Responsible Conduct of Research

Sunnybrook Health Sciences Centre		Policy No:	SRI-043
Title	**Responsible Conduct of Research**	**Original:** *(mm/dd/yyyy)*	10/28/2013
Category	**Sunnybrook Research Institute**	**Reviewed:** *(mm/dd/yyyy)*	
Sub-Category	**Administration**	**Revised:** *(mm/dd/yyyy)*	10/30/2017; 01/06/2020
Issued By:	Executive Director, Research Integrity and Clinical Research Services		
Approved By:	Research Executive Committee, Sunnybrook Research Institute		

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1.0 OBJECTIVE:

To outline the process at Sunnybrook Research Institute (SRI) for receiving, investigating, addressing and reporting allegations of research misconduct.

2.0 BACKGROUND:

To maximize the quality and benefits of research, a positive research environment is required. For researchers, this implies duties of honest and thoughtful inquiry, rigorous analysis, commitment to the dissemination of research results and adherence to professional standards. For many of the funders (the Canadian Institutes of Health Research (CIHR), Natural Sciences and Engineering Research Council of Canada (NSERC), and Social Sciences and Humanities Research Council of Canada (SSHRC) (the Agencies) among them) it requires that institutions that receive government funding have a commitment to foster and maintain an environment that supports and promotes the responsible conduct of research (RCR). This policy has been developed to comply with the requirements of the Tri-Agencies[1] and the University of Toronto Framework to Address Allegations of Research Misconduct.[2]

Further Information on the Agencies' policies and requirements, which outlines the responsibilities of the Agencies, institutions and researchers, is contained in the *Tri-Agency Framework: Responsible Conduct of Research.*[1]

3.0 GENERAL:

Sunnybrook Research Institute expects its members to uphold the highest standards of ethical conduct in every aspect of research, regardless of the source of funding. Its members include employees, medical staff, students and anyone holding an institution, post or office that gives them institute status, such as that of a fellow or a research associate.

In summary: *researchers shall strive to follow the best research practices honestly, accountably, openly and fairly in the search for, and dissemination of, knowledge.*[1]

At a minimum, researchers are responsible for the following:

- *Rigour*: Scholarly and scientific rigour in proposing and performing research; in recording, analyzing and interpreting data; and in reporting and publishing data and findings.
- *Record keeping*: Keeping complete and accurate records of data, methodologies and findings, including graphs and images, in accordance with the applicable funding agreement, institutional policies, laws, regulations, and professional or disciplinary standards in a manner that will allow verification or replication of the work by others.
- *Accurate referencing*: Referencing and, where applicable, obtaining permission for the use of all published and unpublished work, including theories, concepts, data, source material, methodologies, findings, graphs and images.
- *Authorship*: Including as authors, with their consent, all those and only those who have made a substantial contribution to, and who accept responsibility for, the contents of the publication or document. The substantial contribution may be conceptual or material.
- *Acknowledgement*: Acknowledging appropriately all those and only those who have contributed to research, including funders and sponsors.
- *Conflict of interest management*: Appropriately identifying and addressing any real, potential or perceived conflict of interest in accordance with the institution's policy on conflict of interest in research, to ensure that the objectives of the RCR Framework (Article 1.3) are met.[1]

4.0 DEFINITIONS:

4.1 Administrator: The individual appointed by the Responsible Officer to conduct the inquiry.

4.2 Allegation: A report or complaint of observed, suspected or apparent research misconduct[3] or breach/serious breach of agency or institutional policy.

4.3 Complainant: An individual or representative from an organization who has made an allegation or notified an institution or Agency of a potential breach of an Agency and/or institutional policy.

4.4 Respondent: The person against whom an allegation is made.

4.5 Responsible Officer: The central point of contact at a senior administrator level to receive all confidential enquiries, allegations of research misconduct, breaches of policies and information related to allegations. At SRI the Vice-President Research & Innovation (VPRI) is the Responsible Officer. When the VPRI is determined to have a real, potential or perceived conflict of interest or relationship related to the allegation, the allegation shall be referred to the most appropriate senior administrator to act as the Responsible Officer.

4.6 Research misconduct: Includes, but without limitation, fabrication, falsification, plagiarism, destruction of research records, redundant publications, invalid authorship, inadequate acknowledgement, failure to manage conflicts of interest in research appropriately, misrepresentation, mismanagement of funds, and noncompliance with government agencies or SRI policy or requirements for certain types of research, e.g., human research ethics policy, animal care guidelines, etc.

A finding of research misconduct requires that such practice deviates significantly from accepted practices of the relevant research; that the research misconduct be committed intentionally, knowingly or recklessly; and that the allegation be proven by evidence. It does not include honest error or honest differences in interpretations or judgments of data.

4.7 Breach: A breach of the RCR Framework is the failure to comply with any Agency and/or institutional policy throughout the life cycle of a research project, from application for funding, to the conduct of research and the dissemination of research results. It includes all activities related to the research, including the management of Agency funds. Breaches of Agency policies include the following:

a. Fabrication

b. Falsification

c. Destruction of research records

d. Plagiarism

e. Redundant publication or self-plagiarism

f. Invalid authorship

g. Inadequate acknowledgement

h. Mismanagement of conflict of interest

Additionally, breaches also include misrepresentation in an Agency application or related document; mismanagement of grants or award funds; breach of Agency policies or requirements for certain types of research; and breach of agency review processes.

4.7 Serious breach: In determining whether a breach is serious, the Agencies and/or SRI will consider the extent to which the breach jeopardizes the safety of the public or brings the conduct of research into disrepute. This determination will be based on an assessment of the nature of the breach, the level of experience of the researcher, whether there is a pattern of breaches by the researcher and other factors as appropriate. Examples of serious breaches may include:

- recruiting human participants into a study with significant risks or harms without Research Ethics Board approval, or not following approved protocols;
- using animals in a study with significant risks or harms without Animal Care Committee approval, or not following approved protocols;
- deliberate misuse of research grant funds for personal benefit not related to research;
- knowingly publishing research results based on fabricated data;
- obtaining grant or award funds from the Agencies by misrepresenting one's credentials, qualifications or research contributions in an application.

For details of examples of breaches, see RCR Framework Article 3.1.[1]

5.0 SUMMARY OF THE PROCESS AND TIME FRAME:

5.1 Receiving Allegations

a. The Responsible Officer is the central point of contact to receive all confidential enquiries, allegations of research misconduct and information related to allegations.
b. Allegations that involve activities of the Responsible Officer are to be made to the President and CEO.
c. Allegations whereby the Responsible Officer may have a real, potential or perceived conflict of interest or relationship shall be referred to the most appropriate senior administrator to act as the Responsible Officer.
d. The Complainant is encouraged to identify himself/herself when making the allegation; however, anonymous allegations will be considered provided there is sufficient information to allow for an assessment of the allegation without further need for information from the complainant.

e. To the extent possible, the individual making an allegation in good faith or providing information related to an allegation will be protected from reprisals. The privacy of both the Complainant and Respondent will be protected to the extent possible consistent with relevant legislation.
f. Allegations must not be malicious, frivolous or based on rumour. The Complainant is also required to declare any conflict of interest (real, potential or perceived).
g. Upon receipt of an allegation, SRI may independently or at the request of the Agency take immediate action, which could include, but is not limited to, freezing grant accounts, requiring additional authorized signature for all expenses charged to an account or other measures as appropriate.

Where an allegation is related to conduct that occurred at another institution, the institution in receipt of the allegation will contact and work with the other institution to determine which institution is in the best position to conduct the inquiry and investigation (if warranted), and who will act as the point of contact for the allegation.

Upon receipt of an allegation, the Responsible Officer will notify the Executive Director, Research Integrity and appoint an Administrator. The Executive Director, Research Integrity is responsible for ensuring due process is followed for addressing allegations. The Administrator's role is to determine whether the allegation is responsible and there is sufficient information to move forward to an inquiry. If an inquiry is not warranted, then the decision and associated justification are documented and archived.

5.2 Investigating Allegations

Investigating allegations involves a two-stage approach: 1. an inquiry stage to determine if an investigation of the allegation is warranted; 2. an investigation stage to determine if the alleged research misconduct has been committed.

5.2.1 Inquiry

An inquiry is conducted to gather information to determine the veracity of the allegation and if a formal investigation is warranted. It is not the purpose at the inquiry stage to determine if research misconduct has occurred. The inquiry process is as follows:

a. Upon receipt of an allegation the Responsible Officer will appoint an individual ("Administrator") with the necessary expertise, who is without conflict of interest, to conduct the inquiry.
b. The Administrator shall disclose any actual, apparent, perceived or potential conflicts of interest to the Responsible Officer, who may decide, based on disclosure, to appoint a designate.
c. The Responsible Officer will refer the allegation to the designated Administrator.
d. The Respondent should normally be provided with a copy of the allegation within seven working days of its receipt by the Responsible Officer or as delegated to the Administrator.
e. If the allegation involves graduate students or relates to graduate faculty members acting in that capacity, then the allegation shall be communicated by the Responsible Officer to the applicable Dean or School of Graduate Studies (SGS).
f. The Complainant and Respondent will each be sent a separate letter outlining the process and shall be advised of the need to maintain confidentiality.
g. If the allegation, as written, does not contain sufficient information or particulars to permit an assessment, then the Administrator may request that supplementary information be provided in writing. Such supplementary information shall also be shared with the Respondent.
h. If the allegation is not dismissed on jurisdictional grounds, then the Administrator will contact the Respondent for the purposes of discussing the allegation.
i. In conducting the inquiry, the Administrator may consult confidentially within SRI and externally if appropriate to assist in the assessment of whether an investigation is warranted.
j. If the Administrator, in conjunction with the Responsible Officer, determines not to proceed with a formal investigation, then they shall provide written notice of the decision to the Complainant and

the Respondent. The Administrator's notice shall include a brief written summary of the reasons for such a determination.

k. Where the Administrator decides to recommend that a formal investigation be commenced, they shall inform the Responsible Officer and the Responsible Officer will subsequently provide written notice of the decision to the Respondent and the Complainant.
l. If the Administrator has reasonable grounds to believe that the Complainant did not act in good faith, then they will inform the Responsible Officer and write to the Complainant and the Respondent to summarize these grounds.
m. The final report of the inquiry is to be submitted by the Administrator to the Responsible Officer within 60 days of receipt of the allegation. Such a report will be retained by SRI for a period of seven (7) years for record-keeping purposes.

5.2.2 Investigation

If the inquiry leads to the conclusion that an investigation is warranted, the process will be as follows:

a. The Responsible Officer will strike an investigation committee, appointed with the authority to decide whether research misconduct occurred.
b. The investigation committee shall report to the Responsible Officer.
c. The Responsible Officer shall appoint a Chair of the investigation committee who must be a senior member of the hospital or research institute. Administrative support will be provided as necessary.
d. The investigation committee shall include members with the necessary expertise who are without conflict of interest (real, potential or perceived) and at least one external member who has no current affiliation with SRI. The Responsible Officer will not be a member of the committee. The Chair shall ensure investigation committee members are informed of the process, the importance of careful and thorough investigation, vigilance and protecting the reputations of the Complainant and Respondent.
e. The Chair will send a letter to each of the Complainant and Respondent advising them of the appointment of an investigation committee, outlining and further highlighting their respective obligations.
f. The formal investigation should begin within 30 days of the completion of the inquiry and after written notice to each of the Respondent and Complainant of the appointment of the committee. The investigation is to be completed and the final report sent to the Responsible Officer within 90 days after the start of the investigation.
g. The investigation process for determining the validity of an allegation will provide the Complainant and Respondent with an opportunity to be heard as part of the investigation. The investigation will include, but is not limited to, an examination of all the relevant information provided, such as research data and proposals, publications, correspondence, letters, etc.
h. The Complainant, Respondent and witnesses who may have relevant information will be interviewed, and such interviews should be documented in writing and kept as part of the investigation file.
i. The investigation committee will prepare a written report that sets out its findings and decision as to whether or not there is research misconduct. The committee members must agree to the release of the report based on majority rule.
j. The report is delivered to the Responsible Officer, the Complainant and the Respondent.
k. The report is final and not subject to revision; however, the Respondent and Complainant will have up to 15 working days to make submission to the Responsible Officer regarding the findings.
l. The final report will be retained by SRI for a period of seven (7) years for record-keeping purposes.

6.0 ADMINISTRATIVE ACTION:

The Responsible Officer will determine what remedial and/or disciplinary action will be taken by SRI, which could include:

- verbal warning;
- special monitoring of future work;
- verbal warning with a letter to be held temporarily on file in the appropriate office;
- letter of reprimand to the individual's permanent personnel file;
- withdrawal of specific privileges;
- removal of specific responsibilities;
- suspension;
- steps to terminate.

The Responsible Office may consult with other senior administrators when making a decision.

Measures taken and a specified timeframe will be based on the nature and severity of the research misconduct.

7.0 ACCOUNTABILITY:

- The Responsible Officer, taking into account applicable privacy laws and regulations, will inform all affected parties, in a timely manner, of the decision reached by the investigation committee and of any recourse to be taken by SRI.
- If the allegations are determined to be unfounded, then every effort will be made by SRI to protect or restore the reputation of those wrongly subjected to an allegation.

8.0 REPORTING TO RELEVANT AGENCY THROUGH THE SECRETARIAT ON RESPONSIBLE CONDUCT OF RESEARCH:

Subject to any applicable laws, including privacy laws, SRI will inform the relevant agency or Secretariat on Responsible Conduct of Research (SRCR) immediately of any allegations related to activities funded by the agency that may involve significant financial, health and safety, or other risks. Where the SRCR was copied on the allegation or otherwise advised by SRI of an allegation as required, SRI will confirm with the SRCR whether or not it is proceeding with an investigation.

Sunnybrook Research Institute will report to the SRCR the results of an inquiry within two months from the date of receipt of the allegation and the results of an investigation within an additional five months (therefore, a total of seven months from the date of receipt of the allegation that results in an investigation to report to the SRCR) following the associated inquiry, in response to each allegation of policy breaches related to a funding application submitted to an agency or to an activity funded by an agency. Subject to any applicable laws, including privacy laws, each report shall include:

- the specific allegation(s), a summary of the finding(s) and reasons for the finding(s);
- the process and timelines followed for the inquiry and/or investigation;
- the researcher's response to the allegation, investigation and findings, and any measures the researcher has taken to rectify the breach;

- the institutional investigation committee's decisions and recommendations and actions taken by SRI.

The need for and frequency of periodic updates will be jointly determined by the SRCR and SRI.

Allegations pertaining to research activities funded by a public health services unit of the United States Department of Health and Human Services will be managed in accordance with the applicable U.S. government requirements.

9.0 Record Keeping

All documentation, including that distributed to each investigation committee member, shall be returned to the Responsible Officer or delegate who shall maintain detailed documentation of the inquiry and investigation (if applicable) in a confidential and secure manner for a period of seven years.

10.0 PROMOTING AWARENESS AND EDUCATION:

Sunnybrook Research Institute will do as follows:

- Promote awareness of what constitutes the responsible conduct of research, the consequences of research misconduct, as well as the process for addressing allegations, to those engaged in research activities.
- Communicate its policy on the responsible conduct of research within SRI, and make public annual reports with statistics on confirmed findings of breaches of that policy and actions taken, subject to applicable laws, including the privacy laws.
- Communicate within SRI the central point of contact responsible for receiving confidential enquiries, allegations and information related to allegations of research misconduct.

REFERENCES:

[1]Government of Canada [Internet]. Panel on Responsible Conduct of Research, Tri-Agency Framework: Responsible Conduct of Research (2016) [cited 2017 Oct 30]. Available from: http://www.rcr.ethics.gc.ca/eng/policy-politique/framework-cadre/.

[2] University of Toronto [Internet]. Framework to Address Allegations of Research Misconduct [cited 2017 Oct 30]. Available from: http://www.provost.utoronto.ca/public/PDADC/2013_to_2014/Framework_to_Address_Allegations_of_Research_Misconduct_-_Revised.htm.

We also acknowledge the usefulness of the following as a resource in developing this policy:

Mount Sinai Hospital, Joseph and Wolf Lebovic Health Complex [Internet]. Research Misconduct Policy (2013) [cited 2017 Oct 30]. Available from: http://www.mountsinai.on.ca/about_us/policies/31E900C8.pdf/view