

Number:	ASA-412
Title:	Research Ethics Board and Responsible Conduct of Research
Person responsible for enforcement:	Vice-Rector Academic and Research
Entered into force:	November 23 rd , 2016
Approved:	November 23 rd , 2016 by the Council of Administration <i>This document replaces all previous regulations on this subject.</i>
Exception:	No exception to this regulation without prior written authorization from the Council of Administration

In this document, the masculine form is used without prejudice and for conciseness purposes only.

1. Preamble

Saint Paul University confirmed its full compliance with the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) as amended from time to time by a resolution of its Council of Administration (CA) on May 16, 2012.

The TCPS aims to strike an appropriate balance between recognition of the potential benefits of research, and protection of participants from harms or wrongs incurred through taking part in a research, including injustices and breaches to one of the policy's core principles: Respect for Persons.

Saint Paul University also confirms its full compliance with the *Tri-Agency Framework: Responsible Conduct of Research* as amended from time to time.

The University confirms its continued commitment to the highest standards of integrity in all aspects of Research, including seeking funding, conducting Research and reporting the results.

2. Regulations

2.1 Research Ethics Board

In accordance with Article 6.2 of the TCPS, the Research Ethics Board (REB) reports to the Council of Administration. It falls under the purview of the CA to appoint the Chair and the members of the REB.

In accordance with Article 6.4 of the TCPS, the REB shall consist of five members of who have at least one of the following qualifications:

- two members have expertise in relevant research disciplines, fields and methodologies of Saint Paul University;
- one member versed in ethics;
- one member versed in law when it comes to evaluating research projects that have a biomedical component;
- one community member with no affiliation with the institution.

The CA also appoints five substitute members to attend in the absence of a core member.

Each member is appointed for a term not exceeding five years. The mandate may be renewed.

Quorum is obtained at three members. In the case of a project with a biomedical component to review, the quorum is set at four members.

The members of the REB are required to meet face to face. In exceptional cases, the Chair may authorize participation by teleconference or videoconference.

2.2 Role of the REB Chair

In accordance with Article 6.8 of TCPS, the REB Chair is responsible for ensuring that the REB review process conforms to the TCPS's requirements.

The Chair will prepare an annual report that will be presented to the CA.

2.3 Minimal risk to participants

Research in the humanities and the social sciences that poses, at most, minimal risk is not required to be submitted to the REB for review.

Minimal risk is defined as research in which the probability and magnitude of possible harm incurred by participation is no greater than that encountered in the participant's everyday life.

Thus, the review of a proposal submitted by a graduate student as part of a thesis, or a proposal submitted by a faculty member may be delegated to the REB Chair or the designated representative, in accordance with Article 2.9 of the TCPS.

In addition, the review of a proposal submitted by a student related to a course or a major research project is delegated to the faculty, in accordance with Article 6.12. In such cases, review takes place in a manner that must be approved by the Vice-Rector, Academic and Research.

2.4 Risks to Researchers

While it is not a formal part of its responsibilities, the REB may raise issues of safety with the applicants.

Based on the level of risk, the REB will refer these concerns to an appropriate body for review within the institution, usually the Dean for requests submitted by professors and students or the Vice-Rector Academic and Research for proposals submitted by deans.

2.5 Recognition of REB's of other institutions

In accordance with Article 8.1 of TCPS, Saint Paul University and its REB recognize the research ethics certificate of another REB, provided that its institution subscribes to the TCPS.

2.6 Responsible Conduct of Research

Saint Paul University is committed to meeting the requirements of the *Tri-Agency Framework: Responsible Conduct of Research* and endorses all of the policies outlined in this Framework.

This policy is for all the members of University Community that are engaged in Research, including but not limited to:

- employees (all unionized and non-unionized academic and administrative staff as well as those whose salary is paid through sources other than the University's operating funds, such as grants, research grants and external contracts);
- students (full time or part time, special students, at the undergraduate or graduate level);
- with an academic appointments, adjunct and emeritus professors, post-doctoral or clinical fellows, research trainees, including visiting students and volunteers.

The Vice-Rector Academic and Research is responsible for processus de traitement d'allégation de violation de la conduite responsable de la recherche, it being understood that this process should be read in conjunction with the *ri-Agency Framework: Responsible Conduct of Research*.

The Chair of the REB is responsible for reporting on the status and results of investigations to appropriate bodies.

The Office of Research and Ethics is responsible for developing information and awareness-raising activities to highlight the importance of responsible conduct of research. It is also responsible for preparing annual public statistical reports on confirmed cases of violation of conduct responsible for research and on the measures taken.

3. References

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans:
www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

Tri-Agency Framework: Responsible Conduct of Research:
www.rcr.ethics.gc.ca/eng/policy-politique/framework-cadre/

Method to Address Allegations of a Breach of Responsible Conduct of Research

1. OBJECTIVES

The objectives of the present method are to establish minimum requirements for responsible conduct of research, to define what constitutes a breach of responsible conduct of research, and to establish a process for addressing an allegation of a breach of responsible conduct of research.

2. MINIMUM REQUIREMENTS FOR THE RESPONSIBLE CONDUCT OF RESEARCH

Conducting research responsibly means that the individuals involved in research exhibit honest and ethical behaviour at all stages of this work: from the development of the research idea, to the request for funding, the collection, analysis and retention of data as well as the dissemination of the results.

Researchers shall strive to follow the best research practices honestly, accountably, openly and fairly in the search for and in the dissemination of knowledge. In addition, they shall follow applicable University policies, research sponsors' policies or requirements and applicable laws. Without limiting the general interpretation of the previous sentence, at a minimum, researchers are responsible for the following:

- a) providing true, complete and accurate information in their funding applications and related documents and representing themselves, their research and their accomplishments in a manner consistent with the norms of the relevant field;
- b) using grant, contract or award funds in accordance with University policies and with research sponsors' policies or requirements and for providing true, complete and accurate information on documentation for expenditures from research grant or award accounts;
- c) using a high level of rigour in proposing and performing research; in recording, analyzing, interpreting, reporting and publishing research data and findings;
- d) keeping complete and accurate records of research data, methodologies and findings, including graphs and images, in accordance with University policies, research sponsors' policies or requirements, professional and field-specific standards and applicable laws in a manner that will allow verification or replication of the work by others;
- e) referencing and, where applicable, obtaining permission for the use of all published and unpublished work, including research data, source material, methodologies, findings, graphs and images;
- f) including as authors, with their consent, all those and only those who have materially or conceptually contributed to, and share responsibility for, the contents of the publication or document, in a manner consistent with their respective contributions, and authorship policies of relevant publications;
- g) acknowledging, in addition to authors, all contributors and contributions to the research, including writers, funders and sponsors;
- h) appropriately managing any real, potential or perceived conflict of interest;
- i) proactively rectifying a breach of a University policy, research sponsors' policies or requirements, and applicable laws that are made known to the researcher; and
- j) cooperating in an inquiry, investigation and in responding to an allegation or breach of responsible conduct of research.

3. EXAMPLES OF BREACHES OF AGENCY POLICIES BY RESEARCHERS

- a. Fabrication: Making up data, source material, methodologies or findings, including graphs and images.
- b. Falsification: Manipulating, changing, or omitting data, source material, methodologies or findings, including graphs and images, without acknowledgement and which results in inaccurate findings or conclusions.
- c. Destruction of research records: The destruction of one's own or another's research data or records to specifically avoid the detection of wrongdoing or in contravention of the applicable funding agreement, institutional policy or laws, regulations and professional or disciplinary standards.
- d. Plagiarism: Presenting and using another's published or unpublished work, including theories, concepts, data, source material, methodologies or findings, including graphs and images, as one's own, without appropriate referencing and, if required, without permission.
- e. Redundant publication or self-plagiarism: The re-publication of one's own previously published work or part thereof, including data, in any language, without adequate acknowledgment of the source, or justification.
- f. Invalid authorship: Inaccurate attribution of authorship, including attribution of authorship to persons other than those who have made a substantial contribution to, and who accept responsibility for, the contents of a publication or document.
- g. Inadequate acknowledgement: Failure to appropriately recognize contributors.
- h. Mismanagement of conflict of interest: Failure to appropriately identify and address any real, potential or perceived conflict of interest, in accordance with the institution's policy on conflict of interest in research, preventing one or more of the objectives of the Responsible Conduct of Research Framework from being met.
- i. Misrepresentation in an agency application or related document: a) Providing incomplete, inaccurate or false information in a grant or award application or related document, such as a letter of support or a progress report; b) Applying for or holding an agency award when deemed ineligible by NSERC, SSHRC, CIHR or any other research funding organization world-wide for reasons of breach of responsible conduct of research policies such as ethics, integrity or financial management policies; c) Listing of co-applicants, collaborators or partners without their agreement.
- j. Mismanagement of grants or award funds: Using grant or award funds for purposes inconsistent with the policies of the agencies; misappropriating grants and award funds; contravening agency financial policies, namely the *Tri-agency Financial Administration Guide*, agency grants and awards guides; or providing incomplete, inaccurate or false information on documentation for expenditures from grant or award accounts.
- k. Breach of agency policies or requirements for certain types of research: Failing to meet agency policy requirements or, to comply with relevant policies, laws or regulations, for the conduct of certain types of research activities; failing to obtain appropriate approvals, permits or certifications before conducting these activities.
- l. Breach of agency review processes: a) Non-compliance with the conflict of interest and confidentiality policy of the federal research funding organizations; b) Participating in an agency review processes while under investigation.

4. GENERAL PROVISIONS ON PROCESS FOR ADDRESSING AN ALLEGATION

Confidentiality: In order to protect the privacy of both the complainant(s) and respondent(s), the process shall take place in the strictest confidentiality to the extent possible and within the limitations of applicable laws. Any communication or information gathered during the process is confidential except to the extent that disclosure is legally required or is necessary to effectively implement Policy ASA-412 or this method, other applicable University policies, the research sponsors' policies and requirements or to undertake any consequences or remedial measures arising from a decision made under this method.

Role of the Office of Research and Ethics: It shall act as the University's institutional liaison with the research sponsors, the agencies, the Secretariat on Responsible Conduct of Research (SRCC), as well as the University's Research Ethics Board (REB) and any other parties, as may be required.

Interim measures: Pending the final outcome of an inquiry or investigation into an allegation, the University may independently or at the research sponsor's request, in exceptional circumstances, take immediate action to protect the administration of a research sponsor's funds (for example: freezing of grant accounts, requiring a second authorized signature from a University representative on all expenses charged to the researcher's grant accounts). The Vice-Rector Academic and Research (VRAR), in consultation with the director of the Office of Research and Ethics, take whatever action or make whatever arrangements are necessary in his opinion to prevent risk of harm to life or property, and to keep the status quo in order to preserve the ability to render a meaningful final decision on the merits of the allegation.

Timelines: The deadlines mentioned in the process for addressing an allegation are meant to ensure that a complaint is dealt with in a timely fashion and, where applicable, comply with the research sponsors' policies or requirements.

- a) It can be impossible to determine appropriate timelines for addressing an allegation given the unpredictability of each case as well as the volume and nature of the research to be reviewed and the complexity associated with the allegation. Therefore, where no timelines or deadlines are mentioned in this method, the intention is to address an allegation and complete the process within a range of between two to seven months and in any event, to act as expeditiously as possible in light of the nature and complexity of the circumstances of the allegation and in light of other circumstances that may arise during the process. The inquiry should normally be completed within two months of receipt of an allegation and the investigation should normally be completed within five months of completion of the inquiry.
- b) There may be, in exceptional circumstances, reasons to extend a deadline or timeline for addressing an allegation. In such a case, the VRER may, in consultation where necessary with the agencies, SRCR, or other research sponsor, extend a deadline where the delay is incurred in good faith and the extension does not prejudice or harm those involved in the allegation.

5. PROCESS FOR ADDRESSING AN ALLEGATION

5.1 Making an Allegation

A complainant may make an allegation by submitting the allegation in writing to the VRAR. In the event an allegation is received by another person, such allegation shall immediately be referred to the VRAR.

An anonymous allegation may be considered if it consists of sufficient, substantive and verifiable information and if anonymity of the complainant does not prejudice the fairness of the investigation.

In a situation in which the complainant has identified himself when making an allegation, but wishes that his identity not be disclosed, the allegation may be considered if sufficient publically available or independently verifiable corroborating evidence is provided or obtainable or if disclosure of the complainant's identity places that person in plausible jeopardy. However, it is not possible to guarantee confidentiality of the complainant's identity if fairness or evidence gathering during the process of addressing an allegation requires disclosure of identity. Before making an allegation, a person may consult informally and confidentially with the VRAR to learn more about the process outlined in this method.

For research funded by an agency, subject to applicable laws, in particular, privacy laws, the VRAR shall be responsible for immediately advising the SRCR and the relevant agency of an allegation relating to activities funded by the agency that may involve significant financial, health and safety or other significant risks.

The VRAR shall refer the allegation to the Chair of the REB for treatment.

5.2 Receipt of an Allegation and Response

The Chair of the REB will acknowledge receipt of the allegation to the complainant, with a copy to the VRAR, inform the complainant of the procedural steps for responding to the allegation (if the identity of the complainant is known) and, in consultation with the VRAR or such others as the Chair of the REB considers necessary, review the allegation and if necessary and if the identity of the complainant is known, seek clarification from the complainant on the information contained in the allegation.

The Chair of the REB then sends a copy of the allegation to the respondent along with any other information obtained from the complainant, with a copy to the VRAR. The respondent is asked to respond in writing to the allegation within 10 working days from the date the allegation was sent to the respondent. In the absence of a response, the Chair of the REB may proceed to an investigation.

The Chair of the REB will acknowledge receipt of the response to the respondent, if any, review it, in consultation with the VRAR or such others as the Chair of the REB considers necessary, and if necessary, seek clarification from the respondent on the information contained in the response.

5.3 Inquiry

The Chair of the REB determines the following, in consultation with the VRAR, or such others as the Chair of the REB considers necessary, based on the information received in the allegation and in the response:

- a) whether the allegation is an allegation made in good faith and without malice;
- b) whether a breach of responsible conduct of research may have occurred;
- c) what University policy, what research sponsors' policies or requirements, or what applicable laws may have been breached; and
- d) whether an investigation is warranted.

The Chair of the REB, in consultation with the VRAR, or such others as the Chair of the REB considers necessary, may dismiss the allegation, without further inquiry or investigation, if the Chair of the REB determines that the allegation is not an allegation made in good faith and without malice.

In the event that the allegation is determined to be an allegation made in good faith and without malice; and a breach of responsible conduct of research is confirmed (e.g., the respondent admits to and accepts responsibility for the alleged breach of responsible conduct of research); and that further investigation would not uncover any new information pertinent to the matter; the Chair of the REB, in consultation with the VRAR and such others as the Chair of the REB considers necessary, shall:

- a) consider if the respondent's admission is sufficient for a finding of breach of responsible conduct of research; and
- b) whether an investigation by an Investigative Committee is warranted or required under research sponsors' policies or requirements; and
- c) where appropriate, determine what consequences and measures should result from the breach of responsible conduct of research .

Within thirty (30) days of the receipt of the response, the Chair of the REB informs the respondent in writing of the determinations made at the conclusion of the inquiry stage and sends a copy to the VRAR.

The VRAR shall prepare a report on the determinations made at the conclusion of the inquiry containing, at a minimum, the following:

- a) Summary of the specific allegations and the respondent's response to them;
- b) Information and documentation considered;
- c) Summary of the inquiry's findings and reasons for the findings;
- d) The process and time lines for the inquiry;
- e) As attachments to the report, all the documentation reviewed and considered during the inquiry.

Where applicable, the Director of the Office of Research and Ethics shall inform the relevant agency of whether or not the University is proceeding with an investigation by writing to the SRCR.

The Chair of the REB, in consultation with the VRAR, shall on a case-by-case basis determine whether to provide the complainant with relevant portions of the inquiry report. The VRAR shall ensure that the complainant signs a confidentiality agreement as a condition of access to the inquiry report.

5.4 Investigative Committee

If the Chair of the REB determines that an investigation is warranted, the Chair of the REB shall appoint at least three members to an Investigative Committee whose authority shall be to investigate and decide whether a breach of responsible conduct of research has occurred and if so, recommend recourse or remedial action. The Chair of the REB must not be a member of the Investigative Committee.

In selecting the members of the Investigative Committee, the Chair of the REB shall ensure that all members are free of conflict of interest; that at least one member is a person normally considered to be a peer of the respondent and has expertise in the subject matter of the inquiry; and that at least one member is external to the University with no current affiliation to it.

The Investigative Committee shall select its Chair and set its own procedures, which at a minimum, shall provide the complainant and the respondent with an opportunity to meet with the Investigative Committee and allow each of them to be heard and know what information is being considered by the Investigative Committee in addition to what is contained in the allegation, the response and the documentation provided by the complainant and the respondent.

The Investigative Committee shall endeavor to complete its investigation in a timely fashion.

5.5 Investigation Report

Upon completion of the investigation, the Investigative Committee will send to the respondent, with a copy to the Chair of the REB, a written confidential draft investigation report containing the following:

- a) Summary of the specific allegations and the respondent's response to them;
- b) Information and documentation considered;
- c) Summary of the Investigative Committee's findings and reasons for the findings;
- d) The process and time lines for the investigation, including a list of individuals interviewed by the Investigative Committee;
- e) Conclusion on whether or not a breach of responsible conduct of research has occurred;
- f) Recommendations, if any, on any consequences or imposition of corrective or disciplinary measures; and
- g) As attachments to the report, all the documentation reviewed and considered by the Investigative Committee.

The Investigative Committee will provide the respondent with an opportunity to send written comments on the draft investigation report to the Investigative Committee no later than 10 working days after the draft investigation report has been sent.

The Chair of the REB, in consultation with the VRAR, shall on a case-by-case basis determine whether to provide the complainant with the draft investigation report or relevant portions thereof. Any comments made by the complainant on the draft investigation report must be submitted within 10 working days after the draft investigation report has been sent. The Chair of the REB shall ensure that the complainant signs a confidentiality agreement as a condition of access to the investigation report.

The Investigative Committee will consider the comments, if any, of the complainant and of the respondent, append these to the report, and finalize the investigation report. The Investigative Committee will then send the final investigation report to the Chair of the REB with a copy to the VRAR. The Chair of the REB will send a copy of the final confidential investigation report to the respondent, with a copy of the transmittal letter to the VRAR.

5.6 Final Outcome

Upon reviewing the final report of the Investigative Committee, if the report's conclusion is that a breach of responsible conduct of research has occurred, or if a breach of responsible conduct of research is confirmed at the inquiry stage, the Chair of the REB in consultation with the VRAR, decides or recommends on the imposition of any consequences or measures. The Chair of the REB will inform the respondent in writing of the final outcome of the investigation and of any such consequences or measures subject to privacy considerations. The Chair of the REB shall provide a copy of his letter to the VRAR.

Consequences or measures resulting from a breach of responsible conduct of research will depend on circumstances, on the severity of the breach of responsible conduct of research, such as an innocent violation, on any mitigating factors, on considerations to affected researchers or research team and on any applicable University policy, research sponsors' policies or requirements and applicable laws. If a breach of responsible conduct of research has occurred, consideration must be given to taking measures that will prevent such breach from recurring in the future. The following list of potential consequences or measures resulting from a breach of responsible conduct of research provides examples and is not meant to be exhaustive nor necessarily represents a progression in the severity of consequences or measures:

- a) Issuing a letter of concern to the respondent;
- b) Requiring that the respondent correct the research record and provide proof that the research record has been corrected;
- c) Requiring that the respondent withdraw all relevant publications or pending publications;
- d) Requiring that the respondent notify editors of publications in which the research involved was reported;
- e) Ensuring that the units involved are informed about appropriate practices for promoting the proper conduct of research;
- f) Seeking a refund within a defined timeframe of all or part of the funds already paid or spent;
- g) Imposing employee disciplinary measures or other employment consequences; and
- h) Such other consequence or measure available pursuant to applicable laws, research sponsors' policies or requirements or University policies.

Consequences or measures resulting from a finding at the inquiry stage or by the Investigative Committee that a breach of responsible conduct did not occur and that the allegation was not made in good faith or made with malice will depend on circumstances, on any mitigating factors, on considerations to affected researchers or research team and on any applicable University policy, research sponsors' policies or requirements and applicable laws.

The imposition of any consequences or measures, if any, will take effect immediately unless these require the approval or decision of other governing authorities at the University in accordance with applicable University policies.

The Chair of the REB, in consultation with the VRAR, shall on a case-by-case basis determine whether to inform the complainant of the final outcome of the investigation, subject to privacy considerations.

The University will make reasonable efforts within its means to protect or restore the reputation of those who were the subject of an allegation where no breach of responsible conduct occurred or where an allegation was not made in good faith or was made with malice.

Where required by an agency, the SRCR, or a research sponsor, the VRAR shall prepare a report to the agency or the SRCR or the research sponsor on each investigation conducted in response to an allegation related to a funding application submitted to an agency or a research sponsor or to an activity funded by an agency or a research sponsor. The report shall not include information that is not related specifically to the agency or research sponsor funding or personal information about the researchers or other person that is not material to the decision. Subject to applicable laws, in particular, privacy laws, the report shall include the following information:

- a) The specific allegations, a summary of the findings and reasons for the findings;
- b) The process and timelines followed by the inquiry or investigation;
- c) The respondent's response to the allegation, investigation and findings, and any measures the respondent has taken to rectify the breach of responsible conduct of research;
- d) Decision of the Investigative Committee and consequences or measures imposed by the University.

6. APPEAL

Within thirty days from the date the Chair of the REB communicated the final outcome of the allegation, the respondent may appeal the conclusion of the Investigative Committee or the Chair of the REB's decision on consequences or imposition of measures by submitting a written letter of appeal to the Secretary General setting out in detail the reasons for the appeal.

Upon review of the reasons for the appeal, the final report of the Investigative Committee, the decision of the Chair of the REB on consequences or measures, and after consultation with such others as the Secretary General considers necessary, the Secretary General disposes of the appeal.

Once the appeal is disposed of, the Secretary General sends a letter communicating the outcome of the appeal to the respondent, normally within 60 days of reception of the appeal. The Secretary General's decision is final.

The Secretary General shall provide a copy of his letter to the Chair of the REB and to the VRAR.