

Name of Policy: <u>Integrity in Research and Procedures for Investigating Allegations of Research Misconduct</u>		 Effective date: October 20, 2021 Original effective date: December 14, 2009	
Policy Number: 3364-70-21			
Approving Officer: President			
Responsible Agent: Vice President for Research			
Scope: All University of Toledo Campuses			
<input type="checkbox"/>	New policy proposal	<input type="checkbox"/>	Minor/technical revision of existing policy
<input checked="" type="checkbox"/>	Major revision of existing policy	<input type="checkbox"/>	Reaffirmation of existing Policy

(A) Policy Statement

Public confidence in the research and scholarship conducted at the University of Toledo is critical to our mission as a national, public research university. Ensuring the integrity of the research and scholarship conducted at the University of Toledo is everyone’s responsibility. This Policy states the minimum requirements for integrity in research and scholarship conducted at the University of Toledo and the procedures to address allegations of research misconduct.¹

(B) Purpose

The purposes of this Policy are to:

- (1) provide a statement on integrity in research and scholarship.
- (2) encourage the ethical conduct of research and scholarship.
- (3) describe the responsibilities of research personnel, administrators, and others, including students, in the University community.
- (4) establish timely and fair procedures and the responsible parties and offices at the University for handling allegations of misconduct in research or scholarship consistent with federal regulations, sponsor requirements, and best practices.

(C) Scope

This Policy applies to all research and scholarship conducted within the University community or

¹ This Policy is generally based on Public Health Service (PHS) Policies on Research Misconduct (42 CFR Part 93) and NSF’s Research Misconduct regulation (45 CFR Part 689). Language from the regulations or policies have been incorporated, quoted, or modified without indication in the text. Citations have been largely removed from the final policy.

attributed to the University. This Policy applies to all institutional members involved in research and scholarship, including faculty or staff on sabbatical, administrative, or other leaves, including leave without pay, and individuals no longer employed by the University for research or scholarly activities at the University.

This Policy applies to students only when acting in their employment or research service capacity, if they are involved in federally funded or other sponsored research or scholarship or engaged in research or collaborating in research with a faculty or staff member with a goal of a publication, conference, poster, or paper presentation, grant application, grant, prize, or award. It does not apply to internal normal classroom, for-credit, or degree related academic research or scholarship activity that will not be disseminated outside of the University. The research integrity officer and the student's dean, department or program chair, or another person identified by the college dean will resolve disputes regarding this Policy's application to students.

This Policy does not apply to authorship or collaboration disputes unless defined in section D of this Policy or required by the applicable sponsoring agency policies or other University agreements or to allegations of research misconduct relating to instructional or course materials limited to dissemination to University students.

When implementing this Policy, the procedural and substantive requirements of any applicable federal, state, or private funding agency (sponsor) or any other University agreement governing the research involved in the allegation of research misconduct will govern in addition to this Policy. If these other policies are inconsistent with this Policy, the sponsor policy will govern with respect to the inconsistency.

(D) Definitions

- (1) **Admission of Misconduct:** In an admission of research misconduct, the Respondent admits in a signed writing or authenticated record specific conduct that constitutes the allegation(s) of research misconduct in accordance with the definitions in this policy and complies with any applicable requirements of any relevant sponsor or funding agency.
- (2) **Allegation:** The allegation is the initial claim or assertion that an individual may have participated in research misconduct. An allegation may be through any means of communication. If a university official receives an allegation orally, that official must document the name of the person providing the information (if known), a means to communicate with this person (if available), the name of the Respondent, a description of the alleged misconduct, any relevant facts, names of any known witnesses, any known grant information such as title, grant number and source, take possession of any proffered tangible materials, and immediately transmit them to the research integrity officer (RIO). This record constitutes the allegation for purposes of this Policy. However, the University official transmitting the allegation to the RIO is not the complainant under this Policy.
- (3) **Allegation Assessment:** A preliminary determination of whether an allegation is within the scope of this Policy and is sufficiently credible and specific so that an inquiry committee could identify potential evidence of research misconduct.

- (4) Conflict of Interest: A conflict of interest may arise when an individual responsible for carrying out a research misconduct proceeding has an unresolved personal, professional, or financial factor that could compromise their judgment, decisions, or actions regarding the allegation of research misconduct.
- (5) Committee: The word committee may mean either the Inquiry Panel, Investigation Committee, or both, depending on the context.
- (6) Complainant: The Complainant is the person making the allegation of research misconduct in good faith.
- (7) Data Dispute: A Data Dispute is a dispute of access or use of data that involves a disagreement about the ownership, access, security, or use of data among collaborators. A Data Dispute normally does not meet the definition of research misconduct.
- (8) Day: A Day is a business day when The University of Toledo is open and operational for administrative business. The first business day following the triggering event will be the first day for calculating time. If the period is seven or more days, a day is a calendar day. If the period's final day is a day when the University of Toledo is administratively closed, the period shall end the next day that the University is open for regular business unless otherwise instructed by the RIO.
- (9) Deciding Official: The Deciding Official is the University official who makes the final determinations on allegations of research misconduct and institutional action. The Deciding Official is the President or the President's designee. No individual can serve as both the Research Integrity Officer and Deciding Official regarding the same research misconduct proceeding.
- (10) Evidence: Evidence is any data or material, document, tangible item, testimony, or other information offered or obtained during a research misconduct proceeding including the research record that tends to prove or disprove the existence of an alleged fact. Each committee member shall determine the weight and credibility of any evidence before that Committee.
- (11) Extension of Time: The RIO in consultation with the Committee chair may grant an extension of time under this Policy for a good cause. When required, the RIO must obtain approval from the research sponsor prior to granting an extension. The RIO or committee chair will state in the record the reasons for the decision.
- (12) Good Faith:
 - (a) *Good faith*, as applied to a complainant or witness, means having a belief in the truth of one's allegation or testimony.
 - (b) *Good faith* as applied to a committee member means cooperating with

the research misconduct proceeding by carrying out the assigned duties impartially. A committee member does not act in good faith if the acts or omissions of the committee member are dishonest or influenced by personal, professional, or financial conflicts of interest.

- (c) Good faith requires a duty of candor to reveal, if known, potential or apparent conflicts of interest.
 - (d) Mere negligence, conflicts of credibility or differences in opinion are not enough to find bad faith.
- (13) **Honest Error or Difference of Opinion:** Honest error or difference of opinion is an affirmative defense to an allegation of research misconduct. Honest error or difference of opinion should be unintentional or reasonable under the circumstances, and the Respondent should have been acting in good faith at the time the conduct occurred.
 - (14) **Initial Allegation Assessment.** The initial allegation assessment determines whether the allegation meets the criteria for initiating an inquiry or whether the allegation is erroneous, unfounded, or made in bad faith before the RIO constitutes an Inquiry Panel.
 - (15) **Inquiry:** The inquiry is the process under this Policy that makes a preliminary evaluation (without concluding whether research misconduct has occurred) of the available evidence and information from the Respondent, the complainant, and key witnesses to determine whether the allegation is credible, has substance, and if there is sufficient credible evidence of possible research misconduct to warrant an investigation.
 - (16) **Institutional Member:** An institutional member is employed by, affiliated with, or under the University's control. Institutional members include administrative, faculty, teaching and support staff, researchers, clinicians, technicians, fellows, students, and contractors or their employees. All institutional members must cooperate with the RIO in a research misconduct proceeding. Failure to cooperate in a research misconduct proceeding may be grounds for discipline.
 - (17) **Intentionally:** Intentionally means done deliberately with the purpose or design to bring about a result. A person acts intentionally concerning research misconduct when the conscious objective is to cause that result or engage in that conduct.
 - (18) **Investigation:** The investigation under this Policy is the formal development, examination, and evaluation of a factual record to determine whether research misconduct has taken place, by whom, to assess its extent and consequences, to evaluate appropriate action, and to make a recommendation to the DO as to future actions. The Investigation will also determine whether there are additional instances of possible research misconduct that would justify expanding the scope beyond the initial allegations.

- (19) **Knowingly:** Knowingly means that a person has actual knowledge of the true information or acts with deliberate ignorance of the truth or falsity of the information or acts with reckless disregard of the truth or falsity of the information.
- (20) **Meeting:** A meeting under the Policy may be virtual or presential depending on the purpose of the meeting, the participants' needs, and University Policy. The committee chair or RIO should consult with the participants in scheduling the time, place, or manner of a meeting. If a committee intends to record or transcribe a meeting, the RIO or chair will notify the participants before starting the recording.
- (21) **Notice:** Notice is a written or electronic communication served on a person, sent by mail, e-mail, or its equivalent to the last known mailing address, facsimile number, or e-mail address of the addressee.
- (22) **Preponderance of the Evidence:** The preponderance of the evidence is proof by credible information that, compared with the information opposing it, leads to the conclusion that the fact at issue is more probably true than not.
- (23) **Recklessly:** Recklessly is the conscious disregard of a high probability that a result will occur because of a decision to act or to refuse to act when there is an obligation to act, and it is more than mere negligence or inadvertence.
- (24) **Retaliation:** Retaliation is an adverse action taken against a Complainant, witness, committee member, or other participant in a research misconduct proceeding by the University or an institutional member in response to –
 - (a) A good faith allegation of research misconduct; or
 - (b) Good faith participation in a research misconduct proceeding.

Retaliation is strictly prohibited by University Policy.

- (25) **Research and Scholarship:**
 - (a) Research is a systematic experiment, test, study, evaluation, demonstration, or survey designed to develop or contribute to generalizable knowledge (basic research) or specific knowledge (applied research) by establishing, discovering, developing, elucidating, or confirming information about matters studied. Research also includes proposals submitted to funding sources in all fields of science or academia, including science, engineering, mathematics, education, and the results generated from such proposals.
 - (b) Scholarship is the practice of advancing, preserving, and disseminating knowledge and thought through study, reflection, and engagement that extends beyond traditional instructional activities.
 - (c) This Policy uses the terms research and scholarship interchangeably.

- (26) Research Integrity Officer (RIO): The Research Integrity Officer is the University Official responsible for assessing an allegation of research misconduct, overseeing the Inquiry Panel and Investigation Committee, ensuring compliance with state or federal regulations or other policies governing research misconduct, and other such duties regarding the ethical or responsible conduct of research as may be required by law or under university policy. The President will appoint the RIO. The RIO will exercise independent judgement in the processing of a research misconduct proceeding.
- (27) Research Misconduct:
- (a) Research misconduct is fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or scholarship or reporting research or scholarship results.
- (i) Fabrication is making up data or results and recording or reporting them.
 - (ii) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
 - (iii) Plagiarism is appropriating another person's ideas, processes, results, or words without giving appropriate credit. Plagiarism includes both the theft or misappropriation of intellectual property and the substantial unattributed textual copying of another's work.
 - (1) The theft or misappropriation of intellectual property includes the unauthorized use of ideas or unique methods obtained by a privileged or confidential communication, such as a grant or manuscript review.
 - (2) Substantial unattributed textual copying of another's work means the unattributed verbatim or nearly verbatim copying of sentences and paragraphs that materially mislead the ordinary reader regarding the author's contributions.
 - (3) Plagiarism does not include the limited use of identical or nearly identical phrases which describe a commonly-used methodology or previous research unless these uses are substantially misleading to the reader or of great significance.
 - (4) Plagiarism generally does not include disputes regarding the use of intellectual property, authorship, or credit disputes growing out of collaborative research or scholarship.

- (iv) Deliberate violation of laws, regulations, or University policies governing research is research misconduct.²
 - (v) The destruction, absence of, or Respondent's failure to provide research records adequately documenting the research related to the research misconduct proceeding is evidence of research misconduct, if the Committee finds by the preponderance of the evidence that:
 - (1) the Respondent intentionally, knowingly, or recklessly had research records and destroyed them,
 - (2) had the opportunity to maintain the records but did not do so,
 - (3) maintained the records and failed to produce them upon request, or
 - (4) failed to create or maintain records reasonably related to his or her research, and that
 - (5) the Respondent's conduct regarding the research record constitutes a significant departure from accepted practices of the relevant research community.³
 - (b) Research misconduct does not include honest error or differences of opinion.
 - (c) A finding of misconduct requires a significant departure from accepted practices of the relevant research community.
 - (d) The Respondent must commit research misconduct intentionally, knowingly, or recklessly, and
 - (e) A preponderance of the evidence is necessary to support findings of research misconduct.
- (28) Research Misconduct Proceeding: A Research Misconduct Proceeding is any action related to alleged research misconduct taken under this Policy, including

² Examples include failing to comply with guidelines for the protection of human and animal subjects, the use of hazardous chemicals, biologicals, radioactive materials, data retention or data integrity policies or other sponsor requirements, including regulations or policies governing applications for funding or sponsorship of research, export-controlled research or submitting fabricated, false, or plagiarized materials in order to obtain approval for research, sponsorship, or publication. A student's failure to comply with laws, regulations, or University policies as a participant in a degree program should normally be addressed according to the other University policies or the policies of the student's college, department, or program and not under this Policy.

³ This is not an attempt to create a new form of research misconduct. This new provision is to address the issue when there is no research record on which to investigate an allegation of research misconduct and how the Investigation Committee may use the absence of a record when reaching a recommendation. Further, this provision is consistent with PHS policy. See 42 CFR § 93.106(b)(1) and § 93.516.

allegation assessment, inquiry, investigation, and any administrative or procedural requirements of the sponsor, including those taking place after the DO's decision.

- (29) **Research Record:** The research record is the record of data or results that embody the facts resulting from scientific or scholarly inquiry, including but not limited to research proposals, physical and electronic laboratory records, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, primary source materials, archival materials, or any other documents and materials provided to the RIO, the University, or funding source in the course of the research misconduct proceeding, or any data covered by UT Policy 3364-70-02.
- (30) **Respondent.** A Respondent is the person subject of a research misconduct proceeding.
- (31) **Senior Faculty:** A senior faculty member is a person who:
- (a) achieved or is recommended for tenure,
 - (b) has attained the rank of associate or full professor in a tenure track position,
 - (c) has a minimum of 5 years of professional experience in a clinical or equivalent position, including as a lecturer, with a demonstrated record of research or scholarly activities,
 - (d) holds the rank of emeritus or retired from a position that otherwise constitutes senior faculty,
 - (e) is recommended by the Research Council, or
 - (f) holds or held an equivalent rank as described in (a)-(e) at another institution.
- (32) **Sequestration:** Sequestration is the taking possession or control of records and materials, including the research record, potentially related to the research misconduct allegation. The RIO must sequester the relevant research records or other evidence to the extent reasonably possible before notifying the Respondent of the allegation. The process of sequestration must be repeated if additional Respondents are identified during the investigation or to preserve relevant materials or information. The RIO or the Office of Research and Sponsored Programs shall maintain custody of the sequestered materials. Only individuals necessary to investigate the allegation, to preserve the sequestered materials, or the Respondent, Respondent's advisor, or collective bargaining representative will have access. The RIO may impose reasonable access restrictions to assure the security and integrity of the records. The RIO will attempt to minimize the impact of sequestration on the Respondent or other researchers by taking reasonable steps to make the originals or copies of sequestered materials or equipment available to the Respondent or other researchers.

(E) Responsibility

- (1) All institutional members who have good faith knowledge of possible research misconduct are obligated to report it along with the basis for the allegation to the Research Integrity Officer or other officials at The University of Toledo (who will then report the information to the Research Integrity Officer). The Institutional Member shall not inform the proposed respondent or another individual of the proposed allegation of research misconduct.
- (2) Institutional members who learn of possible research misconduct in a context where there is a good-faith argument that their knowledge may be subject to a legal or ethical obligation of confidentiality should seek professional advice before determining whether there is an obligation to report research misconduct under this Policy.
- (3) Institutional Members must maintain the confidentiality of the Respondent, Complainant, and other individuals participating in the investigation. Information regarding a research misconduct proceeding should only be shared with individuals having a need to access the information or protect the participant's reputation including individuals participating in the proceeding and compliance with funding research sponsor requirements.
- (4) Supervisors of institutional members will cooperate with the RIO by assisting institutional members to cooperate in a research misconduct proceeding. This cooperation in the handling of an allegation of research misconduct is essential to the University and the research community.
- (5) The Office of Research and Sponsored Programs shall provide appropriate expertise and reasonable administrative support to the RIO, the Inquiry Panel and the Investigation Committee. The Office of Research and Sponsored Programs will charge additional expenses incurred due to the inquiry or investigation to the college, department, or program of the Respondent's primary appointment.

(F) Procedures for reporting and investigating allegations of research misconduct

- (1) Reporting allegation, inquiry, and investigation.
 - (a) General Comments
 - (i) All assessments, inquiries and investigations will be reviewed and generally will be carried through to completion, and all significant issues will be pursued diligently.
 - (ii) The RIO may close an allegation of research misconduct with the approval of the DO at the inquiry or investigation stage on the basis that the Respondent has submitted in an Admission of Misconduct, if the applicable federal agency or sponsoring organization's requirements regarding early termination of the

research misconduct proceeding are met, or the process described in section F(2)(g) is followed.

- (iii) The University may impose a temporary suspension of duties, pending the conclusion of the assessment, inquiry, or investigation, or take other appropriate action as necessary, including actions intended to protect human or animal subjects, federal funds, sponsor resources, university property, university personnel or to preserve the integrity of the research misconduct proceeding.
- (iv) The University will make reasonable efforts to limit the identity of the Respondent (s), complainant (s), witness(es), or other participants to those who need to know. The University, however, cannot guarantee anonymity or complete confidentiality due to public records law and the need to complete an appropriate investigation. The University may disclose the identity of individuals who report or provide evidence to the Respondent or others, if necessary. Reporting potential academic misconduct or illegal activity to the sponsor, journal, governmental agency, professional association, or another entity having apparent authority to investigate or address the alleged misconduct is not an abuse of confidentiality.
- (v) The University strives for an expeditious and thorough investigation and to provide the Respondent with an opportunity to comment on all allegations during the inquiry and, if initiated, during the investigation.
- (vi) The disclosure and evaluation of any prejudicial conflict(s) of interest are essential to the integrity of a research misconduct proceeding. All individuals who are aware of a potential conflict of interest should disclose it to the RIO. Individuals judged by the RIO or the DO to have a conflict of interest that would jeopardize the credibility of the inquiry or investigation will not be assigned to an Inquiry Panel or Investigation Committee nor have decision-making roles in the process.
- (vii) It is a violation of University Policy to retaliate against an individual for reporting in good faith an allegation of research misconduct, cooperating, or participating in the assessment, inquiry, or investigation of an allegation of research misconduct.
- (viii) The University will make a good faith effort to notify the Respondent (or their advisor) of the steps taken in the process. The Respondent's official university e-mail address is presumptively an appropriate method of communicating with the Respondent or, at the discretion of the RIO, the Respondent's last known mailing address on file with the University. If the

Respondent has not provided current contact information to the University, does not respond to notices, or refuses to cooperate, the research misconduct proceeding will continue. The RIO, Inquiry Panel, or Investigation Committee will document how the Respondent's absence impeded the process. If the Respondent has identified to the RIO an advisor or collective bargaining representative, the RIO, Inquiry Panel, or Investigation Committee may copy the advisor or collective bargaining representative on all communications sent to the Respondent unless otherwise instructed by the Respondent. However, it is the Respondent's duty to keep their advisor or collective bargaining representative informed.

(2) Sponsored Research

- (a) The National Science Foundation, the Public Health Service, and other federal agencies have formal regulations or policies regarding the investigation of allegations of research misconduct involving activities supported by those agencies (See appendix A). Each of these regulations contains a definition of research misconduct, prescribes certain time limits for inquiries and investigations, and requires reporting to the agencies under certain conditions and at specified stages in the process. The University will comply with these regulations or policies when applicable.
- (b) State, local, or private funding sources (sponsors) may have their own policies governing research misconduct proceedings. The University may also have memorandums of agreement, cooperation agreements, or other understandings with other institutions regarding how to process allegations of research misconduct. The RIO will determine the applicability of external regulations or agreements in each particular case. The University will comply with applicable requirements of the sponsor policies or University agreements. If an agreement, policy, or regulation other than or in addition to this Policy may apply to the allegation's investigation, the RIO will notify the Respondent and provide a copy or access to a copy of the other policy.
- (c) The Respondent must disclose all sources of funding or support for all research associated with the research misconduct proceeding.
- (d) The RIO may share information regarding an allegation of research misconduct with the research sponsor as required under the relevant research sponsor regulations or policies or as otherwise appropriate.
- (e) Allegations
 - (i) In conducting the initial assessment, the RIO may rely solely on the information contained in the allegation to determine whether to constitute an Inquiry Panel.
 - (ii) Within five days of receipt of the allegation, the RIO will initiate

the allegation's initial assessment.

- (iii) The RIO shall determine whether the allegation warrants an inquiry. Specifically, the allegation falls within the definition of research misconduct under this Policy, has substance, is sufficiently credible, contains sufficient information so that potential evidence of research misconduct may be identified, and whether to constitute an Inquiry Panel.
- (iv) If the RIO determines that the allegation warrants an Inquiry Panel, the RIO shall prepare an initial assessment referral, which explains the basis for the determination. The RIO shall transmit after sequestration a copy of the initial assessment referral to the Respondent.
- (v) If the allegation does not warrant an inquiry, the RIO shall prepare an initial assessment report that states the basis for the RIO's determination. The RIO may inform the complainant and will provide the Research Council information regarding the general nature of the allegation and the basis for the RIO's initial assessment not to proceed to an Inquiry Panel.
- (vi) The complainant does not have a right to appeal the RIO's initial assessment decision that further inquiry is not warranted but may submit additional information that addresses the RIO's concerns. Upon such a submission, the RIO may reconsider the initial assessment decision.
- (vii) If the RIO concludes that the complainant lacked good faith in making the allegation or that any participant acted in bad faith during the initial assessment, the RIO may refer the matter to other appropriate administrative channels.
- (viii) After the initial assessment, if the RIO does not dismiss the initial allegation, the RIO will form an Inquiry Panel to secure the necessary and appropriate assistance to ensure a thorough and authoritative evaluation of the allegation.
- (ix) The RIO will seek guidance from members of the University Research Council to select the Inquiry Panel members. The Inquiry Panel will consist of at least three senior faculty members, including at least one member of the University Research Council or a Research Council designee, with the additional assistance, if needed, of an expert in the academic discipline involved.
- (x) Upon constituting an Inquiry Panel, the RIO will prepare a written charge for the Inquiry Panel that:
 - (1) informs the Inquiry Panel of its duty of confidentiality.

- (2) describes the allegations and any related issues identified during the initial allegation assessment.
 - (3) states the standards, policy, and procedures that the Inquiry Committee must follow; and
 - (4) provide any other information that RIO deems appropriate.
- (xi) The RIO will notify the DO, Senior Vice-President for Research, and the Respondent's dean or equivalent that the RIO has initiated an inquiry, will oversee the inquiry, and will provide them updates when appropriate.
- (xii) Before notifying the Respondent, the RIO must take all reasonable steps to sequester all the relevant research records and evidence needed to conduct the research misconduct proceeding.
- (xiii) The RIO will make a reasonable effort to notify the Respondent that an inquiry has begun, to provide the Respondent with a statement of the allegation, and the Respondent's rights under this Policy, and an electronic copy of this Policy (or the applicable policy based on the relevant time period). If funding status is known and if applicable, the RIO will provide an electronic copy of the PHS, NSF, or other policy related to research misconduct.
- (xiv) In the case of the inquiry into an allegation of research misconduct where the University is cooperating or collaborating with another institution, the RIO may appoint one or more members of the other institution as Inquiry Panel members or observers. The RIO, when constituting an Inquiry Panel, shall state the scope of the involvement of the other institution's representative(s).
- (xv) The RIO will inform the Respondent of the proposed Inquiry Panel members' names, including the names of any observers. The Respondent has five days to object in writing to the RIO to an Inquiry Panel member based on a conflict of interest. The Respondent must explain the conflict of interest in sufficient and specific detail to allow the RIO to decide the Inquiry Panel member's service on the Inquiry Panel.
- (xvi) Within three days of notice of the inquiry, the Respondent may submit a written response to the allegations. The Respondent is not required to submit this response.
- (xvii) The Respondent may have an advisor or collective bargaining representative present during Respondent's meetings with the Inquiry Panel.

- (1) The RIO must be notified at least 24 hours before the meeting or hearing that an advisor or collective bargaining representative will attend and whether the advisor or collective bargaining representative is an attorney. If the advisor or collective bargaining representative is an attorney, the RIO will notify the Office of Legal Affairs.
 - (2) A Respondent must cooperate by providing evidence, regardless of whether on or in personal property or university property and the Respondent's account of the matter under review during interview(s).
 - (3) An advisor or collective bargaining representative of a Respondent may not interfere with the Inquiry Panel's objectives or the Inquiry Panel's interview of the Respondent or disrupt the process in a manner that prevents an effective interview. Advisors or collective bargaining representatives are not permitted to answer questions on behalf of the Respondent.
 - (4) An advisor or collective bargaining representative should be available on the scheduled dates and times. Meetings will not be rescheduled more than once due to the unavailability of the Respondent, advisor, or collective bargaining representative.
 - (5) During the interview, the Respondent, their advisor, or collective bargaining representative are not permitted to record or photograph the Respondent's interview with the Inquiry Panel. The decision to record the interview is at the discretion of the Inquiry Panel.
- (xviii) The Inquiry Panel, in consultation with the RIO, shall direct its proceedings. The Inquiry Panel may interview or request written statements from any individual with relevant knowledge. The Inquiry Panel may, at its discretion, record or transcribe interviews. The Inquiry Panel may select its chair, or the RIO may appoint a chair.
- (xix) The purpose of an inquiry is to conduct the initial review of the evidence to determine whether to investigate. Therefore, an inquiry does not require a full review of all the evidence related to the allegation. However, the Inquiry Panel, should, if possible, interview the Respondent and Complainant or state in its report why it chose not to do so.
- (xx) If the Inquiry Panel identifies other acts by the Respondent that may constitute research misconduct, the Inquiry Panel will add

new allegations of misconduct in the draft Inquiry Panel report.

- (xxi) New allegations by the Inquiry Panel against someone other than the Respondent will require that the RIO notify the new Respondent of the allegations and provide the new Respondent with an opportunity to object to the current Inquiry Panel members based on a conflict of interest. The new Respondent must explain the conflict of interest in sufficient and specific detail to allow the RIO to decide the Inquiry Panel member's service on the Inquiry Panel.⁴
 - (xxii) The RIO has the discretion to permit the current Inquiry Panel to proceed in evaluating the allegation against the new Respondent or to constitute a new Inquiry Panel, in whole or in part, on the grounds of a conflict of interest of a member of the existing Inquiry Panel.
 - (xxiii) The Inquiry Panel should submit its report within 60 days from the date that the Inquiry Panel is charged. If the inquiry exceeds that timeframe, in consultation with the RIO, the Inquiry Panel's draft report will state the reason for the delay.
 - (xxiv) If the Respondent, Complainant, or a witness refuses to participate in the research misconduct proceeding, the Inquiry Panel will use their best efforts to conclude and state the individual's failure to cooperate and its effect on the proceeding in its report.
- (f) Reporting on the inquiry
- (i) The Inquiry Panel will prepare a written report that includes:
 - (1) the name and position of the Respondent, the names and titles of the Inquiry Panel members, a statement of the allegation,
 - (2) a description of the preliminary evidence reviewed, summaries of the relevant preliminary interviews, and preliminary fact finding,
 - (3) the conclusions of the inquiry including the basis for recommending or not recommending that the allegations warrant an investigation,
 - (4) if the allegation falls within the definition of research

⁴ This is a significant change to deal with new Respondents. The model example would be PI claims that the misconduct was the fault of Post-Doc. Rather than having two simultaneous parallel research misconduct proceedings inquiring into the same allegation and factual events; this change permits the same Inquiry Panel to consider all possible Respondents, unless there is a conflict of interest.

misconduct under the relevant Policy, has substance, and is sufficiently credible and specific so that potential evidence of research misconduct may be identified,

- (5) whether or not an investigation is warranted based on the criteria in this policy and any applicable sponsor policy.
 - (ii) If the Inquiry Panel concludes that the allegation warrants an investigation, the Respondent will have ten days to comment on the draft report. The complainant also may review and comment on that portion of the report directly related to the testimony or other evidence provided by the complainant. Any comments that the Complainant or Respondent submit will be attached as part of the final Inquiry Panel report.
 - (iii) If the inquiry panel determines that an investigation is warranted, the RIO will initiate a formal investigation.
 - (iv) The RIO shall decide in consultation with the Vice-President of Research when to notify external funding sponsors and the content of the notification and will determine if any additional notification(s) are necessary. Reasonable efforts will continue to protect the identity of the Respondent and the Complainant.
 - (v) If the Inquiry Panel concludes that the allegation does not warrant an investigation, the RIO must inform any person involved in the inquiry to whom the Respondent's identity was disclosed or take other reasonable steps to mitigate the damage to the Respondent's reputation.
 - (vi) The chair of the Inquiry Panel will send to the RIO a copy of the draft and final version of the report. The RIO will notify the DO, Vice-President for Research, the Respondent's dean, and any other appropriate University official. A copy of the final Inquiry Panel report will be submitted to the Respondent.
 - (vii) The Office of Research and Sponsored Programs Office shall maintain records of the inquiry for at least seven years after the inquiry's termination whether or not an investigation was warranted.
 - (viii) The RIO will forward an allegation of potential misconduct that does not fall within the definition of research misconduct under this Policy, allegations of bad faith, or failure to cooperate in an alleged misconduct proceeding through other administrative channels as appropriate.
- (g) Investigation

- (i) The formal investigation into an allegation of research misconduct is the responsibility of the Investigation Committee. The Investigation Committee is responsible for developing the factual record, weighing the evidence, making credibility and factual findings, and submitting a report with its findings and recommendations to the RIO and DO.
- (ii) Upon determining that an allegation warrants an investigation, the RIO shall seek the Research Council's advice regarding the Investigation Committee's composition. The RIO may appoint an Investigation Committee of up to five senior faculty members.
 - (1) The Investigation Committee will include at least one member of the University Research Council or its designee. The Investigation Committee may select its chair, or the RIO may appoint a chair.
 - (2) The Investigation Committee may include one or more experts from outside the University, if necessary, to provide subject matter expertise relating to the allegation of research misconduct or to assure an Investigation Committee without conflicts of interest. Proposed Investigation Committee members who are not University of Toledo senior faculty should hold or have held a similar senior rank at their institution.
 - (3) In the case of the investigation into an allegation of research misconduct where the University is cooperating or collaborating with another institution, the RIO may appoint one or more members of the other institution as Investigation Committee members or observers. However, the majority of voting members must be University of Toledo senior faculty. The RIO shall state in the appointment letter the scope of authority of the other institution's representative. The Respondent must be informed as to the nature and extent of the collaboration with the other institution regarding the investigation into the allegation of research misconduct.
 - (4) The Respondent may object to a non-University of Toledo member's service as an Investigation Committee member on the same basis as an objection to a University of Toledo Investigation Committee member.
 - (5) The RIO will inform the Respondent of the names of the proposed Investigation Committee members. The Respondent has five days to object in writing to a committee member based on conflict of interest. The

Respondent must explain the conflict of interest in sufficient detail to allow the RIO to decide about the committee member.

- (6) The RIO may excuse Investigation Committee members at any time because of a conflict of interest or for other good cause. The RIO may then notify the Respondent of a proposed replacement, and the Respondent will have five days to object to the proposed replacement on the grounds of a conflict of interest. Once appointed, the replacement must review the recordings, transcripts, and other evidence at the earliest opportunity. Alternatively, the Investigation Committee may continue without a replacement, so long as the Investigation Committee otherwise meets the requirements of this Policy or the sponsor's policy.
- (iii) The RIO will inform the Respondent in writing of the investigation's initiation, the Investigation Committee's composition, the allegations before the Investigation Committee, the Respondent's obligation to cooperate in the investigation, and the University's retaliation policy.
- (iv) The RIO must charge the Investigation Committee within 30 days after the determination by the RIO that an investigation is warranted. The RIO shall endeavor to charge the Investigation Committee at the earliest opportunity.
- (v) The RIO will initiate and oversee the investigation process and inform the DO, Vice-President for Research, and appropriate dean or equivalent.
- (vi) The Investigation Committee will gather and evaluate evidence and reach a determination within 120 days of its charge as to whether research misconduct has occurred. If so, to what extent and by whom. If the investigation exceeds 120 days, the Investigation Committee, in consultation with the RIO may extend the deadline, explaining the delay in its report. When required by the research sponsor's regulations or policies, the RIO will seek an extension of the from the research sponsor prior to granting an extension.
- (vii) The Investigation Committee will pursue all significant issues and relevant leads diligently, including any evidence of any additional instances of possible research misconduct, and continue the investigation to completion. During the investigation, the Investigation Committee may also determine other potential cases of research misconduct that would justify broadening the scope beyond the initial allegations or to additional respondents. The Investigation Committee will notify the RIO, if there are possible

new allegations.

- (viii) The Investigation Committee may review and inspect the research record, including laboratory notes, grant and contract files, reports, scholarly publications, manuscripts, and other pertinent documents and electronic materials or communications and laboratory or clinical facilities and materials.
- (ix) The Investigation Committee must seek to collect information from and, if possible, interview each Respondent, Complainant, and any other reasonably identified available person who has information regarding any relevant aspect of the investigation, including witnesses identified by the Respondent. The Investigation Committee may request that the Respondent submit a statement as to the evidentiary value of the proposed witness.
- (x) The Investigation Committee must record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the investigation record. The interviewee will have seven days to review the recording or transcript and notify the Investigation Committee in writing about any matter that requires correction or clarification.
- (xi) The Respondent may have an advisor or a collective bargaining representative present during meetings with the Investigation Committee.
- (xii) The RIO must be notified at least 24 hours before the meeting or hearing that an advisor or collective bargaining representative will attend and whether the advisor or collective bargaining representative is an attorney. If the advisor or collective bargaining representative is an attorney, the RIO will notify the University General Counsel's Office.
- (xiii) An advisor or collective bargaining representative may be present during meetings and hearings in which the Respondent is present. Respondents must cooperate by providing the Respondent's account of the matter under review during the interview. An advisor or collective bargaining representative of a Respondent may not interfere with the Committee's objectives or the Committee's interview of the Respondent or disrupt the process in a manner that prevents an effective interview. An advisor or collective bargaining unit representative is not permitted to answer questions on behalf of the Respondent.
- (xiv) An advisor or collective bargaining representative should be to be available on the scheduled dates and times. The Investigation Committee will not reschedule meetings or hearings more than once

due to the unavailability of any party's advisor or collective bargaining representative.

- (xv) The Respondent, advisor or collective bargaining representative are not permitted to record, photograph, or audio record meetings or proceedings.
 - (xvi) The Investigation Committee may discover information leading to a new allegation against someone who is not the Respondent. A new allegation against someone other than the Respondent will require that the RIO to conduct an initial assessment and if necessary, to notify the new potential Respondent of the allegation and provide the new Respondent with an opportunity to object to the members of the current Investigation Committee within five days on the grounds of a conflict of interest or request that the allegation be referred to an Inquiry Panel. The RIO has the discretion to add a new charge to the Investigation Committee then permit the current Investigation Committee to proceed to investigate the allegation against the new Respondent or refer the new allegation to an Inquiry Panel or a new Investigation Committee. The Investigation Committee will prepare a separate report for each respondent.
- (h) A finding of misconduct requires that a preponderance of the evidence establishes that:
- (i) Research misconduct, as defined in this Policy, occurred; and
 - (ii) The research misconduct is a significant departure from accepted practices of the relevant research community; and
 - (iii) The Respondent committed the research misconduct intentionally, knowingly, or recklessly.
 - (iv) The Respondent has the burden of proving by a preponderance of the evidence any affirmative defenses raised, including honest error or a difference of opinion. The Respondent has the burden of proving by the preponderance of the evidence that the alleged conduct that constituted misconduct was in good faith, inadvertent, accidental, or that the alleged misconduct was not a significant deviation from the research norms of the relevant area or discipline of research. Because the relevant area of research of the allegation is not necessarily the same as the discipline of the Respondent's primary appointment, the Investigation Committee shall determine the relevant area of research.
 - (v) The Investigation Committee will prepare a written report on the investigation's formal findings and its recommendations regarding the outcome. The report will include:

- (1) name(s) and title(s) of the Respondent and the nature of the allegation (s) of research misconduct.
- (2) names and titles of the members of the Committee along with their most recent CVs.
- (3) specific allegations of research misconduct investigated.
- (4) identity of all witnesses.
- (5) a statement of findings for each allegation of research misconduct, including:
 - (a) a statement on whether the research misconduct was falsification, fabrication, plagiarism, or deliberate violation of regulations.
 - (b) whether it was committed intentionally, knowingly, or recklessly.
 - (c) whether it was a significant departure from accepted practices of the relevant research community if appropriate; the Investigation Committee will identify the relevant research community and state why these acts are a significant departure from the accepted ethical or professional norms of that community; and
 - (d) a summary of the facts and an analysis which support the factual conclusion of the Investigation considering the merits of any reasonable explanation by the Respondent.
- (6) identification and summary of the research records and evidence reviewed, as well as any evidence taken into custody but not reviewed.
- (7) a summary of the facts and analysis supporting the report's overall conclusions.
- (8) if applicable, identification of any funding agency support, the name of the agency, and documentation sufficient to document the support, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing the agency providing support that are related to the allegation of research misconduct.
- (9) a copy of the University or other Policy under which the

investigation was conducted.

- (10) identification of publications that need correction or retraction, and
- (11) list any current external support or applications for funding that the Respondent had or has pending.
- (12) The DO and the Investigation Committee may consider aggravating and mitigating factors in determining appropriate administrative actions and their terms. The DO and the Investigation Committee may consider other factors as appropriate in each case.
- (13) Administrative actions by the DO (including sanctions, if any), recommended by the Investigation Committee are committed to the DO's sound discretion. However, an Investigation Committee finding that misconduct has occurred should also include recommended disposition by the DO. The Investigation Committee's recommendation may include:
 - (a) limitations on future research, grant applications or grants,
 - (b) limitations on supervising or employing research personnel or students,
 - (c) informal oral or formal written reprimands, suspension, demotion, or termination of employment,
 - (d) remedial actions appropriate for the resolution of the matter, such as correction of the public research record, including publications, conference presentations, grants or grant applications or
 - (e) an explanation why sanctions are inappropriate (e.g., de minimis research misconduct or sufficient other remedial actions have already been taken or will be taken).
- (14) In making its recommendation regarding the resolution, the Investigation Committee may consider:
 - (a) Whether the misconduct was an isolated event or part of a pattern of misconduct,

- (b) Whether it had a significant impact on the research record, human or animal research subjects, other researchers, institutions, or the public welfare,
 - (c) Whether the Respondent accepted or refused to accept responsibility,
 - (d) Whether the Respondent retaliated or threatened retaliation against other individuals involved in any manner with the actions underlying the alleged misconduct or the research misconduct proceeding,
 - (e) Whether the Respondent is or could be ready to participate in future research as a responsible member of the research community,
 - (f) Whether measures or conditions, such as continuing to research under the supervision of another faculty member or mentor could be taken to restore the Respondent to the status of a responsible member of the research community, and
 - (g) Any other relevant factors in mitigation or aggravation that, in the Investigation Committee's opinion would result in a just and fair resolution of the allegation of research misconduct.
- (15) If available, the Investigation Committee may consider the full extent of the damages to the Complainant or research community, if any.
- (16) The Respondent may, without conceding a finding of research misconduct submit evidence or arguments in mitigation of the proposed recommendation as part of the response to the draft Investigation Committee report.
- (17) The Investigating Committee may look to federal or state regulations, e.g., 42 CFR 93.408, 48 CFR 1252.355-70(f), or published determinations of research misconduct cases, e.g., <https://www.nsf.gov/oig/case-closeout/>, https://ori.hhs.gov/content/case_summary, or sources involving analogous conduct for guidance in making its recommendation.
- (18) If requested by the Investigation Committee, the RIO may, consistent with confidentiality obligations, inform the Investigation Committee of the past recommendations at the University under similar circumstances.

- (vi) The Investigation Committee will send a summary of the Investigation Committee report focusing on the information or materials provided by the Complainant to the Complainant.
- (vii) The Respondent will be provided a complete copy of the draft report as well as reasonable access to any unprivileged documents or materials that comprise the record in the research misconduct investigation.
- (viii) The Respondent and Complainant have 30 days to comment on the report, and such comments will become part of the record.
- (ix) The Investigation Committee will consider the written response of the Complainant and Respondent to the draft report, and make such changes, if any, as it finds necessary to the draft report. The Investigation Committee will then vote to recommend the final report to be submitted to the RIO.
- (x) The Investigation Committee will submit its draft and final report and comments, if any received from the Respondent or Complainant to the RIO. The RIO will transmit the final Investigation Committee report and an independent recommendation to the DO with a copy to the Vice President for Research and the Respondent. Within 14 days after receiving the final report, the DO, after consultation with the RIO and Investigation Committee, will decide whether to accept the finding of misconduct and the Investigation Committee's recommendation as to possible administrative action. The DO will notify the RIO if additional time is needed, and the RIO, if appropriate, will contact the research sponsor to request an extension of time. A copy of the final report will be provided to the Respondent.
- (xi) If the DO disagrees with the findings or recommendation of the Investigation Committee,
 - (1) the DO will explain in detail the basis for rejecting the findings or recommendation of the Investigation Committee or
 - (2) the DO may refer the report back to the Investigation Committee with specific instructions for further fact-finding, a more detailed analysis, or to reconsider its recommendations. If necessary, the RIO will contact the funding agency to request an extension of time to permit the Investigation Committee to respond to the DO.
 - (3) the DO will notify the Respondent, the Vice-President for Research, the RIO, the appropriate dean and any other applicable University official of the final decision, and the research sponsor, if appropriate.

- (4) In consultation with the Vice-President for Research and appropriate University official(s), the RIO will then decide whether to notify publishers co-authors, professional associations, licensing agencies, etc. and what information to include in the notification.
- (xii) The Office of Research and Sponsored Programs shall maintain the Investigation Committee's records for at least seven years after completion of the research misconduct proceedings.
- (xiii) The University will undertake efforts, as appropriate and feasible, to restore the reputations of persons alleged to have engaged in misconduct when the DO does not confirm the allegations and undertake measures to protect the positions and reputations of those persons who, in good faith, made allegations or participated in the research misconduct proceeding.
- (xiv) The Respondent may appeal the DO's decision to impose disciplinary actions by following the applicable grievance policy.
- (xv) The Investigation Committee may recommend that unsupported allegations of research misconduct not brought in good faith or failure to cooperate in a research misconduct proceeding be referred to the appropriate university body.
- (i) A finding of research misconduct based on the Admission of Misconduct by the Respondent may be made by the Inquiry Panel or the Investigation Committee in consultation with the RIO and confirmed by the DO when the requirements of this section have meet met:
 - (i) The Respondent has been notified of the allegations of research misconduct.
 - (ii) The Inquiry Panel or Investigation Committee finds by the preponderance of the evidence that the Respondent has:
 - (1) Responded to the allegations and findings; or waived the opportunity;
 - (2) The admission of research misconduct is written, recorded, or transcribed;
 - (3) The admission accepting responsibility must, in the Respondent's own words, contain explicit language that includes the definition of research misconduct such as "I

knowingly intentionally, or recklessly falsified or fabricated results” or “I admit to research misconduct;”

- (4) The admission does not include language of mistake, inadvertence, excuse, justification, or innocent error. However, the Respondent may after the Inquiry Panel or Investigation Committee accepts the Admission of Responsibility then offer a statement or other relevant evidence as an explanation or in mitigation;
 - (5) The admission describes the alleged factual conduct that constitutes research misconduct under this Policy or the funding agency’s policy;
 - (6) There is sufficient independent evidence that supports the admission and for a finding of research misconduct;⁵ and
 - (7) The admission is voluntary, knowing, and complete.
- (iii) The Respondent may not be given any incentive to accept responsibility.
 - (iv) The Respondent’s offer to admit research misconduct before the creation of an Investigation Committee constitutes the Respondent’s consent for the Inquiry Panel to function as an Investigation Committee, and the Inquiry Panel shall submit an Investigation Committee report to the RIO and DO, if the Inquiry Panel accepts the Respondent’s offer to accept responsibility.
 - (v) The RIO should immediately notify the research sponsor, if appropriate, if there is a possibility that the investigation into the allegation of research misconduct will terminate by the Respondent accepting responsibility and ensure that the inquiry panel or investigation committee complies with all of the research sponsor’s policies or regulations governing the acceptance of responsibility in cases involving allegations of research misconduct .
 - (vi) The Inquiry Panel or Investigation Committee must satisfy itself that it has completed a thorough independent investigation and there is no additional credible evidence of other research misconduct by the Respondent. Further, the Inquiry Panel or Investigation Committee must refer any possible allegations or evidence of research misconduct by others to the RIO along with a recommendation whether the possible allegation or evidence

⁵ See section F(2)(f)(i)-(iv).

warrant an inquiry or investigation.

- (vii) The Inquiry Panel or Investigation Committee must explicitly determine the sources of research funding and make an explicit determination whether there was sponsor funding involved before recommending that the DO accept the proffered acceptance of responsibility.
- (viii) Terminating a research misconduct proceeding based on an Admission of Research Misconduct must also comply with the regulations or policies of the research sponsor
- (ix) The RIO should, before the Inquiry Panel or Investigation Committee accepts Respondent's Admission of Research Misconduct, inform the Respondent to take time to seek independent advice as to the University and non-University effects of accepting responsibility for research misconduct. (

(G) Times limits on Commencing Research Misconduct Proceedings under this Policy

- (1) Six-year Limitation: This Policy applies only to research misconduct occurring within six years of the date that the University receives an allegation of research misconduct. If the date of receipt is unclear, the six-year statute of limitation is calculated from the date the RIO is notified of the allegation.
- (2) Exceptions to the Six-Year Limitation: Paragraph (a) of this section does not apply in the following instances:
 - (a) Subsequent Use Exception: The Respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, republication, or other use for the potential benefit of the Respondent of the research record that is alleged to have been fabricated, falsified, or plagiarized.
 - (b) Health or safety of the public exception. If the RIO, following consultation with the sponsor or university officials responsible for the health and safety of the public or animal subjects, determines that the alleged misconduct, if it occurred, would possibly have a continued substantial adverse effect on the health or safety of the public or animal subjects, the statute of limitations may be waived.
 - (c) "Grandfather" exception. If University received the allegation of research misconduct before the effective date of this Policy.
 - (d) Plagiarism limitation. In the case of an allegation of research misconduct by plagiarism, if the alleged materials that were plagiarized still exist, the Inquiry Panel and Investigation Committees will determine as part of their reports whether the statute of limitations should be waived or in their discretion decline to consider the allegation as time-barred.

(H) This Policy is effective as of the date signed by the President of the University. In the case of an on-going or pending research misconduct proceeding, this revised Policy shall apply to the next procedural step. In the case of alleged research conduct that could have taken place under more than one Research Misconduct Policy, the RIO will determine which Policy will govern the research misconduct proceeding and notify the Respondent(s) and provide an electronic copy of the applicable policy.

<p>Approved by:</p> <p><u>/s/</u> Gregory C. Postel, M.D. President</p> <p><u>October 20, 2021</u> Date</p> <p><i>Review/Revision Completed by: Senior Leadership Team, Vice President of Research, and the Research Council</i></p>	<p>Policies Superseded by This Policy:</p> <ul style="list-style-type: none"> • <i>III-2-2 Art. II Compliance with External and Internal Policies, Section 6 Misconduct in Research</i> • <i>02-003 Academic and Scientific Misconduct</i> <p>Initial effective date: December 14, 2009</p> <p>Review/Revision Date: October 9, 2017, August 2018, June 3, 2021</p> <p>Next review date: October 20, 2024</p>
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Appendix A

Research Integrity Officer Responsibilities¹

I. General

The Research Integrity Officer (RIO) has lead responsibility for ensuring that the institution:

- Takes all reasonable and practical steps to foster a research environment that promotes the responsible conduct of research, research training, and activities related to that research or research training, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct.
- Has written policies and procedures for responding to allegations of research misconduct and reporting information about that response to ORI, as required by 42 CFR Part 93.
- Complies with its written policies and procedures and the requirements of 42 CFR Part 93.
- Informs its institutional members who are subject to 42 CFR Part 93 about its research misconduct policies and procedures and its commitment to compliance with those policies and procedures.
- Takes appropriate interim action during a research misconduct proceeding to protect public health, federal funds and equipment, and the integrity of the PHS supported research process.

II. Notice and Reporting to ORI and Cooperation with ORI

The RIO has lead responsibility for ensuring that the institution:

- Files an annual report with ORI containing the information prescribed by ORI.
- Sends to ORI with the annual report such other aggregated information as ORI may prescribe on the institution's research misconduct proceedings and the institution's compliance with 42 CFR Part 93.
- Notifies ORI immediately if, at any time during the research misconduct proceeding, it has reason to believe that health or safety of the public is at risk, HHS resources or interests are threatened, research activities should be suspended, there is reasonable indication of possible violations of civil or criminal law, federal action is required to protect the interests of those involved in the research misconduct proceeding, the

¹ This is a general outline of the duties of the RIO in research misconduct cases with specific references to the obligations and timelines under Public Health Service (PHS) Policies on Research Misconduct – 42 CFR Part 93 – June 2005. The RIO will interpret and implement these responsibilities consistent with the policies or regulations of the sponsoring agency and University of Toledo policies and other applicable agreements.

institution believes that the research misconduct proceeding may be made public prematurely, or the research community or the public should be informed.

- Provides ORI with the written finding by the responsible institutional official that an investigation is warranted and a copy of the inquiry report, within 30 days of the date on which the finding is made.
- Notifies ORI of the decision to begin an investigation on or before the date the investigation begins.
- Within 120 days of beginning an investigation, or such additional days as may be granted by ORI provides ORI with the investigation report, a statement from the DO whether the institution accepts the investigation's findings, a statement of whether the institution found research misconduct and, if so, who committed it, and a description of any pending or completed administrative actions against the respondent.
- Seeks advance ORI approval if the institution plans to close a case at the inquiry, investigation, or appeal stage on the basis that the respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except the closing of a case at the inquiry stage on the basis that an investigation is not warranted or a finding of no misconduct at the investigation stage.
- Cooperates fully with ORI during its oversight review and any subsequent administrative hearings or appeals, including providing all research records and evidence under the institution's control, custody, or possession and access to all persons within its authority necessary to develop a complete record of relevant evidence.

III. Research Misconduct Proceeding

A. General

The RIO is responsible for:

- Promptly taking all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner.
- Taking all reasonable and practical steps to ensure the cooperation of respondents and other institutional members with research misconduct proceedings, including, but not limited to their providing information, research records and evidence.
- Providing confidentiality to those involved in the research misconduct proceeding as required by 42 CFR § 93.108, other applicable law, and institutional policy.

- Determining whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional or financial conflict of interest and taking appropriate action, including recusal, to ensure that no person with such a conflict is involved in the research misconduct proceeding.
- Keeping the Deciding Official (DO) and others who need to know apprised of the progress of the review of the allegation of research misconduct.
- In cooperation with other institutional officials, taking all reasonable and practical steps to protect or restore the positions and reputations of good faith complainants, witnesses, and committee members and to counter potential or actual retaliation against them by respondents or other institutional members.
- Making all reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputation of persons alleged to have engaged in research misconduct, but against whom no finding of research misconduct is made.
- Maintaining records of the research misconduct proceeding, as defined in 42 CFR § 93.317, in a secure manner for 7 years after completion of the proceeding, or the completion of any ORI proceeding involving the allegation of research misconduct, whichever is later, unless custody of the records has been transferred to ORI or ORI has advised that the records no longer need to be retained.
- Taking appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards, of those actions.

B. Allegation Receipt and Assessment

The RIO is responsible for:

- Consulting confidentially with persons uncertain about whether to submit an allegation of research misconduct.
- Receiving allegations of research misconduct.
- Assessing each allegation of research misconduct to determine if an inquiry is warranted because the allegation falls within the definition of research misconduct, is within the jurisdictional criteria of 42 CFR § 93.102(b), and is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

C. Inquiry

The RIO is responsible for:

- Initiating the inquiry process if it is determined that an inquiry is warranted.

- At the time of, or before beginning the inquiry, making a good faith effort to notify the respondent in writing, if the respondent is known.
- On or before the date on which the respondent is notified, or the inquiry begins, whichever is earlier, taking all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding, inventorying the records and evidence and sequestering them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on the instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.
- Appointing an inquiry panel and committee chair as soon after the initiation of the inquiry as is practical. The RIO may permit the inquiry panel to select its own chair.
- Preparing a charge for the inquiry panel in accordance with the institution's policies and procedures.
- Convening the first meeting of the inquiry panel and at that meeting briefing the committee on the allegations, the charge to the committee, and the appropriate procedures for conducting the inquiry, including the need for confidentiality and for developing a plan for the inquiry, and assisting the committee with organizational and other issues that may arise.
- Providing the inquiry panel with needed logistical support, e.g., assisting the committee to obtain expert advice, including forensic analysis of evidence, and clerical support, including arranging witness interviews and recording or transcribing those interviews.
- Being available or present throughout the inquiry to advise the committee as needed and consulting with the committee prior to its decision on whether to recommend that an investigation is warranted on the basis of the criteria in the institution's policies and procedures and 42 CFR § 93.307(d).
- Determining whether circumstances clearly warrant a period longer than 60 days to complete the inquiry (including preparation of the final inquiry report and the decision of the DO on whether an investigation is warranted), approving an extension if warranted, and documenting the reasons for exceeding the 60-day period in the record of the research misconduct proceeding.
- Assisting the inquiry panel in preparing a draft inquiry report, sending the respondent a copy of the draft report for comment (and the complainant if the institution's policies provide that option) within a time period that permits the inquiry to be completed within the allotted time, taking appropriate action to protect the confidentiality of the draft report, receiving any comments from the respondent (and the complainant if the institution's policies provide that option), and ensuring that the comments are attached to the final inquiry report.

- Within 30 days of a decision that an investigation is warranted, providing ORI with the written finding and a copy of the inquiry report and notifying those institutional officials who need to know of the decision.
- Notifying the respondent (and the complainant if the institution's policies provide that option) whether the inquiry found an investigation to be warranted and including in the notice copies of or a reference to 42 CFR Part 93 and the institution's research misconduct policies and procedures.
- Providing to ORI, upon request, the institutional policies and procedures under which the inquiry was conducted, the research records and evidence reviewed, transcripts or recordings of any interviews, copies of all relevant documents, and the allegations to be considered in the investigation.
- If the inquiry panel and RIO decides that an investigation is not warranted, securing and maintaining for 7 years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment by ORI of the reasons why an investigation was not conducted.

D. Investigation

The RIO is responsible for:

- Initiating the investigation within 30 calendar days after the determination that an investigation is warranted.
- On or before the date on which the investigation begins: (1) notifying ORI of the decision to begin the investigation and providing ORI a copy of the inquiry report; and (2) notifying the respondent in writing of the allegations to be investigated.
- Prior to notifying respondent of the allegations, taking all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the research misconduct proceeding that were not previously sequestered during the inquiry.
- In consultation with the Research Council, appointing an investigation committee and committee chair as soon after the initiation of the investigation as is practical.
- Preparing a charge for the investigation committee in accordance with the institution's policies and procedures.
- Convening the first meeting of the investigation committee and at that meeting: (1) briefing the committee on the charge, the inquiry report and the procedures and standards for the conduct of the investigation, including the need for confidentiality and developing

a specific plan for the investigation; and (2) providing committee members a copy of the institution's policies and procedures and 42 CFR Part 93.

- Providing the investigation committee with needed logistical support, e.g., expert advice, including forensic analysis of evidence, and clerical support, including arranging interviews with witnesses and recording or transcribing those interviews.
- Being available or present throughout the investigation to advise the committee as needed.
- On behalf of the institution, the RIO is responsible for each of the following steps and for ensuring that the investigation committee: (1) uses diligent efforts to conduct an investigation that includes an examination of all research records and evidence relevant to reaching a decision on the merits of the allegations and that is otherwise thorough and sufficiently documented; (2) takes reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical; (3) interviews 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, and records or transcribes each interview, provides the recording or transcript to the interviewee for correction, and includes the recording or transcript in the record of the research misconduct proceeding; and (4) pursues diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of any additional instances of possible research misconduct, and continues the investigation to completion.
- Upon determining that the investigation cannot be completed within 120 days of its initiation (including providing the draft report for comment and sending the final report with any comments to ORI), submitting a request to ORI for an extension of the 120-day period that includes a statement of the reasons for the extension. If the extension is granted, the RIO will file periodic progress reports with ORI.
- Assisting the investigation committee in preparing a draft investigation report that meets the requirements of 42 CFR Part 93 and the institution's policies and procedures, sending the respondent (and complainant at the institution's option) a copy of the draft report for his/her comment within 30 days of receipt, taking appropriate action to protect the confidentiality of the draft report, receiving any comments from the respondent (and complainant at the institution's option) and ensuring that the comments are included and considered in the final investigation report.
- Transmitting the draft investigation report to the Office of Legal Affairs for a review of its legal sufficiency.
- Assisting the investigation committee in finalizing the draft investigation report and receiving the final report from the committee.

- Transmitting the final investigation report to the DO and: (1) if the DO determines that further fact-finding or analysis is needed, receiving the report back from the DO for that purpose; (2) if the DO determines whether or not to accept the report, its findings and the recommended institutional actions, transmitting to ORI within the time period for completing the investigation, a copy of the final investigation report with all attachments, a statement of whether the institution accepts the findings of the report, a statement of whether the institution found research misconduct, and if so, who committed it, and a description of any pending or completed administrative actions against the respondent; or (3) if the institution provides for an appeal by the respondent that could result in a modification or reversal of the DO's finding of research misconduct, ensuring that the appeal is completed within 120 days of its filing, or seeking an extension from ORI in writing (with an explanation of the need for the extension) and, upon completion of the appeal, transmitting to ORI a copy of the investigation report with all attachments, a copy of the appeal proceedings, a statement of whether the institution accepts the findings of the appeal proceeding, a statement of whether the institution found research misconduct, and if so, who committed it, and a description of any pending or completed administrative actions against the respondent.

- When a final decision on the case is reached, the RIO will normally notify both the respondent and the complainant in writing and will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of involved journals, collaborators of the respondent, or other relevant parties should be notified of the outcome of the case.

- Maintaining and providing to ORI upon request all relevant research records and records of the institution's research misconduct proceeding, including the results of all interviews and the transcripts or recordings of those interviews.

Appendix B

Selected Federal Research Misconduct Policies

US Department of Health & Human Services, 42 CFR parts 53 and 90, May 17, 2005

https://ori.hhs.gov/front_misconduct

The National Science Foundation (NSF) Regulations, 45 CFR Part 689, March 18, 2002

<https://www.nsf.gov/oig/regulations/>

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