UNIVERSITY OF MARYLAND PROCEDURES FOR ADDRESSING ALLEGATIONS OF RESEARCH MISCONDUCT (SUBJECT TO THE PUBLIC HEALTH SERVICE REGULATION)

I. PURPOSE

This document, the University of Maryland Procedures for Addressing Allegations of Research Misconduct (Subject to the Public Health Service Regulation) ("Procedures"), sets forth the process by which the University of Maryland Policy on Integrity and Responsible Conduct in Scholarly Work ("Policy") will be implemented by the University of Maryland, College Park ("UMD") when an Allegation of Research Misconduct ("Allegation") involves an Institutional Member[1] and may fall under the Public Health Service Policies on Research Misconduct, 42 C.F.R. Part 93 ("the PHS Regulation"), due to the involvement of Public Health Service ("PHS")-supported biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training. Allegations of Research Misconduct related to work that is not PHS-funded, Scholarly Misconduct, and/or Creative Activities Misconduct will be handled under other Procedures as identified in the Policy.

The Office of Integrity and Responsible Conduct ("OIRC") is the unit on campus that implements the Policy and its associated Procedures. The Research Integrity Officer ("RIO") has specific responsibilities for the administration of the Policy and these Procedures as set forth throughout both documents.

OIRC will maintain, update, and publish these Procedures as necessary to comport with relevant laws, regulations, and University System of Maryland ("USM") and UMD policies and procedures.

II. GENERAL

A. Rules of Interpretation

1. Definitions

Terms used in these Procedures have the same meaning as ascribed to them in Section I of the Appendix to the Policy. Defined terms are capitalized throughout the Policy and these Procedures.

2. Time Periods

References to Days in the Policy or these Procedures refer to calendar days. Unless otherwise specified in these Procedures, a Respondent's failure to exercise any right granted hereunder within the stated time period will be deemed a waiver of that right.

[1] This includes any individual who was an Institutional Member at the time the alleged misconduct occurred.

3. Plural Usage

The Policy and these Procedures are written with singular references to a party (*e.g.*, a Respondent) or an Allegation. In cases involving multiple parties or Allegations, the Policy and these Procedures should be construed accordingly.

B. General Procedures Applicable to All Stages of the Institutional Process

1. Respondent Admission

A Respondent's admission of Research Misconduct must be made in writing to the RIO and signed by the Respondent. The Respondent's admission must specify:

- which Research Records were affected;
- the Falsification, Fabrication, and/or Plagiarism that occurred;
- whether the Respondent committed the Research Misconduct Intentionally, Knowingly, or Recklessly; and
- if the Research Misconduct represents a significant departure from Accepted Practices of the Relevant Research Community.

The admission statement must meet all elements required for a Research Misconduct finding under 42 C.F.R. § 93.103 or it cannot be accepted. The RIO will provide the U.S. Department of Health and Human Services ("HHS") Office of Research Integrity ("ORI") with a copy of the admission and a statement describing how it determined that the scope of the misconduct was fully addressed by the admission and confirmed the Respondent's culpability.

UMD will notify ORI in advance if UMD plans to close a Research Misconduct Proceeding at the Assessment, Inquiry, Investigation, or appeal stage on the basis that the Respondent has admitted to committing Research Misconduct or a settlement with the Respondent has been reached. UMD will not close its Research Misconduct Proceeding before providing ORI with the documentation and notification required by 42 C.F.R. § 93.317(a-b).

The IDO will determine whether any information or issues that came to the attention of UMD during the UMD portion of the Research Misconduct Proceeding, prior to or as a result of the admission, should be referred for review under another UMD policy and make the referral as appropriate.

2. Respondent Request for Extension

Any request for extension from a Respondent related to the provision of a response to either the Allegation or a subsequent report (*e.g.*, an Investigation report) must be submitted in writing to the RIO, who will consult with the Institutional Deciding Official ("IDO") before rendering a decision. Any request for an extension from a Respondent related to the submission of an appeal in response to the IDO's final determination must be submitted in writing to the IDO, who will consult with the Provost before rendering a decision.

3. Multiple Respondents

If UMD identifies an additional Respondent during an Inquiry or Investigation, UMD may either conduct a separate Inquiry or Investigation for each new Respondent or add them to the ongoing Proceeding.[2] UMD will give each additional Respondent Notice of and an opportunity to respond to each new Allegation.[3]

4. Multiple Institutions

If the alleged Research Misconduct involves multiple Institutions, UMD may work closely with the other affected Institutions to determine whether a joint Research Misconduct Proceeding will be conducted.[4] 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.[5] By mutual agreement, the joint Research Misconduct Proceeding may include Committee members from the Institutions involved.[6] The determination of whether further Inquiry and/or Investigation is warranted and whether Research Misconduct occurred may be made by the Institutions jointly or tasked to the lead Institution.[7] UMD will make the determination regarding any Institutional Actions to be taken with respect to Respondents and/or Research affiliated with UMD.

5. Multiple Funding Agencies/Sponsors

In the event that a matter to be reviewed under the Policy involves multiple funding agencies/sponsors, the Respondent will be notified of the Procedures to be followed for each Allegation and any required reporting to funding agencies/sponsors will be made in accordance with the specific requirements of each funding agency/sponsor.

6. Interim Actions

At any time during a Research Misconduct Proceeding, appropriate UMD administrators may implement, on an interim basis, Institutional Actions they deem necessary to safeguard Institutional Members, other participants in the Research Misconduct Proceeding, public health or safety, research participants, sponsors' funds or equipment, Evidence, or the integrity of the research environment. These interim Institutional Actions do not indicate that a conclusion has been reached from the Proceeding, and such actions may be revised, revoked, or made permanent upon the completion of the Proceeding conducted under this Policy and associated Procedures, independent of the stage of the process at which the Proceeding concludes. The

[2] § 93.305(d).
[3] § 93.305(d).
[4] § 93.305(e).
[5] § 93.305(e).
[6] § 93.305(e).
[7] § 93.305(e).

Respondent will be notified if it has been determined that interim Institutional Actions will be implemented, revised, revoked, or made permanent.

7. Special Circumstances

At any time during a Research Misconduct Proceeding, UMD will immediately notify ORI and take any necessary interim Institutional Actions if it has reason to believe that any of the following conditions exist:

- health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
- 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; and/or
- HHS may need to take appropriate steps to safeguard Evidence and protect the rights of those involved.[8]

8. Good Faith Allegations and Participation

If UMD determines that a Complainant, Respondent, Witness, Committee member, Unit Head, or any other Institutional Member did not act in Good Faith with regard to their Allegation, testimony, statements, or actions in connection with the Proceeding, appropriate action may be taken against that individual, including referral for disciplinary action, up to and including termination.

9. Appeals and Objections

Determinations made pursuant to the Policy and these Procedures may only be appealed and objections may only be raised in those instances and as expressly presented throughout these Procedures.

10. Breaches of Confidentiality

Any concern regarding breaches of confidentiality should be reported immediately to the RIO. The concern will be investigated as warranted and appropriate. If the concern is substantiated, the associated individual's conduct will be referred to the appropriate administrator or office for further action, including any appropriate disciplinary action, in accordance with applicable USM and UMD policies and procedures.

The engagement of other individuals by OIRC staff or any Committee member during a Committee meeting for the purpose of collecting information necessary for the review of an Allegation will not be deemed a breach of confidentiality under the Policy and these Procedures.

[8] § 93.305(g)(1-6).

11. Conflict of Interest

In the event that an Allegation arises for which an individual with responsibility for some aspect of the implementation of these Procedures (*e.g.*, the RIO, the IDO, the Unit Head, or the UMD official or administrator to whom any appeal and/or recommendation for disciplinary, remedial, or corrective action and/or other sanction would be referred) would have a Conflict of Interest in carrying out their duties, the appointment of another individual to perform those duties will be addressed as follows:

- in the case of a potential conflict on the part of the RIO, the IDO will identify a replacement;
- in the case of a potential conflict on the part of the IDO, the President or their designee will identify a replacement;
- in the case of a potential conflict on the part of the Unit Head, UMD official or administrator, the appropriate Next Level Administrator will identify a replacement; and
- in the case of a potential conflict on the part of any UMD official or administrator to whom any appeal and/or recommendation for disciplinary, remedial, or corrective action and/or other sanction would be referred, the appropriate Next Level Administrator will identify a replacement.

C. Role of Counsel

The Policy affords a Respondent the right to retain and seek advice, at their own cost, from Counsel (lay or legal). The Respondent's Counsel will have no voice or formal role in Committee meetings held in accordance with the Policy and these Procedures. OIRC staff will only communicate directly with the Respondent, not with a Respondent's Counsel.

The Office of General Counsel ("OGC") will act as a legal advisor to UMD with regard to the implementation of the Policy and these Procedures.

D. Role of Resource Person

The Policy affords a Respondent the right to consult a resource person. The role of the resource person, who must be an uninvolved, tenured faculty member without a Conflict of Interest, is to provide guidance regarding the relevant UMD processes and not to serve as an advocate or Counsel.

III. PROCEDURES

A. Reporting and Intake of Allegations of Research Misconduct

1. Reporting Allegations of Research Misconduct

Allegations of Research Misconduct should be brought directly to the attention of the RIO and may be brought through any means of communication (*e.g.*, email, UMD's online reporting system ("EthicsPoint"), phone, or in person).

- RIO email: rio@umd.edu

- EthicsPoint: https://secure.ethicspoint.com/domain/media/en/gui/59349/issues.html
- RIO phone: 1-301-314-1814

UMD will respond to each Allegation of Research Misconduct in a thorough, competent, objective, and fair manner. To the extent possible, an Allegation should be as specific as possible about the nature of the potential Research Misconduct and the specific Research in question, based on the information already available to a Complainant. A Complainant should not attempt to acquire additional information for this purpose.

Allegations of Research Misconduct involving PHS-support for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training (*i.e.*, fall under 42 C.F.R. Part 93) may also be reported to an HHS official (*e.g.*, ORI) through any means of communication.

After bringing forth the initial Allegation, the role of the Complainant is like that of a Witness.

2. Referrals from ORI

When ORI refers an Allegation of Research Misconduct to UMD, UMD will initiate the process to address that Allegation at the stage (*i.e.*, Assessment, Inquiry, or Investigation) indicated by ORI. When ORI directs UMD to initiate at the Investigation stage, UMD will promptly sequester Evidence as described in section III.C.3. of these Procedures and proceed to section III.D. of these Procedures.

UMD will include a copy of ORI's referral in the Institutional Record.

B. Institutional Assessment

1. Purpose

An Assessment's purpose is to determine whether an Allegation warrants an Inquiry.[9] An Assessment is intended to be a review of readily accessible information relevant to the Allegation.[10]

2. Time for Completion

UMD will aim to complete the Assessment within 30 days of its initiation, whenever possible. The RIO may request an extension of the time period for the Assessment for good cause, which will be reviewed and approved by the IDO.

3. Conducting the Assessment

[9] § 93.306(a).
[10] § 93.204.

Upon receiving an Allegation of Research Misconduct, the RIO will promptly determine, based on the review of readily available information, whether the Allegation:

- falls within the definition of Research Misconduct under 42 C.F.R Part 93 (*i.e.*, 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);
- is within the applicability criteria of 42 C.F.R. § 93.102, which apply to Allegations of Research Misconduct involving:
  - applications or proposals for PHS support for biomedical or behavioral extramural or intramural research, biomedical or behavioral research training, or activities related to that research or research training;
  - PHS-supported biomedical or behavioral extramural or intramural research;
  - PHS-supported biomedical or behavioral extramural or intramural research training programs;
  - PHS-supported extramural or intramural 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 (databases) or the dissemination of research information;
  - Research Records produced during PHS-supported research, research training, or activities related to that research or research training; and
  - 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; and
- is sufficiently credible and specific so that potential Evidence of Research Misconduct may be identified.[11]

4. Outcome of the Assessment

a. An Inquiry must be conducted if the Allegation meets the three Assessment criteria listed above in Section III.B.3.

b. If the RIO determines that the requirements for an Inquiry are met, they will:
   - document the Assessment as required in III.B.5.;
   - notify the IDO of their determination and provide the IDO with the aforementioned documentation of the Assessment;
   - notify the Unit Head;
   - promptly sequester all Research Records and other Evidence; and
   - promptly initiate an Inquiry.[12]

c. If the RIO determines that the alleged misconduct does not meet the requirements for an Inquiry, they will:
   - document the Assessment, as required in III.B.5., to permit a later review by ORI of why UMD did not proceed to an Inquiry; and

[11] § 93.306(b-c).
[12] §§ 93.306(b) and 93.306(c).

- notify the IDO of their determination and provide the IDO with the aforementioned documentation of the Assessment.

5. Documentation of the Assessment

a. The RIO must document the process undertaken and the outcome of the Assessment in a report ("Assessment report") which includes:
   - the Allegation assessed;
   - the name, professional alias, and position of the Respondent;
   - any readily accessible information reviewed;
   - whether the Allegation falls within the definition of Research Misconduct under 42 C.F.R. Part 93;
   - whether the Allegation is within the jurisdictional criteria of 42 C.F.R. § 93.102;
   - whether the Allegation is sufficiently credible and specific so that potential Evidence of Research Misconduct may be identified; and
   - whether UMD will proceed to Inquiry.

b. UMD will keep the Assessment report in a secure manner for at least seven (7) years after the completion of the Research Misconduct Proceeding, and upon request, provide them to ORI.

C. Institutional Inquiry

1. Purpose

An Inquiry's purpose is to conduct an initial review of the Evidence to determine whether an Allegation warrants an Investigation.[13] An Inquiry does not require a full review of all related Evidence.[14]

2. Time for Completion

UMD will complete the Inquiry within 90 days of initiating it unless circumstances warrant a longer period, in which case it will sufficiently document the reasons for exceeding the time limit in the Inquiry report.[15]

3. Sequestration of Research Records and Other Evidence

a. Before or at the time the RIO notifies the Respondent of the Allegation, the RIO will:
   - promptly take all reasonable and practical steps to identify and obtain all Research Records and other Evidence, which may include copies of the Data

[13] § 93.307(b).
[14] § 93.307(b).
[15] § 93.307(h).

or other Evidence so long as those copies are substantially equivalent in evidentiary value, needed to conduct the Research Misconduct Proceeding;
- inventory the Research Records and other Evidence and document their chain of custody; and
- sequester the Research Records and other Evidence in a secure manner.

b. Where the Research Records or other Evidence are located on or encompass scientific instruments shared by multiple users, the RIO may elect to obtain copies of the Data or other Evidence from such instruments, so long as those copies are substantially equivalent in evidentiary value to the instruments.

c. The RIO will obtain, inventory, and securely sequester Evidence whenever additional items become known or relevant to the Inquiry or Investigation.[16]

d. UMD will maintain all sequestered Evidence, including physical objects, regardless of whether the Evidence is part of the Institutional Record, in a secure manner for seven (7) years after completion of the Proceeding or the completion of any HHS proceeding involving the Research Misconduct Allegation under subparts D and E of 42 C.F.R. Part 93, whichever is later, unless custody has been transferred to HHS under 42 C.F.R. § 93.318(b) or ORI advises otherwise in writing.

e. When appropriate, the RIO will give the Respondent copies of, or reasonable supervised access to, the sequestered materials.[17]

4. Notifying the Respondent

a. At the time of or before beginning the Inquiry, the RIO will make a Good Faith (diligent) effort to notify the Respondent, in writing and in a timely manner, that an Allegation of Research Misconduct has been raised against them and an Inquiry will be conducted to decide whether to proceed with an Investigation ("Notice of Inquiry").[18] The Notice of Inquiry will include a copy of the Policy and these Procedures. In cases for which UMD conducted an Assessment, the RIO will also attach a copy of the Assessment report to the Notice of Inquiry. A Respondent may submit a written response to the RIO within seven (7) days of receiving the Notice of Inquiry and/or Allegation for which they have been identified as a Respondent. Any requests for extensions from a Respondent related to the provision of a response to the Allegation must be submitted in writing to the RIO, who will consult with the IDO before rendering a decision.

b. If an additional Respondent is identified during the Inquiry, the RIO will notify the additional Respondent of the Allegation specific to them, in a Notice of

[16] §§ 93.305(a)(2) and 93.318.
[17] § 93.305(b).
[18] § 93.307(c).

Inquiry, and provide them copies of the Policy and these Procedures. The Respondent may submit a written response to the RIO within seven (7) days of receiving the Notice of Inquiry and/or Notice of the Allegation for which they have been identified as a Respondent. Any individual identified as an additional Respondent during the Inquiry may submit a written response to the RIO within seven (7) days of receiving notification of the Inquiry and/or Allegation for which they have been identified as a Respondent. Any requests for extensions from a Respondent related to the provision of a response to the Allegation must be submitted in writing to the RIO, who will consult with the IDO before rendering a decision. If UMD identifies additional Respondents during the Inquiry, it may choose to either conduct a separate Inquiry or add the new Respondent to the ongoing Inquiry.[19]

c. If an additional Allegation is raised, the RIO will notify the Respondent in writing.[20] The Respondent may submit a written response to the RIO within seven (7) days of receiving Notice of the additional Allegation for which they have been identified as a Respondent. Any requests for extensions from a Respondent related to the provision of a response to the Allegation must be submitted in writing to the RIO, who will consult with the IDO before rendering a decision.

d. At the time of notification, the RIO will offer the Respondent the opportunity to consult with an uninvolved, tenured faculty member without a Conflict of Interest ("resource person"). The role of the resource person is to provide guidance regarding the relevant UMD processes throughout the Proceeding, and not to act as an advocate or Counsel. The resource person may accompany the Respondent to meetings with the Committee to which they are invited (*i.e.*, when the Committee interviews the Respondent) but will have no voice or formal role in those meetings. OIRC will identify an individual that is appropriate for this role and provide the name of the individual to the Respondent for consideration. The Respondent may submit recommendations for individuals to serve in this role to the RIO for consideration. After consideration of any recommendations made by the Respondent, OIRC will provide the name of the individual selected to serve in this role to the Respondent for consideration. If the Respondent accepts the offer of a resource person, it is the Respondent's responsibility to establish communication with the resource person and consult with them as needed and appropriate, consistent with the Policy and these Procedures.

5. Inquiry Committee

The RIO will convene a Committee or Consortium (hereinafter collectively referred to as "Committee") to conduct an initial review of the Evidence at the Inquiry stage to determine whether an Investigation is warranted.[21]

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[19] §§ 93.310(c)(2) and 93.310(c)(3).
[20] § 93.307(c).
[21] § 93.307(e)(2).

The following procedures will apply to selecting the individual(s) to serve on the Inquiry Committee and charging and convening the Inquiry Committee.

a. *Selecting Committee members.* The RIO will assemble an Inquiry Committee that is composed of one (1) to three (3) individuals who: (1) are faculty members at UMD or another academic Institution as necessary; (2) have relevant scientific, technical, and/or subject matter expertise, as necessary and appropriate; and (3) are free of unresolved potential, perceived, or actual personal, professional, or financial Conflicts of Interest with any of the parties involved in the Research Misconduct Proceeding. UMD may use one or more of the Committee members from an Inquiry in the subsequent Investigation.

b. *Notice to the Respondent of Committee composition.* The RIO will notify the Respondent in writing of the name(s) of the Committee member(s) who will be appointed to conduct the Inquiry. The Respondent will have five (5) days from the receipt of the notification to request, on the basis of bias or Conflict of Interest, that the RIO replace a member of the Inquiry Committee. The RIO, in consultation with the IDO, will consider the request and render a written decision related to the request.

c. *Appointing Committee members and charging the Committee.* Prior to the first Inquiry Committee meeting: (1) each Committee member will first be provided with a confidentiality agreement and a certification related to Conflicts of Interest to sign and return to the RIO; and (2) subsequently, the RIO will notify each Committee member, in writing, of their appointment to the Inquiry Committee and their charge, including their role as part of the Inquiry Committee, the confidentiality requirements related to their participation, the relevant Policy and Procedures for the Inquiry, and the Allegation to be addressed during the Inquiry.

d. *Convening and staffing the Committee.* The RIO will subsequently convene the Inquiry Committee and ensure that each member understands their responsibility to conduct the Research Misconduct Proceeding in compliance with the PHS regulation and in line with the written charge they received. Each Committee member shall be mindful of the confidentiality requirements for the misconduct Proceeding and refrain from discussing the Inquiry or Research Misconduct Proceeding outside of official Inquiry Committee activities. OIRC will provide staff support to the Inquiry Committee and for each Committee meeting.

6. Interviews

a. The Inquiry Committee may interview any Witness, including the Complainant, and/or Respondent that would provide additional information for UMD's review of an Allegation during the Inquiry.

b. If the Inquiry Committee chooses to conduct an interview, it will:

- number all relevant exhibits and refer to any exhibits shown to the interviewee during the interview by that number;
- record and, as necessary, transcribe interviews during the Inquiry and make the transcripts available to the interviewee for correction; and
- include the transcript with any corrections and exhibits in the Institutional Record of the Inquiry.

c. The Respondent will not be present during Witness interviews, but UMD will provide the Respondent with a transcript of each interview, with redactions as appropriate to maintain confidentiality.

7. Determining Whether an Investigation Is Warranted

a. The Inquiry Committee will conduct a preliminary review of the Evidence to determine whether an Investigation is warranted.[22]

b. An Investigation is warranted if:
- there is a reasonable basis for concluding that the Allegation falls within the definition of Research Misconduct under 42 C.F.R. 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 42 C.F.R. § 93.102; and
- preliminary information-gathering and fact-finding from the Inquiry indicates that the Allegation may have substance.[23]

c. The Inquiry Committee will not determine if Research Misconduct occurred, nor assess whether the alleged misconduct was Intentional, Knowing, or Reckless, as such a determination is not made unless and until the case proceeds to an Investigation.[24]

8. Documenting the Inquiry

At the conclusion of the Inquiry, regardless of whether an Investigation is warranted, the Inquiry Committee will prepare a written Inquiry report for each Respondent. The contents of a complete Inquiry report will include:

- the names, professional aliases, and positions of the Respondent and Complainant;
- a description of the Allegation of Research Misconduct;
- details about the PHS support, including, for example, any grant numbers, grant applications, Contracts, and publications listing PHS support;
- the composition of the Inquiry Committee, if used, including name(s), position(s), and subject matter expertise;

[22] § 93.307(b).
[23] § 93.307(f)(1)(i-ii).
[24] § 93.307(f)(1)(ii)(2).

- an inventory of sequestered Research Records and other Evidence and a description of how the sequestration was conducted;
- transcripts of interviews, if transcribed;
- the Inquiry timeline and procedural history;
- any scientific or forensic analyses conducted;
- the basis for recommending that the Allegation warrants an Investigation.
- the basis on which any Allegation does not merit an Investigation;
- any comments on the Inquiry report by the Respondent;
- any Institutional Actions implemented, including communications with journals or funding agencies;[25] and
- documentation of potential Evidence of honest error or difference of opinion.[26]

9. Completing the Inquiry

The RIO will give the Respondent a copy of the draft Inquiry report for review and comment.[27] All comments must be submitted in writing to the RIO within 14 days of the RIO transmitting the draft Inquiry report to the Respondent. Any requests for extensions from a Respondent related to the provision of comments on the draft Inquiry report must be submitted in writing to the RIO, who will consult with the IDO before rendering a decision. The Inquiry Committee will consider comments on the draft Inquiry report and document that consideration in the final Inquiry report.

10. Outcomes from the Inquiry

a. If an Investigation Is Not Warranted

If it is determined through the Inquiry that an Investigation is not warranted, UMD will: (1) keep sufficiently detailed documentation to permit a later review by ORI of why UMD did not proceed to an Investigation; (2) store these records in a secure manner for at least seven (7) years after the termination of the Inquiry; and (3) provide them to ORI upon request. [28]

The RIO will notify the Respondent and the Unit Head of the Inquiry's final outcome and whether Institutional Actions are being considered. The RIO will also provide the Respondent with a copy of the final Inquiry report, the PHS regulation, the Policy, and these Procedures.[29]

UMD will make diligent efforts, if requested by the Respondent, to restore the Respondent's reputation. These efforts shall be undertaken in consultation with the Respondent, provided that they shall: (1) be reasonable and practicable under the circumstances and proportionate to the damage to the Respondent's reputation as a result of the Allegation; (2) be consistent with applicable federal funding agency or other sponsor expectations; and (3) not affect UMD's

[25] § 93.309(a)(1-12).
[26] § 93.307(g)(2).
[27] § 93.307(g)(3).
[28] § 93.309(c).
[29] § 93.308(a).

ability to take action against the Respondent for practices detrimental to the Research that come to UMD's attention as a result of the review of the Allegation under this Policy.

b. If an Investigation is Warranted

If it is determined through the Inquiry that an Investigation is warranted, UMD will: (1) provide written Notice to the Respondent of the decision to conduct an Investigation;[30] and (2) within 30 days of determining that an Investigation is warranted, provide ORI with a copy of the Inquiry report.[31]

When notifying the Respondent of the Inquiry's final outcome, the RIO will provide the Respondent with a copy of the final Inquiry report, the PHS Regulation, the Policy, and these Procedures.[32] The RIO will also notify the Respondent if, at that time, Institutional Actions are being considered.

11. IDO Review of the Inquiry Report and Consideration of Institutional Actions

The RIO will provide the final Inquiry report to the IDO. The IDO will review the Inquiry report, ask any questions of the RIO and/or the Inquiry Committee as needed, and determine if Institutional Actions may be warranted at this stage of the Proceeding. If the IDO determines that Institutional Actions may be warranted, the IDO will follow the *University of Maryland Procedures for Determining Institutional Actions* associated with the Policy. The consideration and implementation of Institutional Actions in relation to the Allegation addressed at the Inquiry stage shall run in parallel to any other UMD processes. The IDO will notify the Respondent if it is determined that Institutional Actions will be implemented under the Policy and associated Procedures.

D. Institutional Investigation

1. Purpose

The purpose of an Investigation is to formally develop a factual record, examine the factual record, and determine whether or not to recommend a finding of Research Misconduct to the IDO, for each Allegation of Research Misconduct being addressed during the Investigation. Based on the outcome of the Investigation, the IDO will make the final decision on findings of Research Misconduct for each Allegation and any Institutional Actions as described in III.E.1.a. of these Procedures.[33]

2. Time for Completion

[30] § 93.308(a).
[31] § 93.309(a).
[32] § 93.308(a).
[33] §§ 93.310 and 93.314.

UMD will begin the Investigation within 30 days after deciding an Investigation is warranted. UMD will complete all aspects of the Investigation within 180 days of beginning the Investigation whenever possible.[34] If the Investigation takes more than 180 days to complete, the RIO, after consultation with the IDO, will ask ORI in writing for an extension and document the reasons for exceeding the 180-day period in the Investigation report.[35]

3. Notification to ORI

The RIO will notify ORI of the decision to begin an Investigation on or before the date the Investigation begins and provide an Inquiry report that meets the requirements of 42 C.F.R. §§ 93.307 and 93.309.

4. Notification of the Respondent

a. The RIO will notify the Respondent in writing of the Allegation to be addressed during the Investigation ("Notice of Investigation") within a reasonable amount of time after determining that an Investigation is warranted, but before the Investigation begins.

b. The RIO will notify the Respondent in writing of any Allegation of Research Misconduct not addressed during the Inquiry or included in the Notice of Investigation within a reasonable amount of time of deciding to pursue such an Allegation. The Respondent may submit a written response to the RIO within seven (7) days of receiving notification of the Allegation. Any requests for extensions from a Respondent related to the provision of a response to the Allegation must be submitted in writing to the RIO, who will consult with the IDO before rendering a decision.

c. If an additional Respondent is identified during the Investigation, the RIO will notify the additional Respondent of the Allegation specific to them in a Notice of Investigation, provide them with a copy of the Policy and these Procedures, and provide them with an opportunity to respond to the Allegation consistent with the PHS regulation.[36] The additional Respondent may submit a written response to the RIO within seven (7) days of receiving the Notice of Investigation and/or Notice of the Allegation for which they have been identified as a Respondent. Any requests for extensions from a Respondent related to the provision of a response to the Allegation must be submitted in writing to the RIO, who will consult with the IDO before rendering a decision. If UMD identifies an additional Respondent during the Investigation, UMD may but is not required to conduct a separate Inquiry for each new Respondent. UMD may initiate a separate

[34] § 93.311(a).
[35] § 93.311(b).
[36] § 93.310(c)(2).

Investigation for the new Respondent or add the new Respondent to the ongoing Investigation.[37]

5. Sequestration of Research Records and Other Evidence

Should additional Research Records or other Evidence become known or relevant to UMD and/or the Investigation, the RIO will promptly take all reasonable and practical steps to obtain the Research Records and other Evidence in line with Section III.C.3.

6. Investigation Committee

During an Investigation, 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 and making recommendations on findings of Research Misconduct.[38] UMD will make diligent efforts to ensure that the Investigation, and the Investigation Committee's work, is thorough, sufficiently documented, and impartial and unbiased to the maximum extent practicable.[39]

a. *Selecting Committee members.* The RIO will assemble an Investigation Committee that is composed of three (3) or more Committee members who: (1) are faculty members at UMD or another academic Institution as necessary; (2) have relevant scientific, technical, and/or subject matter expertise, as necessary and appropriate; and (3) are free of unresolved potential, perceived, or actual personal, professional, or financial Conflicts of Interest with any of the parties involved in the Research Misconduct Proceeding. UMD may use one or more of the same Committee members from an Inquiry in the subsequent Investigation.

b. *Notice to the Respondent of Committee composition.* The RIO will notify the Respondent in writing of the names of the Committee members who will be appointed to conduct the Investigation. The Respondent will have five (5) days from the receipt of the notification to request, on the basis of bias or Conflict of Interest, that the RIO replace a member of the Investigation Committee. The RIO, in consultation with the IDO, will consider the request and render a written decision related to the request.

c. *Appointing Committee members and charging the Committee.* Prior to the first Investigation Committee meeting: (1) each Committee member will first be provided with a confidentiality agreement and a certification related to Conflicts of Interest to sign and return to the RIO; and (2) subsequently, the RIO will notify each Committee member, in writing, of their appointment to the Investigation Committee and their charge, including their role as part of the Investigation Committee, the confidentiality requirements related to their participation, the

[37] §§ 93.310(c)(2) and 93.310(c)(3).
[38] § 93.310.
[39] § 93.310(f).

relevant policies and procedures for the Investigation, and the Allegation to be addressed during the Investigation.

d. *Convening the Committee.* The RIO will subsequently convene the Investigation Committee and ensure that each Committee member understands their responsibility to conduct the Research Misconduct Proceeding in compliance with the PHS Regulation and in line with the written charge they received.[40] Each Committee member shall be mindful of the confidentiality requirements for the misconduct Proceeding and refrain from discussing the Investigation or Research Misconduct Proceeding outside of official Investigation Committee activities. OIRC will provide staff support to the Investigation Committee and for each Committee meeting.

7. Conducting the Investigation

During the Investigation, UMD will diligently pursue all significant issues and leads that are discovered and determined relevant to the Investigation, including any Evidence of additional instances of possible Research Misconduct, and continue the Investigation to completion.[41]

8. Interviews

The Investigation Committee will:

- make a reasonable effort to interview each Respondent, Witness (including the 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;[42]
- number all relevant exhibits and refer to any exhibits shown to the interviewee during the interview by that number;[43]
- record and transcribe interviews during the Investigation and make the transcripts available to the interviewee for correction;[44] and
- include the transcripts with any corrections and exhibits in the Institutional Record of the Investigation.[45]

The Respondent will not be present during the Witnesses' interviews, but UMD will provide the Respondent with a transcript of each interview, with redactions as appropriate to maintain confidentiality.[46]

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[40] § 93.310(f).
[41] § 93.310(j).
[42] § 93.310(g).
[43] § 93.310(g)(2).
[44] §§ 93.310(g)(1) and 93.310(g)(3).
[45] § 93.310(g)(4).
[46] §§ 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. Institutions have the discretion to determine how to do so in practical terms (*e.g.*, by redacting transcripts).

9. Outcomes of the Investigation

a. A finding of Research Misconduct requires that:
   - the Allegation meets the definition of Research Misconduct; and
   - there be a significant departure from Accepted Practices of the Relevant Research Community; and
   - the misconduct be committed Intentionally, Knowingly, or Recklessly; and
   - the Allegation of Research Misconduct be proven by a Preponderance of the Evidence.

b. The Investigation Committee will only recommend a finding of Research Misconduct for an Allegation when all of the above criteria are met.

10. Documenting the Investigation

UMD will document, in writing, the Investigation stage of the Research Misconduct Proceeding in an Investigation report, as described below and consistent with the PHS Regulation. UMD will prepare a separate Investigation report for each Respondent and provide the Respondent the opportunity to comment on a draft of the report in which they are identified as a Respondent.

The draft Investigation report provided to the Respondent will contain the components below, as relevant. The final Investigation report, transmitted to ORI as part of the Institutional Record, will contain all relevant components listed below.

- Description of the nature of the Allegation of Research Misconduct, including any additional Allegation addressed during the Research Misconduct Proceeding.
- Description and documentation of the PHS support, including, for example, any grant numbers, grant applications, Contracts, and publications listing PHS support.
- Description of the specific Allegation of Research Misconduct for consideration in the Investigation of the Respondent.
- Composition of the Investigation Committee, including names, positions, and scientific/technical/subject matter expertise.
- Inventory of sequestered Research Records and other Evidence, except records UMD did not consider or rely on; and a description of how any sequestration was conducted during the Investigation. This inventory must include manuscripts and funding proposals that were considered or relied on during the Investigation.
- Transcripts of all interviews conducted, as described in 42 C.F.R § 93.310(g).
- Identification of the specific published papers, manuscripts submitted but not accepted for publication (including online publication), PHS funding applications, progress reports, presentations, posters, or other Research Records that allegedly contained the Falsified, Fabricated, or Plagiarized material.
- Any scientific or forensic analyses conducted.
- A statement for each separate Allegation of whether the Investigation Committee recommends a finding of Research Misconduct.
    - If the Investigation Committee recommends a finding of Research Misconduct for an Allegation, the Investigation report must, for that Allegation:

        - identify the individual who committed the Research Misconduct;
        - indicate whether the Research Misconduct was Falsification, Fabrication, and/or Plagiarism;
        - indicate whether the Falsification, Fabrication, and/or Plagiarism represents a significant departure from the Accepted Practices of the Relevant Research Community;
        - indicate whether the Falsification, Fabrication, and/or Plagiarism was committed Intentionally, Knowingly, or Recklessly;
        - state whether the Allegation has been proven by a Preponderance of the Evidence;
        - summarize the facts and the analysis that support the conclusion and consider the merits of any explanation by the Respondent;
        - identify the specific PHS support; and
        - identify whether any publications need correction or retraction.
    - If the Investigation Committee does not recommend a finding of Research Misconduct for an Allegation, the Investigation report must provide a detailed rationale.
- List of any current support or known applications or proposals for support that the Respondent has pending with PHS and non-PHS federal agencies.
- If not already provided to ORI, the UMD policies and procedures under which the Investigation was conducted.
- Any comments made by the Respondent on the draft Investigation report and the Investigation Committee's consideration of those comments.

11. Completing the Investigation

The RIO 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.[47] The Respondent will submit any comments on the draft report to the RIO within 30 days of receiving the draft Investigation report.[48] Any requests for extensions from a Respondent related to the provision of comments on the draft Investigation report must be submitted in writing to the RIO, who will consult with the IDO before rendering a decision. The RIO will provide these comments to the Investigation Committee for consideration. The RIO will include the comments on the draft report and documentation of the Investigation Committee's consideration of those comments in the final Investigation report.[49] The RIO will provide the final Investigation report to the IDO.

E. Concluding the Institutional Process

1. Final Determination

a. The IDO will review the final Investigation report, ask any questions of the RIO and/or the Investigation committee as needed, follow the appropriate Procedures

[47] § 93.312(a).
[48] § 93.312(a).
[49] § 93.313(j).

for determining Institutional Actions under the Policy, and communicate the final determinations made on the Allegation of Research Misconduct and any Institutional Actions, as required by 42 C.F.R. §§ 93.218 and 93.314.

The IDO's final written determination will indicate whether UMD found Research Misconduct and, if so, who committed the misconduct.[50] In this statement, the IDO will include a description of relevant Institutional Actions taken or to be taken.[51] The RIO will provide the IDO's written determination and the final Investigation report to the Respondent and the Unit Head. The RIO will include the IDO's final decision in the Institutional Record when transmitting the Institutional Record to ORI.[52]

b. The IDO will determine whether any information or issues that came to the attention of UMD during the UMD portion of the Research Misconduct Proceeding should be referred for review under another UMD policy and make the referral as appropriate.

c. UMD will make diligent efforts to restore the Respondent's reputation, as set forth in Section III.C.10.a., if the Respondent was not found to have engaged in Research Misconduct, and will continue to protect any Complainant, Witness, or other individual involved in the Research Misconduct Proceeding from Retaliation.

2. Institutional Appeal

A Respondent may appeal a finding of Research Misconduct and/or the Institutional Actions included in the IDO's final written determination. The appeal must be made in writing to the IDO within 14 days of the IDO's determination. The IDO will submit the appeal to the Provost for review and decision. The Provost's review of the appeal will be limited to whether or not the Policy and associated Procedures under which the Research Misconduct Proceeding was conducted were adequately followed and/or the appropriateness of the Institutional Actions, respectively.

The Provost may appoint a UMD faculty member or administrator to review the appeal and related Research Misconduct Proceeding records and make recommendations to the Provost ("Provost's designee"). The Provost's designee shall be an individual who does not have an unresolved potential, perceived, or actual Conflict of Interest with the Respondent or Complainant and who has not previously been involved in the Research Misconduct Proceeding and/or appeal. The Provost's designee will be provided with a confidentiality agreement and a certification related to Conflicts of Interest to sign and return to the Provost prior to reviewing the appeal.

[50] § 93.314(a).
[51] § 93.314(b).
[52] § 93.316.

The Provost, or the Provost's designee, may request further information about the Research Misconduct Proceeding in writing from the IDO and/or the RIO. A copy of such information shall be provided to the Respondent.

The Provost shall issue a decision on the appeal within 21 days after the submission of the appeal to the IDO, and inform the IDO of their decision, who will then inform the Respondent. The Provost may extend this review and decision period for good cause by Notice to the Respondent and the IDO.

During appellate proceedings:

- any Institutional Actions prescribed as a consequence of any finding of Research Misconduct, including disciplinary or corrective actions or sanctions, will be on hold; and
- appropriate UMD administrators may implement interim Institutional Actions they deem necessary in accordance with Section II.B.6.

If a Respondent makes an institutional appeal under these Procedures, UMD will promptly notify ORI.

3. The Institutional Record

The Institutional Record comprises:

- the records that UMD compiled or generated during the Research Misconduct Proceeding (except records UMD did not consider or upon which UMD did not rely), which include, but are not limited to:
  - documentation of the Assessment as required by 42 C.F. R. § 93.306(c) and III.B.5. of these Procedures;
  - if an Inquiry is conducted, the Inquiry report and all records (other than drafts of the report) considered or relied upon 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 UMD, and the documentation of any decision not to investigate as required by 42 C.F.R. § 93.309(c);
  - if an Investigation is conducted, the Investigation report and all records (other than drafts of the report) considered or relied upon during the Investigation, including, but not limited to, Research Records, the transcripts of each interview conducted pursuant to 42 C.F.R. § 93.310(g), and information the Respondent provided to UMD;
  - decision by the IDO, such as the written decision from the IDO under 42 C.F.R. § 93.314; and
  - the complete record of any institutional appeal consistent with 42 C.F.R. § 93.315;
- a single index listing all the Research Records and Evidence that UMD compiled during the Research Misconduct Proceeding, except records UMD did not consider or rely upon; and
- a general description of the records that were sequestered but not considered or relied upon.

After the IDO has made a final determination of a Research Misconduct finding in accordance with 42 C.F.R. § 93.314, UMD will transmit the Institutional Record to ORI. The Institutional Record will be consistent with 42 C.F.R. § 93.220 and logically organized.

If a Respondent submits an institutional appeal under these Procedures and UMD has not transmitted its Institutional Record to ORI in accordance with 42 C.F.R. § 93.316 prior to the appeal, UMD will wait until the appeal is concluded to transmit its Institutional Record, ensuring that the complete record of the appeal is included in the Institutional Record consistent with 42 C.F.R. § 93.220(a)(5). If UMD has transmitted its Institutional Record to ORI in accordance with 42 C.F.R. § 93.316 prior to the appeal, UMD will provide ORI a complete record of the appeal once the appeal is concluded.

4. Records Retention

UMD 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 (7) years after the completion of the Proceeding or the completion of any HHS proceeding, whichever is later, unless custody has been transferred to HHS.[53]

[53] § 93.318.