

POLICY AND ADMINISTRATIVE PROCEDURES GOVERNING RESEARCH MISCONDUCT

I. PREAMBLE AND DEFINITION OF RESEARCH MISCONDUCT

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 research and for the preservation of the trust of the public and the research community. The maintenance of accepted standards in research based on these principles is highly regarded by the research community and is a major responsibility of St. John's University ("University"). Consequently, we must establish standards and procedures for our faculty and other staff, researchers, research coordinators, technicians, post-doctoral and other fellows, students, employees, trainees, guest researchers, or collaborators, volunteers, agents, contractual affiliates, contractors, subcontractors and their employees ("Institutional Members") in order to preserve the truth, integrity, and credibility in research, to prevent research misconduct, and to deal efficiently and fairly with good faith allegations or other indications of research misconduct by reporting and responding to allegations of research misconduct in the manner required to meet legal and regulatory requirements and ensure responsibility, safety and integrity in the research community.

Individuals reporting research misconduct must only do so in good faith. Individuals who are accused of committing research misconduct must cooperate with any Inquiry or Investigation. All Institutional Members are required to cooperate with the University in the review of allegations and during the conduct of Inquiries and Investigations, and must provide evidence relevant to research misconduct allegations.

Institutional Members are strictly prohibited from retaliating in any way against Complainants, witnesses, and other individuals involved in reviewing allegations or conducting research misconduct proceedings. Disciplinary measures up to and including termination of employment may be imposed against Institutional Members for retaliatory conduct in violation of this and other University policies.

The purpose of this policy and the procedures set forth herein are to assist the University to:

(1) govern how the University will respond to each allegation of research misconduct in a thorough, competent, objective and fair manner, including precautions to ensure that individuals responsible for carrying out any part of the misconduct proceeding do not have unresolved personal, professional or financial conflicts of interest with the Complainant, the Respondent or any witnesses;

(2) ensure that the University fosters a research and science environment that promotes the responsible conduct of research, research training and activities related to research or research training, discourages research misconduct and deals promptly with allegations of research misconduct;

(3) set forth how the University will take all reasonable and practical steps to protect the positions and reputations of good faith Complainants, witnesses and committee members and protect them from retaliation by the Respondents and other Institutional Members;

(4) take all reasonable and practical steps to ensure the cooperation of the Respondents and other Institutional Members with research misconduct proceedings, including but not limited to their providing information, research, records and evidence;

(5) cooperate with the federal Department of Health and Human Services (HHS) during any research misconduct proceedings or compliance reviews and assists in administering and enforcing any HHS administrative actions imposed on the University or any Institutional Member.

Research misconduct is generally defined as any fabrication, falsification, omission, plagiarism, suppression, theft, misappropriation, or other practice that violates the standards commonly accepted within the research community for proposing, conducting, reviewing research or in reporting results of research. Honest errors or honest differences of opinion, interpretations, or judgments of data are not regarded as research misconduct. Specific acts of research misconduct include, but are not limited to, the following:

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

Falsification or Misrepresentation of Data, which includes (1) reporting experiments, measurements, or statistical analyses never performed; (2) manipulating research materials, equipment, or processes, or altering or omitting data or other manifestations of research to achieve a desired result or such that research is not accurately represented in the research record; (3) falsifying or misrepresenting background information, including biographical data, citation of publications, or status of manuscripts; or (4) selective reporting, including the deliberate suppression of conflicting or unwanted data.

Plagiarism, which is the theft or appropriation of another person's ideas, processes, results or words (intellectual property) and the substantial unattributed textual copying of another's work without giving appropriate credit or a misrepresentation of the words or ideas of another as one's own. It does not include authorship or credit disputes. More subtle practices include misleading or inadequate reference citation and duplicate publication of identical data without adequate reference.

Abuse of Confidentiality, which is the misuse of confidential information or the failure to maintain the confidentiality of such information. This includes the use of ideas and preliminary data gained from (1) access to privileged information through the opportunity for editorial review of manuscripts

submitted to journals; and (2) peer review of proposals considered for funding by agency panels or internal committees.

Other Practices, which seriously deviate from those that are commonly accepted within the research community for proposing, conducting, or reporting research, include, but are not limited to, the following:

Aiding or facilitating acts of academic dishonesty by others.

Violating pertinent federal or University regulations and ethical codes such as those involving the protection and welfare of human subjects and laboratory animals.

Breaching research integrity other than those enumerated above.

A finding of research misconduct requires that there be a significant departure from accepted practices or the relevant research community and the misconduct was committed intentionally, knowingly or recklessly, and the allegation(s) is proven by a preponderance of the evidence.

For purposes of this policy, the following definitions apply:

Complainant is a person who in good faith makes an allegation of research misconduct. Once a Complainant has made a formal allegation of research misconduct, the person must be treated as any other witness in the proceeding. The Complainant is not a "party," does not control nor direct the process, act as a decision maker, nor have unqualified access to the available evidence. The University, not the Complainant has the responsibility to ensure that the allegation(s) is thoroughly and competently investigated to resolution.

Allegation is the disclosure of possible research misconduct through any means of communication (written or oral) delivered to a University official.

Respondent is the person against whom an allegation of research misconduct has been made.

II. APPLICABILITY

The provisions of this policy apply to any Institutional Member or other person compensated by, under the control of or affiliated with the University. The procedures set forth herein are subject to the requirements of law. The University will comply with all applicable federal, state and city laws and regulations with respect to research misconduct.

The general terms of this policy apply to both federally funded and privately funded projects conducted by, through, or in affiliation with the University. Investigations and Inquiries concerning Public Health Services Act ("PHSA") supported research will be reported to the Office of Research Integrity ("ORI") pursuant to the

provisions of 42 C.F.R. Part 93. ORI reporting requirements are indicated where appropriate.

III. PROCEDURES FOR MANAGING REPORTS OF RESEARCH MISCONDUCT: RECEIPT OF REPORTS, PRELIMINARY ASSESSMENT AND INSTITUTIONAL INQUIRIES

(a) **Institutional Members are affirmatively obligated to report observed, suspected or apparent research misconduct to the Institutional Review Board (IRB) Chair.** Upon receiving a report, the IRB Chair (or the IRB Chair's designee, if the IRB Chair is unable or unwilling to serve) will conduct a preliminary assessment to determine whether the matter falls within the definition of what may constitute research misconduct and is sufficiently credible and specific so that potential evidence of research misconduct may be identified, thus warranting further review in the form of an Inquiry.

(b) The assessment period should be brief, preferably concluded within two (2) weeks. The IRB Chair need not interview the Complainant, the Respondent or other witnesses, or gather data beyond any that may have been submitted with the allegation(s), except as necessary to determine whether the allegation(s) is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

(c) If, after assessment, the IRB Chair determines in his or her discretion that a matter does not warrant further review, the IRB Chair shall dismiss it. If, after evaluation, the IRB Chair determines that a matter warrants further review, he/she shall initiate an Inquiry. An Inquiry is a preliminary evaluation of the available evidence and includes testimony from the Respondent, Complainant, and key witnesses to determine whether there is sufficient evidence of research misconduct to warrant an Investigation. The purpose of the Inquiry is not to reach a final conclusion about whether misconduct definitely occurred or who was responsible. The findings of the Inquiry should be set forth in an Inquiry report.

(d) The Inquiry shall be conducted by an *ad hoc* committee of no fewer than three (3) individuals selected by the IRB Chair. The individual(s) selected by the IRB Chair to serve on the *ad hoc* committee must be objective, impartial, and qualified to evaluate the matter. The University will take every reasonable precaution to prevent real or apparent conflicts of interest between the person(s) conducting the Inquiry and the subject(s) of the Inquiry.

The IRB Chair shall notify the Respondent of the names of the individual(s) selected to conduct the Inquiry. If the Respondent elects to do so, he or she shall, in writing and within five (5) calendar days of his or her receipt of the names of the individuals selected to conduct the Inquiry, raise any objections to the IRB Chair. The IRB Chair will review the objections. If the objections are found to have merit by the IRB Chair, those individual(s) to whom the objections pertain will be barred from any participation in the Inquiry process, and shall be replaced by the IRB Chair.

(e) Prior to beginning the Inquiry the IRB Chair shall make good faith efforts to notify the Respondent in writing of the allegation(s) of the matter and that an Inquiry is being initiated. If during the Inquiry there are additional respondents subsequently identified, they must be notified in writing.

(f) On or before the date on which the Respondent is informed of the allegation(s), the IRB Chair shall promptly take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the Inquiry, inventory the records and evidence, and sequester them in a secure manner, except that where the research records or evidence encompass research 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. Where appropriate, the IRB Chair shall give the Respondent copies of, or reasonable, supervised access to the research records. The IRB Chair shall undertake all reasonable and practical efforts to take custody of additional research records or evidence that is discovered during the course of an Inquiry, 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.

(g) The IRB Chair shall prepare a charge for the individual or committee conducting the Inquiry that sets forth:

- (i) the time for completion of Inquiry;
- (ii) the allegation(s) and any related issues identified during the preliminary assessment;
- (iii) 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; and

- (iv) that an Investigation is warranted if the individual or committee determined that there is a reasonable basis for concluding that the matter falls within the definition of research misconduct and that the allegation(s) may have substance based on the review conducted during the Inquiry.

(h) The individual(s) selected to conduct the Inquiry shall conduct such Inquiry as soon as possible and, to the extent practicable, complete the Inquiry within sixty (60) calendar days of initiation.

(i) Such individual(s) conducting the Inquiry shall prepare a written report with full documentation of such Inquiry, including the evidence reviewed and a summary of the interviews conducted. With regard to any interviews conducted, complete summaries or transcripts of these interviews may, in the discretion of the individual(s) selected to conduct the Inquiry, be prepared, provided to the interviewed individual for comment or revision, and included as part of the Inquiry.

(j) The report shall recommend a course of action to the IRB Chair including whether or not the allegation(s) are sufficiently substantive so as to warrant an Investigation as prescribed in Part IV. An Investigation is warranted if there is a reasonable basis for concluding that the allegation(s) falls within the definition of research misconduct and preliminary information gathering and preliminary fact-finding from the Inquiry indicates that the allegation(s) may have substance. If the Inquiry establishes that an Investigation is not necessary, the reasons for this conclusion must be adequately documented in sufficient detail to permit a later assessment by ORI of the reasons why the decision not to conduct an Investigation was made. If the Inquiry establishes that an Investigation is necessary, the reasons for this conclusion must be adequately documented.

The written report shall also include:

- (i) the name and position of the Respondent;
- (ii) a description of the allegation(s);
- (iii) the PHSA support including grant numbers, grant application, contracts and publications listing PHSA support, if applicable;
- (iv) the basis for recommending that the alleged actions warrant an Investigation;
- (v) the evidence reviewed and a summary of any interviews conducted; and
- (vi) any comments on the report by the Respondent or the Complainant.

(k) **If an admission of research misconduct is made by the Respondent, misconduct may be determined at the Inquiry stage.** In such a case, if the research misconduct implicated federally-funded research, the University shall promptly notify ORI to determine the next steps that should be taken.

(l) The Respondent shall be given notice whether an Investigation has been determined to be warranted. The notice must include a copy of the report of the Inquiry and the Respondent will be afforded an opportunity to comment on the report to the individual(s) selected to conduct the Inquiry. If the Respondent elects to comment on the report, he or she shall have ten (10) calendar days of his or her receipt of the report, to submit written comments, and his or her comments shall be made a part of the record.

(m) A complete record of the Inquiry together with the written report of such Inquiry shall be maintained and forwarded to the IRB Chair by the individual(s) selected to conduct the Inquiry.

(n) If, for any reason, the University plans to terminate an Inquiry concerning PHSA funded research without completing all the above requirements, a report of such planned termination, including a description of the reasons for such termination shall be made to ORI.

(o) Throughout the Inquiry process and to the extent reasonably possible, all reasonable steps will be taken to preserve and protect the reputation and rights of both the Respondent and the Complainant. To the extent reasonably possible, the Inquiry process will be kept confidential and will not be disclosed, except as is necessary to facilitate a complete and comprehensive Inquiry, as is required under Part VI, or to comply with the law. If it is determined that the allegation(s) in the complaint were made in bad faith, that determination shall be forwarded to the appropriate University officials.

(p) If new evidence is brought to the attention of the IRB Chair after the completion of the Inquiry but prior to the institution of an Investigation, if any, as prescribed in Part IV, the IRB Chair may determine in his or her discretion that the matter be referred back to the individual(s) selected to conduct the Inquiry or that new individual(s) be appointed to reopen the Inquiry.

(q) Consistent with the procedures prescribed herein, the IRB Chair and/or the individual(s) selected to conduct the Inquiry shall have at any time the authority to supplement and clarify applicable procedures, provided that adequate notice is given to the individuals affected by such actions.

(r) Sufficiently detailed documentation of the Inquiry must be secured and maintained for seven (7) years after the termination of the Inquiry. These documents must be provided, upon request, to the President, the Provost, ORI, or other authorized HHS personnel.

IV. PROCEDURES FOR INVESTIGATIONS

(a) If, after evaluation of the report submitted pursuant to the Inquiry process prescribed in Part III, the IRB Chair determines in his or her discretion that a matter does not warrant further review, the IRB Chair shall dismiss the matter. If the IRB Chair determines in his or her discretion that a matter does warrant further review, the IRB Chair shall initiate an Investigation within thirty (30) calendar days of the completion of the Inquiry process. In addition, the IRB Chair shall decide in his or her discretion whether interim administrative action is appropriate. When an Investigation concerns PHSA funded research, ORI will be notified by the authorized Institutional Official, on or before the date that an Investigation has been initiated and shall be sent a copy of the Inquiry report.

(b) The University will notify the Respondent in writing of the allegation(s) within a reasonable amount of time after determining that an Investigation is warranted, but before the Investigation begins. The University will give the Respondent written notice of any new allegation(s) of research misconduct within a reasonable amount of time after deciding to pursue allegation(s) not addressed during the Inquiry or in the initial notice of the Investigation.

(c) The Investigation shall be conducted by an *ad hoc* committee of no fewer than three (3) individuals ("Investigation Committee") selected by the IRB Chair. The individual(s) selected to conduct the Investigation must have the professional time and resources, be objective, impartial, and qualified to evaluate the complaint. Individuals appointed to the Investigation Committee may have also served on the Inquiry Committee. The IRB Chair shall notify the Respondent of the names of the individual(s) selected to conduct the Investigation. If the Respondent elects to do so, he or she shall, in writing and within five (5) calendar days of his or her receipt of the names of the individuals selected to conduct the Investigation, raise any objections to the IRB Chair. If the objections are found to have merit by the IRB Chair, those individual(s) to whom the objections pertain will be barred from any participation in the Investigation, and shall be replaced by the IRB Chair.

(d) Before or at the time of notifying the Respondent, and whenever any additional items become known or relevant to the Investigation, the Investigation Committee shall promptly 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. Where appropriate, the IRB Chair shall give the Respondent copies of, or reasonable, supervised access to the research records. The IRB Chair shall undertake all reasonable and practical efforts to take custody of additional research records or evidence that is discovered during the course of a research misconduct proceeding, 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.

(e) The IRB Chair will define the subject matter of the Investigation in a written charge to the Investigation Committee that:

- (1) describes the allegation(s) and related issues identified during the Inquiry;
- (2) identifies the Respondent;
- (3) informs the Investigation Committee that it must conduct the Investigation as prescribed in this policy;
- (4) defines research misconduct;
- (5) informs the Investigation 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;
- (6) informs the Investigation Committee that the Respondent has the burden of proving by a preponderance of the evidence any affirmative defenses raised, including honest error or difference of opinion;
- (7) informs the Investigation 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; (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
- (8) informs the Investigation Committee that it must prepare or direct the preparation of a written Investigation report that meet the requirements of this policy.

(f) The Investigation Committee shall conduct the Investigation as soon as possible. The Investigation process shall be completed in its entirety (including conducting the Investigation, providing a draft report for comment, preparing the final

report and submitting the report to ORI) within 120 calendar days from initiation of the Investigation, absent exceptional circumstances. For PHSA funded research, any extension of time must be specifically granted by ORI. In any event, specific ORI requirements, with regard to extensions, timing provisions, or otherwise, will be followed by the Investigation Committee and communicated to the Respondent. Wherever ORI is not involved, the Investigation Committee may extend the time period in their discretion by notice of such fact to the Respondent, and the Respondent may request an extension of such time in writing directed to the Investigation Committee, and the Investigation Committee may extend such period in their discretion by notice of such fact to the Respondent.

(g) The Investigation Committee shall interview the Respondent and provide a full and fair opportunity for the Respondent to be informed of and defend against the allegation(s) of the complaint. The Investigation Committee shall afford the Respondent an opportunity to respond to the allegation(s) of the complaint, both orally and in writing, and to provide information for consideration by the committee.

(h) The Investigation Committee shall interview the Complainant and any other available person who has been reasonably identified as having information regarding any relevant aspects of the Investigation, including witnesses identified by the Respondent. With regard to any interviews conducted, complete summaries or transcripts of these interviews may, in the discretion of the Investigation Committee, be prepared, provided to the interviewed individual for comment or revision, and included in the record of the Investigation.

(i) The Investigation Committee shall pursue diligently all significant issues and leads discovered that are determined relevant to the Investigation, including any evidence of additional instances of possible research misconduct, and continue the Investigation to completion.

(j) The Investigation Committee shall create a detailed record of the Investigation and prepare a written report with full documentation of such Investigation including, but not limited to:

- (1) description of the nature of the allegation(s) of research misconduct, including identification of the Respondent, and the specific allegation(s) of research misconduct considered in the Investigation;
- (2) description and documentation of the PHSA support, if any, including any grant numbers, grant allocations, contracts and publications listing PHSA support;
- (3) description of the specific allegation(s) of research misconduct for consideration in the Investigation;

- (4) the institutional policies and procedures under which the Investigation was conducted, unless those policies and procedures were provided to ORI previously;
- (5) the research records and evidence that were reviewed and any evidence taken into custody but not reviewed; and
- (6) review of reports, scholarly publications, manuscripts, and other documents including research data and proposals, publications, correspondence, and memoranda of telephone conversations; inspection of laboratory or clinical facilities and materials; and, whenever reasonably possible, interviewing of parties with an involvement in or knowledge of the matter;
- (7) for each separate allegation of research misconduct identified during the Investigation, a statement of finding as to whether misconduct did or did not occur and if it is determined to have occurred, the following information must be contained for each statement of finding included in the report:
 - i. identify whether the research misconduct was falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly;
 - ii. 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 the 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;
 - iii. identify the specific PHSA support;
 - iv. identify whether any publications need correction or retraction;
 - v. identify the person(s) responsible for the misconduct; and
 - vi. list any current support or known applications or proposals for support that the Respondent has pending with non-PHSA federal agencies.

(9) The report shall also include and the Investigation Committee shall consider any comments made by the Respondent and Complainant on the draft Investigation report.

(k) If the allegation(s) in the complaint are not substantiated by the Investigation, the reasons for this conclusion must be adequately documented. If the allegation(s) in the complaint are substantiated by the Investigation, the reasons for this

conclusion must be adequately documented, and the Investigation Committee shall recommend to the IRB Chair appropriate administrative and disciplinary action against the Respondent which may include, but not be limited to, the following:

- (1) In cases involving PHSA funded research, notification to ORI of the findings of the Investigation, a copy of the Investigation report, all attachments, any appeals, a statement of whether research misconduct was found and if so, by whom, whether the IRB Chair accepts the Investigation finding, any pending or completed administrative actions against the Respondent and appropriate restitution of funds as may be required;
- (2) Withdrawal of all pending abstracts and publications emanating from the research misconduct in question and notification to the editors of journals in which previous abstracts and papers have appeared;
- (3) Notification to other institutions and sponsoring agencies with which the individual has been affiliated if there is reason to believe that the validity of previous research may be questionable; and
- (4) Appropriate action under Article 10 the University Statutes, where such action is justified by the seriousness of the substantiated research misconduct.

(l) Throughout the Investigation process all reasonable steps will be taken to preserve and protect the reputation and rights of both the Respondent and the Complainant. To the extent reasonably possible, the Investigation process will be kept confidential and will not be disclosed except as is necessary to facilitate a complete and comprehensive Investigation, or as is required under Part VI, or to comply with the law. If the alleged research misconduct is not substantiated by the Investigation, and depending upon the particular circumstances and the views of the Respondent, the IRB Chair may consider notifying those individuals aware of, or included in, the Investigation of the final outcome, publicizing the final outcome in any forum in which the allegation of research misconduct was previously publicized and expunging any and all references to the research misconduct allegation from the Respondent's personnel file. Furthermore, if it is determined that the allegation(s) in the complaint were made in bad faith, that determination shall be forwarded to the appropriate University officials.

(m) Consistent with the procedures prescribed herein, the IRB Chair and/or the Investigation Committee shall have at any time the authority to supplement and clarify applicable procedures, provided that adequate notice is given to the individuals affected by such actions.

(n) The Respondent shall be given a copy of the draft report of the Investigation and a copy or supervised access to the evidence on which the report is

based and afforded an opportunity to comment on the report to the committee. If the Respondent elects to comment on the report, he or she shall, in writing and within seven (7) calendar days of his or her receipt of the report, notify the Investigation Committee of his or her intention to do so, and his or her comments shall be submitted within thirty (30) calendar days of the date on which the Respondent received the draft report and evidence. Comments of the Respondent shall be made a part of the record.

(o) The University may provide the Complainant a copy of the draft report or relevant portions of the draft report. Any comments of the Complainant must be submitted within thirty (30) calendar days of the date the Complainant received the report or relevant portions of the report.

(p) A complete record of the Investigation together with the report of such Investigation shall be maintained and forwarded to the IRB Chair by the Investigation Committee.

(q) The IRB Chair shall either accept the report or reject the report. If the IRB Chair rejects the report, any member of the Investigation Committee shall have the right to appeal the report's rejection to the Provost, provided the appeal is in writing and submitted within ten (10) calendar days of the date the members of the Investigation Committee receive notice of the rejection. The Provost shall have the right to direct the IRB Chair to accept the report, and the Provost's decision in this regard shall be final and binding on the IRB Chair. If the IRB Chair rejects the report and no member of the Investigation Committee files a timely appeal, the matter is concluded.

(r) If, for any reason, the University plans to terminate an Investigation involving PHSA funded research without completing all the above requirements, a report of such planned termination, including a description of the reasons for such termination shall be made to ORI.

(s) If new evidence is brought to the attention of the IRB Chair after the completion of the Investigation process, the IRB Chair may determine in his or her discretion that the matter be referred back to the Investigation Committee or that a new committee be appointed to reopen the Investigation.

(t) Unless custody has been transferred to HHS or ORI has advised the University in writing that it no longer needs to retain the records, records of research misconduct proceedings shall be securely maintained for 7 years after completion of the proceeding or the completion of any PHSA proceeding involving the research misconduct allegation(s), whichever is later.

V. APPEALS

The Respondent may appeal all or any part of the decision of the IRB Chair with respect to the administrative and disciplinary action to be taken against the Respondent as prescribed in Part IV. The Respondent shall serve upon the Provost a petition, in writing, for an appeal within ten (10) calendar days after the Respondent receives notice of the decision of the IRB Chair.

(a) The Provost, in his or her discretion, shall have the power to affirm, reverse, or modify the decision of the IRB Chair. The Provost shall base his or her decision upon the petition, the record of the Investigation conducted by the Investigation Committee, and the Investigation Committee's report of the Investigation. The Provost's decision shall be final.

VI. REPORTING REQUIREMENTS

(a) Unless an extension has been granted, the University must, within the 120-day period for completing the Investigation, or the 120-day period for completion of any appeal, submit the following to ORI: (1) a copy of the final Investigation report with all attachments; (2) a statement of whether the IRB Chair has accepted the findings of the Investigation report, or the outcome of the appeal; (3) a statement of whether the Investigation Committee found misconduct and, if so, who committed the misconduct; and (4) a description of any pending or completed administrative actions against the Respondent.

(b) As noted in Part III and Part IV, during Inquiries and Investigations, confidentiality will be maintained to the extent reasonably possible. However, when mandated by governmental regulations or contractual requirements, the appropriate agencies or individuals will be informed in conformity therewith, and copies of the complete record of the Inquiry and Investigation and the report of the Inquiry and Investigation, may, in whole or in part, be provided to such agencies or individuals. Furthermore, if there is a reasonable indication of (1) possible criminal violation; (2) immediate health hazard; (3) need to protect funds or equipment; (4) immediate need to protect the interests of the Complainant, accused, or other involved or affected individuals, including the research community or the public; or (5) probable public reporting of the matter, the Senior Administrator may, in his or her discretion, authorize immediate notification of the appropriate agencies or individuals.

VII. CONCLUSION

The integrity of the University should never be in question. Thus, the University and the research community within it must do everything possible to prevent all forms of research misconduct. It is for these reasons that these standards and procedures have been established. These standards and procedures are designed to help facilitate the handling of alleged research misconduct and, above all, to promote and maintain high ethical standards in research and to protect the integrity of research and of the University.