begins.[139] If any additional respondent(s) are identified during the investigation, the institution will notify them of the allegation(s) and provide them an opportunity to respond consistent with the PHS regulation.[140] If the institution identifies additional respondents during the investigation, it may choose to either conduct a separate inquiry or add the new respondent(s) to the ongoing investigation.[141] The institution 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.[142]

Convening an Investigation Committee

After vetting investigation committee members for conflicts of interest and appropriate scientific expertise, UNE will convene the committee and ensure that the members understand their responsibility to conduct the research misconduct proceedings in compliance with the PHS regulation.[143]

- Committee Composition: The investigation committee typically consists of three to five members, appointed by the RIO. Members must include scientific experts with relevant methodological knowledge to evaluate the specific allegations. A non-conflicted senior faculty member will be designated as the committee chair, unless the RIO documents a justified exception.
- External Members: For complex or highly specialized cases, the investigation committee will include, when available, external members or subject matter experts to provide additional expertise. If external participation is not feasible, the RIO must document the rationale for proceeding without external experts.
- Confidentiality: All investigation committee members, as well as any internal or external subject matter experts assisting the committee, must sign a confidentiality agreement prior to participating in the investigation.

- Investigation Plan: Within ten (10) business days of convening, the committee will prepare a written investigation plan, which will be incorporated into the institutional record. The plan will typically include:

    1. A list of individuals to be interviewed;
    2. Any forensic, statistical, or other analyses to be conducted;
    3. An expected timeline for completion of the investigation and frequency of committee meetings; and
    4. A list of documentary evidence and research records to complete the investigation.

    The RIO will review the plan to ensure it is thorough, feasible, and consistent with regulatory and institutional requirements. General Counsel may be consulted if needed. The investigation plan may be updated during the investigation if new information arises or additional evidence becomes available, and all updates will be documented in the institutional record.

- Tracking and Documentation: The committee will track progress against the plan, including completed interviews, analyses performed, and evidence reviewed. Any deviations from the plan will be documented and justified in the institutional record. The final investigation report will reflect adherence to the plan, including any updates or deviations, to ensure the investigation is thorough, impartial, and well-documented.

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).[144] The institution will use diligent efforts to ensure that the investigation is thorough, sufficiently documented, and impartial and unbiased to the maximum extent practicable.[145] The institution will notify the respondent in writing of any additional allegations raised against them during the investigation.[146]

Conducting Interviews

UNE will interview each 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 respondent.[147] The institution will number all relevant exhibits and refer to any exhibits shown to the interviewee during the interview by that number.[148] The institution will record and transcribe interviews during the investigation and make the transcripts available to the interviewee for correction.[149] The institution will include the transcript(s) with any corrections and exhibits in the institutional record of the investigation.[150] The respondent will not be present during the witnesses' interviews, but the institution will provide the respondent with a transcript of each interview, with redactions as appropriate to maintain confidentiality.[151]

To ensure thorough, consistent, and documented interviews during the investigation, the following procedures will be employed:

- Scheduling and Notification: The committee will schedule interviews promptly and provide the interviewee with written notice of the date, time, location, and purpose of the interview. Interviews will be conducted in a private and neutral setting to protect confidentiality and minimize potential retaliation. Reasonable accommodations will be provided as needed.

- Confidentiality and Legal Guidance: All investigation committee members and any internal or external subject matter experts assisting with interviews must maintain confidentiality and sign a confidentiality agreement prior to participating. Interviewees (respondents, complainants, and witnesses) are reminded verbally and/or in writing of their obligation to maintain confidentiality of the proceedings. The committee may consult with General Counsel as needed regarding questions of privilege, confidentiality, or retaliation.
- Respondent's Rights: The respondent will be advised that they are entitled to consult with an attorney of their choice, and at their expense, or an advisor of their choice as long as that advisor is not a witness or UNE personnel involved in or likely to be involved in the research misconduct inquiry and investigation process. The attorney or advisor may be present during an interview or meetings in an advisory capacity but may not disrupt the process or interfere with the interview and may not address substantive matters during the interview.
- Interviewee Rights and Responsibilities: Interviewees will be informed their responsibility to provide accurate and complete information. The institution prohibits retaliation against any individual who participates in, provides information to, or assists with the investigation. Any suspected retaliation must be promptly reported to Human Resources.
- Interview Sequence and Respondent Participation: The person or persons conducting the interviews may order and number interviews in their best judgment, although it is usually preferable to conduct witness interviews before the respondent's interview, allowing the committee to clarify factual issues before interviewing the respondent. The respondent may propose additional witnesses; however, the committee will determine which witnesses are relevant and necessary for a thorough and unbiased investigation. The respondent will be interviewed prior to the committee's deliberations.
- Recording and Documentation: All interviews conducted during the investigation will be recorded and transcribed. Each interviewee (including respondents, complainants, and witnesses) will receive a copy of their own transcript within ten (10) business days of the interview, unless a written justification for delay is documented by the committee, and will have ten (10) business days to review the transcript for accuracy or to provide corrections. The transcript, along with any corrections, will be maintained in the institutional record. Transcripts will be authenticated and indexed as part of the complete investigation record.
- Exhibit Handling: All exhibits used or referenced during the interview will be numbered, inventoried, and included in the institutional record.
- Follow-Up: If new information arises during an interview that affects the scope of the investigation, the committee may schedule additional interviews or request supplemental documentation. Interviews will be conducted and completed in a timely manner, typically within the overall timeframe established for the investigation phase.

Quorum and Voting Procedures

Quorum: A quorum, defined as a majority of the appointed committee members, must be present for the committee to conduct interviews, deliberate, or vote. Committee members may participate in

meetings or interviews in person or through secure remote means, provided confidentiality can be maintained. If quorum is lost during a meeting, the committee must suspend deliberations and voting until quorum is reestablished.

Participation and Voting: Committee members must participate in deliberations and must review the complete evidentiary record – including transcripts, recordings, or written summaries – of any interviews or meetings they did not attend. Members who have received the full record are eligible to vote on committee determinations. Findings or recommendations will be based on a majority vote of the full committee, unless institutional policy or the committee's charge specifies a different threshold. Only members without conflicts of interest or unresolved bias concerns may participate in deliberations or voting.

Documenting the Investigation

UNE will complete all aspects of the investigation within 180 days.[152] The institution will conduct the investigation, prepare the draft investigation report for each respondent, and provide the opportunity for respondents to comment.[153] 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.[154] 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.[155] The investigation report for each respondent will include:

1. Description of the nature of the allegation(s) of research misconduct, including any additional allegation(s) addressed during the research misconduct proceeding.
2. 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 respondent has pending with PHS and non-PHS Federal agencies.
3. Description of the specific allegation(s) of research misconduct for consideration in the investigation of the respondent.
4. Composition of investigation committee, including name(s), position(s), and subject matter expertise.
5. Inventory of sequestered research records and other evidence, except records the institution did not consider or rely on.[156] 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.
6. Transcripts of all interviews conducted.
   Note: Transcripts of interviews included in the draft investigation report may be redacted to protect the identities of complainants or witnesses, or to mitigate legitimate concerns about retaliation. Redactions will not remove factual content necessary for the respondent to meaningfully review and comment on the draft report. The rationale for any redactions will be documented in the institutional record.
7. 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.

8. Any scientific or forensic analyses conducted.
9. A copy of these policies and procedures.
10. Any comments made by the respondent and complainant(s) on the draft investigation report and the committee's consideration of those comments.
11. A statement for each separate allegation of whether the committee recommends a finding of research misconduct.[157]

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 respondent; (f) identify the specific PHS support; and (g) state whether any publications need correction or retraction.[158]

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.[159]

The investigation committee should also provide a list of any current support or known applications or proposals for support that the respondent has pending with PHS and non-PHS Federal agencies.[160]

Completing the Investigation

UNE will give the 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.[161] The respondent will submit any comments on the draft report to the institution within 30 days of receiving the draft investigation report.[162] If UNE 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.[163] The institution will add any comments received to the investigation report.[164]

- Draft Report to Complainant: If the institution elects to provide the complaint(s) with a copy of the draft investigation report or relevant portions of it for comment, any portions shared will be limited to what is necessary to verify factual accuracy and ensure completeness of the record. Materials will be redacted as appropriate to protect confidentiality of individuals involved and to minimize risks of retaliation. Complainants will be informed that their feedback should focus on factual accuracy, completeness, or identification of missing information, not on the investigation committee's analysis, conclusions, or recommended findings.

- Legal Review: The investigation committee may consult with General Counsel prior to releasing the draft investigation report to ensure legal sufficiency, proper confidentiality protections,

adequate redaction of sensitive information, and compliance with institutional policies and applicable laws.

- Review and Incorporation of Feedback: The investigation committee will review all comments submitted by the respondent and complainant(s). Clarifications, factual corrections, or relevant additional information will be incorporated directly into the final investigation report or addressed in an appendix if not incorporated. The institutional record will document all comments received, any substantive changes made to the draft report, and the committee's rationale for not incorporating suggested revisions, if applicable.
- Access to Research Records and Evidence: When provided supervised access to research records and other evidence by the investigation committee, the respondent may take personal notes. Copying, photographing, or removing any materials from the designated review area requires prior approval from the investigation committee. All notes and materials must be handled in a manner that protects confidentiality and preserves the integrity of the institutional record.

IDO Review of the Investigation Report

The IDO will review the investigation report and make a final written determination of whether the institution found research misconduct and, if so, who committed the misconduct.[165] In this statement, the IDO will include a description of relevant institutional actions taken or to be taken.[166]

Creating and Transmitting the Institutional Record

After the IDO has made a final determination of research misconduct findings, UNE will add the IDO's written decision to the investigation report and organize the institutional record in a logical manner.[167]

The institutional record consists of the records that were compiled or generated during the research misconduct proceeding, except records the institution did not rely on.[168] 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.[169] The institutional record also includes the IDO's final decision and any information the respondent provided to the institution.[170] The institutional record must also include a general description of the records that were sequestered but not considered or relied on.[171]

If the respondent filed an appeal, the complete record of any institutional appeal also becomes part of the institutional record.[172] UNE will wait until the appeal is concluded to transmit the institutional record to ORI.[173] After the IDO has made a final written determination, and any institutional appeal is complete, the institution must transmit the institutional record to ORI.[174]

Communications and Notifications

Method of Communication

Formal Communications: All formal notifications related to allegations, assessments, inquiries, and

investigations of research misconduct will be issued in writing. Communications may be delivered by institutional e-mail or certified mail.

Confidentiality: Notifications will be limited to individuals with a legitimate need to know and will comply with applicable confidentiality requirements, including protection of respondent, complainant, and witness identities to the extent permitted by law and institutional policy.

Recordkeeping: Copies of all notifications and communications will be maintained by the RIO or other designated institutional official in accordance with institutional record-retention requirements and any applicable sponsor regulations.

Communications with Journals, Collaborators, and Compliance Committees

Scientific Journals and Publishers: The RIO notify journal editors or publishers only when necessary to protect the integrity of the research record or to comply with sponsor or regulatory obligations. Ordinarily, such communications will occur after the investigation has reached final findings. However, earlier notification (e.g., at the inquiry phase) may occur when:

1. There is credible risk that the published or submitted work is unreliable;
2. Immediate action (such as an expression of concern or pause in peer review) is necessary to prevent dissemination of potentially invalid findings, or
3. Required by a federal agency or sponsor.

All communications will occur in consultation with General Counsel and relevant leadership and will avoid premature disclosure of allegations or unsubstantiated concerns.

External Collaborators and Research Partners: The RIO will notify external collaborators, subawardees, or partnering institutions only when necessary fulfill collaborative responsibilities or to safeguard shared data, samples, or ongoing research activities. As a general rule, notification will occur after final institutional findings, unless earlier communication is needed to:

1. Protect human or animal subjects;
2. Prevent misuse of loss of shared research materials or data;
3. Address immediate compliance or contractual risks; or
4. Respond to a sponsor or regulatory requirement.

Notifications will be factual and limited to information needed to support collaborative obligations.

Research Compliance Committees (IACUB, IBC, IRB): The RIO will notify relevant research compliance committees when alleged misconduct – at any stage – may impact approved protocols, participant safety, animal welfare, biosafety, data integrity, or regulatory compliance. Committees may take independent regulatory action as permitted by their governing regulations (e.g., protocol suspension, modification requirements). Final outcomes of the research misconduct proceedings will be communicated to these committees when necessary to inform ongoing or future research oversight responsibilities.

Notifications to Institutional Leadership

Initial Notifications: The RIO will notify key institutional leaders at defined stages of the research misconduct process to ensure appropriate oversight and compliance.

- Department Chairs and Deans will be notified when a formal inquiry is opened, unless doing so would compromise the integrity of the process or pose a risk to individuals or evidence.
- General Counsel will be notified at the assessment stage of an allegation to ensure timely legal guidance, preservation of records, and coordination on institutional risk.
- Human Resources will be notified when an allegation, assessment, inquiry, or investigation may require personnel-related actions, including interim administration measures, employment consequences, workplace restrictions, or concerns affecting workplace safety or conduct.
- Senior institutional leadership – typically the Vice President for Research, Provost, or equivalent – will be briefed when (1) an inquiry or investigation is initiated, (2) there is significant regulatory, financial, or reputational risk, or (3) sponsor-required notifications have been or will be made.

Progress and Outcome Reports: Leadership will receive periodic updates on the status of inquiries and investigations, as well as written notification on final findings and recommended institutional actions.

Sponsor and Regulatory Notifications: The RIO will inform leadership when required notifications to federal agencies or sponsoring entities are issued, including initial reports, updates, and final investigation reports.

Confidentiality and Data Security

UNE is committed to protecting the privacy and security of all individuals and information involved in research misconduct proceedings. Disclosure of the identity of respondents, complainants, and witnesses while conducting the research misconduct proceedings is limited, to the extent possible, to those who need to know, as determined by UNE, consistent with a thorough, competent, objective, and fair research misconduct proceeding, and as allowed by law. Those who need to know may include applicable research compliance or oversight committees, journals, editors, publishers, co-authors, and collaborating institutions. Except as may otherwise be prescribed by applicable law, confidentiality must be maintained for any records or evidence from which research subjects might be identified. Disclosure is limited to those who need to know to carry out a research misconduct proceeding.

Access to records, evidence, and identifying information related to allegations, assessments, inquiries, and investigations will be strictly limited to individuals with a legitimate need to know. The RIO will implement appropriate access controls for both physical and electronic records, including locked storage for hardcopy materials, restricted file directories and role-based permissions for electronic materials, and use of secure, institutionally approved platforms for data storage and communication.

Individuals who have sustained or ongoing access to sensitive information – such as inquiry and investigation committee members, administrative staff supporting the RIO, and internal/external subject matter experts – will be required to sign confidentiality agreements reflecting their obligations under institutional policy and applicable regulations. Witnesses, complainants, and respondents will be reminded of confidentiality expectations at the time of interview or contact, consistent with institutional policy and federal requirements, but they are generally not required to sign separate confidentiality agreements. All participants are expected to refrain from unauthorized disclosure of information learned through the process.

Confidentiality will be maintained as much as is reasonably possible, consistent with the need to conduct a full, fair, and timely review; comply with federal, state, or sponsor requirements; and protect the integrity of the research record and individual safety. Unauthorized disclosure of confidential information may result in institutional corrective or disciplinary action, in accordance with applicable policies and employment procedures. Data security measures and access restrictions will remain in place throughout the assessment, inquiry, investigation, and record-retention periods as required by institutional and regulatory standards.

With respect to UNE, the limitations on disclosure of the identity of respondents, complainants, and witnesses no longer applies once UNE has made a final determination of research misconduct findings.

Retaliation and Interim Measures

UNE strictly prohibits retaliation against any individual who, in good faith, makes an allegation of research misconduct, cooperates with a research misconduct proceeding, or otherwise participates in related assessments, inquiries, or investigations. Retaliation includes any adverse action, threat, intimidation, harassment, or change in terms or conditions of employment or academic status taken because of an individual's participation in the research misconduct process. Individuals who believe they have experienced or witnessed retaliation are expected to report concerns promptly to Human Resources. Reports of retaliation will be reviewed promptly and addressed through appropriate institutional procedures.

To protect the integrity of the research environment and secure the safety and well-being of all participants, the institution may implement interim measures at any stage of the misconduct process. Interim measures are administrative actions designed to be neutral, non-punitive, and tailored to the needs of the situation. Such measures may include, but are not limited to:

- Modifications to supervisory or reporting relationships;
- Adjustments to research, teaching, or administrative duties;
- Restrictions on access to certain facilities, equipment, data, or human/animal subjects;
- Sequestration of research materials;
- Temporary reassignment to alternative duties; or
- Issue no-contact directives.

Interim measures are not disciplinary in nature and do not represent a finding of wrongdoing. They are

intended solely to preserve evidence, protect research participants and staff, and maintain the integrity of the review.

The RIO will coordinate the implementation of interim protections in consultation with relevant institutional offices, such as Human Resources, General Counsel, research compliance committees, and academic leadership. Individuals subject to or affected by interim measures will be informed of the rationale for the action and the expected duration, and the measures will be reviewed periodically to ensure they remain necessary and proportionate. Violations of interim measures or substantiated acts of retaliation may result in corrective or disciplinary action under applicable institutional policies.

Appeals Process

For research misconduct findings when the research did not implicate the PHS regulation, the respondent may appeal the findings and recommended actions resulting from a formal investigation of research misconduct. Appeals are limited to the investigation phase and do not apply to the preliminary inquiry, which is a confidential assessment to determine whether an investigation is warranted.

The Institutional Deciding Official (IDO), who is independent of the RIO and any inquiry or investigation committees, serves as the designated appeals authority. Appeals must be submitted in writing to the IDO within 15 calendar days of receiving the written investigation report. The appeal must clearly state the grounds, which may include:

1. Procedural Error: A significant deviation from the institution's established procedures that could have materially affected the findings or recommended actions.
2. New Evidence: The discovery of relevant evidence not available during the investigation that could materially affect the findings or recommended actions.

Upon receiving the appeal, the IDO will review submitted materials, may request additional information, and may consult with institutional offices, including the RIO, Human Resources, or General Counsel, as appropriate. After review, the IDO will issue a written decision within 25 calendar days of receipt the appeal. The IDO may extend the timeframe for good cause, provided that the reason for the extension is documented and the respondent is notified in writing. The IDO's decision may affirm, modify, or remand the findings or recommendations. The IDO's decision is final within the institution. Where applicable, the institution will notify relevant federal agencies, sponsors, or other oversight bodies of the final appeal decision in accordance with regulatory requirements.

Throughout the appeals process, confidentiality and data security will be maintained in accordance with institutional policy, and any interim protections established during the investigation will remain in effect unless modified by the IDO.

Other Procedures and Special Circumstances

Multiple Institutions and Multiple Respondents

If the alleged research misconduct involves multiple institutions, UNE may work closely with the other affected institutions to determine whether a joint research misconduct proceeding will be conducted.[175] 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.[176] By mutual agreement, the joint research misconduct proceeding may include committee members from the institutions involved.[177] 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.[178]

If the alleged research misconduct involves multiple respondents, UNE may either conduct a separate inquiry for each new respondent or add them to the ongoing proceedings.[179] The institution must give additional respondent(s) notice of and an opportunity to respond to the allegations.[180]

Respondent Admissions

UNE 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 respondent has admitted to committing research misconduct or a settlement with the respondent has been reached.[181] If the respondent admits to research misconduct, the institution will not close the case until providing ORI with the respondent's signed, written admission. [182] 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.[183] The institution must not close the case until giving ORI a written statement confirming the respondent's culpability and explaining how the institution determined that the respondent's admission fully addresses the scope of the misconduct.[184]

Other Special Circumstances

At any time during the misconduct proceedings, UNE 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.[185]

Records Retention

UNE 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.[186]

Case Closure

A research misconduct case will be considered closed when all stages of the inquiry or investigation have been completed, any appeals have been resolved, and the Institutional Deciding Official (IDO) has issued the final institutional decision. At closure, the RIO will ensure that all required documentation, reports, and correspondence are complete, accurate, and properly organized.

The UNE Office of Research Integrity & Compliance (ORIC) is responsible for maintaining the official institutional record, including electronic files, reports, and physical artifacts associated with the case. The ORIC will document the transfer of custody of records to ORI or other relevant agencies when required and will maintain an inventory of physical artifacts, including research materials, notebooks, or other evidence, to ensure traceability.

The RIO will notify relevant institutional leadership, compliance offices (e.g., Human Resources, research compliance committees), and, where applicable, external agencies or sponsors, that the case has been formally closed. Notification will indicate the final disposition of the case, any corrective or disciplinary actions taken, and any follow-up measures required to protect research integrity, participants, or the research record.

Following closure, access to case records and materials will continue to be governed by institutional confidentiality and data security policies. The RIO and the ORIC may conduct a post-closure review to identify procedural improvements, training needs, or other institutional actions to prevent future research misconduct. Closure of a case does not preclude subsequent review if new evidence emerges or additional misconduct related to the same research is identified.

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[1] ORI has made use of extensive endnotes citing to the regulations at 42 CFR Part 93 in order to serve as a reference to Institutions.
[2] 42 CFR Part 93 § 93.300(c).
[3] § 93.100.
[4] § 93.300(a).
[5] § 93.102(b)(1).
[6] § 93.102(b)(2).
[7] § 93.102(b)(3).
[8] § 93.102(b)(4).
[9] § 93.102(b)(5).
[10] § 93.102(b)(6).
[11] § 93.104(a).
[12] § 93.104(b)(1).
[13] §§ 93.104(b)(1) and 93.318.
[14] § 93.104(b)(2).
[15] § 93.102(c).

[16] §93.200.
[17] §93.202.
[18] §93.203.
[19] §93.204.
[20] §93.206.
[21] §93.210.
[22] §93.211.
[23] §93.212.
[24] §93.214.
[25] §93.215.
[26] §93.216.
[27] §93.218.
[28] §93.219.
[29] §93.220.
[30] §93.221.
[31] §93.222.
[32] §93.223.
[33] §93.227.
[34] §93.228.
[35] §93.230.
[36] §93.231.
[37] §93.233.
[38] §93.234.
[39] §93.235.
[40] §93.236.
[41] §93.237.
[42] §93.238.
[43] §93.240.
[44] §93.241.
[45] §§ 93.106(a) and 93.302(a)(4)(ii).
[46] § 93.106(a)
[47] § 93.241.
[48] § 93.300(f).
[49] § 93.300(g-h).
[50] § 93.106(c).
[51] § 93.106(b). Applicable to all confidentiality requirements in this section.
[52] § 93.305.
[53] §§ 93.317 and 93.220.
[54] § 93.318.
[55] §93.318(b).
[56] §93.305(g).
[57] §93.106(a).
[58] §§ 93.300(b) and 93.305(f)(1).
[59] §93.300(d).
[60] §93.308(b).
[61] §93.307(c).
[62] §93.300(b).
[63] §93.305(b).
[64] §§ 93.308(a) and 93.307(g).

[65] §§ 93.310(c) and 93.310(g)(5).
[66] § 93.312.
[67] § 93.105(b).
[68] §§ 93.105 and 93.103(c).
[69] §§ 93.105 and 93.304(c).
[70] §§ 93.305(f) and 93.300(d).
[71] § 93.300(b).
[72] § 93.300(d).
[73] § 93.233.
[74] § 93.218.
[75] § 93.307(e)(2).
[76] § 93.306(b).
[77] § 93.306(c).
[78] § 93.306(c)(3).
[79] § 93.318.
[80] § 93.206.
[81] § 93.214.
[82] § 93.237.
[83] §§ 93.105(b)(2) and 93.105(b)(3).
[84] § 93.105(b)(1).
[85] § 93.105(b).
[86] § 93.310(g)(5).
[87] §§ 93.307(g)(3) and 93.312.
[88] §§ 93.103 and 93.317(b).
[89] § 93.214(b).
[90] § 93.305(f).
[91] § 93.307.
[92] § 93.310(g).
[93] § 93.313.
[94] § 93.313(j).
[95] § 93.310(c)(3).
[96] § 93.305(d).
[97] § 93.214(a).
[98] § 93.218.
[99] § 93.218.
[100] § 93.314.
[101] § 93.220(a)(4).
[102] § 93.306(a).
[103] § 93.204.
[104] § 93.306(b-c).
[105] §§ 93.306(b) and 93.306(c).
[106] §§ 93.306(c)(2) and 93.318.
[107] §§ 93.306(c)(3) and 93.318.
[108] § 93.307(a)(1-3).
[109] § 93.307(b).
[110] Id.
[111] § 93.307(h).
[112] §§ 93.305(a) and 93.318.
[113] §§ 93.305(a)(2) and 93.318.

[114] § 93.307(c).
[115] § 93.307(c).
[116] § 93.305(b).
[117] § 93.305(d).
[118] Id.
[119] § 93.307(c).
[120] § 93.307(e)(2).
[121] § 93.307(b).
[122] § 93.307(e)(3).
[123] § 93.307(f)(i-ii).
[124] § 93.307(f)(ii)(2).
[125] § 93.309(a)(1-12).
[126] § 93.307(g)(2).
[127] § 93.307g(3).
[128] § 93.308(b).
[129] § 93.308(a).
[130] § 93.308(b).
[131] Id.
[132] § 93.309(c).
[133] § 93.308(a).
[134] § 93.309(a).
[135] § 93.308(b).
[136] §§ 93.310 and 93.314.
[137] § 93.310(j).
[138] § 93.310(a-b).
[139] § 93.310(a-c).
[140] § 93.310(c)(2).
[141] §§ 93.310(c)(2) and 93.310(c)(3).
[142] § 93.318.
[143] § 93.310(f).
[144] § 93.310.
[145] § 93.310(f).
[146] § 93.310(c)(1).
[147] § 93.310(g).
[148] § 93.310(g)(2).
[149] §§ 93.310(g)(1) and 93.310(g)(3).
[150] § 93.310(g)(4).
[151] §§ 93.106, 93.300(d), and 93.310(g)(5). Institutions must, to the extent possible, provide confidentiality to respondents, complainants, and witnesses and protect complainants, witnesses, and committee members from retaliation. It is up to institutions to determine how to do so in practical terms (e.g., by redacting transcripts).
[152] § 93.311(a).
[153] § 93.312.
[154] § 93.316.
[155] § 93.311(b).
[156] § 93.313(e).
[157] § 93.313(a-k).
[158] § 93.313(k)(1)(i-vii).
[159] § 93.313(k)(2).
[160] § 93.313(k)(3).

[161] § 93.312(a).
[162] Id.
[163] § 93.312(b).
[164] § 93.313(j).
[165] § 93.314(a).
[166] § 93.314(b).
[167] §§ 93.220(a)(4) and 93.316.
[168] § 93.220.
[169] §§ 93.220(a)(1-3) and 93.220(b).
[170] § 93.220(a)(3-4).
[171] § 93.220(c).
[172] § 93.220(5).
[173] § 93.315(b).
[174] § 93.316.
[175] § 93.305(e).
[176] Id.
[177] Id.
[178] Id.
[179] § 93.305(d).
[180] Id.
[181] § 93.317(a).
[182] § 93.317(b).
[183] §§ 93.103 and 93.317(b).
[184] § 93.317(b).
[185] § 93.305(g)(1-6).
[186] § 93[i].318.