1. Introduction

North Carolina Central University (NCCU) is committed to providing an environment wherein the discovery and the free exchange of knowledge take place and are welcome. NCCU believes, however, that it is the concomitant responsibility of those producing discoveries and sharing knowledge to subscribe to the highest standards (norms, rules, and procedures) of the research community. Investigators must ensure research integrity and must adhere to generally accepted models of ethics in research, including, but not limited to, issues of honesty, fairness, respect, and affording appropriate credit to others.

It is the University’s position and that of each individual, internally and externally associated with the university, to be vigilant in the pursuit of truth and in the prevention of misconduct in research. To the degree misconduct should occur, it is the university’s pledge to fully support individuals who, in good faith, root out and expose such misconduct.

2. Scope

This regulation and the associated procedures apply to all individuals at NCCU engaged in research that is supported by or for which support is requested from PHS. The PHS regulation at 42 C.F.R. Part 93, Subpart A applies to any research, research-training or research-related grant or cooperative agreement with PHS. This regulation applies to any person paid by, under the control of, or affiliated with the institution, such as scientists, trainees, technicians and other staff members, students, fellows, guest researchers, or collaborators at NCCU.

The regulation 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
NCCU and PHS. Any change from normal procedures also must ensure fair treatment to the subject of the inquiry or investigation. Any significant variation should be approved in advance by the Research Integrity Officer (or Misconduct in Research Committee) of NCCU.

3. Definitions

3.1. **Allegation** means a disclosure of possible research misconduct through any means of communication to an institutional official of Health and Human Services official.

3.2. **Conflict of interest** means the real or apparent interference of one person's interests with the interests of another person, where potential bias may occur due to prior, existing, or reasonable future personal or professional relationships.

3.3. **Deciding Official** means the institutional official who makes final determinations on allegations of research misconduct and any responsive institutional actions. The Deciding Official will not be the same individual as the Research Integrity Officer and should have no direct prior involvement in the institution's inquiry, investigation, or allegation assessment. The Deciding Official at NCCU is the Provost.

3.4. **Good faith** means having a belief in the truth of one’s allegation or testimony that a reasonable person in the complainant’s position could have based on the information known to the complainant or witness. An allegation is not in good faith if it is made with knowing or reckless disregard for information that would negate the allegation or testimony. Good faith as applied to a misconduct member means cooperating with the research misconduct proceeding by carrying out the duties assigned impartially for the purpose of helping the institution meet its responsibilities. A committee member has not acted in good faith if acts or omissions are dishonest or influenced by personal, professional, or financial conflicts of interests with those involved in the misconduct proceedings.

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

3.6. **Investigation** means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred and, if so, to determine the responsible person and the seriousness of the misconduct.

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

3.8. **PHS** means the U.S. Public Health Service, an operating component of the Department of Health and Human Services (DHHS).

3.9. **PHS Responsibilities** as set forth in 42 C.F.R. Part 93, Subpart D, entitled "Responsibility of U.S. Department of Health and Human Services" are to review, assess, and assist in the investigation of misconduct in research process.

3.10. **PHS support** means PHS grants, contracts, or cooperative agreements or applications thereof for biomedical or behavioral research, research training, or activities.

3.11. **Research** refers to any systematic experiment, study, evaluation, or demonstration or survey that results in data collection for the purpose of increasing public knowledge through written (manuscripts, reports, grant application) or oral communications (presentations, radio, TV, etc).

3.12. **Research Integrity Officer** means the institutional official responsible for assessing allegations of research misconduct and determining when such allegations warrant inquiries and for
overseeing inquiries and investigations.

3.13. **Research record** means any data, document, computer file, computer diskette, or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported research that constitutes the subject of an allegation of research misconduct. A research record includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; and patient research files.

3.14. **Respondent** means the person against whom an allegation of research misconduct is directed or the person whose actions are the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.

3.15. **Responsibilities of Institutions** as stated in 42 CFR Part 93 Subpart C includes compliance with assurance that there are institutional policies and procedures in place to execute proper proceedings for investigating and reporting misconduct in research.

3.16. **Retaliation** means any adverse action taken against a complainant, witness, or committee member by an institution or one of its members in response to a good faith allegation or good faith cooperation.

3.17. **Research misconduct or misconduct in science** means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the research community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.

3.18. **Research misconduct proceedings** means any action related to alleged research misconduct encompassed by this regulation or the PHS regulation, including but not limited to, preliminary assessments of allegations, inquiries, investigations, grievances, oversight reviews, hearings and administrative appeals.

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

4. **Rights and Responsibilities**

4.1. **Research Integrity Officer**

4.1.1 The chair of the Misconduct in Research Committee will serve as the Research Integrity Officer. The Misconduct in Research Committee will appoint the chair of that committee. The Research Integrity Officer for the university will have primary responsibility for implementation of the procedures set forth in this document. Therefore, it is imperative that the Research Integrity Officer be an institutional official who is well qualified to handle the procedural requirements involved and is sensitive to the varied demands made on those who conduct research, those who are accused of misconduct, and those who report apparent misconduct in good faith.

4.1.2 The Research Integrity Officer (RIO) is expected to have the responsibility of ensuring that the institution:

4.1.2.1 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.

4.1.2.2 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.

4.1.2.3 Complies with its written policies and procedures and the requirements of 42 CFR Part 93.

4.1.2.4 Informs its institutional members who are subject to 42 CFR Part 93 about its research misconduct policies and procedures and its commitment to compliance with those policies and procedures.

4.1.2.5 Takes appropriate interim action during a research misconduct proceeding to protect public health, federal funds and equipment, and the integrity of the PHS supported research process.

4.1.3 The responsibilities of the RIO include the following duties related to research misconduct proceedings:

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

4.1.3.2 Receive allegations of research misconduct;

4.1.3.3 Assess each allegation of research misconduct in accordance with 6.1. of this regulation to determine whether it falls within the definition of research misconduct and warrants an inquiry;

4.1.3.4 As necessary, take interim action and notify ORI of special circumstances, in accordance with 5.5. of this regulation;

4.1.3.5 Sequester research data and evidence pertinent to the allegation of research misconduct in accordance with 6.3. of this regulation and maintain it securely in accordance with this regulation and applicable law and regulation;

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

4.1.3.7 Notify the respondent and provide opportunities for him/her to review/ comment/respond to allegations, evidence, and committee reports in accordance with 4.3. of this regulation.

4.1.4 The Research Integrity Officer will appoint the inquiry and investigation committees and ensure that necessary and appropriate expertise is represented to carry out a thorough and authoritative evaluation of the relevant evidence in an inquiry or investigation. The Research Integrity Officer will attempt to ensure that confidentiality is maintained to the extent possible.

4.1.5 The Research Integrity Officer will assist inquiry and investigation committees and all institutional personnel in complying with these procedures and with applicable standards imposed by government or external funding sources. The Research Integrity Officer is also responsible for maintaining the integrity (confidentiality and security) of the files, documents, and evidence during the proceedings.

4.1.6 The Research Integrity Officer will report to the appropriate funding agency Research Integrity Officer (e.g., ORI) as required. The RIO will keep the funding agency or ORI apprised of any developments during the course of the inquiry or investigation that may affect current or potential funding (e.g., DHHS) for the individual(s) under investigation and will keep the funding agency informed of the proceedings to ensure appropriate use of Federal funds and otherwise protect the public interest.

4.2 Whistleblower or Complainant
4.2.1 The whistleblower/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 Research Integrity Officer has determined that the whistleblower may be able to provide pertinent information on any portions of the draft report, these portions will be given to the whistleblower for comment.

4.2.2 The whistleblower is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with an inquiry or investigation.

4.3. Respondent

4.3.1 The respondent will be informed of the allegations when an inquiry is opened and notified in writing of the final determinations and resulting actions. The respondent will also have the opportunity to be interviewed by and present evidence to the inquiry and investigation committees, to review the draft inquiry and investigation reports, and to have the advice of counsel.

4.3.2 The respondent is responsible for maintaining confidentiality and cooperating with the process and procedure of an inquiry or investigation. If the respondent is not found guilty of research misconduct, he or she has the right to receive institutional assistance in restoring his or her reputation.

4.4. Deciding Official

The Deciding Official will receive the inquiry and/or investigation report and any written comments made by the respondent or the whistleblower on the draft report. The Deciding Official will consult with the Research Integrity Officer or other appropriate officials and will determine whether to conduct an investigation, whether misconduct occurred, whether to impose sanctions, and whether to take other appropriate administrative actions [see 11. Institutional Administrative Actions].

5. General Policies and Principles

5.1. Responsibility to Report Misconduct

All employees or individuals associated with NCCU should report observed, suspected, or apparent misconduct in science to the Research Integrity Officer or any other member of the Misconduct in Research Committee. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may call the Research Integrity Officer at [919-530-7016] to discuss the suspected misconduct informally. If the circumstances described by the individual do not meet the definition of research misconduct, the Research Integrity Officer will refer the individual or the 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 Research Integrity Officer or any member of the Misconduct in Research Committee and will be counseled about appropriate procedures for reporting allegations.

5.2. Protecting the Complainant/Whistleblower

5.2.1 The Research Integrity Officer will monitor the treatment of individuals who bring allegations of misconduct or of inadequate institutional response thereto, and those who cooperate in inquiries or investigations. The Research Integrity Officer will ensure that these persons will not be retaliated against in the terms and conditions of their employment or other status at the institution and will review instances of alleged retaliation for appropriate action.

5.2.2 Employees should immediately report any alleged or apparent retaliation to the Research Integrity Officer.
Integrity Officer.

5.2.3 Also the institution, to the maximum extent possible, will protect the privacy of those who report misconduct in good faith. For example, if the whistleblower requests anonymity, the institution will make an effort to honor the request during the allegation assessment or inquiry within applicable policies and regulations and state and local laws, if any. The whistleblower will be advised that if the matter is referred to an investigation committee and the whistleblower's testimony is required, anonymity may no longer be guaranteed. NCCU will undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations.

5.3. Protecting the Respondent

5.3.1 Inquiries and investigations will be conducted in a manner that will ensure fair treatment to the respondent(s) in the inquiry or investigation and confidentiality without compromising public health and safety or policies and procedures of the inquiry or investigation.

5.3.2 Institutional employees accused of research misconduct 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.

5.4. Cooperation with Inquiries and Investigations

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

5.5. Preliminary Assessment of Allegations

Upon receiving an allegation of research misconduct, the Research Integrity Officer will immediately assess the allegation to determine whether there is sufficient evidence to warrant an inquiry, determine the funding agency involved (whether PHS support or PHS applications for funding), and whether the allegation falls under the definition of misconduct in research. This process may take up to 10 days.

6. Conducting the Inquiry

6.1. Initiation and Purpose of the Inquiry

Following the preliminary assessment, if the Research Integrity Officer determines that the allegation provides sufficient information to allow specific follow-up, determines funding source (e.g., PHS support), and falls under the definition of research misconduct, he or she will immediately initiate the inquiry process (Figure 1). In initiating the inquiry, the Research Integrity Officer should identify clearly the original allegation and any related issues that should be evaluated. The purpose of the inquiry is to make a preliminary evaluation of the available evidence and testimony of the respondent, whistleblower, and key witnesses to determine whether there is sufficient evidence of possible research misconduct to warrant an investigation. The purpose of the inquiry is not to reach a final conclusion about whether misconduct definitely occurred or who was responsible. The findings of the inquiry must be set forth in an inquiry report.

6.2. Sequestration of the Research Records

After determining that an allegation falls within the definition of misconduct in research and involves PHS funding, the Research Integrity Officer must ensure that all original research records and materials relevant to the allegation are immediately secured. The Research Integrity Officer may consult with ORI for advice and assistance in this regard. The Institution will take steps to ensure
that the records are secured and accurate inventory of evidence is maintained.

6.3.  Appointment of the Inquiry Committee

6.3.1 The Misconduct in Research Committee at NCCU will serve as a standing committee authorized to add or reuse members or to use experts when necessary to evaluate specific allegations. Within 10 days of the initiation of the inquiry, the Research Integrity Officer, in consultation with other institutional officials as appropriate, will direct the committee to meet. The inquiry committee should consist of individuals who can conduct an unbiased and impartial investigation; individuals who with appropriate expertise who do not have unresolved personal, professional, or financial conflicts of interests with those involved with the investigation. These individuals may be scientists, subject matter experts, administrators, lawyers, or other qualified persons, and they may be from inside or outside the institution.

6.3.2 The Research Integrity Officer will notify the respondent of the proposed inquiry committee membership in 10 days of its first meeting (see time line in Figure 2). If the respondent submits a written objection to any appointed member of the inquiry committee or expert based on bias or conflict of interest (within 5 days; see time line in Figure 2), the Research Integrity Officer will determine whether to replace the challenged member or expert with a qualified substitute.

6.4.  Charge to the Committee and the First Meeting

6.4.1 The Research Integrity Officer will prepare a charge for the inquiry committee that describes the allegations and any related issues identified during the allegation assessment and states that the purpose of the inquiry is to make a preliminary evaluation of the evidence and testimony of the respondent, whistleblower, and key witnesses to determine whether there is sufficient evidence of possible research misconduct to warrant an investigation as required by the PHS regulation. The purpose is not to determine whether research misconduct definitely occurred or who was responsible.

6.4.2 At the committee's first meeting, the Research Integrity Officer 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, and answer any questions raised by the committee. The Research Integrity Officer and institutional counsel will be present or available throughout the inquiry to advise the committee as needed.

6.5.  Inquiry Process

Once it has been determined that the reported behavior meets the definition of research misconduct an inquiry committee will be formed. An inquiry committee will normally interview the whistleblower, the respondent, and key witnesses in addition to examining relevant research records and materials. Then the inquiry committee will evaluate the evidence and testimony obtained during the inquiry. After consultation with the Research Integrity Officer and institutional counsel, the committee members will decide whether there is sufficient evidence of possible research misconduct to recommend further investigation. The scope of the inquiry does not include deciding whether misconduct occurred or conducting exhaustive interviews and analyses.

7.  The Inquiry Report

7.1.  Elements of the Inquiry Report

7.1.1 A written inquiry report must be prepared that states the name and title of the committee members and experts, if any; the allegations; the funding support; a summary of the inquiry process used; a list of the research records reviewed; summaries of any interviews; a description of the evidence in sufficient detail to demonstrate whether an investigation is warranted; and the
committee's determination as to whether an investigation is recommended and whether any other actions should be taken if an investigation is not recommended.

7.1.2 Institutional counsel will review the report for legal sufficiency.

7.2 Comments on the Draft Report by the Respondent and the Whistleblower

The Research Integrity Officer will provide the respondent with a copy of the draft inquiry report for comment and rebuttal and will provide the whistleblower, if he or she is identifiable, with portions of the draft inquiry report that address the whistleblower's role and comments in the investigation.

7.2.1 Confidentiality

The Research Integrity Officer may establish reasonable conditions for review to protect the confidentiality of the draft report.

7.2.2 Receipt of Comments

Within 14 calendar days of their receipt of the draft report (see time line in Figure 2), the whistleblower and respondent will provide their comments, if any, to the inquiry committee. Any comments that the whistleblower or respondent submits on the draft report will become part of the final inquiry report and record. Based on the comments, the inquiry committee may revise the report as appropriate.

7.3 Inquiry Decision and Notification

7.3.1 Decision by Deciding Official

The Research Integrity Officer will transmit the final report and any comments to the Deciding Official (usually the Provost), who will make the determination of whether findings from the inquiry provide sufficient evidence of possible research misconduct to justify conducting an investigation. The inquiry is completed when the Deciding Official makes this determination, which will be made within 60 days (see time line in Figure 2) of the first meeting of the inquiry committee. Any extension of this period will be based on good cause and recorded in the inquiry file.

7.3.2 Notification

The Research Integrity Officer will notify both the respondent and the whistleblower in writing of the Deciding Official's decision about whether to proceed to an investigation and will remind them of their obligation to cooperate in the event an investigation is opened. The Research Integrity Officer will also notify all appropriate institutional officials of the Deciding Official's decision.

7.4 Time Limit for Completing the Inquiry Report

The inquiry committee will normally complete the inquiry and submit its report in writing to the Research Integrity Officer no more than 60 calendar days (see time line in Figure 2) following its first meeting, unless the Research Integrity Officer approves an extension for good cause. If the Research Integrity Officer approves an extension, the reason for the extension will be entered into the records of the case and with the report. The respondent also will be notified of the extension.

8 Conducting the Investigation

8.1 Purpose of the Investigation

If the Deciding official determines from the inquiry report that an investigation is warranted a full scale investigation is begun within 30 days of the decision to begin an investigation. The entire investigation process must be completed within 120. The purpose of the investigation is to explore
detail the allegations, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged misconduct involves 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.

8.2. Sequestration of the Research Records

8.2.1 The Research Integrity Officer will immediately sequester any additional pertinent research records that were not previously sequestered during the inquiry following the decision to begin an investigation. This sequestration should occur before or at the time the respondent is notified that an investigation has begun.

8.2.2 The need for additional sequestration of records 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.

8.3. Appointment of the Investigation Committee

8.3.1 The Research Integrity Officer, in consultation with other institutional officials as appropriate, will appoint an investigation committee and the committee chair within 10 days (see time line in Figure 3) of the notification to the respondent that an investigation is planned or as soon thereafter as practicable. The investigation committee should consist of individuals who can conduct an unbiased and impartial investigation; individuals who with appropriate expertise who do not have unresolved personal, professional, or financial conflicts of interests with those involved with the investigation. These individuals may be scientists, administrators, subject matter experts, lawyers, 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.

8.3.2 The Research Integrity Officer will notify the respondent of the proposed committee membership within 5 days. If the respondent submits a written objection to any appointed member of the investigation committee or expert, the Research Integrity Officer will determine whether to replace the challenged member or expert with a qualified substitute.

8.4. Charge to the Committee and the First Meeting

8.4.1. Charge to the Committee

8.4.1.1 The Research Integrity Officer 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, define research misconduct, and identify the name of the respondent. The charge will state that the committee is to evaluate the evidence and testimony of the respondent, whistleblower, and key witnesses to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, to what extent, who was responsible, and its seriousness.

8.4.1.1 During the investigation, if additional information becomes available that substantially changes the subject matter of the investigation or that would suggest additional respondents, the committee will notify the Research Integrity Officer, who will determine whether it is necessary to notify the respondent of the new subject matter or to provide notice to additional respondents.

8.4.2. The First Meeting
The Research Integrity Officer, 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 these instructions and, where PHS funding is involved, the PHS regulation.

8.4.3. Investigation Process

8.4.3.1 The investigation committee will be appointed and the process initiated within 30 days of the completion of the inquiry, if findings from that inquiry provide a sufficient basis for conducting an investigation.

8.4.3.2 The investigation will normally involve examination of all documentation including, but not necessarily limited to, relevant research records, computer files, proposals, manuscripts, publications, correspondence, memoranda, and notes of telephone calls. Whenever possible, the committee should interview the whistleblower(s), the respondent(s), and other individuals who might have information regarding aspects of the allegations. Interviews of the respondent should be tape recorded or transcribed. All other interviews should be transcribed, tape recorded, or summarized. Summaries or transcripts of the interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file.

9. The Investigation Report

9.1. Elements of the Investigation Report

The final report submitted to ORI must describe the policies and procedures under which the investigation was conducted, describe how and from whom information relevant to the investigation was obtained, state the findings, and explain the basis for the findings. The report will include the actual text or an accurate summary of the comments of any individual(s) found to have engaged in misconduct as well as a description of any sanctions imposed and administrative actions taken by the institution. Additionally, the report shall include all original records and documents including recorded or transcripted interviews. These documents will retained for 7 years in a secure manner.

9.2. Comments on the Draft Report

9.2.1. Respondent

The Research Integrity Officer will provide the respondent with a copy of the draft investigation report for comment and rebuttal. The respondent will be allowed 14 days to review and comment on the draft report. The respondent's comments will be attached to the final report. The findings of the final report should take into account the respondent's comments in addition to all the other evidence.

9.2.2. Whistleblower

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

9.2.3. 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.

9.2.4. Confidentiality
In distributing the draft report, or portions thereof, to the respondent and whistleblower, the Research Integrity Officer 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 Research Integrity Officer may request the recipient to sign a confidentiality statement or to come to his or her office to review the report.

9.3. Institutional Review and Decision

9.3.1 Based on a preponderance of the evidence, the Deciding Official (usually the Provost) will make the final determination whether to accept the investigation report, its findings, and the recommended institutional actions. If the Deciding Official rejects the investigation report, findings, and/or recommendations, then, the Deciding Official will explain in detail the basis for rendering a decision different from that of the investigation committee in the institution's letter accompanying the investigation report to ORI. The Deciding Official's explanation should be consistent with the PHS definition of research misconduct, the institution's policies and procedures, and the evidence reviewed and analyzed by the investigation committee. The Deciding Official may also return the report to the investigation committee with a request for further fact-finding or analysis. The Deciding Official's determination, together with the investigation committee's report, constitutes the final investigation report for purposes of ORI review.

9.3.2 When a final decision on the case has been reached, the Research Integrity Officer will notify both the respondent and the whistleblower in writing. In addition, the Deciding Official 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 Research Integrity Officer is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

9.4. Transmittal of the Final Investigation Report to ORI

After comments have been received and the necessary changes have been made to the draft report, the investigation committee should transmit the final report with attachments, including the respondent's and whistleblower's comments, to the Deciding Official, through the Research Integrity Officer.

9.5. Time Limit for Completing the Investigation Report

An investigation should ordinarily be completed within 120 days of its initiation, with the initiation being defined as the first meeting of the investigation committee. This includes conducting the investigation, preparing the report of findings, making the draft report available to the subject of the investigation for comment, submitting the report to the Deciding Official for approval, and submitting the report to the ORI.

10. Requirements for Reporting to Funding Agency

10.1. An institution's decision to initiate an investigation must be reported in writing to the funding agency (e.g., Director of ORI in Washington, DC) on or before the date the investigation begins. 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 research misconduct, and the PHS applications or grant number(s) involved. The funding agency must also be notified of the final outcome of the investigation and must be provided with a copy of the investigation report. Any significant variations from the provisions of the institutional policies and procedures should be explained in any reports submitted to the funding agency (e.g., ORI).

10.2. If an institution plans to terminate an inquiry or investigation for any reason without
completing all relevant requirements of the PHS regulation, the Research Integrity Officer will submit a report of the planned termination to ORI, including a description of the reasons for the proposed termination.

10.3. If the institution determines that it will not be able to complete the investigation in 120 days, the Research Integrity Officer will submit to the funding agency (e.g., 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 Research Integrity Officer will file periodic progress reports as requested by the ORI or the funding agency.

10.4. When PHS funding or applications for funding are involved and an admission of research misconduct is made, the Research Integrity Officer 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, without prior approval from ORI, accept an admission of research misconduct as a basis for closing a case or not undertaking an investigation.

10.5. The Research Integrity Officer will notify the funding agency at any stage of the inquiry or investigation if:

10.5.1. there is an immediate health hazard involved; or

10.5.2. there is an immediate need to protect Federal funds or equipment; or

10.5.3. there is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is (are) the subject of the allegations as well as his/her co-investigators and associates, if any; or

10.5.4. it is probable that the alleged incident is going to be reported publicly; or

10.5.5. the allegation involves a public health sensitive issue, e.g., a clinical trial; or

10.5.6. there is a reasonable indication of possible criminal violation. In this instance, the institution must inform ORI within 24 hours of obtaining that information.

11. Institutional Administrative Actions

11.1 NCCU will take appropriate administrative actions against individuals when an allegation of misconduct has been substantiated.

11.2 If the Deciding Official determines that the alleged misconduct is substantiated by the findings, he or she will decide on the actions to be taken, after consultation with the Research Integrity Officer. The actions may include:

11.2.1 withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found.

11.2.2 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;

11.2.3 restitution of funds as appropriate.

12. Other Considerations

12.1. Termination of Institutional Employment or Resignation Prior to Completing Inquiry or Investigation
12.1.1 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 misconduct procedures.

12.1.2 If the respondent, without admitting to the misconduct, elects to resign his or her position prior to the initiation of an inquiry, but after an allegation has been reported, or during an inquiry or investigation, the inquiry or investigation will proceed. If the respondent refuses to participate in the process after resignation, the committee will use its best efforts to reach a conclusion concerning the allegations, noting in its report the respondent's failure to cooperate and its effect on the committee's review of all the evidence.

13. Restoration of the Respondent's Reputation

If the institution finds no misconduct and ORI concurs, after consulting with the respondent, the Research Integrity Officer will undertake reasonable efforts to restore the respondent's reputation. Depending on the particular circumstances, the Research Integrity Officer should consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in forums in which the allegation of research misconduct was previously publicized, and/or expunging all reference to the research misconduct allegation from the respondent's personnel file. Any institutional actions to restore the respondent's reputation must first be approved by the Deciding Official.

14. Protection of the Whistleblower

Regardless of whether the institution or ORI determines that research misconduct occurred, the Research Integrity Officer will undertake reasonable efforts to protect whistleblowers that made allegations of research misconduct in good faith and others who cooperate in good faith with inquiries and investigations of such allegations. Upon completion of an investigation, the Deciding Official will determine, after consulting with the whistleblower, what steps, if any, are needed to restore reputation of the whistleblower. The Research Integrity Officer is responsible for implementing any steps the Deciding Official approves. The Research Integrity Officer will also take appropriate steps during the inquiry and investigation to prevent any retaliation against the whistleblower.

15. Allegations Not Made in Good Faith

If relevant, the Deciding Official will determine whether the whistleblower's allegations of research misconduct were made in good faith. If an allegation was not made in good faith, the Deciding Official will determine whether administrative action should be taken against the whistleblower.

16. Interim Administrative Actions

Institutional officials will take interim administrative actions, as appropriate, to protect Federal funds and ensure that the purposes of the Federal financial assistance are carried out.

17. Record Retention

After completion of a case and all ensuing related actions, the Research Integrity Officer will prepare a complete file, including the records of any inquiry or investigation and copies of all documents and other materials furnished to the Research Integrity Officer or committees. The Research Integrity Officer will keep the file in a secure place with restricted access for a minimum of seven (7) 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.