WEILL CORNELL MEDICAL COLLEGE AND
WEILL CORNELL GRADUATE SCHOOL OF MEDICAL SCIENCES
POLICY AND PROCEDURES GOVERNING RESEARCH INTEGRITY

This policy applies to allegations of research misconduct (as defined below) involving a person who at the time of the alleged research misconduct was employed by, was an agent of, or was affiliated by contract or agreement with Weill Cornell Medical College (WCMC) and/or Weill Cornell Graduate School of Medical Sciences (GSMS) (collectively, the "Institution"). Accordingly, the policy shall apply to all faculty, non-faculty academic staff, non-academic staff, medical and graduate students and graduate trainees who are engaged in the conduct of research, regardless of the source of funding, if any. For individuals holding primary faculty appointments at another institution, this document applies only to those functions performed as members of the faculties of WCMC or GSMS.

This policy applies to all allegations of research misconduct that occurred within six (6) years prior to the date of the allegation. However, exceptions to the six (6) year time frame may apply in instances where the Institution determines that the alleged misconduct, if it occurred, could have a substantially adverse effect on the health or safety of the public; if the respondent (as defined herein) continues or renews any incident of alleged research misconduct through the citation, republication or other use for his or her potential benefit; or under certain grandfather exceptions set forth under relevant laws.

I. PREAMBLE

Truth, integrity, and credibility are critical and distinctive principles of any educational and research institution. Adherence to these principles is essential for the efficient progress of scientific research and to preserve the trust of the public in the research community. The maintenance of accepted standards in research based on these principles is highly regarded by the scientific community and is a major responsibility of WCMC and the GSMS. Consequently, these institutions must set standards and procedures for their members in order to preserve truth, integrity, and credibility in research, to prevent research misconduct, and to deal efficiently and fairly with allegations or other indications of research misconduct. At all levels of the Institution, support for quality rather than quantity of research should be stressed.

II. DEFINITIONS

A. For the purposes of this policy, research misconduct is defined as scientific misconduct (as defined in Section (II)(A)(1) below) and other conduct that seriously deviates from acceptable research practices.

1. **Scientific Misconduct. Scientific misconduct** is generally defined as any act that violates the standards of integrity in proposing, performing or reviewing research or in reporting research results. Such acts include, but are not limited to:

* **Fabrication** means the making up of data or results and recording or reporting them.

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

* **Falsification** means the manipulation of research materials, equipment or processes or changing or omitting data or results such that the research is not accurately represented in the research record.

2. **Other conduct that seriously deviates from acceptable research practices.** Examples of conduct that seriously deviates from acceptable research practices include:

* **Abuse of Confidentiality** means misuses of confidential information or failure to maintain the confidentiality of such information, e.g., "stealing" of information obtained through review of research proposals, manuscripts, etc.

* **Violation of pertinent federal or institutional regulations and ethical codes**, e.g. those involving the protection of human subjects and the welfare of laboratory animals.

* **Aiding or Facilitating** acts of academic dishonesty by others.

* **Breaches of research integrity** other than those enumerated above that seriously deviate from those that are commonly accepted in the research community for proposing, conducting, reviewing or reporting research.

Honest error or honest differences in interpretation or judgment of data are not regarded as research misconduct.

B. Other Definitions:

1. **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 the institutional research integrity officer.

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

3. **Deciding Official (DO)** means the institutional official who makes final determinations on allegations of research misconduct and any institutional administrative actions. This person shall be the Dean of the GSMS.

4. **Evidence** means any document, tangible item, or testimony offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact.

5. **Good faith,** as applied to a complainant or witness, means having a belief in the truth of one's allegation or testimony that a reasonable person in the complainant's or witness's position could have based on the information known to the complainant or witness at the time. An allegation or cooperation

with a research misconduct proceeding 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 committee member means cooperating with the purpose of helping an institution meet its responsibilities under this policy.

6. **Inquiry** means preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures set forth herein.

7. **Institutional member** means a person who is employed by, is an agent of, or is affiliated by contract or agreement with WCMC or GSMS. Institutional members may include, but are not limited to, officials, tenured and untenured faculty, teaching and support staff, researchers, research coordinators, clinical technicians, postdoctoral and other fellows, students, volunteers, agents, and contractors, subcontractors, and subawardees, and their employees.

8. **Investigation** means the formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation for a finding of research misconduct which may include a recommendation for other appropriate actions.

9. **Reportable Scientific Misconduct** means fabrication, falsification or plagiarism in proposing, performing or reviewing research or in reporting research results, when such activities involved the use of funds from the federal public health service.

10. **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.

11. **Records of research misconduct proceedings** means: (1) the research records and evidence secured for the research misconduct proceeding pursuant to this policy, except to the extent the Research Integrity Officer determines and documents that those records are not relevant to the proceeding or that the records duplicate other records that have been retained; (2) the documentation of the determination of irrelevant or duplicate records; (3) the inquiry report and final documents (not drafts) produced in the course of preparing that report, including the documentation of any decision not to investigate; (4) the investigation report and all records (other than drafts of the report) in support of the report, including the recordings or transcripts of each interview conducted; and (5) the complete record of any appeal.

12. **Research Integrity Officer (RIO)** means the institutional official responsible for: (1) assessing allegations of research misconduct to determine if they fall within the definition of research misconduct, and warrant an inquiry; (2) overseeing inquiries and investigations; and (3) the other responsibilities described in this policy. This person shall be the Associate/Assistant Dean of Research Integrity and is reachable at ResearchIntegrity@med.cornell.edu.

13. **Research record** means the record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to a government agency or an institutional official by a respondent in the course of the research misconduct proceeding.

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

15. **Retaliation** means an adverse action taken against a complainant, witness, or committee member by this institution or one of its institutional members in response to (1) a good faith allegation of research misconduct; or (2) good faith cooperation with a research misconduct proceeding.

III. GUIDING PRINCIPLES FOR PRESERVING RESEARCH INTEGRITY

The administration, faculty, students and other staff all share in the responsibility for preserving research integrity and preventing research misconduct. Together they must create an atmosphere that promotes high ethical standards and fosters honest research. Within this framework, it is the Institution's obligation to establish standards and responsibilities for its members, and to hold its members accountable for transgression of this policy. Faculty and students are required to follow the Institution's Standards of Ethical Conduct. The Institution considers violation of the tenets described under the "Preamble" to represent a major breach of contract between the faculty or staff member and the Institution. Mechanisms for dealing with instances of alleged research misconduct are described herein. Institution and its members will implement the policy in a manner consistent with the spirit of sustaining an atmosphere of research integrity, and in accordance with all applicable laws, rules and policies.

A. Responsibility to Report Misconduct. All institutional members will report observed, suspected, or apparent research misconduct to the RIO. Any institutional official who receives an allegation of research misconduct must report it immediately 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 ResearchIntegrity@med.cornell.edu or call 212-821-0612 to discuss the suspected research misconduct informally, which may include discussing it anonymously and/or hypothetically. At any time, an institutional member may have confidential discussions and consultations about concerns of possible misconduct with the RIO and will be counseled about appropriate procedures for reporting allegations.

B. Cooperation with Research Misconduct Proceedings. Institutional members shall 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. In research misconduct proceedings that involve Reportable Scientific Misconduct, institutional members shall cooperate with the relevant government agencies.

C. Confidentiality. The identity of respondents and complainants shall be limited to those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding. Except as otherwise prescribed by law, the disclosure of any records or evidence from which research subjects might be identified shall be limited to those who need to know in order to carry out a research misconduct proceeding. Written confidentiality agreements or other mechanisms may be used 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. The RIO is responsible for ensuring that all the notices and opportunities provided for in this policy, and when relevant, appropriate federal regulations, are provided to respondents.

F. Interim Administrative Actions. 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 research process. In the event of such a threat, the RIO will, in consultation with other institutional officials and, if the allegations involve Reportable Scientific Misconduct with the Health and Human Services Office of Research Integrity ("ORI"), take appropriate interim action to protect against any such threat. Interim action might include additional monitoring of the research process and the handling of, if applicable, 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 that involves Reportable Scientific Misconduct, notify ORI immediately if he/she has reason to believe that any of the following conditions exist:

- Health or safety of the public is at risk, including an immediate need to protect human or animal subjects. The Chairperson(s) of the IRB and/or IACUC, as well as the institutional official(s) responsible for this/these Committee(s) shall be promptly notified of such action;
- 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.

G. Maintaining Records. The Institution will maintain records of research misconduct proceedings in a secure manner for seven (7) years after completion of the proceeding. In cases that involve

Reportable Scientific Misconduct, the Institution will also maintain such records in a secure manner for seven (7) years after the completion of any PHS proceeding involving the research misconduct allegation and must provide any information, documentation, research records, evidence or clarification requested by ORI to carry out its review of an allegation or of the Institution's handling of such allegation.

H. Termination or Resignation Prior to Completing Inquiry or Investigation. The termination of the respondent's institutional employment or affiliation, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the research misconduct proceeding or otherwise limit any of the Institution's responsibilities under this policy. If the respondent, without admitting to the research misconduct, elects to resign his or her position after Institution receives an allegation of research misconduct, the assessment of the allegation will proceed, as well as the inquiry and investigation, as appropriate. If the respondent refuses to participate in the process after resignation, the RIO and any inquiry or investigation committee will use their best efforts to reach a conclusion concerning the allegations, noting in the report the respondent's failure to cooperate and its effect on the evidence.

IV. SPECIFIC RESPONSIBILITIES

A. Responsibilities of Faculty and Other Institutional Members:

- Upholding intellectual honesty is the responsibility of all institutional members, especially scientific leaders and laboratory directors. These individuals must set the example by maintaining the highest ethical standards, encouraging open communication within and amongst laboratories and laboratory workers, and instituting procedures for self-regulation and peer review of ongoing research. Faculty and staff are urged to discuss research ethics to heighten awareness of these issues.

- Laboratory directors and scientific leaders must accept special responsibility for the appropriate supervision and teaching of other staff and students, and ultimately must assume responsibility for the validity of all research communications emanating from their laboratories.

- Carefully recorded experimental protocols and methods are strong deterrents to research misconduct. It is the responsibility of the researcher to ensure that records are maintained to adequately document the work performed.

- Faculty and staff members should insist on the appropriate accreditation of authorship for their own work and should cite appropriate references to research performed outside their laboratories. The contributions of other investigators should be appropriately acknowledged in all scientific publications. Authorship should be attributed only to those individuals who have contributed significantly to the research, have reviewed the manuscript critically, and who are prepared to support the validity of the data presented.

- The faculty and other Institutional members should report to the RIO observed, suspected, or apparent research misconduct or any allegations of research misconduct which are brought to their attention.

- Faculty and other Institutional members should understand their obligations to report

observed research misconduct and shall cooperate with research misconduct proceedings.

- Department Chairpersons have primary responsibility for the academic activities of members of their departments, including the responsibility to maintain appropriate standards of research integrity and shall cooperate with research misconduct proceedings.

B. Responsibility of the RIO:

The DO will appoint the RIO who will have primary responsibility for implementation of the Institution's policies and procedures on research misconduct. The RIO will be an institutional official who is well qualified to administer the procedures and is sensitive to the varied demands made on those who conduct research, those who are accused of research misconduct, those who make good faith allegations of research misconduct, and those who may serve on inquiry and investigation committees.

The responsibilities of the RIO 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, in accordance with Section III.F. of this policy;

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

- Provide confidentiality to those involved in the research misconduct proceeding as required applicable law and institutional policy;

- Notify the respondent and provide opportunities for him/her to review/comment/respond to allegations, evidence, and committee reports in accordance with this policy;

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

- 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 counter potential or actual retaliation against them by respondents or other institutional members;

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

- Notify and make reports to ORI as required by applicable law;

- Ensure that administrative actions, taken by the Institution and, when applicable, 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

- Maintain records of the research misconduct proceeding and when applicable make them available to ORI in accordance with this policy

C. Responsibilities of Complainant. The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the inquiry and investigation. Ordinarily, the complainant will be interviewed at the inquiry stage and given the transcript or recording of the interview for correction. The complainant must be interviewed during an investigation, and be given the transcript or recording of the interview for correction.

D. Responsibilities of 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;

- An opportunity to comment on the inquiry report and have his/her comments attached to the report;

- Be notified of the outcome of the inquiry, and receive a copy of the inquiry report that includes a copy of the institution's policies and procedures on research misconduct;

- 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;

- 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;

- In instances of Reportable Scientific Misconduct, consult with counsel or a personal advisor of his or her own choosing and at his or her own expense and any such counsel or advisor, when interacting with the Institution, will serve in an advisory (as opposed to representative) capacity only;

- Have interviewed during the investigation witnesses who have 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; 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 received and that the comments will be considered by the Institution and addressed in the final report.

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 the Institution's Office of University Counsel, the DO may terminate the Institution's review of an allegation if the respondent admits the research misconduct or if a settlement has been reached or for any other reason. When appropriate, the Institution will, pursuant to relevant federal regulations, inform ORI of its termination of review. The respondent will have the opportunity to request an institutional appeal of a determination of research misconduct as provided in Section VII.

E. Deciding Official. The DO will consult with the RIO in assessing an allegation. The DO will also receive the inquiry report and after consulting with the RIO, decide whether an investigation is warranted. Any finding that an investigation is warranted must be made in writing by the DO and must, in cases that involve Reportable Scientific Misconduct, be provided to ORI, together with a copy of the inquiry report within 30 days of the finding.

The DO will appoint the individual(s) to conduct the inquiry ("Inquiry Committee") and investigation ("Investigation Committee"), ensure that those committees are properly staffed and that there is expertise appropriate to carry out a thorough and authoritative evaluation of the evidence.

The DO will receive the investigation report and, after consulting with the RIO and other appropriate officials, decide the extent to which the Institution accepts the findings of the investigation and, if research misconduct is found, decide what, if any, institutional administrative actions are appropriate. In instances that involve Reportable Scientific Misconduct, the DO shall ensure that the final investigation report, the findings of the DO and a description of any pending or completed administrative action are provided to ORI, as required by applicable law.

V. PROCEDURES: CONDUCTING THE ASSESSMENT AND INQUIRY

A. Allegations. Any report of alleged or apparent research misconduct should be brought immediately to the attention of the RIO who will promptly, in consultation with the DO, assess the allegation to determine whether it is sufficiently credible and specific so that potential evidence of research misconduct may be identified and whether the allegation falls within the definition of research misconduct in this policy. An inquiry must be conducted if these criteria are met. In the event that the RIO and DO disagree as to whether the inquiry should be conducted, an inquiry will be conducted. If the allegation involves the safety of human and/or animal subjects in research, then the

RIO shall promptly bring the allegation to the attention of the Chairperson (s) of the Institutional Review Board (IRB) and/or of the Institutional Animal Care and Use Committee (IACUC) as well as the institutional official (s) responsible for this/these Committee(s). The DO, RIO, IRB Chair and/or IACUC Chair will determine whether review by the IRB or IACUC shall constitute the assessment or inquiry process required under this policy.

The assessment period should be brief. In conducting the assessment, the RIO may, but 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, as provided in paragraph C of this section. If the RIO and DO determine that an inquiry need not be conducted, the DO may direct that the respondent engage in appropriate activities, such as taking the Tri-institutional course on responsible conduct in research or its equivalent.

B. Initiation and Purpose of the Inquiry. If the RIO determines that the criteria for an inquiry are met, he or she shall promptly 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. An investigation is warranted if there is a reasonable basis for concluding the allegation falls within the definition of research misconduct and the preliminary information gathering and fact finding from the inquiry indicates that the allegation may have substance.

C. Notice to Respondent; Sequestration of Research Records. At the time of or before beginning an inquiry, the RIO will make a good faith effort to inform the respondent of the allegations in writing, if the respondent is known. If the inquiry subsequently identifies additional respondents, they must be notified in writing. The RIO will also inform the faculty or staff member responsible for the respondent and such faculty or staff member should in turn notify the relevant department chairperson of the allegation promptly. In cases where the respondent is a student, RIO will also inform the appropriate academic official.

On or before the date on which the respondent is notified, or the inquiry begins, whichever is earlier, the RIO will take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence and sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.

D. Appointment of the Inquiry Committee. The DO, in consultation with other institutional officials as appropriate, will appoint an individual or an ad hoc inquiry committee and committee chair within 10 days of the initiation of the inquiry or as soon thereafter as practical. The inquiry committee will consist of individuals selected from among the faculty and administration who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry. Such individual(s) must be objective, impartial, and fair.

The RIO will notify the respondent of the names of the individual(s) solicited to conduct the

inquiry. The respondent may raise objections to the individual(s) conducting the inquiry on the basis of unresolved conflicts of interest and within 10 days from the date that the RIO communicates the Inquiry Committee composition to the respondent. The RIO shall consider these objections and make the final determination of whether a conflict exists.

E. Charge to the Inquiry 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 provided in this policy 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 applicable law.

At the Inquiry Committee's first meeting, the RIO will review the charge with the Inquiry Committee, discuss the allegations, any related issues, and the appropriate procedures for conducting the inquiry, assist with organizing plans for the inquiry, and answer any questions raised by the committee. The RIO will be present or available throughout the inquiry to provide advice as needed.

F. The Inquiry Process. The Inquiry Committee shall conduct a prompt inquiry into the alleged misconduct, affording the respondent an opportunity to comment on the allegations, and prepare a written report including full documentation of the proceedings of the inquiry. The inquiry will generally involve interviewing the complainant, the respondent and key witnesses as well as examining relevant research records and materials. Evidence will then be evaluated including the testimony obtained during the inquiry.

The inquiry report shall include the following information: (1) the name and position of the respondent, (2) a description of the allegations of research misconduct, (3) whether the alleged misconduct involved PHS support and information regarding that support, (4) the basis for recommending or not recommending that the allegations warrant an investigation, (5) comments on the draft report by the respondent or complainant, (6) the evidence reviewed and (7) summary of relevant interviews. A complete record of the proceedings of the inquiry shall be maintained and forwarded to the DO together with the written inquiry report. It should be noted that this record, in whole or in part, may be provided to authorized agencies.

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 these Policies and Procedures Governing Research Integrity. The RIO 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 of receipt. The complainant shall execute a confidentiality agreement prior to receiving a copy of the inquiry report. Any comments that are submitted 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 Inquiry Committee will deliver the final report to the RIO.

The proceedings of the inquiry will be kept confidential and will not be disclosed except as necessary to facilitate a complete and comprehensive investigation, or as required by applicable federal, state or other agency regulations. If the allegation involves use of human and/or animal subjects in research then the Chairperson (s) of the IRB and/or IACUC, as well as the institutional official (s) responsible for this/these committees, shall be provided with the report of the inquiry.

Based upon the findings of the inquiry, the DO will decide whether it is necessary to undertake a formal investigation and whether interim administrative action is necessary and appropriate. If the DO determines that a formal investigation is necessary, and if the allegation involved Reportable Scientific Misconduct, the RIO will provide ORI with the DO's written decision and a copy of the inquiry report within 30 calendar days of the DO's decision that an investigation is warranted. Additionally, in such cases, 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. The RIO will also notify those institutional officials who need to know of the DO's decision.

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 and of the reasons why an investigation was not conducted. If the allegations involved Reportable Scientific Misconduct, these documents must be provided to ORI or other authorized HHS personnel upon request.

G. Time for Completion of Inquiry. The inquiry, including the 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. If the RIO determines that the circumstances warrant longer than 60 days to complete, the inquiry report should include documentation of the reasons for exceeding the 60-day period.

VI. PROCEDURES: THE INVESTIGATION PROCESS

A. **Initiation.** The investigation must begin within 30 calendar days after the determination by the DO that an investigation is warranted.

B. **Notice.** On or before the date on which the investigation begins, the RIO must notify the respondent in writing of the allegations to be investigated. If the investigation involves Reportable Scientific Misconduct, the RIO must at the same time notify the ORI Director of the decision to begin the investigation and provide ORI a copy of the inquiry report. 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.

C. **Records.** 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. Where the research records or evidence encompass scientific data, notebooks or 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. The need for additional sequestration of records for the investigation may occur for any number of reasons, including 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.

D. **Composition of Investigation Committee.** The DO shall name an individual or an ad hoc committee and a committee chair to hear the formal charges against the respondent within 10 days of the beginning of the investigation or as soon thereafter as practical. The Investigation Committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the investigation and should include individuals with the necessary and appropriate scientific expertise to carry out a thorough and authoritative evaluation of the evidence reviewed, evaluate issues related to the allegation, interview the respondent and complainant and conduct the investigation. The committee will also include person(s) reasonably knowledgeable about federal and institutional regulations applicable to research involving human and/or animal subjects when such issues are involved in the allegation. The respondent will be informed of the proposed composition of the committee and will have the opportunity to raise objection to individual appointees on the basis of unresolved conflicts of interest within 10 calendar days of receiving notice of the composition. The DO shall consider the objections and make a final determination as to whether a conflict exists.

E. **Responsibilities of Investigation Committee.** The committee shall fully investigate and document the charges set forth, and recommend appropriate action based on an examination of all research recordings and evidence relevant to reaching a decision on the merits of each allegation. Since the committee's findings will serve as a factual basis for its recommendation and for any disciplinary action against the respondent, the Committee must take reasonable steps to ensure an impartial, unbiased and thorough investigation to the maximum extent possible. The committee shall create a detailed record of the proceedings including but not necessarily limited to relevant research data and proposals, publications, correspondence, and memoranda of telephone calls. Interviews shall be conducted of all complainant(s) or respondent(s), as well as other available individuals reasonably identified as having information regarding the allegations, including witnesses identified by respondent(s). Recordings or transcriptions of these interviews must be prepared and provided to the interviewed party for comment or revision, and included as part of the record of the investigation file. 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.

F. **Charge to the Investigation Committee and the First Meeting.** 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 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.

The RIO 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 policy, and if the allegation involves Reportable Scientific Misconduct, a copy of the relevant federal regulations. The RIO will be present or available throughout the investigation to advise the committee as needed.

G. **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;

- In investigations that involve Reportable Scientific Misconduct, 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, in cases that involve Reportable Scientific Misconduct, those policies and procedures were provided to ORI previously;

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

- Includes a statement of findings for each allegation of research misconduct identified during the investigation. Each statement of findings must: (1) identify whether the research misconduct was falsification, fabrication, or plagiarism, or other practices defined as research misconduct under this policy and whether such research misconduct 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) if applicable, 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) if applicable, list any current support or known applications or proposals for support that the respondent has pending with non-PHS federal agencies.

- Includes recommendations for the DO of appropriate disciplinary actions which may include, but not be limited to the following:

    - Notification to the sponsoring agency of the findings of the investigation and appropriate restitution of funds as required;

    - Withdrawal of all pending abstracts and publications emanating from the research in question and notification to the editors of journals in which previous abstracts and paper have appeared;

    - Notification to other institutions and sponsoring agencies with which the respondent has been affiliated if there is reason to believe that the validity of previous research may be questionable;

    - Appropriate action to terminate the appointment or employment or alter the status of faculty or staff members, including imposing a probationary period, where such action is justified by the seriousness of the misconduct;

    - Special monitoring of future work;

    - Removal from a particular project; and/or

    - Requiring that the respondent engage in appropriate activities, such as taking the Tri-institutional course on responsible conduct in research or its equivalent.

H. **Comments on the Draft Report and Access to Evidence.** The draft report of the Investigation Committee and, concurrently, a copy of, or supervised access to, the evidence on which the report is based, will be made available to the respondent. The respondent will have the opportunity to respond in writing within 30 days from the date he/she received the draft report. The respondent's comments must be included in the final report.

Relevant portions of the draft report that address the role and opinion of the complainant shall also be made available to complainant. Complainant comments must be submitted within 30 days of the date on which he/she received the draft report and the comments must be included and considered in the final report. If the allegations involve use of human and/or animal subjects in research then the report will be made available to the Chairperson(s) of the IRB and/or IACUC as appropriate as well as to the institutional official(s) responsible for this/these Committee(s).

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.

I. **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. The report, in whole or in part, may be made available to the chairperson(s) of the IRB and/or IACUC, the institutional official(s) responsible for these committee(s) when the issues include research involving human and/or animal subjects.

When a final decision on the case has been reached, the RIO will normally notify both the respondent and the complainant in writing. In cases involving Reportable Scientific Misconduct, after informing ORI, the DO will also 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 RIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

If the alleged research misconduct is not substantiated by the inquiry or by the formal investigation, every effort shall be made by the DO to restore the reputation and integrity of the individual accused of research misconduct. Furthermore, if it is determined that the allegations were made in bad faith, appropriate action against the complainant should be taken. If new evidence is brought to the attention of the DO at any time, he or she may determine at his or her discretion that the matter be referred back to the Investigation committee, or that a new committee be appointed to re-open the case.

J. **Timing.** The investigation must be conducted in a thorough and expeditious manner, and must be completed within 120 days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft report for comment and, in investigations that involve

Reportable Scientific Misconduct, sending the final report to ORI. However, if the RIO determines that the investigation will not be completed within this 120-day period, the RIO will document the reason for the delay. In cases that involve Reportable Scientific Misconduct, if the RIO will submit to ORI a written request for an extension, setting forth the reasons for exceeding the 120- day limit. 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.

VII. APPEAL

The respondent shall be given an opportunity to appeal a determination of research misconduct on the ground that the process pursued in reaching the determination did not comply with this policy. A respondent may not appeal factual determinations.

The respondent(s) shall serve upon the Provost for Medical Affairs ("Provost") a petition, in writing, for an appeal within ten (10) days after the decision of the DO is issued. The Provost shall have the power to affirm, reverse, or modify the decision and any such actions will be taken within one hundred and twenty (120) days of the filing of the appeal.

The Provost will base his decision upon the written appeal and the record of the Investigation and DO's decision. No additional evidence may be introduced into the record on appeal. The respondent may only appeal the finding of research misconduct on the basis that due process was violated or procedural errors were committed. Any appeal will be reviewed for abuse of discretion and failure to follow procedures. The Provost's decision will be final. Any findings of research misconduct and any sanctions determined by the DO are not subject to review and are not appealable under the Academic Grievance Procedures.

VIII. CONCLUSION

The integrity of an institution should never be in question. Thus, the Institution and the scientific community within it must do everything possible to prevent research fraud or other research misconduct. It is for this reason that these guidelines were established. These guidelines help to facilitate the handling of alleged research misconduct and above all, they promote and maintain high ethical standards in research, and protect the integrity of scientific research and of the Institution.

Approved by the EFC and GFC - July 2007