RUTGERS ROBERT WOOD JOHNSON MEDICAL SCHOOL
NEW BRUNSWICK, NEW JERSEY

GRADUATE MEDICAL EDUCATION MANUAL

POLICY#: V.5
SECTION: RESPONSIBILITIES & SUPERVISION
SUBJECT: RESEARCH MISCONDUCT

I. PURPOSE

To establish policy and procedures for the University's response to allegations, reports and apparent occurrences of research misconduct involving research for which the University is the applicant or grantee, or which is proposed or conducted by or under the direction of any employee or agent of the University in connection with his or her institutional responsibilities. The objective of this policy is to ensure the prompt and appropriate investigation of alleged or apparent misconduct while protecting the rights of individuals, both those who report misconduct and those about whom allegations are made.

This policy is intended to implement the Federal Law 42 U.S.C. Section 289b and the regulations promulgated pursuant thereto, 42 CFR Parts 50 and 93.

II. APPLICABILITY

This policy applies to faculty members, housestaff, trainees, students (including postdoctoral fellows), volunteers, attending physicians and staff members.

Time limitations: This policy applies only to research misconduct occurring within six (6) years of the date the University or the research sponsor receives an allegation of research misconduct, with the following exceptions:

A. **subsequent-use exception**: the respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, re-publication or other use of the research record that is alleged to have been fabricated, falsified or plagiarized for the potential benefit of the respondent;

B. **health or safety-of-the-public exception**: the alleged research misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public in the opinion of the University or the sponsor.

III. ACCOUNTABILITY

Under the direction of the President, the Executive Vice President for Academic and Clinical Affairs shall ensure compliance with this policy. The Vice President for Academic Affairs shall implement this policy.

IV. DEFINITIONS

A. **Research misconduct** – fabrication, falsification or plagiarism, committed intentionally, knowingly or recklessly, in proposing, performing or reviewing research, or in reporting research results. Research misconduct does not include

honest error, conflicting data, differences of opinion, or differences in interpretations or judgments about data or experimental design.

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

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

Plagiarism is the appropriation of another person's ideas, processes, results or words without giving appropriate credit. Authorship or credit disputes, and "self-plagiarism" of an author's work from one paper to another or from a paper to a grant application are not ordinarily considered plagiarism.

B. **EVPACA** – Executive Vice President for Academic and Clinical Affairs.

C. **VPAA** – Vice President for Academic Affairs.

D. **DHHS** – Department of Health and Human Services.

E. **PHS** – Public Health Service.

F. **ORI** – Office of Research Integrity.

G. **Complainant** – the individual who made an allegation of research misconduct.

H. **Respondent** – the individual against whom the allegation was made.

I. **Good faith** – as applied to a complainant or witness, shall mean having a belief in the truth of one's allegation or testimony, which a reasonable person in the complainant's or witness's position would have, based on the information known to the complainant or witness at the time. An **allegation is not in good faith or is made in bad faith** if the complainant knew or had reason to know it was false, or if the allegation was made with reckless disregard for or willful ignorance of information that would negate the allegation.

J. **Inquiry** – preliminary information gathering and preliminary fact finding.

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

L. **Investigation** – formal development of a factual record and examination of that record leading to a recommendation to make or not to make a finding of research misconduct, and which may include recommendations for other appropriate actions, including administrative actions.

V. POLICY

A. RUTGERS Robert Wood Johnson Medical School, administration, staff, students and volunteers have an important responsibility to maintain high ethical standards in scientific research, research training programs, and activities related to such research or training. These standards include validity, accuracy and honesty in proposing and performing research, in collecting, analyzing and reporting research results, and in reviewing the research of others. Failure to observe these principles that result in research misconduct damages the general public trust, the entire scientific community, and the University's image. In addition, University personnel who commit research misconduct breach their obligations to the University.

RUTGERS Robert Wood Johnson Medical School faculty, administration, staff, students and volunteers also have the responsibility to report known or suspected instances of research misconduct to the appropriate Campus Committee on Research Integrity (see Section V.F. below).

B. The evidentiary standards for a finding of research misconduct shall be as follows:

1. **Standard of proof**: the University finding of research misconduct must be proved by a preponderance of the evidence.

2. **Burden of proof**: the University has the burden of proof for making a finding of research misconduct. The destruction, absence of, or respondent's failure to provide research records adequately documenting the questioned research is evidence of research misconduct where the University establishes by a preponderance of the evidence that the respondent intentionally, knowingly, or recklessly had research records and destroyed them; had the opportunity to maintain the records but did not do so, or maintained the records and failed to produce them in a timely manner; and that the respondent's conduct constitutes a significant departure from accepted practices of the relevant research community.

C. The University shall make reasonable and practical efforts to assure that:

1. the positions and reputations of those reporting alleged misconduct in good faith, witnesses in misconduct proceedings, and members of the Campus Committees and Investigative Panels are protected or restored, and that these individuals are protected from retaliation;
2. appropriate action will be taken against individuals who attempt to retaliate against those reporting misconduct in good faith, witnesses in misconduct proceedings, and members of the Campus Committees and Investigative Panels;

3. appropriate action will be taken against individuals found to have made unsubstantiated allegations in bad faith;

the reputations of respondents against whom no finding of research misconduct is made are protected or are restored if requested and as appropriate.

D. Confidentiality

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. However, confidentiality may not be maintained if the allegation is determined to be false and is found to be made in bad faith. Protection of confidentiality does not preclude disclosures that are necessary in the process of handling allegations of misconduct; are in the public interest or in the University's interest; are required by federal or state statute or regulations, University policy or rules of the research sponsor; or are a component of sanctions and/or corrective actions in the resolution of allegations of misconduct.

Except as may otherwise be prescribed by applicable law, confidentiality shall be maintained for any records or evidence from which research subjects might be identified. Disclosure is limited to those who have a need to know to carry out a research misconduct proceeding.

E. Immediate Notification

At any time during the course of the preliminary assessment, inquiry, investigation or other research misconduct proceeding, the following notifications shall immediately be made:

If the Campus Committee or Investigative Panel becomes aware of a risk to human subjects or deviations in an Institutional Review Board (IRB)-approved protocol, or other breach of University policy regarding human subjects research, the chair of the Committee or Panel shall notify the Executive Director of Human Subjects Protection and the Campus IRB Chair.

2. If the Campus Committee or Investigative Panel becomes aware of the commission of a criminal act, the Chair shall notify Public Safety.

3. If the Campus Committee or Investigative Panel becomes aware of incidents or complaints of retaliation, harassment or discrimination against a complainant, respondent, witness, Campus Committee or Investigative Panel member, the Chair shall notify the VPAA and the Office of Compliance Auditing. The Office of Compliance Auditing shall perform investigations as appropriate.

4. If the Campus Committee or Investigative Panel becomes aware of non-compliance with federal or state law or regulation or with University policy, the Chair shall notify the Office of Business Conduct and the Office of Legal Management.

If the Campus Committee or Investigative Panel becomes aware of any facts that may affect current or potential federal or other funding for the respondent, or facts that the funding agency or sponsor needs to know to ensure appropriate use of federal or other funds and otherwise protect the public interest, the Chair shall notify the VPAA who shall apprise ORI or the pertinent funding agency or sponsor.

At any time during a research misconduct proceeding, the VPAA shall be informed and shall notify immediately ORI (in the case of research conducted under a PHS grant or if the research results were used in a PHS grant, fellowship or contract application), or another funding agency or sponsor if there is reason to believe that any of the following conditions exist:

a. Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.

b. DHHS resources or interests are threatened.

c. Research activities should be suspended.

d. There is reasonable indication of possible violations of civil or criminal law.

e. Federal action is required to protect the interests of those involved in the research misconduct proceeding.

f. The University believes the research misconduct proceeding may be made public prematurely so that DHHS may take appropriate steps to safeguard evidence and protect the rights of those involved.

g. The research community or public should be informed.

F. Campus Committees on Research Integrity

Three Campus Committees on Research Integrity shall be established, one each for Newark, Piscataway/New Brunswick and Camden/Stratford. These Committees shall be called together by the Chairperson or his/her designee on an as-needed basis to review allegations and reports of research misconduct and apparent instances of misconduct.

1. Membership

Membership of the Campus Committees shall consist of tenured faculty members representing the Schools on that campus. Members shall represent a mixture of the basic and clinical sciences, and shall have strong research experience and other appropriate qualifications to judge the issues raised by allegations of research misconduct.

a. The Newark Committee shall have seven members, two faculty members from New Jersey Medical School (one of which shall be from the basic sciences and the other from the clinical sciences), and one faculty member each from the Graduate School of Biomedical Sciences-Newark Division, New Jersey Dental School, School of Health Related Professions, School of Nursing, and School of Public Health.

b. The Piscataway/New Brunswick Committee shall have six members, three faculty members from RUTGERS Robert Wood Johnson Medical School(representing both the basic and clinical sciences) and one faculty member each from the Graduate School of Biomedical Sciences-Piscataway Division, School of Health Related Professions, and School of Public Health.

b. The Camden/Stratford Committee shall have six members, one faculty member each from RUTGERS Robert Wood Johnson Medical School-Camden, School of Osteopathic Medicine, Graduate School of Biomedical Sciences-Stratford Division, School of Nursing, School of Health Related Professions and School of Public Health.

2. Appointment

Members shall be appointed by the EVPACA upon the recommendations of the Deans.

3. Term of Appointment

Members of the Campus Committees shall serve for terms of three years which may be renewed. In the event of an extended absence or resignation of a Campus Committee member, an alternate to serve out the term shall be appointed by the EVPACA in the same manner as original appointments.

4. Chair

Each Campus Committee shall elect a chairperson who should be at the rank of full professor, and who shall serve for a term of two years. The Chairperson or designee shall call all meetings in response to the receipt by any member of the Campus Committee of a report or allegation of research misconduct.

5. Functions

The functions of the Campus Committees shall be to:

a. receive reports or allegations of research misconduct, which can be written or oral statements or other communications, from any source within or external to the University about University individuals working and/or studying on that campus or whose

primary academic appointment is at a School on that campus; however, when appropriate, any given allegation may be assigned by the Campus Committee for action to another Campus Committee;

b. conduct inquiries of allegations of research misconduct, and send resulting reports to the EVPACA; and

c. supply the VPAA with the information needed to make the University's annual submission to ORI pursuant to 42 CFR Parts 50 and 93.

6. Expenses of the Campus Committees

Expenses related to the general functioning and training of the Campus Committees shall be borne by the Schools on that campus.

G. Inquiry

The inquiry shall involve information gathering and preliminary fact finding to determine whether an allegation of research misconduct or apparent instance of misconduct has substance and warrants further investigation.

1. Preliminary Assessment

On behalf of the Campus Committee, the chairperson shall perform a preliminary assessment of an allegation or report to determine if an inquiry is warranted. Criteria warranting an inquiry are: whether the allegation falls within the definition of research misconduct as set forth in Section IV.A; and whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified. This determination shall take place within ten (10) working days of the Committee's receipt of the allegation or report, and shall be final. When an inquiry is not felt to be warranted, the Committee's reasons shall be documented and the complainant shall be informed. The identification of the respondent shall be kept confidential from everyone without a need to know.

In the case of research disputes when an inquiry is not felt to be warranted, the Committee may recommend other resources at the School or University, including the services of the School's research ombudsperson.

2. Initiation of Inquiry

The Campus Committee (hereinafter the Inquiry Committee) shall meet to begin the inquiry within ten (10) working days of the chair's determination that the allegation warrants an inquiry.

3. Notification of Inquiry

At the time of or before the initiation of the inquiry, the respondent, the complainant, the Dean of the appropriate School, the President/CEO of the pertinent patient care unit or the Vice President of the pertinent administrative unit (in the case of a non-faculty respondent who is an employee of such unit), and the VPAA shall be notified in writing of the inquiry by the Chairperson of the Inquiry Committee. If the Inquiry Committee subsequently identifies additional respondents, the Chairperson shall notify them in writing. Under certain circumstances set forth in Section V.E., ORI in the case of research conducted under a PHS grant, or another pertinent funding agency must be immediately notified.

4. Rights and Obligations of the Respondent

The respondent shall be informed of the charges, of the opportunity to be heard, as well as the obligation to cooperate fully, and that unreasonable refusal to supply relevant material or other uncooperative behavior shall constitute violation of this policy.

5. Sequestering of the Research Record and Evidence

No later than the time the respondent is notified of the allegation and/or the inquiry begins, whichever is earlier, the Inquiry Committee shall, with the assistance of the Dean's or Vice President's office and/or of campus security and/or Information Services & Technology personnel if necessary, take all reasonable and practical steps to obtain custody of any original data, research records and evidence, and other material and documents necessary to the conduct of the inquiry and potential future investigation, and sequester them in a secure manner. 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. An inventory shall be made of each item removed. This inventory shall be signed by the Inquiry Committee Chairperson or designee, and a copy given to the respondent. Efforts should be made to permit the research to continue while the inquiry and other procedures go forward. Where appropriate, the Committee Chairperson or designee shall give the respondent copies of or reasonable supervised access to the sequestered research records and evidence during the proceedings. Materials sequestered shall be stored in a manner to ensure their preservation.

In the event, during the course of the inquiry, future investigation or other research misconduct proceeding, there is a need for additional research records or evidence necessary for the conduct of the proceedings, all reasonable and practical efforts will be made to take custody of, inventory and sequester such records or evidence, 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.

6. Conflict of Interest/Bias

It is the responsibility of each member of the Inquiry Committee to divulge potential conflicts of interest. In the event that any member of the Inquiry Committee has any real or apparent, unresolved personal, professional or financial conflicts of interest or bias with respect to the respondent, complainant, witnesses or case, that member shall be recused. Such conflicts include, but are not limited to, involvement with the research in question, competition with the respondent, and a previous or ongoing close personal, professional or academic relationship with respondent, complainant or witnesses.

7. Staff to Inquiry Committee

The EVPACA and the Vice President for Legal Management shall assign non-voting staff to assist the Inquiry Committee. Staff shall consider themselves and their activities for the Inquiry Committee as strictly confidential.

8. Consultants and *Ad Hoc* Members for Inquiry Committee

For purposes of the inquiry, the Inquiry Committee in its discretion, may seek expert scientific advice and/or decide to add *ad hoc* members such as experts in a particular field.

9. Duration of Inquiry

The Inquiry Committee shall complete the inquiry and prepare a written report for the EVPACA summarizing the conduct of the inquiry and the reasons for its recommendations within sixty (60) calendar days from the date the inquiry began. If circumstances warrant a longer period, the record shall include documentation of the reasons for exceeding the 60-day period, and the respondent shall be so notified in writing.

10. Recommendations of Inquiry Committee

The Inquiry Committee shall decide by majority opinion whether to recommend that the allegation warrants an investigation to formally examine and evaluate all relevant facts to determine if misconduct has occurred. A recommendation for investigation is warranted if:

a. there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct, and

b. the preliminary information gathering and preliminary fact finding from the inquiry indicate that the allegation has substance.

If the Inquiry Committee does not recommend an investigation, the reasons for this decision shall be documented in sufficient detail to permit future assessments of this decision by ORI or another sponsor or agency. The Inquiry Committee may make recommendations to the EVPACA

regarding reasonable and practical actions to protect or restore the reputation of the respondent, and should consult with the respondent in this regard. The Inquiry Committee may also make recommendations to the EVPACA concerning actions against a complainant found to have made unsubstantiated allegations in bad faith. The Inquiry Committee may also make recommendations to the EVPACA about the conduct of the research in question or related matters in order to mitigate problems and/or ameliorate circumstances brought to the attention of the committee during the inquiry but which did not warrant an investigation.

If the Inquiry Committee recommends an investigation and finds there is a high probability that false or misleading information has been or may be disseminated to the scientific community and that such dissemination could cause significant harm, the Committee may recommend that the EVPACA, if he or she initiates an investigation, inform the following individuals of the existence and status of the investigation: (1) editors of scientific journals in which articles or other publications concerning the research under investigation have been published or are pending publication; and (2) program directors of scientific meetings at which the research under investigation is scheduled to be presented.

11. Report of Inquiry Committee

A written report summarizing the conduct of the inquiry and the reasons for the Inquiry Committee's recommendation shall be prepared for the EVPACA. The respondent shall be given a copy of the report and the opportunity to provide written comments on the report. The respondent's comments, if any, shall be made part of the record. Comments of the respondent about the Committee's recommendation must be filed with the Committee within five (5) working days of receipt of the report. The complainant shall be notified in writing of the Committee's recommendation. Relevant portions of the report may be provided to the complainant for comment at the discretion of the Inquiry Committee.

12. Decision and Actions of the SVPAA

The EVPACA has the sole discretion to accept, reject, modify or seek additional information about the recommendation of the Inquiry Committee. The EVPACA shall make a final decision concerning the recommendation of the Inquiry Committee within ten (10) working days of receipt of the Committee's report.

a. If the EVPACA decides that further investigation is not warranted, the case shall be closed. The reasons for the EVPACA's decision shall be documented in sufficient detail to permit future assessments of this decision by ORI or another sponsor or agency.

The EVPACA shall notify in writing the respondent, the complainant, all individuals interviewed or otherwise informed of the allegation, and the appropriate Dean or Vice President of the

disposition of the allegation. In the event that ORI or another pertinent funding agency or sponsor was notified during the inquiry, under the circumstances enumerated in Section V.E., the same shall be informed by the EVPACA of the finding of no cause following the inquiry, and that the University considers the case closed. If requested and appropriate, and in consultation with the respondent, all reasonable and practical efforts shall be undertaken to protect or restore the reputation of the respondent.

If the EVPACA finds that the allegation was made in bad faith, he/she shall determine whether and what administrative actions should be taken against the complainant pursuant to applicable University policies, procedures or contracts.

At the appropriate time following notifications of the EVPACA's decisions, all research records, original data and other evidence and materials sequestered by the Inquiry Committee from the respondent or complainant or furnished by others shall be returned, and the return documented by signed receipts.

The Chairperson of the Inquiry Committee shall gather the original records of the proceedings of the inquiry and copies of all pertinent documents and other materials furnished to the Committee. This file shall be sent to the EVPACA who shall seal it and retain it in a locked confidential cabinet for at least seven (7) years, and preferably indefinitely, after termination of the inquiry. The records shall, upon request, be provided to authorize personnel representing the funding agency or sponsor. Otherwise, access to materials in the file shall be available only upon authorization of the EVPACA for exceptional cause.

b. If the EVPACA decides that further investigation is warranted, the EVPACA shall initiate an investigation. All files accumulated by the Inquiry Committee in this matter shall be transferred to the Office of the EVPACA.

The EVPACA shall provide notice in writing to the respondent, the complainant, the appropriate Dean or Vice President, and the Vice President of Legal Management of the decision to perform an investigation before the investigation begins. If the research in question was funded by the PHS or if the research results were used in a PHS grant, fellowship or contract application, the EVPACA, on or before the date the investigation begins, will write to the Director of ORI reporting the decision to initiate an investigation and attaching a copy of the inquiry report, which shall include the following information:

1) the name and position of the respondent;

2) a description of the allegation of research misconduct;

3) the PHS support, including grant numbers, grant applications, contracts, and publications listing PHS support;

4) the basis for deciding that the alleged actions warrant an investigation; and

5) any comments on the report by the respondent or the complainant.

If the research in question was funded by an agency or sponsor other than the PHS which has similar reporting requirements, the EVPACA, within 30 days of deciding that an investigation is warranted, will communicate the same information as above to the director of that agency or sponsor. The EVPACA may also decide to notify certain editors of journals or program directors of scientific meetings.

13. Expenses of the Inquiry

Expenses of inquiries shall be borne by the Dean or Vice President in whose School or Unit the respondent's research in question has been or is being conducted.

H. Investigation

The investigation shall be a formal, thorough and documented examination and evaluation of all relevant facts, research records and other evidence to determine if a recommendation should be made that research misconduct has occurred. It shall include interviewing the complainant and the respondent as well as others who might have relevant information; reviewing original data, research records and other evidence and documents; talking with experts; considering materials and/or comments submitted by the respondent and complainant; reviewing relevant literature, publications, correspondence, memos, etc. An investigation shall begin within thirty (30) days after the EVPACA's decision that an investigation is warranted.

1. Notice to and Rights and Obligations of Respondent

Before the investigation begins, the respondent shall be notified in writing of the allegations to be considered in the investigation, the opportunity to be heard and to present witnesses, and the obligation to cooperate fully with the investigation. Such notice shall inform the respondent that the investigation may recommend: (a) whether or not research misconduct has occurred; and/or (b) if the actions or conduct investigated are/is otherwise unacceptable within the University for proposing, performing or reviewing research or reporting research results. The respondent shall also be informed that unreasonable refusal to supply relevant material or other uncooperative behavior constitutes violation of this policy.

The respondent shall be given written notice of all new or additional allegations to be considered in the investigation which were not stated in the original notice of the investigation.

2. Formation of Investigative Panel

An investigative panel shall be appointed by the EVPACA, consisting of three scientists with strong research experience and other appropriate qualifications to judge the issues raised in the investigation. These individuals may be internal to the University or external. University faculty serving on investigative panels must be tenured. Members of the Inquiry Committee shall not be appointed to the Investigative Panel.

3. Conflict of Interest/Bias

Individuals appointed to the Investigative Panel shall not have any real or apparent, unresolved personal, professional or financial conflicts of interest or bias with respect to the respondent, complainant, witnesses, or case. For example, Panel members should not be involved with the research in question, should not be professional competitors with the respondent, and should not have a previous or ongoing close professional or academic relationship with the respondent, complainant or witnesses.

4. Objections to Proposed Investigative Panel Members

The respondent and the complainant shall be informed of the proposed membership of the Investigative Panel. If the respondent or the complainant objects to the participation of any member of the Investigative Panel based upon personal, professional or financial conflict of interest or bias with respect to the respondent, complainant, witnesses, or case, this objection must be made in writing within five (5) working days to the EVPACA who shall decide whether to replace the challenged member. The decision of the EVPACA shall be final. Such challenges to the membership of the Investigative Panel must be resolved prior to the official appointment of the members by the EVPACA.

5. Charge to Investigative Panel

The EVPACA shall administer the charge to the Panel. The official date of the initiation of the investigation shall be the date of the first meeting of the Investigative Panel. This shall be within thirty (30) calendar days of the decision of the EVPACA that an investigation is warranted.

6. Chairperson of Investigative Panel

The Investigative Panel shall choose its chairperson at its first meeting.

7. Staff to Investigative Panel

The EVPACA and the Vice President for Legal Management shall assign non-voting staff to assist the Investigative Panel. Staff shall consider

themselves and their activities for the Investigative Panel as strictly confidential.

8. Conduct of Investigation

a. Procedural Protections

Every effort shall be made to ensure a comprehensive, impartial, unbiased and expeditious investigation. The respondent shall have the opportunity to examine all evidence forwarded to the Panel, to present evidence to the Panel, including witnesses on the respondent's behalf, and to ask questions of the witnesses, including the complainant. Anonymous third-party statements will not be considered as evidence.

b. Security

Files shall be kept in a central location in a locked cabinet, accessible only to the appropriate individuals taking part in the investigation.

c. Testimony before the Investigative Panel

Tape recordings shall be made of all testimony given. Documentation (including original data) substantiating the Investigative Panel's findings will be carefully secured, prepared and maintained. Transcriptions of each taped interview shall be provided to the person interviewed for comment and correction, and included as part of the record of the investigation.

d. Sequestering of Additional Research Records and Evidence

To the extent not already carried out earlier, the University or the Investigative Panel shall secure, inventory and sequester in a secure manner additional pertinent original research data, research records and evidence, and other material and documents from the respondent or others, per the procedures in Section V.G.5 of this policy, before or at the time the respondent is notified of the investigation, and whenever additional items become known or relevant to the investigation.

e. Consultants for Investigative Panel

The Investigative Panel may seek additional expert scientific advice.

f. Broadening/Change in Subject Matter of Investigation

If, during the investigation, information becomes available which the Panel considers substantially related to the original charge from the EVPACA, the Panel may broaden the scope of its charge

and must give written notice to the respondent of the new scope. If the Panel does not consider the new information substantially related to the original charge, the Panel may refer the new information to the Campus Committee as the basis of a new allegation.

9. Duration of Investigation

The investigation shall be completed within eighty (80) calendar days of its initiation date to allow sufficient time for review of the Investigative Panel's report by the respondent and the EVPACA, and submission of the University's report, including the decision of the EVPACA, to the funding agency, within a total of one hundred and twenty (120) calendar days of the initiation of the investigation. If the investigation cannot be completed within these time limits, the University may request an extension of time from ORI (in the case of research conducted under a PHS grant or if the research results were used in a PHS grant, fellowship or contract application) or from another pertinent funding agency or sponsor if required. If such an extension is granted, the respondent shall be so notified.

10. Recommendation of Investigative Panel

The requirements for reaching a recommendation of research misconduct are:

a. there was fabrication, falsification or plagiarism in proposing, performing or reviewing research, or in reporting research results;

b. the fabrication, falsification or plagiarism was committed intentionally, knowingly or recklessly; and

c. the allegation was proved by a preponderance of the evidence.

The Investigative Panel's recommendation shall be the majority opinion. There may be a minority report. The results of any vote taken shall be made known to the EVPACA in the written report of the Investigative Panel.

11. Report of the Investigative Panel

Upon conclusion of its investigation, the Investigative Panel shall prepare a draft written report. A copy of the draft report shall be given to the respondent with the opportunity to provide written comments on the report, which must be considered and addressed by the Panel before issuing the final report. Concurrently, the respondent must be given a copy of or supervised access to the evidence on which the report was based. At the discretion of the Investigative Panel, the complainant may be provided with those portions of the draft report that address his/her

role and opinions in the investigation. Comments, if any, from the respondent and complainant must be filed with the Panel within thirty (30) calendar days of receipt of the Panel's draft report. These comments shall be made part of the final report and considered by the EVPACA. A copy of the final report shall also be given to the appropriate Dean or Vice President.

The contents of the final investigation report must include:

a. Allegations – description of the nature of the allegations of research misconduct;

b. If applicable, the PHS support – description and documentation of the PHS support, including any grant numbers, grant applications, contracts, and publications listing PHS support;

c. Institutional charge – description of the specific allegations of research misconduct considered in the investigation;

d. Policies and procedures – inclusion of this policy (if not already provided to ORI or another sponsor with the inquiry report);

e. Research records and evidence – identification and summary of the research records and evidence reviewed, and identification of any evidence taken into custody but not reviewed;

f. Statement of recommendations – for each separate allegation of research misconduct identified during the investigation, the recommendation as to whether research misconduct did or did not occur; if the recommendation was that research misconduct did occur:

    1) Whether the research misconduct was falsification, fabrication or plagiarism committed intentionally, knowingly or recklessly;

    2) a summary of the facts and the analysis which support the conclusion and consideration of the merits of any reasonable explanation by the respondent;

    3) identification of the specific PHS support, if any;

    4) whether any publications need correction or retraction;

    5) the person(s) responsible for the misconduct; and

    6) any current support or known applications or proposals for support that the respondent has pending with non-PHS federal or other agencies or sponsors.

g. Comments of respondent and complainant - inclusion and consideration of any comments made by the respondent and complainant on the draft investigation report.

The report may make recommendations about corrective measures, if any, to be taken.

The report may also include recommendations that a finding be made that the respondent has engaged in practices that are unacceptable within the University for proposing, performing or reviewing research, or reporting research results, whether or not research misconduct was found. The report may make recommendations about corrective actions, if any, to be taken under these circumstances.

The report may also include the Panel's concerns that violations of other University policies or of federal or state regulations may have occurred, with recommendations to refer these concerns for administrative action.

In addition, the Panel may make recommendations concerning notification of law enforcement agencies, professional societies, licensing boards, journal editors, collaborators of the respondent or other concerned parties of the outcome of the investigation.

In the event of a recommendation that there be no finding of misconduct, the Investigative Panel, after consultation with the respondent, may make recommendations to the EVPACA regarding actions to protect or restore the reputation of the respondent. The Investigative Panel may also make recommendations to the EVPACA concerning actions against a complainant found to have made unsubstantiated allegations in bad faith.

The Investigative Panel may also make recommendations to the EVPACA about the conduct of the research in question or related matters in order to mitigate problems and/or ameliorate circumstances brought to the attention of the Panel during the investigation but which did not warrant a finding of misconduct.

12. Expenses of the Investigation

The expenses of the investigation, including external consultants' fees if any, shall be borne by the pertinent Dean or Vice President.

13. Decision and Actions of the SVPAA

The EVPACA shall review the final report of the Investigative Panel and shall make a final decision in writing on behalf of the University.

The EVPACA may make one of the following decisions:

a. finding of no misconduct: If requested and appropriate, all reasonable and practical efforts shall be made, in consultation with the respondent, to protect or restore the reputation of the

respondent, and appropriate action shall be taken against complainants found to have made unsubstantiated allegations in bad faith.

b. finding of misconduct: The decision shall include the EVPACA's determination about the appropriate corrective actions. The EVPACA shall either accept the Investigative Panel's recommendation about corrective actions or impose alternatives. Discipline imposed for research misconduct shall be exempt from grievance and arbitration proceedings. The EVPACA may direct the authors to withdraw from publication all pending abstracts and papers that are considered to be of questionable scientific validity as a result of the finding, and may notify the editors of journals, books and other publications in which the respondent's previous papers and abstracts have appeared during the preceding five years.

c. finding that actions or conduct investigated are/is unacceptable within the University for proposing, performing or reviewing research or for reporting research results, but do/does not constitute research misconduct. The decision shall include the EVPACA's determination about appropriate corrective actions.

14. Notification of Decision of SVPAA

The SVPAA shall provide a copy of his/her final decision to the respondent, the complainant, the Investigative Panel, the pertinent Dean or Vice President, and the Vice President for Legal Management.

The SVPAA shall forward to ORI (in the case of research conducted under a PHS grant or if the research results were used in a PHS grant, fellowship or contract application) or to another external funding agency or sponsor a copy of his/her final decision, together with the Investigative Panel's final report with all attachments, and any pending or completed institutional administrative actions against the respondent.

The SVPAA shall inform editors of scientific journals and program directors of scientific meetings who had been notified of the existence of an investigation, and all individuals interviewed or otherwise informed of the allegation of the outcome of the investigation.

I. Termination of the Case

1. Creation, Sealing, Storage of and Access to the File

The EVPACA shall ensure that the complete file, including the original records of all proceedings conducted by the Inquiry Committee and by the Investigative Panel, copies of all documents and other materials furnished to the Committee and the Panel, and transcripts of recordings of all interviews, is sealed and retained in a locked confidential cabinet for at least seven (7) years, and preferably indefinitely, after termination of the investigation. Access to materials in the file shall be available only to ORI

in the case of research funded by PHS or if the research results were used in a PHS grant, fellowship or contract application, or to another sponsor with similar requirements, or upon authorization of the EVPACA for exceptional cause.

2. Return of Sequestered Data and Other Materials

The EVPACA shall decide on a case-by-case basis when the research records, original data, evidence and other original materials sequestered during the inquiry or investigation may be returned. Among the determining factors in this decision are the requirements of pertinent government agencies or other sponsor.

J. Investigation by Federal Agencies

Under 42 CFR Parts 50 and 93, federal agencies have reserved the right to perform their own investigation in cases involving federally funded research at any time prior to, during, or following the University's investigation, and to impose corrective actions of their own in addition to those imposed by the University.

K. Withdrawal of Allegation by Complainant

If the complainant withdraws his or her allegation prior to the completion of the inquiry or investigation, the proceedings shall continue if sufficient information is available to warrant such continuance.

L. If Respondent leaves the University

If the respondent leaves the University prior to the completion of the inquiry or investigation, the inquiry and investigation, if any, shall nevertheless continue according to the procedures described above, and the respondent shall be afforded full opportunity to participate. The EVPACA may inform the respondent's new employer, if any and if known, of the existence and status of the investigation and of the final findings of the investigation.

M. Admission of Research Misconduct by Respondent

If the respondent admits to research misconduct prior to the completion of the inquiry or investigation, the admission must be in writing and must detail the full scope of the misconduct. An inquiry and investigation should ordinarily be conducted and continued to conclusion if doing so will uncover the scope of the misconduct or other problems and result in recommendations to the EVPACA. Under these circumstances, the inquiry and investigation shall be conducted according to the procedures described above. If the Inquiry Committee believes that no purpose will be served by an investigation, it may make that recommendation to the EVPACA, and the inquiry may serve as the investigation. In this event, the EVPACA shall notify in advance ORI (if the research in question was funded by PHS, or if the research results in question were used in a PHS grant, fellowship or contract application), or another sponsor with similar requirements if the University plans to close the case prior to conclusion of a full

investigation based on the respondent's admission of guilt or for any other reason. By Direction of the President:

Vice President for Academic Affairs

Rutgers Biomedical and Health Sciences Policy Code: 00-01-20-60:00
Adopted: 07/15/89
Amended: 02/28/06 & 10/12/0