Responsible Conduct of Research

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TABLE OF CONTENTS

POLICY STATEMENT

To outline the process at Sunnybrook Research Institute (SRI) for receiving, investigating, addressing and reporting allegations of research misconduct. 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 and the University of Toronto Framework to Address Allegations of Research Misconduct and is consistent with the requirements of other granting agencies and sponsors of research at SRI

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 (RCR Framework).

DEFINITIONS

Administrator: One or more individuals appointed by the Responsible Officer to conduct the inquiry.

Agency: Means any one of the Tri-Agencies including the Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, Secretariat on the Responsible Conduct of Research and/or any other funding agency.

Allegation: A declaration, statement or assertion communicated in writing to an Institution or Agency to the effect that there has been, or continues to be, a breach or one or more Agency and/or Institutional policies, the validity of which has not been established.

Breach: A breach of the RCR Framework is the failure to comply with any Agency and/or Institutional policy applicable 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 data or 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.

Serious breach: In determining whether a breach is serious, SRI and/or the Agencies 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, and/or not adhering to requirements to obtain informed consent as approved by the Research Ethics Board);
- 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/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

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

Institution: Means Sunnybrook Health Sciences Centre, Sunnybrook Research Institute, and/or the University of Toronto.

Respondent: An individual who is identified in an allegation as having possibly breached Agency and/or Institutional policy.

Responsible Officer: Means the VP, Research and Innovation or designate identified in writing.

Research misconduct: Any practice deviates seriously from the commonly accepted ethics/integrity standards or practices of the relevant research community; 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.

POLICY

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.

Researchers shall strive to follow the best research practices honestly, accountably, openly and fairly in the search for, and dissemination of, knowledge.

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.

PROCEDURE

ALLEGATIONS

Prior Assessment

Prior to making an allegation:

- Complainants are encouraged to informally address the issues with the potential Respondent. This approach may be relevant where the issue may appear to be minor or where there appears to be a potential misunderstanding.
- Individuals who are uncertain about whether to make an allegation may discuss the matter with the Responsible Officer or designate with or without naming the potential Respondent. In this situation, the Responsible Officer shall not inform the potential Respondent of such discussions as such discussions do not constitute an allegation under this policy.

Receiving Allegations

a. The Responsible Officer or designate is the central point of contact to receive all confidential enquiries, allegations of research misconduct and information related to allegations.
b. Allegations received by a different person shall be promptly referred to the Responsible Officer.
c. Allegations that involve activities of the Responsible Officer shall be submitted to the President and CEO. 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. Where an allegation involves the activities of a physician, the Responsible Officer will notify the Institution's Chief Medical Executive.
e. Allegations must be written, dated and signed by the Complainant.
f. The Complainant shall set out all relevant information, state the reasonable grounds on which the allegation is based, and include supporting evidence, if available.
g. The Complainant is also required to declare any conflict of interest (real, potential or perceived) at the time of making the allegation.
h. Allegations must not be malicious, frivolous or based on rumour.
i. Allegations must be based on facts which have not been the subject of a previous investigation.
j. Anonymous allegations may be considered provided there is sufficient information to allow for an assessment of the allegation without further need for information from the complainant. Complainants who indicate they do not want to be identified will be treated as anonymous. Anonymous complainants shall not receive any communication regarding the status and/or outcome of the process to address the allegation.
k. 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.
l. 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 who will conduct the inquiry and investigation (if warranted).

When an allegation involves an individual with an affiliation at the University of Toronto (UofT), the Responsible Officer will notify the UofT office of Research Oversight and Compliance.

When an allegation involves graduate students or graduate faculty members, the applicable Dean or School of Graduate Studies will be notified.

When an allegation involves a Respondent with an affiliation at a different University other than UofT, the Responsible Officer will notify that University's Responsible Officer.

Two-Step Approach

Addressing allegations involves a two-step approach: 1. an inquiry step to determine if an investigation of the allegation is warranted; 2. an investigation step to determine if the alleged research misconduct has occurred.

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. Exceptions to timelines outlined below should be explained and documented accordingly.

The inquiry process is as follows:

a. Upon receipt of an allegation that meets the criteria as set out above, the Responsible Officer will appoint one or more individual(s)

("Administrator") with the necessary expertise, who is/are 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 different Administrator.
c. The Responsible Officer will refer the allegation to the designated Administrator.
d. The Complainant and Respondent will each be sent a separate letter outlining the process and a copy of this policy, and shall be advised of the need to maintain confidentiality.
e. 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.
f. The Administrator will contact the Respondent for the purposes of discussing the allegation.
g. 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.
h. The Administrator will make a decision based on the information they obtain, irrespective of whether individuals choose to cooperate with the inquiry.
i. The Administrator shall notify the Responsible Officer in writing of their determination of whether an investigation is warranted or not, and the reasons.
j. The Responsible Officer shall provide written notice of the decision to the Complainant and the Respondent and shall include a brief written summary of the reasons for such a determination.
k. The final report of the inquiry should normally be submitted by the Administrator to the Responsible Officer within two (2) months of receipt of the allegation. Such a report will be retained by SRI for a period of seven (7) years for record-keeping purposes.

Investigation

When an inquiry leads to the conclusion that an investigation is warranted, the process will be as follows. All reasonable efforts will be made to meet appropriate timelines; exceptions should be explained and documented accordingly:

a. The Responsible Officer will strike a committee to perform the investigation ("**Investigating Committee**").
b. The Investigating Committee shall report to the Responsible Officer.
c. The Investigating Committee shall have a minimum of three members with at least one independent member with no current Sunnybrook Health Sciences Centre, SRI or University of Toronto affiliation.
d. The Responsible Officer shall appoint a Chair of the Investigating Committee who must be a senior member of the hospital or research institute. The Administrator for the inquiry shall not be the Chair nor a member of the investigating committee. The Responsible Officer will assign administrative support to the Investigating Committee.
e. The Investigating Committee shall include members with the necessary expertise who are without conflict of interest (real, potential or perceived). The Responsible Officer will not be a member of the committee. The Chair shall ensure Investigating Committee members are informed of the process, the importance of careful and thorough investigation, vigilance and protecting the reputations of the Complainant and Respondent.
f. The Chair will notify the Complainant and Respondent in writing advising them of the appointment of an Investigating Committee and their respective obligations.
g. The formal investigation should normally begin within thirty (30) calendar 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 normally to be completed and the final report sent to the Responsible Officer within ninety (90) days after the start of the investigation. The start of the investigation is considered the date of the first convened meeting of the Investigating Committee.
h. 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.
i. The Complainant, Respondent and witnesses who may have relevant information may be requested for interview, and such interviews should be documented in writing and kept as part of the investigation file.
j. The Respondent and Complainant may have legal counsel or a representative present when meeting with the Investigating Committee. At any point, the Chair of the Investigating Committee may ask the Hospital legal counsel to be present as well.
k. The Investigating Committee will prepare a written report that sets out its findings, recommendations 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.
l. The report is delivered to the Responsible Officer.
m. The Responsible Officer shall provide a summary of the report to the Respondent. It is up to the Responsible Officer to determine how much information in the report should be disclosed and to whom, including the Complainant.
n. The report is final and not subject to revision; however, the Respondent will have up to fifteen (15) working days from the receipt of the report summary to make submission to the Responsible Officer regarding the findings. Following the 15 day period, the Responsible Officer will make a final decision on whether to accept the report and its recommendations.
o. Where there is a finding of research misconduct involving a physician, the Institution's Chief Medical Executive will be notified to determine reporting to the College of Physicians and Surgeons of Ontario (CPSO).
p. The final report will be retained by SRI for a period of seven (7) years for record-keeping purposes.
q. Where applicable, SRI will keep the University of Toronto's office of Research Oversight and Compliance informed of the outcome.

REMEDIAL ACTION

The Responsible Officer will determine what remedial and/or disciplinary action will be taken by SRI, which could include, but is not limited to:

- 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;
- require modifications to publications;
- require withdrawal of publications;
- 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.

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.

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.

- Where applicable, SRI should normally report to the SRCR the results of an inquiry within two (2) months from the date of receipt of the allegation and the results of an investigation within an additional five (5) months (following the associated inquiry. This reporting applies to each allegation of policy breaches related to a funding application submitted to an agency or to an activity funded by an agency. The report to the SRCR will be made in accordance with the RCR framework.

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

SRI will submit an annual report to the SRCR on applicable aggregate Responsible Conduct of Research data.

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. SRI will submit an annual report to the Office of Research Integrity in accordance with applicable reporting obligations.

RECORD KEEPING

Documentation related to the inquiry and investigation (if applicable) shall be maintained by SRI in a confidential and secure manner for a period of seven years. Documentation distributed to Investigating Committee members shall be either returned to the Responsible Officer or designate, or securely deleted or shredded in accordance with institutional policies.

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.
- Ensure researchers understand their responsibility for familiarizing themselves with the principles of responsible conduct of research and for the application of these principles to foster a positive and constructive research-working environment.
- Ensure that researchers with oversight roles understand their responsibility to provide appropriate supervision of, and training to, their trainees and research personnel in responsible conduct of research. 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.

ACKNOWLEDGEMENT

We acknowledge the usefulness of the Mount Sinai Hospital Research Misconduct policy and the Unity Health Research Misconduct

policy in developing this policy.

APPENDICES AND REFERENCES:

[1]Government of Canada [Internet]. Panel on Responsible Conduct of Research, Tri-Agency Framework: Responsible Conduct of Research (2021) Available from: https://rcr.ethics.gc.ca/eng/framework-cadre-2021.html#a7-B

[2] University of Toronto [Internet]. Framework to Address Allegations of Research Misconduct . Available from: https://memos.provost.utoronto.ca