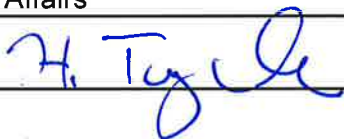


**ADMINISTRATIVE PROCEDURE  
ADMIN-22  
RESEARCH INTEGRITY**

Number: ADMIN-22	Name: Research Integrity
Purpose: This procedure outlines the process required pursuant to Marshall University Policy 20 (UPGA-13) related to research misconduct.	
Responsible Unit: Academic Affairs	
Approved by: 	Approval Date: 5-28-24

**1. Summary.**

- 1.1 This procedure outlines the process required pursuant to Marshall University Policy 20 (UPGA-13) related to **research misconduct**. This procedure uses defined terms with specific meanings as defined in UPGA-13. Defined terms used in this procedure are in **bold** wherever they appear.
- 1.2 This procedure and related UPGA-13 policy are consistent with 42 CFR Part 93. In the case of any conflict between this procedure, UPGA-13 policy and 42 CFR Part 93, the regulation prevails.
- 1.3 This procedure and related policy do not apply to authorship or collaboration disputes and are applicable only to **allegations of research misconduct** that occurred within six years of the date Marshall, or the U.S. Department of Health and Human Services (HHS) received the **allegation**, subject to the subsequent use, health or safety of the public, and grandfather exceptions as outlined in 42 CFR § 93.105(b).

2. **Research Integrity Officer (RIO).** The University employee, appointed by the President of Marshall University, responsible for assessing **allegations of research misconduct**, conducting **investigations** of such **allegations** and for

implementing the administrative procedures. A detailed listing of the responsibilities for the **RIO** are outlined in Attachment A.

### **3. Responsibility to Report Misconduct.**

- 3.1 All employees or individuals associated with Marshall University have the obligation to report to an **institutional official** (See UPGA-13, Section 2.15) potential **research misconduct** as they become aware of it, in a reasonable amount of time and to cooperate in any **investigation** of such behavior. This includes authors who become aware of accusations of **misconduct** concerning their publications.
- 3.2 Informal requests for information or consultation of any University official concerning **research misconduct** will not, in and of itself, be construed as formal charges of **research misconduct**.
- 3.3 If the **allegation** is not **research misconduct**, the **RIO** may refer the **allegation** to other offices for resolution.

### **4. Confidentiality.**

- 4.1 The **RIO** shall, as required by 42 CFR § 93.108: (1) limit disclosure of the identity of **respondents** and **complainants** to those who need to know in order to carry out a thorough, competent, objective, and fair **research misconduct proceeding**; and (2) except as otherwise prescribed by law, limit the disclosure of any records or **evidence** from which **research** subjects might be identified to those who need to know in order to carry out a **research misconduct proceeding**. The **RIO** may use written confidentiality agreements or other mechanisms to ensure that the recipient does not make any further disclosure of identifying information.

### **5. Respondent.**

- 5.1 The **respondent** is responsible for maintaining confidentiality and cooperating with the conduct of an **inquiry** and **investigation**. The **respondent** is entitled to:
  - 5.1.1 A **good faith** effort from the **RIO** to notify the **respondent** in writing at the time of or before beginning an **inquiry**;
  - 5.1.2 An opportunity to comment on the **inquiry report** and those comments attached to the report;
  - 5.1.3 Be notified of the outcome of the **inquiry**, and receive a copy of the **inquiry report** that includes a copy of, or refers to 42 CFR Part 93, and Marshall's policies and procedures on **research misconduct**;

- 5.1.4 Be notified in writing of the **allegations** to be investigated within a reasonable time after the determination that an **investigation** is warranted, but before the **investigation** begins and be notified in writing of any new **allegations**, not addressed in the **inquiry** or in the initial notice of **investigation**, within a reasonable time after the determination to pursue those **allegations**;
  - 5.1.5 Be interviewed during the **investigation**, have the opportunity to correct the recording or transcript;
  - 5.1.6 Have witnesses interviewed during the **investigation** that have been reasonably identified as having information on relevant aspects of the **investigation**;
  - 5.1.7 Receive a copy of the draft **investigation** report and, concurrently, a copy of, or supervised access to the **evidence** on which the report is based and be notified that any comments must be submitted within 30 days of the date on which the copy was received and that the comments will be considered by Marshall and addressed in the final report.
- 5.2 The **respondent** has the opportunity to admit that **research misconduct** occurred, and that **respondent** committed the **research misconduct**. Upon an admission, the **Deciding Official** with the advice of the **RIO**, may terminate Marshall's review of the **allegation** that was been admitted, if the Marshall's acceptance of the admission and any proposed settlement is approved by HHS's Office of Research Integrity (ORI).

## 6. Deciding Official.

- 6.1 The **Deciding Official (DO)** will receive the **inquiry report** and after consulting with the **RIO** and/or other Marshall officials, decide whether an **investigation** is warranted under the criteria in 42 CFR § 93.307(d). Any finding that an **investigation** is warranted must be made in writing by the **DO** and must be provided to ORI, together with a copy of the **inquiry** report meeting the requirements of 42 CFR § 93.309, within 30 days of the finding. If it is found that an **investigation** is not warranted, the **DO** and the **RIO** will ensure that documentation of the **inquiry** is retained for at least 7 years after termination of the **inquiry**, so that ORI may assess the reasons why Marshall decided not to conduct an **investigation**.
- 6.2 The **DO** will receive the **investigation** report and, after consulting with the **RIO** and/or other Marshall officials, decide the extent to which Marshall accepts the findings of the **investigation** and, if **research misconduct** is found, decide what, if any, institutional administrative actions are appropriate. The **DO** shall ensure that the final **investigation** report, the findings of the **DO** and a description of any pending or completed administrative actions are provided to ORI, as required by 42 CFR § 93.315.

## 7. Conducting the Assessment and Inquiry.

- 7.1 Upon receiving an **allegation** of **research misconduct**, the **RIO** will assess the **allegation** to determine whether it is submitted in good faith; fits within the definition of **research misconduct**; is within the six-year time limit and does not meet an exception to the six-year time limit; and is sufficiently credible and specific so that potential **evidence** of **research misconduct** may be identified. If these criteria are met, an **inquiry** will be conducted.
- 7.2 The assessment period should be brief, preferably concluded within thirty (30) days, or as soon as practicable, depending upon the complexity of the **allegation**.
- 7.3 The **RIO** will ensure that the dean of the college in which the **respondent** is employed is informed of the **allegation**. If the **allegation** does not name a specific **respondent**, the **RIO**, in consultation with the dean, will determine, to the extent possible, the roles and responsibilities of the individuals involved in the questioned **research** in order to name one or more **respondents**.
- 7.4 In conducting the assessment, the **RIO** need not interview the **complainant**, **respondent**, or other witnesses, or gather data beyond any that may have been submitted with the **allegation**, except as necessary to determine whether the **allegation** is sufficiently credible and specific so that potential **evidence** of **research misconduct** may be identified. The **RIO** shall, on or before the date on which the **respondent** is notified of the **allegation**, obtain custody of, inventory, and sequester all **research records** and **evidence** needed to conduct the **research misconduct proceeding**. (See Attachment B, Sequestration and Retention of Records).
- 7.5 If the **RIO** determines that the criteria for an **inquiry** are met, the **RIO** will immediately initiate the **inquiry** process. The purpose of the **inquiry** is to conduct an initial review of the available **evidence** to determine whether to conduct an **investigation**. An **inquiry** does not require a full review of all the **evidence** related to the **allegation**. If the **RIO** and dean do not concur on the final decision of the preliminary assessment, the preliminary assessment report will include each decision, and the **DO** will make the final determination.
- 7.6 Marshall's jurisdiction encompasses **allegations** related to all **research** conducted while a **respondent** was under the oversight of Marshall; as part of their employment or student duties; using facilities or equipment provided by Marshall; or research otherwise affiliated with Marshall.

Marshall does not have jurisdiction over **allegations** related to **research** conducted at another university or another research entity.

- 7.7 If the **RIO** finds that an **allegation** is not under the jurisdiction of Marshall, the **RIO** will refer the **allegation** to the appropriate office at the home institution.
- 7.8 If the **RIO** finds that an **allegation** fails to indicate possible **research misconduct**, if the **complainant** is known, **the complainant** will be notified if the **allegation** is dismissed.
- 7.9 At the time of or before beginning an **inquiry**, the **RIO** must make a **good faith** effort to notify the **respondent** in writing, if the **respondent** is known. If the **inquiry** subsequently identifies additional **respondents**, they must be notified in writing. On or before the date on which the **respondent** is notified, or the **inquiry** begins, whichever is earlier, the **RIO** must take all reasonable and practical steps to obtain custody of all the **research records** and **evidence** needed to conduct the **research misconduct proceeding**, inventory the records and **evidence** and sequester 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 such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.
- 7.10 The **RIO**, in consultation with other Marshall officials as appropriate, will appoint an **inquiry** committee as soon as is practical. The **inquiry** committee must consist of individuals who have no unresolved **conflicts of interest** with those involved with the **inquiry** and should include individuals with the appropriate scientific expertise to evaluate the **evidence** and issues related to the **allegation**, interview the principals and key witnesses, and conduct the **inquiry**.

## 8. Inquiry Committee.

- 8.1 The **RIO** will prepare a charge for the **inquiry committee** that:
  - 8.1.1. Establishes a time for the **inquiry's** completion;
  - 8.1.2. Outlines the **allegation** and any related issues identified during the assessment;
  - 8.1.3. States that the purpose of the **inquiry** is to conduct an initial review of the **evidence**, including the testimony of the **respondent**, **complainant** and key witnesses, to determine whether an **investigation** is warranted, not to determine whether **research misconduct** definitely occurred or who was responsible;

- 8.1.4. Explains that an **investigation** is warranted if the committee determines: (1) there is a reasonable basis for concluding that the **allegation** falls within the definition of **research misconduct** and is within the criteria of 42 CFR § 93.102(b); and (2) the **allegation** may have substance, based on the committee's review during the **inquiry**;
  - 8.1.5. Informs the **inquiry committee** that it will prepare or direct the preparation of a written report of the **inquiry** that meets the requirements of this policy and 42 CFR § 93.309(a).
- 8.2. When the **inquiry committee** first convenes, the **RIO** will review the charge with the committee, discuss the **allegations**, any related issues, the appropriate procedures for conducting the **inquiry**, assist the committee with organizing plans for the **inquiry**, and answer any questions raised by the committee. The **RIO** will be present or available throughout the **inquiry** to advise the committee as needed.
- 8.3. The **inquiry committee** will interview the **complainant** (if known), the **respondent**, and key witnesses as well as examining relevant **research records** and materials. Then, the **inquiry committee** will evaluate the **evidence**, including the testimony obtained during the **inquiry**. After consultation with the **RIO**, the committee members will decide whether an **investigation** is warranted based on the criteria in this policy and 42 CFR § 93.307(d). The scope of the **inquiry** is not required to and does not need to include a decision of whether misconduct definitely occurred, or determine definitely who committed the **research misconduct**, or conducting exhaustive interviews and analyses. However, if an admission of **research misconduct** is made by the **respondent**, misconduct may be determined at the **inquiry** stage if all relevant issues are resolved.
- 8.4. The **inquiry**, including preparation of the final **inquiry** report and the decision of the **DO** on whether an **investigation** is warranted, must be completed within 60 calendar days of initiation of the **inquiry**, unless the **RIO** determines that circumstances clearly warrant a longer period. If the **RIO** approves an extension, the **inquiry** record must include the reasons for exceeding the 60-day period.
- 8.5. The **inquiry** report must include the following information:
  - 8.5.1. the name and position of the **respondent**;
  - 8.5.2. a description of the **allegations** of **research misconduct**;
  - 8.5.3. the PHS support, including, for example, grant numbers, grant applications, contracts and publications listing PHS support;
  - 8.5.4. the basis for recommending or not recommending that the **allegation** warrants an **investigation**;
  - 8.5.5. comments on the draft report made by the **respondent** or

## **complainant.**

- 8.6 The **RIO** shall notify the **respondent** whether the **inquiry** found that an **investigation** is warranted, includes a copy of the draft **inquiry** report for comment within 10 working days, and provides a copy of Marshall's policies and procedures on **research misconduct**.
- 8.7 Any comments that are submitted by **respondent** or **complainant** will be attached to the final **inquiry** report. Based on the comments, the **inquiry** committee may revise the draft report as appropriate and prepare it in final form. The committee will deliver the final report to the **RIO**.
- 8.8 General Counsel's office may review the **inquiry** report for legal sufficiency. Modifications should be made as appropriate in consultation with the **RIO** and the **inquiry committee**.
- 8.9 The **RIO** will transmit the final **inquiry** report and any comments to the **DO**, who will determine in writing whether an **investigation** is warranted. The **inquiry** is completed when the **DO** makes this determination.
- 8.10 If the final decision from the **inquiry** is that an **investigation** is warranted, the **RIO** will inform any cognizant oversight agency or funding entity of the **allegation**, within 30 calendar days, and will keep the oversight agency or funding entity informed as required.
- 8.11 If the **DO** decides that an **investigation** is not warranted, the **RIO** shall secure and maintain for seven (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. These documents must be provided to ORI or other authorized HHS personnel upon request.

## **9. Investigation.**

- 9.1 The **investigation** is not intended to be a formal legal proceeding. Therefore, Marshall does not consider it necessary for any party, including the University, to be represented by counsel. **Respondent** may, at **respondent's** expense, obtain the advice of counsel in connection with such **proceedings**. If **respondent** chooses to be represented by an attorney, notice must be given to the **RIO** at least five (5) business days prior to the scheduled meeting and a University assigned advisor will no longer be provided.
- 9.2 The purpose of the **investigation** is to determine whether the **allegation** constitutes **research misconduct** based upon a **preponderance of the evidence** standard and to recommend the appropriate corrective actions

or sanctions.

- 9.3 During the **investigation**, diligent efforts will be made to ensure the **investigation** is thorough and sufficiently documented and includes examination of all research records and **evidence** relevant to reaching a decision on the merits of the **allegation**. The **investigation** will also determine whether there are additional instances of possible **research misconduct** that would justify broadening the scope beyond the initial **allegations**.
- 9.4 Once the **DO** determines that an **investigation** is warranted, the **investigation** must begin within 30 calendar days.
- 9.5 The **investigation panel** will interview each **respondent**, each **complainant** (if known), 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**.
- 9.6 The **investigation panel** will have the appropriate expertise to ensure a thorough evaluation of the **evidence**. The panel may include consultants, from within or outside of Marshall, with the appropriate expertise to aid the panel in evaluating the **evidence** and/or recommending appropriate corrective actions or sanctions. The panel will be chosen by Marshall.
- 9.7 The **investigation panel** must consider if: (1) there was a significant departure from accepted practices of the relevant **research** community; and (2) the **misconduct** was committed **intentionally, knowingly, or recklessly**; and (3) the **allegation** was proven by a **preponderance of the evidence**.
- 9.8 If the **investigation panel** determines that **research misconduct** is substantiated by the **investigation** findings, the **RIO** will make recommendations on administrative actions that can be taken against the **respondent**.
- 9.9 If the **investigation panel** determines the **respondent** did not commit **research misconduct**, Marshall may, to the extent possible, work with the **respondent** to rectify any injury done to the reputation of **respondent**, including providing a letter of the results of the **investigation**.
- 9.10 The charge to the **investigation panel** comes from the **RIO** and includes:
  - 9.10.1. **Allegation** and related issues identified during the **inquiry**;
  - 9.10.2. Identity of **respondent**;
  - 9.10.3. Instruction that **investigation** will be conducted according to this procedure;



- 9.10.4. Definition of **research misconduct**;
  - 9.10.5. Information that the committee must evaluate the **evidence** and testimony to determine whether, based on a **preponderance of the evidence**, **research misconduct** occurred and, if so, the type and extent of it and who was responsible;
  - 9.10.6. Information to the committee that in order to determine that the **respondent** committed **research misconduct** it must find that a **preponderance of the evidence** establishes that: (1) **research misconduct**, as defined in this procedure, occurred (**respondent** has the burden of proving by a **preponderance of the evidence** any **affirmative defenses** raised, including **honest error** or a **difference of opinion**); (2) the **research misconduct** is a significant departure from accepted practices of the relevant research community; and (3) the **respondent** committed the **research misconduct intentionally, knowingly, or recklessly**; and
  - 9.10.7. The committee must prepare or direct the preparation of a written **investigation** report that meets the requirements of this policy and 42 CFR § 93.313.
- 9.11 The **RIO** will convene the first meeting of the **investigation panel** to review the charge, the **inquiry** report, and the prescribed procedures and standards for the conduct of the **investigation**, including the necessity for confidentiality and for developing a specific **investigation** plan. The **investigation committee** will be provided with a copy of this procedure and all related **research misconduct** policies, along with 42 CFR Part 93. The **RIO** will be present or available throughout the **investigation** to advise the committee as needed.
- 9.12 The **investigation** should be completed within 120 days of its beginning, including conducting the **investigation**, preparing the report of findings, providing the draft report for comment and sending the final report to ORI. However, if the **RIO** determines that the **investigation** will not be completed within this 120-day period, the **RIO** will submit a written request for an extension to ORI, explaining the reasons for the delay. The **RIO** will ensure that periodic progress reports are filed with ORI, if ORI grants the request for an extension and directs the filing of such reports.

## 10. Investigation Report.

- 10.1 The **investigation committee** and the **RIO** are responsible for preparing a written draft report of the **investigation** that:
  - 10.1.1. Describes the nature of the **allegation of research misconduct**, including identification of the **respondent**;
  - 10.1.2. Describes and documents the PHS support, including, for

- example, the numbers of any grants that are involved, grant applications, contracts, and publications listing PHS support;
- 10.1.3. Describes the specific **allegations of research misconduct** considered in the **investigation**;
  - 10.1.4. Includes Marshall's **research misconduct** policies and procedures under which the **investigation** was conducted, unless those policies and procedures were provided to ORI previously;
  - 10.1.5. Identifies and summarizes the **research records** and **evidence** reviewed and identifies any **evidence** taken into custody but not reviewed; and
  - 10.1.6. Includes a statement of findings for each **allegation of research misconduct** identified during the **investigation**.
  - 10.1.7. Each statement of finding must:
    - 10.1.7.1. Identify whether the **research misconduct** was **falsification, fabrication, or plagiarism**; and
    - 10.1.7.2. Whether the **misconduct** was committed **intentionally, knowingly, and/or recklessly**; and
    - 10.1.7.3. Summarizes the facts and the analysis that support the conclusion and consider the merits of any reasonable explanation by the **respondent**, including any effort by **respondent** to establish by a **preponderance of the evidence** that it was not **research misconduct** because of **honest error** or a **difference of opinion**; and
    - 10.1.7.4. Identify the specific PHS support; and
    - 10.1.7.5. Identify whether any publications need correction or retraction; and
    - 10.1.7.6. Identify the person responsible for the **misconduct**; and
    - 10.1.7.7. List any current support or known applications or proposals for support that the **respondent** has pending with non-PHS federal agencies.
- 10.2 The **RIO** must give the **respondent** a copy of the draft investigation report for comment and, concurrently, a copy of, or supervised access to the **evidence** on which the report is based. The **respondent** is allowed 30 calendar days from the date the draft report is received to submit comments to the **RIO**. The **respondent's** comments must be included and considered in the final report.
- 10.3 When distributing the draft report to the **respondent** the **RIO** will inform the **respondent** of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. Such as, the **RIO** may require that **respondent** sign a confidentiality agreement.

## 11. Decision by Deciding Official.

- 11.1 The **RIO** will assist the **investigation committee** in finalizing the draft **investigation** report, including ensuring that the **respondent's** comments are included and considered, and transmit the final **investigation** report to the **DO**.
- 11.2 The **DO** will determine whether:
  - 11.2.1. Marshall accepts the **investigation report**, its findings, and the recommended institutional actions; and
  - 11.2.2. The appropriate institutional actions in response to the accepted findings of **research misconduct**.
- 11.3 If the **DO's** determination varies from the findings of the **investigation committee**, the **DO** will explain in writing the detailed basis for rendering a decision different from the findings of the **investigation committee**. Additionally, the **DO** may return the report to the **investigation committee** with a request for further fact-finding or analysis.
- 11.4 When a final decision is made, the **DO** will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the **respondent** in the work, or other relevant parties should be notified of the outcome of the case. The **RIO** is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.
- 11.5 If the **DO** determines that **research misconduct** is substantiated by the findings, the **DO** will decide on the appropriate actions to be taken, after consultation with the **RIO**. The administrative actions may include a variety of sanctions, up to and including termination and/or expulsion from Marshall. The seriousness of the misconduct, along with the nature of the misconduct (e.g., **knowingly, intentionally, recklessly**), any **mitigating factors**, whether the incident was isolated, or part of a pattern, will be factors considered in determining sanctions.

## 12. Notice to ORI and Retention of Records.

- 12.1 Unless an extension has been granted by ORI, the **RIO** must—within the 120-day period for completing the **investigation**—submit the following to ORI:
  - 12.1.1. A copy of the final **investigation** report with all attachments; and
  - 12.1.2. A statement of whether Marshall accepts the findings of the **investigation** report; and

- 12.1.3. A statement of whether Marshall found **research misconduct** and, if so, who committed the **misconduct**; and
- 12.1.4. A description of any pending or completed administrative actions against the **respondent**.
- 12.2 The **RIO** must maintain and provide to ORI upon request “records of **research misconduct proceedings**” as defined by 42 CFR § 93.317. Unless custody has been transferred to HHS or ORI has advised in writing that the records no longer need to be retained, records of **research misconduct proceedings** must be maintained in a secure manner for seven (7) years after completion of the **proceeding** or the completion of any PHS **proceeding** involving the **research misconduct allegation**.
- 12.3 The **RIO** will also provide any information, documentation, **research records, evidence** or clarification requested by ORI to carry out its review of an **allegation of research misconduct** or of Marshall’s handling of such an **allegation**.
- 12.4 The **RIO** must notify ORI in advance if there are plans to close a case at the **inquiry** or **investigation** stage on the basis that **respondent** has admitted guilt, a settlement with the **respondent** has been reached, or for any other reason, **except**: (1) closing of a case at the **inquiry** stage on the basis that an **investigation** is not warranted; or (2) a finding of no **research misconduct** at the **investigation**.
- 12.5 Termination of the **respondent's** employment, by resignation or otherwise, or after a student graduates or withdraws from Marshall before or after an **allegation** of possible **research misconduct** has been reported, will not terminate the **research misconduct proceeding** or limit Marshall’s responsibilities under 42 CFR Part 93.
- 12.6 Should the **respondent**, without admitting the **allegation of misconduct**, resign from Marshall after an **allegation of research misconduct** was received, the assessment of the **allegation** will proceed, as well as any **inquiry** and **investigation** that is necessary. If the **respondent** refuses to participate in the process after resignation, the **RIO** and any **inquiry** or **investigation panel** will use their best efforts to reach a conclusion concerning the **allegations**, noting in the report the **respondent's** failure to cooperate and its effect on the **evidence**.

### **13. Restoration of the Respondent's Reputation.**

- 13.1 If the final finding is no **research misconduct** occurred and when required by 42 CFR Part 93, ORI concurs, the **RIO** must, at the request of the **respondent**, undertake all reasonable and practical efforts to restore the **respondent's** reputation. Depending on the circumstances, the **RIO**

will consider notifying those individuals aware of or involved in the **investigation** of the final outcome, publicizing the final outcome in any forum in which the **allegation of research misconduct** was previously publicized, and expunging all reference to the **research misconduct allegation** from the **respondent's** personnel file. Any institutional actions to restore the **respondent's** reputation should first be approved by the **DO**.

## ATTACHMENT A RIO RESPONSIBILITIES

The **Research Integrity Officer (RIO)** has lead responsibility for ensuring that Marshall:

- A.1 Complies with its written policies and procedures and the requirements of 42 CFR Part 93.
- A.2 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**.
- A.3 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.
- A.4 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.
- A.5 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.

### **B. Notice and Reporting to ORI and Cooperation with ORI**

The **RIO** has lead responsibility for ensuring that Marshall:

- B.1 Files an annual report with ORI containing the information prescribed by ORI.
- B.2 Sends to ORI with the annual report such other aggregated information as ORI may prescribe on Marshall's **research misconduct proceedings** and Marshall's compliance with 42 CFR Part 93.
- B.3 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**, Marshall believes that the **research misconduct proceeding** may be made public prematurely, or the research community or the public should be informed.
- B.4 Provides ORI with the written finding by the responsible institutional official that an **investigation** is warranted and a copy of the **inquiry** report, within thirty (30) days of the date on which the finding is made.
- B.5 Notifies ORI of the decision to begin an **investigation** on or before the date the **investigation** begins.
- B.6 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 of whether Marshall accepts the **investigation's** findings, a

statement of whether Marshall found **research misconduct** and, if so, who committed it, and a description of any pending or completed administrative actions against the **respondent**.

- B.7 Seeks ORI advance approval if Marshall plans to close a case at the **inquiry** or **investigation** 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.
- B.8 Cooperates fully with ORI during its oversight review and any subsequent administrative hearings or appeals, including providing all research records and **evidence** under Marshall's control, custody, or possession and access to all persons within its authority necessary to develop a complete record of relevant **evidence**.

### C. Research Misconduct Proceeding

The RIO is responsible for:

- C.1 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.
- C.2 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**.
- C.3 Providing confidentiality to those involved in the **research misconduct proceeding** as required by 42 CFR § 93.108, other applicable law, and Marshall policy.
- C.4 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**.
- C.5 Keeping the **DO** and others who need to know apprised of the progress of the review of the **allegation** of **research misconduct**.
- C.6 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.
- C.7 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.
- C.8 Assisting the **DO** in implementing the decision to take administrative

- action against any **complainant**, witness, or committee member determined by the **DO** not to have acted in **good faith**.
- C.9 Maintaining records of the **research misconduct proceeding**, as defined in 42 CFR § 93.317, in a secure manner for seven (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.
- C.10 Ensuring that administrative actions taken by Marshall and ORI are enforced and taking appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards, of those actions.

#### D. Allegation Receipt and Assessment

The **RIO** is responsible for:

- D.1 Consulting confidentially with persons uncertain about whether to submit an **allegation of research misconduct**.
- D.2 Receiving **allegations of research misconduct**.
- D.3 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.

#### E. Inquiry

The **RIO** is responsible for:

- E.1 Initiating the **inquiry** process if it is determined that an **inquiry** is warranted.
- E.2 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.
- E.3 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.
- E.4 Appointing an **inquiry committee** and committee chair as soon after the initiation of the **inquiry** as is practical.
- E.5 Preparing a charge for the **inquiry committee** in accordance with



- Marshall's policies and procedures.
- E.6 Convening the first meeting of the **inquiry committee** 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.
  - E.7 Providing the **inquiry committee** with needed logistical support, e.g., expert advice, including forensic analysis of **evidence**, and clerical support, including arranging witness interviews and recording or transcribing those interviews.
  - E.8 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 Marshall's policies and procedures and 42 CFR § 93.307(d).
  - E.9 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**.
  - E.10 Assisting the **inquiry committee** in preparing a draft **inquiry** report, sending the **respondent** a copy of the draft report for comment 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 ensuring that the comments are attached to the final **inquiry** report.
  - E.11 Receiving the final **inquiry** report from the **inquiry committee** and forwarding it, together with any comments the **RIO** may wish to make, to the **DO** who will determine in writing whether an **investigation** is warranted.
  - E.12 Within thirty (30) days of a **DO** 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.
  - E.13 Notifying the **respondent** whether the **inquiry** found an **investigation** to be warranted and including in the notice copies a reference to 42 CFR Part 93 and Marshall's **research misconduct** policies and procedures.
  - E.14 Providing to ORI, upon request, Marshall's 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**.
  - E.15 If the **DO** 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.

## F. Investigation

The **RIO** is responsible for:

- F.1 Initiating the **investigation** within 30 calendar days after the determination by the **DO** that an **investigation** is warranted.
- F.2 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.
- F.3 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**.
- F.4 In consultation with other **institutional officials** as appropriate, appointing an **investigation committee** and committee chair as soon after the initiation of the **investigation** as is practical.
- F.5 Preparing a charge for the **investigation committee** in accordance with Marshall's policies and procedures.
- F.6 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 Marshall's policies and procedures and 42 CFR Part 93.
- F.7 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.
- F.8 Being available or present throughout the **investigation** to advise the committee as needed.
- F.9 On behalf of Marshall, 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.
- F.10 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.
- F.11 Assisting the **investigation** committee in preparing a draft **investigation** report that meets the requirements of 42 CFR Part 93 and Marshall's policies and procedures, sending the **respondent** a copy of the draft report for comment within thirty (30) days of receipt, taking appropriate action to protect the confidentiality of the draft report, receiving any comments from the **respondent** and ensuring that the comments are included and considered in the final **investigation** report.
- F.12 Transmitting the draft **investigation** report to the Office of General Counsel for a review of its legal sufficiency.
- F.13 Assisting the **investigation committee** in finalizing the draft **investigation** report and receiving the final report from the committee.
- F.14 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 Marshall accepts the findings of the report, a statement of whether Marshall found **research misconduct**, and if so, who committed it, and a description of any pending or completed administrative actions against the **respondent**.
- F.15 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.
- F.16 Maintaining and providing to ORI upon request all relevant research records and records of Marshall's **research misconduct proceeding**, including the results of all interviews and the transcripts or recordings of those interviews.

## ATTACHMENT B SEQUESTRATION AND RETENTION OF RECORDS

### A. Regulatory Authority and Requirements

42 CFR Part 93 requires Marshall to identify, sequester, and protect **evidence** pertinent to the review of an **allegation of research misconduct** in a timely manner. The federal regulation 42 C.F.R. §93.305 states:

**Responsibility for maintenance and custody of research records and evidence.** An institution, as the responsible legal entity for the PHS supported research, has a continuing obligation under this part to ensure that it maintains adequate records for a research misconduct proceeding. The institution must—

(a) Either before or when the institution notifies the Respondent of the allegation, inquiry or investigation, promptly take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester 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 such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments;

(b) Where appropriate, give the Respondent copies of, or reasonable, supervised access to the research records;

(c) Undertake all reasonable and practical efforts to take custody of additional research records or evidence that is discovered during the course of a research misconduct proceeding, 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 such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments; and

(d) Maintain the research records and evidence as required by §93.317.

The regulation states that for an institutional **inquiry**, 42 C.F.R. §93.307(3)(b), that on or before the date on which the **respondent** is notified or the **inquiry** begins, **whichever is earlier**, Marshall must promptly take all reasonable and practical steps to obtain custody of all the **research records**; and for an

institutional **investigation**, 42 C.F.R. §93.310(d), to the extent Marshall has not already done so at the **allegation** or **inquiry** stages, take all reasonable and practical steps to obtain custody of all the **research records** including whenever additional items become known or relevant to the **investigation**.

Under this procedure, the **RIO** has the responsibility and authority to sequester any relevant **evidence** at the earliest opportunity in a **research misconduct proceeding**; the **RIO** shall take immediate action to sequester all data or other materials relevant to the **allegation**, on or before the date on which the **respondent** is notified of the **allegation**, and shall obtain custody of, and sequester in a secure manner, all **research records** that have become known and are relevant to the **investigation**.

Under UPGA-13, the **research record** is defined as: "The record of experimental methods, data, and results, whether in physical or electronic form, that embodies the facts related to and resulting from scientific inquiry. The **research record** includes but is not limited to research proposals, grant or contract applications, laboratory notebooks and records, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, animal facility records; human and animal subject protocols; consent forms; medical charts; records of telephone calls or e-mail correspondence; and patient files."

Basic assumptions and core principles when preparing for sequestration of **research records** are:

- A.1 In the absence of information identifying the specific **respondent**, the corresponding author of any questioned manuscript or publication is considered the putative **respondent**. The first author is also typically considered a putative **respondent**.
- A.2 For grant proposals, the principal investigator, as designated in the grant proposal, is considered the putative **respondent**.
- A.3 A primary goal in the meeting to notify a putative **respondent** about the **allegation** is to determine the responsibility of the **respondent** for each specific **allegation**.
- A.4 Sequestration should encompass all email, electronic, and physical records relevant to the **allegation**.
- A.5 The practice is that when there is doubt, sequester broadly. Any sequestered data that is subsequently determined to be unrelated to the **allegation** may be returned to the **respondent**.
- A.6 Should new **allegations** or identification of **respondent** necessitate the sequestration of additional materials, email accounts, etc., steps will be taken to do so as soon as possible according to these procedures.

## **B. Sequestration**

### **B.1 Email**

Email sequestration is handled separately from sequestration of other types of electronic **research records**. Marshall email services and the contents of the sequestered email account are transferred to the Vice President of Research, under specific conditions listed below.

**Prior to Respondent's notification of allegations:**

- B.1.1 When **respondent** is identified, the **RIO** will send a notification email to the Office of General Counsel, the Information Technology Office, and the Vice President for Research. The email will state that Marshall is in receipt of an **allegation** of possible **research misconduct** and will request that a litigation hold be put on one or more email accounts for each **respondent**. The request will state that the hold be done without notification to the **respondent**.
- B.1.2 If **respondent** is unknown, litigation holds will be placed as broadly as needed (e.g., all Marshall authors listed on a questioned manuscript or publication). The litigation holds are to be done in the background and have no impact on the individuals. Once specific **respondents** are identified, unnecessary holds can be lifted.

**Subsequent to Respondent's notification of allegations:**

- B.1.3 If during an **inquiry** or an **investigation** a need arises for specific emails, the **RIO** will make the request through the Office of General Counsel for the specific email that the committee requires and will provide potential search terms and a justification for what is being requested. Searches will be approved by General Counsel and will be conducted by the Information Technology Office.
- B.1.4 If emails contain protected health information (PHI) or other HIPAA protected information they will be screened for PHI by the privacy officer prior to release to the committee.

**B.2 Non-email based electronic file sequestration**

**Prior to Respondent's notification of allegations:**

- B.2.1 Based on the **allegation**, the **RIO** and Information Technology Office staff will assess the specific electronic data to sequester, the likely format of the data, and how it will be stored.
- B.2.2 The **RIO** and IT staff will contact the local college to determine how many and what types of computer systems, file servers, networked laboratory machines, etc., the **respondent** uses.
- B.2.3 The **RIO** and IT staff will:

- B.2.3.1 determine what electronic files can be forensically imaged in the background prior to notifying the **respondent** of the **allegation**;
- B.2.3.2 establish and initiate a plan to capture all available electronic images prior to **respondent's** notification – if it can be done silently in the background;
- B.2.3.3 determine if any cloud-based services may hold relevant data and whether it is possible to access relevant files (Marshall hosted verses external vendor).

**Subsequent to Respondent's notification of allegations:**

- B.2.4 The **RIO** will arrange for IT staff to assist with electronic records capture subsequent to meeting with the **respondent**.
- B.2.5 The IT staff will:
  - B.2.5.1 Make forensic images of any computer system that could not be remotely imaged before meeting with the **respondent**. This may include laptops, stand-alone analytical machines, or other systems not connected to the network;
  - B.2.5.2 Pull hard drives for imaging – note location, machine number, serial number, equipment tags, take photos of system;
  - B.2.5.3 When necessary, sequester entire system (e.g., laptops, Macs) – note location, machine number, serial number, equipment tags;
  - B.2.5.4 Capture data from lab machines where drives cannot be removed (e.g., those running lab instruments); and
  - B.2.5.5 Determine encryption status on all systems.
- B.2.6 For personally owned computers containing Marshall data:
  - B3.3.1 Student owned machines need a consent form signed for imaging their personal computer.
  - B3.3.2 No consent form is needed for machines owned by faculty.
- B.2.7 For sequestration of research records for students, the **RIO** must obtain a signed a FERPA release form and/or the student must allow the records to be sequestered.

**B.3 Physical files and materials sequestration**

**Prior to Respondent's notification of allegations:**

- B.3.1 The **RIO** will determine what physical evidence needs to be sequestered and any special storage requirements that might be needed (e.g., freezer, refrigerator, protected from light, biohazardous, radioactive, strong odor).
- B.3.2 Identify and acquire appropriate secure storage based on any special needs.
- B.3.3 Determine the different locations where evidence may be found (e.g., office spaces, lab spaces, core facilities). If multiple sites are involved, plan for parallel or sequential sequestration processes and coordinate with the college for assistance.
- B.3.4 If possible, arrange sequestration during a time that minimizes the presence of extraneous people.

**Subsequent to Respondent's notification of allegations:**

- B.3.5 The **RIO** will go with **respondent** directly to all locations identified as having physical evidence. There should be at least two people present during all phases of sequestration and copying of **evidence**.
- B.3.6 **Respondent** will be asked to identify all physical evidence (lab notebooks, documents, any kind of physical record, slides, x-ray films, blots, etc.) related to the **allegation**.
- B.3.7 If a sequestration sheet is generated while the **RIO** is with the **respondent**, **respondent** will sign the sheet. Once initial sequestration is complete, the **RIO** will create a data sequestration log listing all the materials sequestered. The **RIO** will send a copy of the log to **respondent**.

**C. Access to sequestered materials**

- C.1 Access to sequestered materials may be provided to the investigative bodies looking into the **allegation** and to any other person who has a legitimate reason related to the university process to require access (e.g. Office of General Counsel). Removal is to be documented in an access log.
- C.2 Supervised access to any physical, sequestered material shall be provided to the **respondent**, and to any other person who requires access, as determined by the **RIO** to have a legitimate reason.
  - C.2.1 Requests for data review must be submitted to the **RIO**. A date and time of data review will be coordinated that is mutually agreeable to Marshall and requesting party.
  - C.2.2 A Marshall staff member must be present with the sequestered materials at all times during the supervised review.