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A person who, at the time of the alleged research misconduct, was employed by, was an agent of, or was affiliated by contract or agreement with this institution;<sup>1</sup> and

(1) PHS support biomedical or behavioral research, research training or activities related to that research or research training, such as the operation of tissue and data banks and the dissemination of research information, (2) applications or proposals for PHS support for biomedical or behavioral research, research training or activities related to that research or research training, or (3) plagiarism of research records produced in the course of PHS supported research, research training or activities related to that research or research training. This includes any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application or proposal for PHS funds resulted in a grant, contract, cooperative agreement, or other form of PHS support.<sup>2</sup>

This statement of policy and procedures does not apply to authorship or collaboration disputes and applies only to allegations of research misconduct that occurred within six years of the date the institution or HHS received the

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words without giving appropriate credit. Research misconduct does not include honest error or differences of opinion.

15. Research Misconduct Ptqeggf kpi 0öTgugctej "o kœqpf wev'r tqeggf kpi ö'o gcpu'cp{" actions related to alleged research misconduct, including but not limited to, allegation assessments, inquiries, investigations, oversight reviews by the relevant office of any involved funding entity, hearings and administrative appeals.

16. Research Rgeqtf 0öTgugctej "tgeqtf ö'o gcpu'vj g'tgeqtf "qh'f cv'qt "tguwmu'vj cv'go dqf {" the facts resulting from scientis7(c)-15(i)18(e)2( )-9(o(r)-6(qu)-19(i)18(r)-26(i)18(e)-15 )-9(h)20(e)--6(c)

forth in Appendix A. These responsibilities include, but are not limited to, the following duties related to research misconduct proceedings:

Consult confidentially with persons uncertain about whether to submit an allegation of research misconduct;

Receive allegations of research misconduct;

Assess each allegation of research misconduct in accordance with Section V.A. of this policy to determine whether it falls within the definition of research misconduct and warrants an inquiry;

As necessary, take interim action and notify ORI of special circumstances, in accordance with Section IV.F of this policy;

Obtain research data and evidence pertinent to the allegation of research misconduct in accordance with Section V.C. of this policy and maintain it securely in accordance with this policy and applicable law and regulation;

Provide confidentiality to those involved in the research misconduct proceeding as required by 42 CFR § 93.108, and subject to other applicable law, and institutional policy;

Notify the respondent and provide opportunities for the respondent to review/ comment/respond to allegations, evidence, and committee reports in accordance with Section III.C. of this policy;

Inform respondents, complainants, and witnesses of the procedural steps in the research misconduct proceeding;

Appoint, after consultation Provost and Executive Vice President of Academic Affairs (EVP), the chair and members of the inquiry and investigation committees, ensure that those committees are properly staffed and that there is expertise appropriate to carry out a thorough and authoritative evaluation of the evidence;

Determine whether each person involved in handling an allegation of

faith complainants, witnesses, and committee members and counter potential or actual retaliation against them by respondents or other institutional members;

Keep the Deciding Official and others who need to know apprised of the progress of the review of the allegation of research misconduct;

Notify and make reports to ORI as required by 42 CFR Part 93;

Ensure that administrative actions taken by the institution and ORI are enforced and take appropriate action, if necessary, to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards of those actions; and

Maintain records of the research misconduct proceeding and make them available to ORI in accordance with Section VIII.F of this policy.

#### B. Complainant

The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the inquiry and investigation. As a matter of good practice, the complainant should be interviewed at the inquiry stage and given the transcript or recording of the interview for correction. The complainant must be interviewed during an investigation, and be given the transcript or recording of the interview for correction.<sup>3</sup> On the basis of a case-by-case determination, the institution may provide to the complainant for comment: (1) relevant portions of the inquiry report (within a timeframe that permits the inquiry to be completed within 60 days of its initiation); and (2) the draft investigation report or relevant portions of it. Comments on the draft investigation report be submitted within 30 days of the date on which the complainant received the draft report. The institution will consider any comments made by the complainant on the draft investigation report and include those comments in the final investigation report.

#### C. Respondent

The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry and investigation. The respondent is entitled to:

A good faith effort from the RIO to notify the respondent in writing at the time of or before beginning an inquiry;<sup>4</sup>

An opportunity to comment on the inquiry report and have his/her comments attached to the report;<sup>5</sup>





investigation is warranted must be made in writing by the DO and must be

C. Confidentiality

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 should use written confidentiality agreements or other mechanisms to ensure that the recipient does not make any further disclosure of identifying information.

D. Protecting complainants, witnesses, and committee members

Institutional members may not retaliate in any way against complainants, witnesses, or committee members. Institutional members should immediately report any alleged or apparent retaliation against complainants, witnesses or committee members to the RIO, who shall review the matter and, as necessary, make all reasonable and practical efforts to counter any potential or actual retaliation and protect and restore the position and reputation of the person against whom the retaliation is directed.

E. Protecting the Respondent

As requested and as appropriate, the RIO and other institutional officials shall make all reasonable and practical efforts 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.<sup>13</sup>

During the research misconduct proceeding, the RIO is responsible for ensuring that respondents receive all the notices and opportunities provided for in 42 CFR Part 93 and the policies and procedures of the institution. Respondents may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice and may bring the counsel or personal adviser to interviews or meetings on the case. In the event the respondent desires counsel to be present at interviews and meetings then the la



and sequester all research records and evidence needed to conduct the research misconduct proceeding, as provided in paragraph C. of this section.

B. Initiation and Purpose of the Inquiry

If the RIO determines that the criteria for an inquiry are met, he or she 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.<sup>17</sup>

C. Notice to Respondent; Sequestration of Research Records

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.<sup>18</sup> The RIO may consult with ORI for advice and assistance in this regard.









On or before the date on which the investigation begins, the RIO must: (1) notify the ORI Director of the decision to begin the investigation and provide ORI a copy of the inquiry report; and (2) notify the respondent in writing of the allegations to be investigated. The RIO must also give the respondent written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the inquiry or in the initial notice of the investigation.<sup>24</sup>

The RIO will, prior to notifying respondent of the allegations, take 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. The need for additional sequestration of records for the investigation may occur for any number of reasons, including the institution's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.<sup>25</sup>

#### C. Appointment of the Investigation Committee

The RIO, in consultation with other institutional officials as appropriate, will appoint an investigation committee and the committee chair as soon after the beginning of the investigation as is practical. The investigation committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the investigation and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the respondent and complainant and conduct the investigation. Individuals appointed to the



Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;<sup>27</sup>

Interview 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 record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of the investigation;<sup>28</sup> and

Pursue 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 continue the investigation to completion.<sup>29</sup>

F. Time for Completion

The investigation is to be completed within 120 days of beginning it, 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, he/she will submit to ORI a written request for an extension, setting forth 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.<sup>30</sup>

## VIII. The Investigation Report

A. Elements of the Investigation Report

The investigation committee and the RIO are responsible for preparing a written draft report of the investigation that:

Describes the nature of the allegation of research misconduct, including identification of the respondent. Vj g'tgur qpf gpwau'e&0'qt'tguwo g'o c{"dg" included as part of the identification.

Includes the institutional policies and procedures under which the investigation was conducted, unless those policies and procedures were provided to ORI previously;

Identifies and summarizes the research records and evidence reviewed and identifies any evidence taken into custody but not reviewed; and

Includes a statement of findings for each allegation of research misconduct identified during the investigation.<sup>31</sup> Each statement of findings must: (1) identify whether the research misconduct was falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly; (2) summarize 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 he or she did not engage in research misconduct because of honest error or a difference of opinion; (3) identify the specific PHS support; (4) identify whether any publications need correction or retraction; (5) identify the person(s) responsible for the misconduct; and (6) list any current support or known applications or proposals for support that the respondent has pending with non-PHS federal agencies.



may reopen the investigation if circumstances so dictate. The Provost and Executive Vice President for Academic Affairs decision will be binding on all parties and will be conveyed to all involved in a timely fashion, but must be conveyed within thirty working days. In the case of termination, the Provost Vice President for Academic Affairs decision may be appealed to The Texas State University System Board of Regents. All evidence, as well as the record of the proceedings, will be made available to that Board.

If an appeal is made by the respondent, the appeal must be completed within 120 days of its filing, unless ORI finds good cause for an extension, based upon the ~~lpuwkwkpa'y tkwp'tgs wgu'hqt"cp"gz vpuakp"vj~~ cv explains the need for the extension. If ORI grants an extension, it may direct the filing of periodic progress reports.

E. Notice to ORI of Institutional Findings and Actions

Unless an extension has been granted, the RIO must, within the 120-day period for completing the investigation or the 120-day period for completion of any appeal,







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- <sup>12</sup> 42 CFR § 93.309(c)  
<sup>13</sup> 42 CFR § 93.304(k)  
<sup>14</sup> 42 CFR § 93.304(h)  
<sup>15</sup> 42 CFR § 93.318  
<sup>16</sup> 42 CFR § 93.307(a)  
<sup>17</sup> 42 CFR § 93.307(c)  
<sup>18</sup> 42 CFR §§ 93.305, 93.307(b)  
<sup>19</sup> 42 CFR § 93.304(b)  
<sup>20</sup> 42 CFR § 93.307(g)  
<sup>21</sup> 42 CFR § 93.309(a)  
<sup>22</sup> 42 CFR § 93.309(a) and (b)  
<sup>23</sup> 42 CFR § 93.310(a)  
<sup>24</sup> 42 CFR § 93.310(b) and (c)  
<sup>25</sup> 42 CFR § 93.310(d)  
<sup>26</sup> 42 CFR § 93.310(e)  
<sup>27</sup> 42 CFR § 93.310(f)  
<sup>28</sup> 42 CFR § 93.310(g)  
<sup>29</sup> 42 CFR § 93.310(h)  
<sup>30</sup> 42 CFR § 93.311  
<sup>31</sup> 42 CFR § 93.313  
<sup>32</sup> 42 CFR § 93.313(f)  
<sup>33</sup> 42 CFR §§ 93.312(a), 93.313(g)  
<sup>34</sup> 42 CFR § 93.315  
<sup>35</sup> 42 CFR § 93.317(b)  
<sup>36</sup> 42 CFR §§ 93.300(g), 93.403(b) and (d)  
<sup>37</sup> 42 CFR § 93.316(a)  
<sup>38</sup> 42 CFR § 93.304(k)  
<sup>39</sup> 42 CFR § 93.304(l)

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## Appendix A

### Research Integrity Officer Responsibilities

#### I. General

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

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

#### II. Notice and Reporting to ORI and Cooperation with ORI

The RIO has lead responsibility for ensuring that the institution:

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

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protect the interests of those involved in the research misconduct proceeding, the institution believes that the research misconduct proceeding may be made public prematurely, or the research community or the public should be informed.

- Provides ORI with the written finding by the responsible institutional official that an investigation is warranted and a copy of the inquiry report, within 30 days of the date on which the finding is made.
- Notifies ORI of the decision to begin an investigation on or before the date the investigation begins.
- Within 120 days of ~~AMCID 5>BDC BT1gn0 0 1 429.29 652.0BT2n invn~~

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- Providing confidentiality to those involved in the research misconduct proceeding as required by 42 CFR § 93.108, other applicable law, and institutional policy.
  - Determining whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional or financial conflict of interest and taking appropriate action, including recusal, to ensure that no person with such a conflict is involved in the research misconduct proceeding.
  - Keeping the Deciding Official (DO) and others who need to know apprised of the progress of the review of the allegation of research misconduct.
  - In cooperation with other institutional officials, taking all reasonable and practical steps to protect or restore the positions and reputations of good faith complainants, witnesses, and committee members and to counter potential or actual retaliation against them by respondents or other institutional members.
  - Making all reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputation of persons alleged to have engaged in research misconduct, but against whom no finding of research misconduct is made.
  - Assisting the DO in implementing his/her decision to take administrative action against any complainant, witness, or committee member determined by the DO not to have acted in good faith.
  - Maintaining records of the research misconduct proceeding, as defined in 42 CFR § 93.317, in a secure manner for 7 years after completion of the proceeding, or the completion of any ORI proceeding involving the allegation of research misconduct, whichever is later, unless custody of the records has been transferred to ORI or ORI has advised that the records no longer need to be retained.
  - Ensuring that administrative actions taken by the institution and ORI are enforced and taking appropriate action to notify other involved f(di)18(n)2rcP-9()-6(e)418(nv)20(o)-39(1)18(v)20(e)4

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

### **C. Inquiry**

The RIO is responsible for:

- Initiating the inquiry process if it is determined that an inquiry is warranted.
- At the time of, or before beginning the inquiry, making a good faith effort to notify the respondent in writing, if the respondent is known.
- On or before the date on which the respondent is notified, or the inquiry begins, whichever is earlier, taking all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding, inventorying the records and evidence and sequestering them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on the instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.
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investigation is warranted and 42 CFR § 93.307(d).

- Determining whether circumstances clearly warrant a period longer than 60 days to complete the inquiry (including preparation of the final inquiry report and the decision of the DO on whether an investigation is warranted), approving an extension if warranted, and documenting the reasons for exceeding the 60-day period in the record of the research misconduct proceeding.
- Assisting the inquiry committee in preparing a draft inquiry report, sending the respondent a copy of the draft report for comment (and the complainant if the inquiry is warranted), and taking appropriate action to protect the confidentiality of the draft report, receiving any comments from the respondent (and the complainant if the inquiry is warranted) and attaching those comments to the final inquiry report.
- 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.
- Within 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.
- Notifying the respondent (and the complainant if the inquiry is warranted) whether the inquiry found an investigation to be warranted and including in the report the reasons for the finding and the institutional policies and procedures.
- Providing to ORI, upon request, the institutional policies and procedures under which the inquiry was conducted, the research records and evidence reviewed, transcripts or recordings of any interviews, copies of all relevant documents, and the allegations to be considered in the investigation.
- If the 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.

#### **D. Investigation**

The RIO is responsible for:



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recording or transcript in the record of the research misconduct proceeding; and (4) pursues diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of any additional instances of possible research misconduct, and continues the investigation to completion.

- Upon determining that the investigation cannot be completed within 120 days of its initiation (including providing the draft report for comment and sending the final report



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- When a final decision on the case is reached, the RIO will normally notify both the respondent and the complainant in writing and will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of involved journals, collaborators of the respondent, or other relevant parties should be notified of the outcome of the case.
  - Maintaining and providing to ORI upon request all relevant research records and records and the transcripts or recordings of those interviews.