

BRONSON HEALTHCARE GROUP

Policies & Procedures For Responding To Allegations Of Research  
Misconduct

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# Policies and Procedures for Responding to Allegations of Research Misconduct

## I. Introduction

### Purpose

This policy outlines the process at Bronson Methodist Hospital, or any Bronson Healthcare Group affiliate (“Institution”) to respond to, investigate, and report any allegations of research misconduct.

### Scope

This statement of policies and procedures applies to allegations of research misconduct involving 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.

A finding of research misconduct requires that:

- 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 be proven by a preponderance of the evidence.<sup>1</sup>

This statement of policy and procedure was written to comply with the Public Health Service (PHS) Policy on research Misconduct, 42 CFR § 93, and the Federal Policy on research misconduct issued by the Office of Research Integrity (ORI). The policies and procedures apply except when specifically excluded. All exclusions relate to requirements for reporting to the Office of Research Integrity. Such reporting requirements are limited to research sponsored by the U.S. Public Health Service.

This statement of policy and procedure 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 allegation, subject to the subsequent use, health or safety of the public, and grandfather exceptions in 42 CFR § 93.105(b).

### Responsibility

The Senior VP of Legal and Legislative Affairs, Corporate Compliance Officer, will serve as the Institutional Official who has the primary responsibility for implementation of the Institution’s policies and procedures on research misconduct.

## **II. Definitions**

Research Misconduct: means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Fabrication is making up data or results and recording or reporting them. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. Research misconduct does not include honest error or differences of opinion.<sup>2</sup>

Respondent: means the person against whom an allegation of research misconduct is directed or who is the subject of a research conduct proceeding.<sup>3</sup>

Complainant: means a person who in good faith makes an allegation.<sup>4</sup>

Allegation: means a disclosure of possible research misconduct through any means of communication. The disclosure may be by written or oral statement or other communication to an Institutional or HHS official.<sup>5</sup>

## **III. General Policies and Principles**

### Responsibility to Report Misconduct

All Institutional members will report observed, suspected, or apparent research misconduct. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may meet with or contact the RIO to discuss the suspected research misconduct informally, which may include discussing it anonymously and/or hypothetically. If the circumstances described by the individual do not meet the definition of research misconduct, the RIO will refer the individual or allegation to other officials with responsibility for resolving the problem.

### Cooperation with Research Misconduct Proceedings

Institutional members will cooperate with Institutional officials in the review of allegations and the conduct of inquiries and investigations. Institutional members, including respondents, have an obligation to provide evidence to research misconduct allegations to the Institution.

The Institution will cooperate fully and on a continuing basis with ORI during its oversight reviews of this Institution and its research misconduct proceedings and during the process under which the respondent may contest ORI findings of research misconduct and proposed HHS administrative actions. This includes providing, as necessary to develop a complete record of relevant evidence, all witnesses, research records, and other evidence under the Institution's control or custody, or in the possession of, or accessible to, all persons that are subject to the Institution's authority.

The Institution will cooperate with and assist ORI and HHS, as needed, to carry out administrative actions HHS may impose as a result of a final finding of research misconduct by HHS.

#### Confidentiality

To the extent allowed by law, the identity of respondents and complainants will be maintained securely and confidentially and will not be disclosed except to: (1) those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding; and (2) ORI as it conducts its review of the research misconduct proceeding and any subsequent proceedings.

To the extent allowed by law, any information obtained during the research misconduct proceeding that might identify the subjects of research will be maintained securely and confidentially and will not be disclosed, except to those who need to know in order to carry out the research misconduct proceeding.

#### Ensuring a Fair Research Misconduct Proceeding

The Institution will take all reasonable steps to ensure an impartial and unbiased misconduct proceeding to the maximum extent practicable, including participation of persons with appropriate scientific expertise who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry or investigation.<sup>6</sup>

#### 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 Institution, 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.

#### Protecting the Respondent

As requested and as appropriate, the Institution will 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>7</sup>

#### Interim Administrative Actions and Notifying ORI of Special Circumstances

Throughout the research misconduct proceeding, the Institution will review the situation to determine if there is any threat of harm to public health, federal funds and equipment, or the integrity of the PHS supported research process. In the event of such a threat, the Institution will, in consultation with other Institutional officials and ORI, take appropriate action to protect against any such threat.<sup>8</sup>

## **IV. Conducting the Assessment and Inquiry**

### Assessment of Allegations

Upon receiving an allegation of research misconduct, the Institution will immediately assess the allegation to determine if: (1) it meets the definition of research misconduct in; (2) it involves PHS supported research (in jurisdictional criteria of 42 CFR § 93.102(b)); (3) it is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

### Initiation and Purpose of Inquiry

If the Institution determines that the criteria for an inquiry are met, he/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 full review of all the evidence related to the allegation.<sup>9</sup>

### Notice to Respondent & Sequestration of Research Records

At the time of or before beginning an inquiry, the Institution 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 Institution 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 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>10</sup> (42 CFR § 93.305, 93.307(b))

### Inquiry Process

The inquiry process includes reviewing the evidence, preparing the inquiry report, determining if an investigation is warranted and providing the respondent a reasonable opportunity to comment on the inquiry report. The process will normally involve interviewing the complainant, the respondent, and key witnesses as well as examining relevant research records and materials.

### Time for Completion

The inquiry, including preparation of the final inquiry report and the decision on whether an investigation is warranted, will be completed within 60 calendar days on initiation of the inquiry, unless the Institution determines that circumstances clearly warrant a longer period.

### Inquiry Report

The inquiry report will contain the following information:

- The name and position of the respondent;
- Description of the allegations of research misconduct;

- The PHS support, including for example, grant numbers, grant applications, contracts and publications listing PHS support;
- The basis for recommending or not recommending that the allegations warrant an investigation;
- Any comments on the report by the respondent or the complainant.<sup>11</sup>
- If the inquiry takes longer than 60 days to complete, the inquiry record must include documentation of the reasons for exceeding the 60-day period.<sup>12</sup>

#### Institutional Decision

The Institution will determine whether an investigation is necessary, whether the matter should be dropped, or whether some other appropriate action is indicated.

#### Notification to Respondent and Opportunity to Comment

The Institution will notify the respondent whether the inquiry found an investigation to be warranted, include a copy of the draft inquiry for comment and include a copy of the Institution's policies and procedures on research misconduct (and refer to 42 CFR Part 93 if applicable to PHS-funded research).<sup>13</sup>

The Institution may notify the complainant who made the allegation whether the inquiry found that an investigation is warranted. The Institution may provide relevant portions of the report to the complainant for comment.

### **V. Conducting the Investigation**

#### Initiation and Purpose

The investigation will begin within 30 days after determining that an investigation is warranted.<sup>14</sup> The purpose of the investigation is to develop a factual record by exploring the allegations in detail and examining the evidence in depth, leading to recommended findings on whether research misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible research misconduct that would justify broadening the scope beyond the initial allegations.

#### Notifying Respondent & Sequestration of Research records

On or before the date on which the investigation begins, the Institution will notify the respondent in writing of the allegations to be investigated. The Institution will 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>15</sup>

The Institution will, prior to notifying the respondent of the allegations, take all reasonable and practice 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 procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.<sup>16</sup>

## Investigation Process

The Institution will:

- Use diligent efforts to ensure that 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 each allegation.<sup>17</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: and<sup>18</sup>
- 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>19</sup>

## 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 if applicable sending the final report to ORI.<sup>20</sup>

## Investigation Report

The Institution will prepare a written draft report of the investigation that:

- Describes the nature of the allegation of research misconduct, including the identification of the respondent;
- Describes and documents the PHS support, including for example, the numbers of any grants that are involved, grant application, contracts and publications listing PHS support (if applicable);
- Describes the specific allegations of research misconduct considered in the investigation;
- 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. Each statement of findings will:
  - Identify whether the research misconduct was falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly;
  - 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;
  - Identify the specific PHS support (if applicable);

- Identify whether any publications need correction or retraction;
- Identify the person(s) responsible for the misconduct; and
- List any current support or known applications or proposals for support that the respondent has pending with non-PHS federal agencies.<sup>21</sup>

#### Comments on the Draft Report and Access to Evidence

The Institution will 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 will be allowed 30 days from the date he/she received the draft report to submit comments to the Institution. The respondent's comments will be included and considered in the final report.<sup>22</sup>

#### Decision

When a final decision on the case has been reached, the Institution will notify the respondent and complainant in writing. After informing the ORI (when applicable), the Institution 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 Institution is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

### **VI. Notification and Reporting Requirements to Office of Research Integrity applicable to PHS-funded research only)**

Within 30 days of the decision that an investigation is warranted and no later than the date in which the investigation begins, the Institution will provide ORI with the Institution's written decision and a copy of inquiry report.<sup>23</sup>

The Institution will provide the following information 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, and copies of all relevant documents; and
- The charges for the investigation to consider

If the Institution determines that the investigation will not be completed within the 120-day period, he/she will submit to ORI a written request for an extension, setting forth the reasons for the delay. The Institution 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>24</sup>

Unless an extension has been granted, the Institution must within 120-day period for completing the investigation submit the following to ORI:

- A copy of the final investigation report with all attachments
- A statement of whether the Institution accepts the findings of the investigation report
- A statement of whether the Institution found misconduct and if so, who committed the misconduct; and

- A description of any pending or completed administrative actions against the respondent.<sup>25</sup>

The Institution is also responsible for providing any information, documentation, research records, evidence or clarification requested by the ORI to carry out its review of an allegation of research misconduct or of the Institution's handling of such an allegation.<sup>26</sup>

If an investigation is to be terminated for any reason without completing all relevant federal requirements, the Institution will submit a report of the planned termination to ORI and include the reasons for the termination. ORI will then decide whether further investigations should be undertaken.

The Institution will report to ORI any proposed settlements, admissions of research misconduct, or Institutional findings of misconduct that arise at any stage of a misconduct proceeding, including the allegation and inquiry stages.

The Institution will keep ORI apprised of any developments during the course of the investigation that may affect current or potential DHHS funding for the individual(s) under investigation.

At any time during a research misconduct proceeding, the Institution will notify ORI immediately if there is 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 violations of civil or criminal law.
- Federal action is required to protect the interests of those involved in the research misconduct proceeding.
- The Institution believes that the research misconduct proceeding may be made public prematurely, so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved.
- The research community or public should be informed.<sup>27</sup>

## **VII. Retention and Maintenance of Records**

The Institution will maintain and provide to ORI upon request "records of research misconduct proceedings" as defined in 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 7 years after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation.<sup>28</sup>

## **VIII. Sanctions and Administrative Actions**

If the Institution determines that research misconduct is substantiated by the findings, appropriate actions will be taken. The administrative actions may include:

- Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found;
- Removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment;
- Restitution of funds to the grantor agency as appropriate; and
- Other action appropriate to the research misconduct.

## **IX. Appeals**

The Institution may provide for an appeal by the respondent that could result in a reversal or modification of the Institution's findings of research misconduct. The appeal will be completed within 120 days of its filing, unless ORI finds good cause for an extension, based upon the Institution's written request for an extension that explains the need for the extension. If ORI grants an extension, it may direct the filing of periodic progress reports.<sup>29</sup>

## **X. Other Considerations**

### Termination or Resignation Prior to Completing Inquiry or Investigation

The termination of the respondent's Institutional employment, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the research misconduct proceeding or otherwise limit any of the Institution's responsibilities.

If the respondent, without admitting to the misconduct, elects to resign his or her position after the Institution receives an allegation of research misconduct, the assessment of the allegation will proceed, as well as the inquiry and investigation, as appropriate based on the outcome of the preceding steps. If the respondent refuses to participate in the process after resignation, the Institution and any inquiry or investigation committee 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.

### Restoration of the Respondent's Reputation

Following a final finding of no research misconduct, including ORI concurrence where required by 42 CFR Part 93, the Institution must, at the request of the respondent, undertake all reasonable and practical efforts to restore the respondent's reputation.<sup>30</sup>

### Protection of the Complainant, Witnesses, and Committee Members

During the research misconduct proceeding and upon its completion, regardless of whether the Institution or ORI determines that research misconduct occurred, the Institution must undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any complainant who made allegations of research misconduct in good faith and of any witness and persons who cooperate in good faith with the research misconduct proceeding.<sup>31</sup>

### Allegations Not Made in Good Faith

If relevant, the Institution will determine whether the complainant's allegations of research misconduct were made in good faith. If the Institution determines that there was an absence of good faith he/she will determine whether any administrative action should be taken against the person who failed to act in good faith.

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<sup>1</sup> 42 CFR § 93.104

<sup>2</sup> 42 CFR §93.103

<sup>3</sup> 42 CFR§ 93.225

<sup>4</sup> 42 CFR § 93.203

<sup>5</sup> 42 CFR § 93.302

<sup>6</sup> 42 CFR 93.300(b), 93.310(f)

<sup>7</sup> 42 CFR 93.304(k)

<sup>8</sup> 42 CFR 93.304(h)

<sup>9</sup> 42 CFR 93.307(c)

<sup>10</sup> 42 CFR 93.305, 93.307(b)

<sup>11</sup> 42 CFR 93.309

<sup>12</sup> 42 CFR 93.307(g)

<sup>13</sup> 42 CFR 93.308(a)

<sup>14</sup> 42 CFR 93.310(a)

<sup>15</sup> 42 CFR 93.310(b)(c)

<sup>16</sup> 42 CFR 93.310(d)

<sup>17</sup> 42 CFR 93.310(d)

<sup>18</sup> 42 CFR 93.310(g)

<sup>19</sup> 42 CFR 93.310(h)

<sup>20</sup> 42 CFR 93.311(a)

<sup>21</sup> 42 CFR 93.313

<sup>22</sup> 42 CFR 93.312(a), 93.313(g)

<sup>23</sup> 42 CFR 93.310(b)

<sup>24</sup> 42 CFR 93.311

<sup>25</sup> 42 CFR 93.315

<sup>26</sup> 42 CFR 93.300(g), 93.304(b)(d)

<sup>27</sup> 42 CFR 93.318

<sup>28</sup> 42 CFR 93.317(b)

<sup>29</sup> 42 CFR 93.314

<sup>30</sup> 42 CFR 93.304(k)

<sup>31</sup> 42 CFR 93.304(i)