

**Colgate University Policy and Procedures for  
Responding to Allegations of Research Misconduct**

January 2014

**Table of Contents**

<b>I. INTRODUCTION</b>	<b>3</b>
<b>A. GENERAL POLICY</b>	<b>3</b>
<b>B. SCOPE</b>	<b>3</b>
<b>II. DEFINITIONS</b>	<b>4</b>
<b>III. RIGHTS AND RESPONSIBILITIES</b>	<b>5</b>
<b>A. RESEARCH INTEGRITY OFFICER</b>	<b>5</b>
<b>B. COMPLAINANT</b>	<b>6</b>
<b>C. RESPONDENT</b>	<b>6</b>
<b>D. DECIDING OFFICIAL</b>	<b>7</b>
<b>IV. GENERAL POLICIES AND PRINCIPLES</b>	<b>7</b>
<b>A. RESPONSIBILITY TO REPORT MISCONDUCT</b>	<b>7</b>
<b>B. COOPERATION WITH RESEARCH MISCONDUCT PROCEEDINGS</b>	<b>7</b>
<b>C. CONFIDENTIALITY</b>	<b>7</b>
<b>D. PROTECTING COMPLAINANTS, WITNESSES, AND COMMITTEE MEMBERS</b>	<b>8</b>
<b>E. PROTECTING THE RESPONDENT</b>	<b>8</b>
<b>F. COOPERATION WITH INQUIRIES AND INVESTIGATIONS</b>	<b>8</b>
<b>G. INTERIM ADMINISTRATIVE ACTIONS AND NOTIFYING ORI OF SPECIAL CIRCUMSTANCES</b>	<b>8</b>
<b>V. CONDUCTING THE ASSESSMENT AND INQUIRY</b>	<b>9</b>
<b>A. PRELIMINARY ASSESSMENT</b>	<b>9</b>
<b>B. INITIATION AND PURPOSE OF THE INQUIRY</b>	<b>9</b>
<b>C. NOTICE TO RESPONDENT; SEQUESTRATION OF RESEARCH RECORDS</b>	<b>9</b>
<b>D. APPOINTMENT OF THE INQUIRY COMMITTEE</b>	<b>10</b>
<b>E. CHARGE TO THE COMMITTEE AND FIRST MEETING</b>	<b>10</b>
<b>F. INQUIRY PROCESS</b>	<b>11</b>
<b>G. TIME FOR COMPLETING THE INQUIRY REPORT</b>	<b>11</b>
<b>VI. THE INQUIRY REPORT</b>	<b>11</b>
<b>A. ELEMENTS OF THE INQUIRY REPORT</b>	<b>11</b>
<b>B. COMMENTS ON THE DRAFT REPORT BY THE RESPONDENT AND THE COMPLAINANT</b>	<b>11</b>
<b>C. INSTITUTIONAL DECISION AND NOTIFICATION</b>	<b>12</b>
<b>VII. CONDUCTING THE INVESTIGATION</b>	<b>13</b>
<b>A. INITIATION AND PURPOSE</b>	<b>13</b>
<b>B. NOTIFYING RESPONDENT; SEQUESTRATION OF RESEARCH RECORDS</b>	<b>13</b>
<b>C. APPOINTMENT OF THE INVESTIGATION COMMITTEE</b>	<b>13</b>
<b>D. CHARGE TO THE COMMITTEE AND THE FIRST MEETING</b>	<b>13</b>
<b>E. INVESTIGATION PROCESS</b>	<b>14</b>
<b>F. TIME FOR COMPLETION</b>	<b>15</b>

**Colgate University Policy and Procedures for  
Responding to Allegations of Research Misconduct**

<b>VIII. THE INVESTIGATION REPORT</b>	<b>15</b>
<b>A. ELEMENTS OF THE INVESTIGATION REPORT</b>	<b>15</b>
<b>B. COMMENTS ON THE DRAFT REPORT AND ACCESS TO EVIDENCE</b>	<b>16</b>
<b>C. INSTITUTIONAL REVIEW AND DECISION BY DECIDING OFFICIAL</b>	<b>16</b>
<b>IX. REQUIREMENTS FOR REPORTING TO ORI</b>	<b>17</b>
<b>X. INSTITUTIONAL ADMINISTRATIVE ACTIONS</b>	<b>18</b>
<b>XI. OTHER CONSIDERATIONS</b>	<b>18</b>
<b>A. TERMINATION OR RESIGNATION PRIOR TO COMPLETING INQUIRY OR INVESTIGATION</b>	<b>18</b>
<b>B. RESTORATION OF THE RESPONDENT'S REPUTATION</b>	<b>18</b>
<b>E. PROTECTION OF THE COMPLAINANT, WITNESSES AND COMMITTEE MEMBERS</b>	<b>18</b>
<b>C. ALLEGATIONS NOT MADE IN GOOD FAITH</b>	<b>19</b>
<b>XII. RECORD RETENTION</b>	<b>19</b>
<b>NOTES:</b>	<b>20</b>

**APPENDIX A - RESEARCH INTEGRITY OFFICER RESPONSIBILITIES**

# Colgate University Policy and Procedures for Responding to Allegations of Research Misconduct

## I. INTRODUCTION

### A. General Policy

At Colgate University, we believe that honesty and integrity are fundamental values in a community dedicated to learning, personal development, and a search for understanding. Colgate University is committed to upholding the highest standards of research integrity and does not condone nor will it tolerate research misconduct by any member of the University community. While breaches in such standards are rare, they must be dealt with promptly and fairly in order to preserve the integrity of the research community and of the University.

This policy applies to allegations of research misconduct, which means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.

- **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.<sup>1</sup>

### B. Scope

This policy and the associated procedures apply to all research at Colgate University, including that which is supported by or for which support is requested from the U.S. Public Health Service (PHS).<sup>2</sup>

This policy applies to any person paid by or under the control of the institution, such as scientists, trainees, technicians and other staff members, faculty, students, fellows, guest researchers, or collaborators at Colgate University.<sup>3</sup> In the case of undergraduate students involved in alleged scientific misconduct, this policy and the associated procedures shall apply in those instances where: 1) the research in question is supported by federal agencies; or 2) the student independently submitted a manuscript for peer-reviewed publication, with the intent of influencing the science surrounding the topic, without the participation of the faculty research advisor. Student matters may also, as appropriate, be handled under The Colgate University Academic Honor Code guidelines.

This policy and associated procedures will normally be followed when an allegation of possible misconduct in science is received by an institutional official. Particular circumstances in an individual case may dictate variation from the normal procedure deemed in the best interests of Colgate University.

## **Colgate University Policy and Procedures for Responding to Allegations of Research Misconduct**

### **II. DEFINITIONS**

**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 official.

**Complainant** means a person who in good faith makes an allegation of research misconduct.

**Deciding Official (DO)** means the Colgate University Provost and Dean of the Faculty or his/her designee who makes final determinations on allegations of scientific misconduct and any responsive institutional actions. The DO will not be the same individual as the Research Integrity Officer (RIO) and should have no direct prior involvement in the institution's inquiry, investigation, or allegation assessment.

**Inquiry** means preliminary information-gathering and initial fact-finding to determine whether an allegation or apparent instance of research misconduct warrants an investigation.

**Institutional Members** means any person paid by or under the control of the institution, such as scientists, trainees, technicians and other staff members, faculty, students, fellows, guest researchers, or collaborators at Colgate University.

**Investigation** means the formal development of a factual record and the examination of all relevant facts to determine if research misconduct has occurred and, if so, to determine the responsible person and the seriousness of the misconduct.

**Office of Research Integrity (ORI)** is the office within the U.S. Department of Health and Human Services (DHHS) that is responsible for the scientific misconduct and research integrity activities of the U.S. Public Health Service.

**PHS** means the U.S. Public Health Service, an operating component of the DHHS.

**PHS support** means PHS grants, contracts, or cooperative agreements or applications thereof.

**Research** means a systematic gathering of data, information and facts for the advancement of knowledge..

**Research Integrity Officer (RIO)** means the institutional official responsible for assessing allegations of scientific misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations.

## **Colgate University Policy and Procedures for Responding to Allegations of Research Misconduct**

**Respondent** means the person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

### **III. RIGHTS AND RESPONSIBILITIES**

#### **A. Research Integrity Officer**

The Provost and Dean of the Faculty will appoint the Research Integrity Officer (RIO), usually an associate dean, who will serve as the initial point of contact for and allegation of research misconduct and will have primary responsibility for implementation of the institution's policies and procedures on research misconduct set forth in this document.

These responsibilities include 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 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;
- Sequester research data and evidence pertinent to the allegation of research misconduct and maintain it securely;
- Provide confidentiality to those involved in the research misconduct proceeding;
- Notify the respondent and provide opportunities for him/her to review/comment/respond to allegations, evidence, and committee reports;
- Inform respondents, complainants, and witnesses of the procedural steps in the research misconduct proceeding;
- Appoint 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 research misconduct has an unresolved personal, professional, or financial conflict of interest and take appropriate action, including recusal, to ensure that no person with such conflict is involved in the research misconduct proceeding;
- In cooperation with other institutional officials, take 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;
- 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 necessary;
- Ensure that administrative actions taken by the institution and ORI are enforced and take appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards of those actions; and

## **Colgate University Policy and Procedures for Responding to Allegations of Research Misconduct**

- Maintain records of the research misconduct proceeding and make them available to ORI.

### **B. Complainant**

The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with an inquiry or investigation. The complainant has an obligation to respect the reputation of the respondent by refraining from activities potentially harmful or damaging to the reputation of the respondent.

The complainant will have an opportunity to testify before the inquiry and investigation committees, to review portions of the inquiry and investigation reports pertinent to his/her allegations or testimony, to be informed of the results of the inquiry and investigation, and to be protected from retaliation. Also, if the RIO has determined that the complainant may be able to provide pertinent information on any portions of the draft report, then these portions will be given to the whistleblower for comment.<sup>4</sup>

### **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>5</sup>
- An opportunity to comment on the inquiry report and have his/her comments attached to the report;<sup>6</sup>
- Be notified of the outcome of the inquiry, and receive a copy of the inquiry report;<sup>7</sup>
- 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 (within 30 days after the institution decides to begin an investigation), 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;<sup>8</sup>
- Be interviewed during the investigation, have the opportunity to correct the recording or transcript, and have the corrected recording or transcript included in the record of the investigation;<sup>9</sup>
- Have interviewed during the investigation any witness who has been reasonably identified by the respondent as having information on relevant aspects of the investigation, have the recording or transcript provided to the witness for correction, and have the corrected recording or transcript included in the record of investigation;<sup>10</sup> and
- 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

## **Colgate University Policy and Procedures for Responding to Allegations of Research Misconduct**

received and that the comments will be considered by the institution and addressed in the final report.<sup>11</sup>

The respondent should be given the opportunity to admit that research misconduct occurred and that he/she committed the research misconduct. With the advice of the RIO and/or other institutional officials, the Deciding Official may terminate the institution's review of an allegation that has been admitted, if the institution's acceptance of the admission and any proposed settlement is approved by ORI.<sup>12</sup>

### **D. Deciding Official**

The Provost and Dean of the Faculty shall serve as the Deciding Official (DO), and will receive the inquiry and/or investigation report and any written comments made by the respondent or the whistleblower on the draft report. The DO will consult with the RIO or other appropriate officials and will determine whether to conduct an investigation, whether misconduct occurred, whether to impose sanctions, or whether to take other appropriate administrative actions.<sup>13</sup>

## **IV. GENERAL POLICIES AND PRINCIPLES**

### **A. Responsibility to Report Misconduct**

All employees or individuals associated with Colgate University should report observed, suspected, or apparent research misconduct to the RIO. 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 at the office of the Provost and Dean of the Faculty 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 offices or officials with responsibility for resolving the problem.

At any time, an employee may have confidential discussions and consultations about concerns of possible misconduct with the RIO and will be counseled about appropriate procedures for reporting allegations. Should an individual observe or suspect scientific misconduct involving the RIO, the individual may contact the Provost and Dean of the Faculty.

### **B. Cooperation with Research Misconduct Proceedings**

All employees or individuals associated with Colgate University will cooperate with the RIO and other institutional officials in the review of allegations and the conduct of inquiries and investigations. Institutional members, including respondents, have an obligation to provide evidence relevant to research misconduct allegations to the RIO or other institutional officials.

### **C. Confidentiality**

The RIO shall (1) limit disclosure of the identity of respondents and complainants to

## **Colgate University Policy and Procedures for Responding to Allegations of Research Misconduct**

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>14</sup>

During the research misconduct proceeding, the RIO is responsible for ensuring that respondents receive all the notices and opportunities provided for in 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.

### **F. Cooperation with Inquiries and Investigations**

Institutional employees will cooperate with the RIO and other institutional officials in the review of allegations and the conduct of inquiries and investigations. Employees have an obligation to provide relevant evidence to the RIO or other institutional officials on misconduct allegations.

### **G. Interim Administrative Actions and Notifying ORI of Special Circumstances**

Throughout the research misconduct proceeding, the RIO 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 RIO will, in consultation with other institutional officials and ORI, take appropriate interim action to protect against any such threat.<sup>15</sup> Interim action might include additional monitoring of the research process and the handling of federal funds and equipment, reassignment of personnel or of the responsibility for the handling of federal funds and equipment, additional review of research data and results or delaying publication. The RIO shall, at any time during a research misconduct proceeding, notify ORI immediately if he/she has reason to believe that any of the following conditions exist:



## **Colgate University Policy and Procedures for Responding to Allegations of Research Misconduct**

- 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 a reasonable indication of possible violations of civil or criminal law;
- Federal action is required to protect the interests of those involved in the research misconduct proceeding;
- The research misconduct proceeding may be made public prematurely and HHS action may be necessary to safeguard evidence and protect the rights of those involved; or
- The research community or public should be informed.<sup>16</sup>

### **V. CONDUCTING THE ASSESSMENT AND INQUIRY**

#### **A. Preliminary Assessment**

Upon receiving an allegation of scientific misconduct, the RIO will assess the allegation to determine whether the allegation falls within the definition of research misconduct, and is sufficiently credible, significant, and specific so that the potential evidence of research misconduct may be identified.<sup>17</sup>

The assessment period should be brief, preferably concluded within a week. 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.

#### **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>18</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

## **Colgate University Policy and Procedures for Responding to Allegations of Research Misconduct**

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>19</sup> The RIO may consult with ORI or other pertinent federal agencies for advice and assistance in this regard.

### **D. Appointment of the Inquiry Committee**

The RIO, in consultation with other institutional officials as appropriate, will appoint an inquiry committee and committee chair as soon after the initiation of the inquiry as is practical.

The inquiry committee should consist of individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry.<sup>20</sup> These individuals may be scientists, subject matter experts, administrators, or other qualified persons, and they may be from inside or outside the institution.

The RIO shall notify the respondent of the names of the committee members to give the respondent an opportunity to object to a proposed member based upon a personal, professional, or financial conflict of interest. Objections must be filed within 10 calendar days. If an objection is filed, the RIO will determine whether to replace the challenged member or expert with a qualified substitute.

### **E. Charge to the Committee and First Meeting**

The RIO will prepare a charge for the inquiry committee that:

- Sets forth the time for completion of the inquiry;
- Describes the allegations and any related issues identified during the allegation assessment;
- 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;
- States 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 jurisdictional criteria of 42 CFR § 93.102(b); and, (2) the allegation may have substance, based on the committee's review during the inquiry.
- Informs the inquiry committee that they are responsible for preparing or directing the preparation of a written report of the inquiry that meets the requirements of this policy and 42 CFR § 93.309(a).
- At the committee's first meeting, the RIO will review the charge with the committee, discuss the allegations, any related issues, and the appropriate procedures for conducting the inquiry, assist the committee with organizing plans for the inquiry,

## **Colgate University Policy and Procedures for Responding to Allegations of Research Misconduct**

and answer any questions raised by the committee. The RIO will be present or available throughout the inquiry to advise the committee as needed.

### **F. Inquiry Process**

The inquiry committee will normally interview the complainant, 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 normally include deciding whether misconduct definitely occurred, determining definitely who committed the research misconduct or conducting exhaustive interviews and analyses. However, if a legally sufficient admission of research misconduct is made by the respondent, misconduct may be determined at the inquiry stage if all relevant issues are resolved. In that case, the institution shall promptly consult with ORI to determine the next steps that should be taken. See Section IX.

### **G. Time for Completing the Inquiry Report**

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 documentation of the reasons for exceeding the 60-day period.<sup>21</sup>

## **VI. THE INQUIRY REPORT**

### **A. Elements of the Inquiry Report**

A written inquiry report must be prepared that includes the following information: (1) the name and position of the respondent; (2) a description of the allegations of research misconduct; (3) the external support pertinent to the allegation, including, for example, grant numbers, grant applications, contracts and publications listing the support; (4) the basis for recommending or not recommending that the allegations warrant an investigation; (5) any comments on the draft report by the respondent or complainant;<sup>22</sup> (6) the names and titles of the committee members and experts who conducted the inquiry; (7) a summary of the inquiry process used; (8) a list of the research records reviewed; (9) summaries of any interviews; (10) and whether any other actions should be taken if an investigation is not recommended.

Institutional counsel may be asked to review the report for legal sufficiency. Modifications should be made as appropriate in consultation with the RIO and the inquiry committee.

### **B. Comments on the Draft Report by the Respondent and the Complainant**

## **Colgate University Policy and Procedures for Responding to Allegations of Research Misconduct**

The RIO shall notify the respondent whether the inquiry found an investigation to be warranted, include a copy of the draft inquiry report for comment within 10 days, and include a copy of or refer to 42 CFR Part 93 and the institution's policies and procedures on research misconduct.<sup>23</sup>

The institution may notify the complainant whether the inquiry found an investigation to be warranted and provide relevant portions of the inquiry report to the complainant for comment within 10 days. A confidentiality agreement should be a condition for access to the report.

Any comments that are submitted by the 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.

### **C. Institutional Decision and Notification**

#### **Decision by Deciding Official**

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.

#### **Notification**

Within 30 calendar days of the DO's decision that an investigation is warranted, the RIO will also notify those institutional officials who need to know of the DO's decision. Where PHS funding is involved, the RIO will also provide ORI, or other pertinent agency as required by regulation, with the DO's written decision and a copy of the inquiry report.

The RIO must provide the following information to ORI upon request: (1) the institutional policies and procedures under which the inquiry was conducted; (2) the research records and evidence reviewed, transcripts, or recordings of any interviews, and copies of all relevant documents; and (3) the charges to be considered in the investigation.<sup>24</sup>

The RIO and DO shall determine what if any information to provide to the complainant at various stages in the process, balancing the complainant's legitimate interest in the proceeding, its progress, and its outcome, with the need to safeguard the integrity and confidentiality of the process

#### **Documentation of Decision Not to Investigate**

If the DO decides that an investigation is not warranted, the RIO shall secure and maintain 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. These documents must be provided to ORI or other authorized HHS personnel upon request.

## **Colgate University Policy and Procedures for Responding to Allegations of Research Misconduct**

### **VII. CONDUCTING THE INVESTIGATION**

#### **A. Initiation and Purpose**

The investigation must begin within 30 calendar days after the determination by the DO that an investigation is warranted.<sup>25</sup> The purpose of the investigation is to develop explore the allegations in detail, to examine the evidence in depth, and to determine 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. This is particularly important where the alleged research misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice. The findings of the investigation will be set forth in an investigation report.

#### **B. Notifying Respondent; Sequestration of Research Records**

On or before the date on which the investigation begins, the RIO must 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>26</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>27</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 real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegation, interview the respondent and complainant and conduct the investigation. These individuals may be scientists, administrators, subject matter experts, or other qualified persons, and they may be from inside or outside the institution. Individuals appointed to the investigation committee may also have served on the inquiry committee.

#### **D. Charge to the Committee and the First Meeting**

## **Colgate University Policy and Procedures for Responding to Allegations of Research Misconduct**

### **Charge to the Committee**

The RIO will define the subject matter of the investigation in a written charge to the committee that:

- Describes the allegations and related issues identified during the inquiry;
- Identifies the respondent;
- Informs the committee that it must conduct the investigation as prescribed in paragraph E. of this section;
- Defines research misconduct;
- Informs the committee that it 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;
- Informs 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 policy, 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
- Informs the committee that it must prepare or direct the preparation of a written investigation report that meets the requirements of this policy.

### **First Meeting**

The RIO, with the assistance of institutional counsel, will convene the first meeting of the investigation committee 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 statement of policy and procedures and where PHS funding is involved, the PHS regulation. The RIO will be present or available throughout the investigation to advise the committee as needed.

### **E. Investigation Process**

The investigation committee and the RIO must:

- 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>28</sup>
- Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;<sup>29</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

## **Colgate University Policy and Procedures for Responding to Allegations of Research Misconduct**

correction, and include the recording or transcript in the record of the investigation;<sup>30</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>31</sup>

### **F. Time for Completion**

An investigation should normally 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.

In the case of PHS funding, 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>32</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;
- 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;
- 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.<sup>33</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

## **Colgate University Policy and Procedures for Responding to Allegations of Research Misconduct**

non-PHS federal agencies.<sup>34</sup>

### **B. Comments on the Draft Report and Access to Evidence**

#### **1. Respondent**

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 will be allowed 30 days from the date he/she received the draft report to submit comments to the RIO. The respondent's comments must be included and considered in the final report.<sup>35</sup>

#### **2. Complainant**

The RIO will provide the complainant, if he or she is identifiable, with those portions of the draft investigation report that address the complainant's role and opinions in the investigation. The report should be modified, as appropriate, based on the complainant's comments.

#### **3. Institutional Counsel**

The draft investigation report will be transmitted to the institutional counsel for a review of its legal sufficiency. Comments should be incorporated into the report as appropriate.

#### **4. Confidentiality**

In distributing the draft report, or portions thereof, to the respondent, and complainant the RIO will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. For example, the RIO may require that the recipient sign a confidentiality agreement.

### **C. Institutional Review and Decision by Deciding Official**

The RIO will assist the investigation committee in finalizing the draft investigation report, including ensuring that the respondent's and complainant's comments are included and considered, and transmit the final investigation report to the DO, who will determine in writing: (1) whether the institution accepts the investigation report, its findings, and the recommended institutional actions; and (2) the appropriate institutional actions in response to the accepted findings of research misconduct. If this determination varies from the findings of the investigation committee, the DO will, as part of his/her written determination, explain in detail the basis for rendering a decision different from the findings of the investigation committee. Alternatively, the DO may return the report to the investigation committee with a request for further fact-finding or analysis.

When a final decision on the case has been reached, the RIO will normally notify both the respondent and the complainant in writing. In addition, the DO will determine whether law enforcement agencies, professional societies, professional licensing boards,



## **Colgate University Policy and Procedures for Responding to Allegations of Research Misconduct**

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.

### **IX. REQUIREMENTS FOR REPORTING TO ORI**

#### **Allegations and Admissions of Scientific Misconduct when PHS Funding is Involved**

An institution's decision to initiate an investigation must be reported in writing to ORI, on or before the date the investigation begins.<sup>20</sup> At a minimum, the notification should include the name of the person(s) against whom the allegations have been made, the general nature of the allegation as it relates to the PHS definition of scientific misconduct, and the PHS applications or grant number(s) involved.<sup>21</sup> ORI must also be notified of the final outcome of the investigation and must be provided with a copy of the investigation report.<sup>22</sup> Any significant variations from the provisions of the institutional policies and procedures should be explained in any reports submitted to ORI.

If an institution plans to terminate an inquiry or investigation for any reason without completing all relevant requirements of the PHS regulation, the RIO will submit a report of the planned termination to ORI, including a description of the reasons for the proposed termination.<sup>23</sup>

If the institution determines that it will not be able to complete the investigation in 120 days, the RIO will submit to ORI a written request for an extension that explains the delay, reports on the progress to date, estimates the date of completion of the report, and describes other necessary steps to be taken. If the request is granted, the RIO will file periodic progress reports as requested by the ORI.<sup>24</sup>

When PHS funding or applications for funding are involved and an admission of scientific misconduct is made, the RIO will contact ORI for consultation and advice. Normally, the individual making the admission will be asked to sign a statement attesting to the occurrence and extent of misconduct. When the case involves PHS funds, the institution cannot accept an admission of scientific misconduct as a basis for closing a case or not undertaking an investigation without prior approval from ORI.<sup>25</sup>

- The RIO will notify ORI at any stage of the inquiry or investigation if:
- There is an immediate health hazard involved;<sup>2</sup>
- There is an immediate need to protect Federal funds or equipment;<sup>27</sup>
- There is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any;<sup>28</sup>
- It is probable that the alleged incident is going to be reported publicly; or<sup>29</sup>
- The allegation involves a public health sensitive issue, *e.g.*, a clinical trial; or
- There is a reasonable indication of possible criminal violation. In this instance, the institution must inform ORI within 24 hours of obtaining that information.<sup>30</sup>

## **Colgate University Policy and Procedures for Responding to Allegations of Research Misconduct**

### **X. INSTITUTIONAL ADMINISTRATIVE ACTIONS**

If the DO determines that research misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consultation with the RIO. 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.

### **XI. OTHER CONSIDERATIONS**

#### **A. 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.

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 RIO and any inquiry or investigation committee will use its 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.

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

If the institution finds not misconduct and ORI concurs, the RIO will, at the request of the respondent, undertake all reasonable and practical efforts to restore the respondent's reputation.<sup>36</sup> Depending on the particular circumstances and the views of the respondent, the RIO should 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.

#### **E. 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 RIO must undertake all reasonable and practical efforts to protect the position and reputation

## **Colgate University Policy and Procedures for Responding to Allegations of Research Misconduct**

of, or to counter potential or actual retaliation against, any complainant who made allegations of research misconduct in good faith and of any witnesses and committee members who cooperate in good faith with the research misconduct proceeding.<sup>37</sup>

The DO will determine, after consulting with the RIO, and with the complainant, witnesses, or committee members, respectively, what steps, if any, are needed to restore their respective positions or reputations or to counter potential or actual retaliation against them. The RIO is responsible for implementing any steps the DO approves.

### **C. Allegations Not Made in Good Faith**

If relevant, the DO will determine whether the complainant's allegations of research misconduct were made in good faith, or whether a witness or committee member acted in good faith. If the DO 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.

## **XII. RECORD RETENTION**

After completion of a case and all ensuing related actions, the RIO will prepare a complete file, including the records of any inquiry or investigation and copies of all documents and other materials furnished to the RIO or committees. The RIO will keep the file for three years after completion of the case to permit later assessment of the case. ORI or other authorized DHHS personnel will be given access to the records upon request.<sup>34</sup>

## Colgate University Policy and Procedures for Responding to Allegations of Research Misconduct

### NOTES:

---

- <sup>1</sup> 42 CFR § 93.103
- <sup>2</sup> 42 CFR § 93.102
- <sup>3</sup> 42 CFR § 93.214
- <sup>4</sup> 42 CFR § 93.310(g)
- <sup>5</sup> 42 CFR §§ 93.304(c), 93.307(b)
- <sup>6</sup> 42 CFR §§ 93.304(e), 93.307(f)
- <sup>7</sup> 42 CFR § 308(a)
- <sup>8</sup> 42 CFR § 310(c)
- <sup>9</sup> 42 CFR § 310(g)
- <sup>10</sup> 42 CFR § 310(g)
- <sup>11</sup> 42 CFR §§ 93.304(f), 93.312(a)
- <sup>12</sup> 42 CFR § 93.316
- <sup>13</sup> 42 CFR § 93.309(c)
- <sup>14</sup> 42 CFR § 93.304(k)
- <sup>15</sup> 42 CFR § 93.304(h)
- <sup>16</sup> 42 CFR § 93.318
- <sup>17</sup> 42 CFR § 93.307(a)
- <sup>18</sup> 42 CFR § 93.307(c)
- <sup>19</sup> 42 CFR §§ 93.305, 93.307(b)
- <sup>20</sup> 42 CFR § 93.304(b)
- <sup>21</sup> 42 CFR § 93.307(g)
- <sup>22</sup> 42 CFR § 93.309(a)
- <sup>23</sup> 42 CFR § 93.308(a)
- <sup>24</sup> 42 CFR § 93.309(a) and (b)
- <sup>25</sup> 42 CFR § 93.310(a)
- <sup>26</sup> 42 CFR § 93.310(b) and (c)
- <sup>27</sup> 42 CFR § 93.310(d)
- <sup>28</sup> 42 CFR § 93.310(e)
- <sup>29</sup> 42 CFR § 93.310(f)
- <sup>30</sup> 42 CFR § 93.310(g)
- <sup>31</sup> 42 CFR § 93.310(h)
- <sup>32</sup> 42 CFR § 93.311
- <sup>33</sup> 42 CFR § 93.313
- <sup>34</sup> 42 CFR § 93.313(f)
- <sup>35</sup> 42 CFR §§ 93.312(a), 93.313(g)
- <sup>36</sup> 42 CFR § 93.304(k)
- <sup>37</sup> 42 CFR § 93.304(l)