Wake Forest Baptist Medical Center	**Policy on Research Integrity** 03-005-0002 RARI –P-02	**Type:**	**Tier 3**
		Original Effective Date:	**9-26-2006**
		Current (Revised) Date:	**8-1-17**
		Contact:	**Office of Regulatory Affairs and Research Integrity**
Approval Signature:		**Date of Signature:**	10/13/17
Name and Title: Christopher O'Byrne, Vice President, Research Administration and Operations			

1) **General Policy Statement:** It is in the best interest of the public and of academic medicine to prevent misconduct in research and to deal effectively and responsibly when misconduct is alleged or substantiated. The maintenance of public trust requires adherence to the ethical principles that govern scientific research, and is the responsibility of the faculty, staff and administration of an academic medical center to ensure the credibility and trustworthiness of research conducted.

   It is the policy of Wake Forest Baptist Medical Center (hereinafter WFBMC or Institution) to inquire into and, if necessary, to investigate and resolve in a timely and fair manner all instances of alleged research misconduct and to comply with sponsor requirements for reporting cases of possible misconduct when sponsored project funds are involved.

   a) Scope: This policy applies to faculty, staff, students, and other individuals engaged in research activities under the oversight of WFBMC regardless of funding source. Allegations of research misconduct involving students are subject to the applicable disciplinary rules and policies of the relevant school, but will also be reviewed, as appropriate, under this policy. In addition, WFBMC's subcontractors, collaborators and other third parties are expected to comply with their respective policies for reviewing and investigating research misconduct allegations.

   This policy does not address, and specifically excludes, fiscal improprieties and issues concerning the ethical treatment of human or animal subjects, authorship disputes, sexual harassment or discrimination, general matters not within the definition of scientific misconduct and criminal matters.

   In addition, because of the inherent unfairness and the difficulties presented by any attempt to assess stale evidence, allegations of misconduct based on events that occurred six or more years ago will not be subject to review under this policy unless clear and convincing mitigating circumstances are present, as determined by the Research Integrity Officer.

   b) Responsible Department/Party/Parties:
      i. Policy Owner: Clinical Translational Science Institute (CTSI)
      ii. Procedure: Office of Regulatory Affairs and Research Integrity
      iii. Supervision: Office of Regulatory Affairs and Research Integrity
      iv. Implementation: Office of Regulatory Affairs and Research Integrity

2) **Definitions:** For purposes of this Policy, the following terms and definitions apply:
   a) **WFBMC**: Wake Forest Baptist Medical Center and all affiliated organizations including Wake Forest University Health Sciences (WFUHS), North Carolina Baptist Hospital (NCBH), all on-site subsidiaries as well as those off-site governed by WFBMC policies and procedures.

b) **Research misconduct** is defined as fabrication, falsification, plagiarism, in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does **not** include honest error or differences of opinions.

I. **Fabrication** is making up data or results and recording or reporting them.

II. **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.

III. **Plagiarism** is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

c) Serious deviation from accepted practices includes but is not limited to:

- Stealing, destroying, or damaging the research property of others with the intent to alter the research record; and
- Directing, encouraging, or knowingly allowing others to engage in fabrication, falsification, or plagiarism

Other Relevant Definitions

a. Allegation refers to any evidence found by or written or oral statement of possible research misconduct made to an institutional official or research integrity officer, including department chairs, and deans.

b. Complainant refers to an individual(s) who, in good faith, submits an allegation of research misconduct.

c. Conflict of interest and commitment refers to a divergence between a faculty member's interests and his/her professional obligations to WFBMC, such that an independent observer might reasonably question whether the faculty member's professional actions or decisions are determined by considerations other than the best interest of WFBMC.

d. Deciding Official means the Institutional official (who, for the purposes of this Policy, is the Dean of the Wake Forest University School of Medicine) who makes final determinations on reports of scientific misconduct and any responsive Institutional actions.

e. Good faith allegation refers to an allegation made with the honest belief that research misconduct may have occurred. 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 or willful ignorance of facts that would disprove the allegation.

Inquiry refers to the initial process and preliminary information gathering activities for determining whether an allegation or apparent instance of research misconduct warrants an investigation.

Investigation refers to the formal examination and evaluation of all available relevant facts to determine if research misconduct has occurred, if so, to determine the responsible

person(s) and the seriousness of the research misconduct.

Preponderance of the evidence means proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.

Research refers to any systematic investigation, including research development, testing, and reporting, designed to develop or contribute to generalizable knowledge. The term encompasses basic research, applied research, and research training activities in biomedical and behavioral sciences.

Research Integrity Officer (RIO) refers to the institutional official appointed by the Dean of the School of Medicine to have primary responsibility for implementing and adhering to the procedures of this policy. The Research Integrity Officer has primary Institutional responsibility for assessing all reports of research misconduct and determining when such reports warrant inquiries and for overseeing inquiries and investigations. The Assistant Dean for Regulatory Affairs and Research Integrity is the Research Integrity Officer for WFBMC.

Research personnel

- *Faculty members* refers to professors, associate professors, assistant professors, and instructors. The term faculty includes individuals designated as "visiting" or "adjunct".
- *Students* refers to those individuals enrolled or participating in an academic program of Wake Forest University.
- *Other trainees* include, but are not limited to: pre-doctoral and post-doctoral trainees and fellows.
- *Research Staff* include, but are not limited to: administrators who support research activities, clinical research coordinators, individuals specifically granted Principal Investigator status, visiting scholars and other individuals conducting research at WFBMC.

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, and/or reported research that constitutes the subject of an allegation of scientific 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

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

Retaliation means an 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 of

research misconduct or of inadequate response thereto; or good faith cooperation with a research misconduct proceeding.

Sequestration refers to the collection and segregation of research records, equipment, and other tangible or intangible information for the specific purpose of assessing allegations as part of the research misconduct process. The Office of Regulatory Affairs and Research Integrity, under the direction of the Research Integrity Officer, has the authority and responsibility for sequestration of research records relative to research misconduct allegations at WFBMC. All appropriate rights are accorded to the respondent in the act of sequestrating research records, as outlined in **the *Role and Responsibilities of the Respondent*** section of this policy.

Sponsored Programs refers to research, training and instructional projects involving funds, materials, gifts, or other compensation from external governmental or non-governmental organizations under agreements with Wake Forest University Health Sciences (WFUHS) or WFBMC.

3) Roles and Responsibilities

Institution

The Institution holds the responsibility for responding to credible reports of allegations of research misconduct and has the burden of proof for making a finding of research misconduct.

Research Integrity Officer (RIO)

The Assistant Dean of Regulatory Affairs and Research Integrity serves as the Research Integrity Officer (RIO) has primary responsibility for overseeing this policy and implementing procedures associated with this policy. The RIO assesses allegations of research misconduct, determining when such allegations warrant inquiries, and oversees the inquiry and investigation processes. The RIO oversees the activities of the inquiry and investigation committees, and institutional personnel involved in proceedings governed by this policy, ensuring compliance with this policy and its implementing procedures.

If, during the course of research misconduct proceedings, a respondent admits guilt or a complainant withdraws the allegations, the RIO ensures the matter is handled and closed with appropriate due diligence and, as required, notifies federal oversight agencies. The RIO ensures proper and timely reporting to relevant external agencies and maintains files of all relevant documents and ensures the confidentiality and security of the files, including sequestered records and documentation of research misconduct proceedings.

Office of Regulatory Affairs and Research Integrity

The Office of Regulatory Affairs and Research Integrity, within the Clinical Translational Science Institute (CTSI), serves as WFBMC's independent and objective agent in research misconduct proceedings. This office supports and facilitates the inquiry and investigation process and has an obligation to maintain strict confidentiality relative to any research misconduct allegation proceedings. The Office of Regulatory Affairs and Research Integrity has the authority to appropriately sequester research records and/or other relevant information and documentation relative to allegations of research

misconduct. The Office of Regulatory Affairs and Research Integrity is also responsible for educating complainants, respondents, and committee members about WFBMC's process for research misconduct proceedings and for providing support and guidance to the committee members throughout the research misconduct proceeding.

Complainant

The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with an inquiry and investigation. The complainant has the opportunity to submit evidence to the inquiry and investigation committees. The complainant has the opportunity to appear before the inquiry committee, if requested and will be given the opportunity to be interviewed by and present evidence to the investigation committee. If the RIO or committees determine that the complainant may be able to provide pertinent information or clarification to any portion of the committees' draft reports, these portions may be given to the complainant for comment. The complainant will be informed in writing of the results of the inquiry and investigation.

Respondent

The respondent is responsible for maintaining confidentiality and cooperating with an inquiry and investigation.

The respondent is informed in writing of the final determinations and any resulting actions. The respondent has the opportunity to submit evidence to the inquiry and investigation committees, and will have an opportunity to be interviewed by and present evidence to inquiry and investigation committees. The respondent will be given the opportunity to review and comment upon the draft inquiry and investigation committee reports.

Inquiry Committee

The inquiry committee is responsible for conducting an initial review of the available evidence to determine whether or not to conduct an investigation. An inquiry does not require a full review of all the evidence related to the allegations, but will determine whether the allegations of research misconduct appear to be well-founded, the seriousness of the alleged research misconduct, and the scope of the alleged incident. The inquiry committee may also identify, in the course of its duties, issues that would justify broadening the scope beyond the initial allegations, and may recommend that the committee examine these issues. If the inquiry committee expands the scope of the research misconduct process beyond the initial allegations, the RIO will notify the respondent in writing and the respondent will be given an opportunity to respond to the additional issues. The inquiry committee prepares a final report that meets the requirements as outlined in the implementing procedures of the policy, including recommending whether each allegation warrants an investigation and the basis for its recommendation. It is **not** the responsibility of the inquiry committee to make a final determination on the merits of the allegations.

Investigation Committee

The investigation committee is responsible for conducting a thorough examination of all facts and evidence relevant to the allegations, including interviewing the respondent, complainant, and others as necessary and appropriate, to determine based on a

preponderance of evidence whether research misconduct has occurred and, if so, to determine the responsible person(s) and the nature and seriousness of the research misconduct. The investigation committee may also identify, in the course of its duties, issues that would justify broadening the scope beyond the initial allegations, and may recommend that the committee examine these issues. If the investigation committee expands the scope of the research misconduct process beyond the initial allegations, the RIO will notify the respondent in writing and the respondent will be given an opportunity to respond to the additional issues. The investigation committee prepares a final report that meets the requirements as outlined in the implementing procedures of the policy, including a finding for each allegation of whether research misconduct occurred, the nature and seriousness of the misconduct, and the responsible individual(s).

Inquiry and Investigation Committee Chairs

The Inquiry and Investigation Committee chairs are selected by the Research Integrity Officer, who serves as the individual who takes the lead in drafting the respective Committee reports based on the Committee's findings. Working with the RIO, the Inquiry and Investigation Committee chairs handle the compilation of comments from the other committee members into the final committee report and ensure the report is distributed to the committee members for final signature. The elements of the committee report must be in accordance with the required elements outlined in the implementing procedures section of this policy. The committee chair ensures that the respondent is afforded the opportunity to comment, that the respondent's comments are considered by the committee, and that the respondent's comments are reflected in and/or attached to the final committee report.

4) Policy Guidelines:

a) General Requirements:

i.) Responsibility to Report Research Misconduct

All employees or other individuals associated with WFBMC should report promptly, any concerns regarding possible research misconduct. If an employee or individual is uncertain about whether the concern qualifies as research misconduct, he or she may contact the Research Integrity Officer (RIO) to discuss the concern informally and confidentially. If the circumstances described by the individual do not meet the definition of research misconduct, the RIO may refer the individual or allegation to other offices with responsibility for resolving the concern as necessary and appropriate.

Reports can be made on an informal (oral) or formal (written) basis. Formal allegations should be submitted in sufficient detail to permit a preliminary assessment into whether an inquiry is warranted. Reasonable efforts will be made to review and resolve informal reports of alleged misconduct; however, such reports will not be processed through the procedures set out below unless they are submitted in writing or confirmed separately through available evidence.

ii.) Requirements for Findings of Research Misconduct

A finding of research misconduct requires that:

- There be a significant departure from accepted practices of the relevant research community; and
- The research misconduct be committed intentionally, knowingly, or recklessly; and
- The allegation be proven by a preponderance of evidence

iii.) Cooperation with Inquiries and Investigations

Individuals covered under this policy must cooperate with the RIO and other institutional officials in the review of allegations and during inquiries and investigations. Such individuals also have an obligation to provide relevant information to the RIO or other institutional officials about research misconduct allegations. Moreover, individuals covered under this policy shall cooperative fully and on a continuing basis with ORI during its oversight reviews of this institution and its research misconduct proceedings and during the process under which the respondent may contest ORI findings of research misconduct and proposed HHS administrative actions

Failure to cooperate is a violation of this policy and may result in disciplinary action.

iv.) Protection and Restoration of Reputations

Respondents

Inquiries and investigations are conducted in a manner that ensures fair treatment to the respondent and confidentiality to the extent possible without compromising public health and safety or thoroughly carrying out the needs of an inquiry and/or investigation.

WFBMC will undertake all reasonable, practical, and appropriate efforts to protect and restore the reputation of any person alleged to have engaged in research misconduct, but against whom no finding of research misconduct was made, if that person or his/her legal counsel or other authorized representative requests that WFBMC do so.

Complainants

Institutional officials who receive or learn of a report of research misconduct will treat the complainant with fairness and respect and, when the report has been made in good faith, will take reasonable steps to protect and restore the position and reputation of any complainant, witness, or committee member and to counter potential or actual retaliation against those complainants, witnesses and committee members. Any alleged or apparent retaliation should be reported to the RIO or other institutional official.

v.) Interim Protective Actions

At any time during a research misconduct proceeding, WFBMC shall take appropriate interim actions to protect public health, federal funds and equipment, and the integrity of PHS supported research process. The necessary actions will vary according to the circumstance of each case, but actions that may be necessary which include delaying the

publication of research results, providing for closer supervision of one or more researchers, requiring approvals for actions relating to the research that did not previously require approval, auditing pertinent records, or taking steps to contact other institutions that may be affected by an allegation of research misconduct.

vi.) Confidentiality

Efforts will be taken to ensure confidentiality is maintained. Disclosure of the identity of respondents and complainants in research misconduct proceedings is limited, to the extent possible, to those who need to know, consistent with a thorough, competent, objective and fair research misconduct proceeding, and as allowed by law. The applicable laws and regulations may require the institution to disclose the identity of respondents and complainants to federal oversight agencies pursuant to the agency's review of institutional research misconduct proceedings.

vii.) Legal Counsel

WFBMC nor the respondent may have legal counsel present at the proceedings of the inquiry and investigation committees, except at the invitation of the committees, which shall be at the sole discretion of the committees. Should counsel be invited, the invitation will be extended to both parties. When invited, legal counsel may observe but shall not participate in the proceedings. With the prior approval of the committees, which approvals shall be in the sole discretion of the committees, the respondent may be accompanied by a non-attorney colleague at the meetings of the committees. When approved, the non-attorney colleague may observe but shall not participate in the proceedings.

viii.) Prevention of Research Misconduct

The Institution strives to provide an open and stimulating environment for creativity and individual thought where faculty and staff members will develop independently and productively. It is intended that this climate will promote high ethical standards and enhance the research process.

The Institution will provide training to faculty, staff and other individuals involved in research to promote the responsible conduct of research and discourage research misconduct.

5) Review/Revision/Implementation

a) Review Cycle: This policy shall be reviewed by the Office of Regulatory Affairs and Research Integrity at least every three years from the effective date.

b) Office of Record: After authorization, the Legal Department shall house this policy in a policy database and shall be the office of record for this policy.

6) Related Policies

No Retaliation
Harassment

7) Governing Law or Regulations

42 CFR Part 93

8) Attachments

Appendix A: Procedures for Reviewing Alleged Scientific Research Misconduct

9) Revision Dates: June 22, 2017

Appendix A

Procedures for Reviewing Alleged Scientific Research Misconduct

RARI –P-02-01

1.1 General

a. The procedures for evaluating and responding to allegations of research misconduct proceed in three stages:

- A preliminary assessment of the allegations to determine if the report requires further inquiry
- An inquiry to determine if there is sufficient credible evidence to justify an investigation
- An investigation to make definitive findings of fact and reach conclusions

b. A finding of research misconduct requires:

- That there be a significant departure from accepted practices of the relevant research community;
- The misconduct be committed intentionally, knowingly or recklessly; and
- The allegation be proven by a preponderance of the evidence.

1.2 Preliminary Assessment of the Allegation

Allegation Assessment

Allegations of research misconduct should be reported to the Research Integrity Officer (RIO), who will determine if the allegations fall under the definition of research misconduct and whether the report requires further attention and inquiry. The purpose for the preliminary assessment is to determine the appropriate roles and responsibilities of WFBMC, its personnel, and oversight agencies with respect to evaluating the allegations, as well as to identify individuals, information and data relevant to the allegation.

Determination to Conduct an Inquiry

If, after assessing the allegation, the RIO finds that there is a reasonable basis for concluding that the allegation warrants further action and meets the definition of research misconduct, as defined in WFBMC's *Policy on Research Integrity*, a research misconduct inquiry will be initiated.

Determination to Dismiss an Allegation

If, after assessing the allegation, the RIO finds that the allegation does not warrant

further action and/or does not meet the definition of research misconduct as defined in the policy, the RIO will formally dismiss the allegation. The RIO need not notify the respondents of such allegations but will notify the Complainant that the allegations will not be pursued under WFBMC's *Policy on Research Integrity.*

The Research Integrity Officer will document the determination related to the preliminary assessment of all allegations, regardless of their disposition, in sufficient detail to permit later assessment of that determination. Documentation will be maintained as outlined in the record retention requirements for these procedures.

1.3 Conducting the Inquiry

Purpose of Inquiry

Once the RIO determines that the preliminary assessment of the allegations of misconduct warrants further follow-up he/she will initiate the inquiry process. The purpose of the inquiry is to determine whether the allegation of research misconduct warrants an investigation based on an initial review of the available evidence. The purpose of the inquiry is not to make a final determination of whether research misconduct occurred or who was responsible.

Timeframe for Completing the Inquiry

The inquiry committee should be convened within 30 days of the determination to convene an inquiry. The inquiry committee will complete the inquiry and submit its report in writing to the RIO no more than 60 calendar days following its first meeting, unless the RIO approves an extension for good cause. If the RIO approves an extension, the reason for the extension will be entered into the records of the case and the report. The respondent will also be notified of the extension.

Sequestration

As soon as the RIO determines that an inquiry is required he/she will take all reasonable and practicable steps to:

a. Secure and take custody of all the relevant research records and evidence needed to conduct the research misconduct proceeding;

b. Inventory the records, and evidence; and

c. Sequester records and evidence in a secure manner.

The respondent may be asked to assist the RIO with location and identification of research records relevant to the Inquiry.

Individuals may not interfere with the Institution's right to access, obtain and sequester all relevant records.

As new evidence becomes known, the RIO will take custody of any additional research records and evidence relevant to the inquiry. Research records and evidence are not limited to those of the respondent, but include all research records and evidence the RIO determines to be relevant to the Inquiry. The RIO may obtain the

assistance of other individuals to assist in obtaining and sequestering records.

Notifications

Within 15 days of the determination to convene an Inquiry, the RIO should notify the respondent in writing of the allegation (s). This notification establishes the beginning of the inquiry process. Respondent notification includes:

- The specific allegation(s)
- The rights and responsibilities of the respondent including the institutional policy on retaliation and the need to maintain confidentiality during the inquiry;
- The role of the inquiry committee;
- A description of the inquiry process; and
- Copies of WFBMC's *Policy on Research Integrity* and *WFBMC's Procedures for Reviewing Alleged Scientific Research Misconduct*

The notification to the respondent will be copied to, the Deciding Official , the VP for Research Administration, the respondent's department chair and other institutional officials as deemed appropriated by the RIO.

Selection of Inquiry Committee

The RIO will appoint a minimum of three full-time faculty members to serve on the inquiry committee. The faculty members must be at the level of Associate Professor or above who:

- Have the necessary scientific expertise to evaluate the evidence and issues related to the allegation;
- Have no personal, professional, or financial conflicts of interest with the complainant or respondent;
- Have no supervisory or mentor relationship with the respondent or Complainant;
- Has not been a close collaborator or co-investigator with the respondent or Complainant;
- Has not been a party to a scientific controversy with the respondent or Complainant; and
- Falls within any other circumstance that might appear to compromise the individual's objectivity in reviewing the allegations.

The RIO will designate one member to chair the Committee. The RIO will serve as an ex officio, non-voting member of the inquiry committee. Administrative assistance will be provided as needed and Institutional Legal Counsel will be available to advise the committee.

Charge to the Inquiry Committee

The RIO provides the charge to the inquiry committee, which includes:

- Purpose of the inquiry
- Definition of research misconduct
- Timeframe for completion
- Identification of respondent
- Specific Allegations to be evaluated
- Copies of WFBMC's *Policy on Research Integrity* and *Procedures for Reviewing Alleged Scientific Research Misconduct*
- Responsibilities of the inquiry committee, including:
    - Initial review of evidence; including review of documentation and evidence;
    - Interviews of complainant, respondent and/or others if deemed necessary and appropriate;
    - Preparation of a final report; and

Additional experts other than those appointed to the committee may need to be consulted during the inquiry to provide special expertise to the committee regarding the analysis of specific evidence. These individuals are strictly advisory and do not vote, but they may participate in interviews of witnesses if permitted by the committee. The experts chosen may be from inside or outside of the Institution.

Members of the committee, experts, witnesses and other attendees will agree in writing to observe the confidentiality of the proceeding and any information, documents, materials, testimony or other evidence reviewed as part of the inquiry. Outside of the official proceedings of the committee, they may not discuss the proceedings with the respondent or complainant, witnesses, or anyone else not authorized by the RIO to have knowledge of the inquiry.

The RIO will replace any committee member or expert who for whatever reason becomes unable to participate in the proceedings or who is determined by the RIO at any time during the proceedings to have an actual or potential conflict of interest.

1.4 The Inquiry Report

At the conclusion of an inquiry, the inquiry committee prepares a written report of its findings and recommendations. The required elements of the inquiry report are:

- Name and title of the committee members and experts, if applicable;
- Committee charge, i.e., identification of respondent and description of allegation(s;;
- A summary of the inquiry process, i.e., in accordance with *WFBMC's Policy on Research Integrity* and *WFBMC's Procedures for Reviewing Alleged Research Misconduct*;
- A list of research records reviewed;

- The basis for the inquiry's committee's recommendations for each allegation;
- Identification of any federal support;
- Summaries of interviews if applicable; and
- Committee determination as to whether an investigation is recommended and/or other actions that should be taken.

The RIO will transmit the final report with the committee's findings and recommendations to the Deciding Official, who will make the determination whether findings from the inquiry provide sufficient evidence of possible scientific misconduct to justify conducting an investigation. The inquiry is completed when the Deciding Official makes this determination, which will be made within 60 days of the first meeting of the inquiry committee (unless an extension of time has been granted by the RIO).

The notice will include a copy of the final inquiry report and reference to this Institutional policy.

1.5 Conducting the Investigation

Purpose of Investigation

Once it has been determined that the criteria for an investigation have been met, the RIO will initiate the investigation process within 30 calendar days. The purpose of the investigation is to determine, based on a preponderance of the evidence, whether research misconduct has occurred and, if so, to determine the responsible person (s) and the nature and seriousness of the research misconduct.

Timeframe for Completing the Investigation

The investigation committee is generally convened within 30 days of the determination to convene an investigation. All aspects of the Investigation, including conducting the investigation, preparing the report of finding, providing the draft report for comments and distribution of the final report must be completed within 120 days of beginning the investigation.

If the investigation cannot be completed within 120 days, an extension of the time limit may be requested in writing. The request for an extension of time to complete the investigation is made in writing by the RIO to the Office of Research Integrity for formal approval.

Sequestration of Records

As soon as possible after the initiation of the Investigation the RIO will 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 RIO may obtain the assistance of other individuals to assist in obtaining and sequestering records. Upon obtaining any additional research records, the RIO will inventory, record and secure all records.

Notifications

Within 15 days of the determination to convene an investigation, the RIO notifies the respondent in writing of the decision to convene an investigation. Respondent notification includes:

- The specific allegations;
- The research project in question;
- The study sponsor, if applicable;
- The rights and responsibilities of the respondent;
- The role of the investigation committee;
- Describe the institution's policy on non-retaliation;
- The need to maintain confidentiality;
- The investigation process timeline; and
- Copies of WFBMC's *Policy on Research Integrity and Procedures for Reviewing Alleged Scientific Research Misconduct.*
- For PHS supported research, the notice will include reference to the Public Health Service Policies on Research Misconduct, 42 CFR Part 93.

A copy of the final Inquiry report will be provided as an attachment to the notice.

For PHS supported research, the notice will also include the source of PHS funding; the fact that the Office of Research Integrity (ORI) will perform an oversight review of the report regarding PHS issues; and an explanation of the respondent's right to request a hearing before the DHHS Departmental Appeals Board if there is an ORI finding of misconduct under the PHS definition. The Research Integrity Officer will notify the ORI Director of the decision to begin an investigation on or before the date the investigation begins and provide an inquiry report that meets the requirements as is outlined in 42 CFR § 93.307 and 42 CFR § 93.309 in the Office of Research Integrity (ORI).

The notification to the Respondent will be copied to, the Deciding Official, the VP for Research Administration, the Respondent's departmental chair and other institutional officials as deemed appropriated by the RIO.

The RIO will also notify the complainant, in writing, of the Deciding Officials decision to proceed with an investigation. The notice will include a copy of the final inquiry report and reference to the *Policy Research Integrity.*

Selection of Investigation Committee

The RIO will appoint a minimum of full-time faculty members to serve on the investigation committee and select one member to chair the committee. The RIO will serve as an ex officio, non-voting member of the investigation committee. Administrative assistance will be provided as needed and Institutional Legal Counsel will be available to advise the committee.

Members of the inquiry committee may also serve on the investigation committee if

deemed appropriate by the RIO. The investigation committee must include faculty members at the level of Associate Professor or above who:

- Have the necessary scientific expertise to evaluate the evidence and issues related to the allegation;
- Have no personal, professional, or financial conflicts of interest with the complainant or respondent;
- Have no supervisory or mentor relationship with the respondent or Complainant;
- Has not been a close collaborator or co-investigator with the respondent or complainant;
- Has not been a party to a scientific controversy with the Respondent or complainant; and
- Falls within any other circumstance that might appear to compromise the individual's objectivity in reviewing the allegations.

When appropriate, the RIO, in consultation with the investigation committee, may appoint experts from outside of WFBMC to serve on the investigation committee. The respondent will be notified in writing of the proposed investigation committee membership. The respondent will be given an opportunity to object to any proposed member based on a personal, professional, or financial conflict of interest. The respondent will submit any objections within 7 days of notification of the potential committee membership. The RIO will make the final determination of whether any such conflicts exist.

Responsibilities of Investigation Committee

The investigation committee is responsible for conducting a thorough examination of all facts and evidence to the investigation to determine, based on a preponderance of evidence, whether research misconduct has occurred and, if so, to determine the responsible person(s) and the nature and seriousness of the research misconduct. The investigation committee may also identify, in the course of its duties, if there are issues which would justify broadening the scope of the misconduct proceeding beyond the initial allegation.

The investigation committee must interview the complainant, the respondent, and any other available persons who have been reasonably identified as having information relevant to the investigation. Interviews are recorded or transcribed and provided to the interviewee for correction. The investigation committee comes to a finding for each allegation determining whether research misconduct occurred, by whom and to what extent, taking into account that a finding of research misconduct requires a preponderance of evidence, a significant departure from accepted practices in the relevant scientific community, and the research misconduct must have been committed intentionally, knowingly and recklessly. The investigation committee summarizes its

findings and recommendations in written report to Deciding Official. The decision will be based on a simple majority vote of all appointed committee members.

Charge to Investigation Committee

The RIO provides the charge to the investigation committee, which includes:

- Purpose of the investigation
- Definition of research misconduct
- Requirements for findings of research misconduct
- Timeframe for completion
- Identification of respondent
- Specific Allegations to be evaluated
- Responsibilities of the investigation committee, including:
    - Examination of evidence; including review of all relevant documentation;
    - Interviews of complainant and respondent;
    - Interviews of other persons as necessary and appropriate;
    - A finding, for each allegation, determining whether research misconduct occurred, and if so, to determine the responsible person and the nature and seriousness of the research misconduct;
    - Preparation of a final report; and
- Copies of WFBMC's *Policy on Research Integrity* and *Procedures for Reviewing Alleged Scientific Research Misconduct*

Members of the committee, experts, witnesses and attendees will agree in writing to observe the confidentiality of the proceeding and any information, documents, materials, testimony or other evidence reviewed as part of the Investigation. Outside of the official proceedings of the committee, they may not discuss the proceedings with the respondent or complainant, witnesses, or anyone else not authorized by the RIO to have knowledge of the Investigation.

1.6 The Investigation Report

At the conclusion of an investigation, the investigation committee will prepare a written report that summarizes its findings and recommendations. The required elements of the investigation committee report include:

- Purpose of the investigation;
- Definition of research misconduct;
- Requirements for findings of research misconduct;

- Timeframe for completion;
- Identification of respondent;
- Specific allegation(s) to be evaluated;
- Responsibilities of the investigation committee, including:
    - Examination of evidence, including review of all relevant documentation;
    - Interviews of complainant and respondent;
    - Interviews of other persons as necessary and appropriate;
    - A finding, for each allegation, determining whether research misconduct occurred, and if so, to determine the responsible person and the nature and seriousness of the research misconduct;
    - Preparation of a final report; and
    - Copies of WFBMC's *Policy for Reviewing Alleged Research Misconduct* and *Procedures for Reviewing Alleged Research Misconduct.*

The Investigation Committee will submit a draft Investigation report to the RIO, who will provide the Respondent with a copy of the draft report for comment and rebuttal. The respondent must provide any written comments within 30 days of receipt of the draft investigation committee report. The Committee will review any submitted comments, revise the report as they feel appropriate, and submit a final copy of the inquiry Report to the RIO. The written comments submitted will be attached to the final report.

In addition, the RIO may provide the complainant with those portions of the draft investigation report that address the complainant's role and opinions in the investigation.

Institutional Decision

If the investigation committee finds that research misconduct has occurred, the RIO will transmit the final Investigation report and any comments to the Deciding Official who will determine whether the allegations of research misconduct are substantiated.

Institutional Actions

If the Deciding Official determines that the findings of research misconduct are substantiated, he/she will then decide on the appropriate actions to be taken. Such action may include, without limitation, removal from a specific project; letter of reprimand; special monitoring of future work; probation; suspension; salary reduction; demotion; or termination. In consultation with the Institutional Legal Department, institutional administrators may release appropriate information to the public about the incident, particularly when public funds were used in supporting the research.

Finding of no misconduct

If the allegations of research misconduct are not substantiated, WFBMC will undertake all reasonable, practical, and appropriate efforts to protect and restore the reputation of any person alleged to have engaged in research misconduct, but against whom no finding of research misconduct was made, if that person or his/her legal counsel or other authorized representative requests that WFBMC do so. In addition, appropriate

disciplinary action may be taken against any individual whose involvement in the research misconduct proceedings as was determined by the Deciding Official to have been malicious or intentionally dishonest.

Notifications

The respondent is notified in writing of the results of the investigation, including a copy of the final investigation report with all attachments. The RIO notifies the department chair or equivalent in the respondent's department. As required, the RIO notifies federal oversight agencies in writing of the investigation committee's findings, whether the institution accepts the investigation committee's findings and any completed or pending institutional actions or sanctions. The formal notification to the federal Office of Research Integrity (ORI) includes a copy of the investigation report with all attachments. The RIO will also notify the complainant of the results of the investigation.

Institutions and sponsoring agencies with which the individual has been affiliated will be notified if there is reason to believe that the validity of previous research might be questionable.

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

The RIO must notify the Office of Research Integrity in advance of plans to close a case at the inquiry, investigation or appeal stage because the Respondent has admitted guilt, a settlement with the Respondent has been reached, or for any other reason other than a finding that no inquiry is warranted, or no research misconduct has occurred.

Notifying the Office of Research Integrity (ORI) of circumstances that may require protective actions

At any time during the assessment period or research misconduct proceedings, or in the case of PHS-sponsored research the RIO will notify the appropriate funding and oversight agency(ies) if:

- Public health or safety is at risk
- Agency resources or interests are threatened
- Research activities should be suspended;
- There is reasonable indication of possible violations of civil or criminal law;
- Federal action is required to protect the interests of those involved in the investigation; or if
- It is probable that the reported incident is going to be reported publicly and the research community or public should be informed

1.1 Record Retention

All documentation and records related to allegations of research misconduct, regardless of whether they resulted in an inquiry or investigation will be retained and secured by the RIO in the Office of Regulatory Affairs and Research Ethics for a period of seven years from the date of the receipt of the allegation. All documentation and records related to research misconduct inquiries and investigation will be retained and secured for a period of seven years from the date of the completion of the research misconduct proceedings.