



The Heart and Stroke Foundation of Canada (Heart & Stroke)

Framework:

Responsible Conduct of Research

June 2017

THE HEART AND STROKE FOUNDATION OF CANADA (HEART & STROKE) FRAMEWORK: RESPONSIBLE CONDUCT OF RESEARCH¹

¹ The Heart & Stroke policy was adapted from the Tri-Agency Framework: Responsible Conduct of Research <http://www.rcr.ethics.gc.ca/eng/policy-politique/framework-cadre/>

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1. HEART & STROKE FRAMEWORK: RESPONSIBLE CONDUCT OF RESEARCH

1.1 Introduction

The search for knowledge about ourselves and the world around us is a fundamental human endeavour. Research is a natural extension of this desire to understand and to improve the world in which we live, and its results have both enriched and improved our lives and human society as a whole.

In order 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 the use of professional standards. For HEART & STROKE and institutions that receive Foundation funding, it calls for a commitment to foster and maintain an environment that supports and promotes the responsible conduct of research.

This Framework sets out the responsibilities and corresponding policies for researchers, institutions, and Heart & Stroke that together help support and promote a positive research environment. It specifies the responsibilities of researchers with respect to research integrity, applying for funding, financial management, and requirements for conducting research, and defines what constitutes a breach of HEART & STROKE policies. For institutions, it details the minimum requirements for institutional policies for addressing allegations of all types of policy breaches, and institutions' responsibilities for promoting responsible conduct of research and reporting to Heart & Stroke. This Framework also sets out the process to be followed by Heart & Stroke when addressing allegations of breaches of HEART & STROKE policies.

1.2 Scope

This Framework describes HEART & STROKE policies and requirements related to applying for and managing HEART & STROKE research funds, the performance of research, the dissemination of results, and the processes that institutions and Heart & Stroke follow in the event of an allegation of a breach of an HEART & STROKE policy.

The host institution shall develop and administer a policy(ies) to address allegations of policy breaches by researchers that meets the minimum requirements set out in the Framework. The institution applies this policy(ies) to all HEART & STROKE research conducted under its auspices or jurisdiction. In addition, researchers who apply for or hold HEART & STROKE funding are required by HEART & STROKE to adhere to the Framework.

1.3 Objectives

The objectives of the Framework are to:

- a) ensure that the funding decisions made by Heart & Stroke are based on accurate and reliable information;
- b) ensure donor funds for research are used responsibly and in accordance with funding requirements;

- c) promote and protect the quality, accuracy, and reliability of research funded by Heart & Stroke; and
- d) promote fairness in the conduct of research and in the process for addressing allegations of policy breaches.

2. RESPONSIBILITIES OF RESEARCHERS

2.1 HEART & STROKE Research Integrity Policy

Heart & Stroke *Research Integrity Policy's* purpose is to support Heart & Stroke in discharging its mandate to promote and assist research and in discharging its responsibility to foster a positive research environment.

2.1.1 Scope

Heart & Stroke requires that all researchers applying for, in receipt of, or who have held HEART & STROKE funds comply with the Policy.

2.1.2 Promoting Research Integrity

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, researchers shall follow the requirements of applicable institutional policies and professional or disciplinary standards and shall comply with applicable laws and regulations. At a minimum, researchers are responsible for the following:

- a) Rigour: Scholarly and scientific rigour in proposing and performing research; in recording, analyzing, and interpreting data; and in reporting and publishing data and findings.
- b) Record keeping: Keeping complete and accurate records of data, methodologies and findings, including graphs and images, in accordance with institutional policies, laws, regulations, and professional or disciplinary standards in a manner that will allow verification or replication of the work by others.
- c) 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.
- d) 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.
- e) Acknowledgement: Acknowledging appropriately, all those and only those who have contributed to research, including funders and sponsors.
- f) Conflict of interest management: Appropriately identifying and addressing any real, potential or perceived conflict of interest², in accordance with the institution's policy on conflict of interest in research, in order to ensure that the objectives of the Framework (Section 1.3) are met.

2.2 Applying for and Holding HEART & STROKE Funding

² A Conflict of Interest (COI) exists when an individual has personal or organizational interests in a decision or outcome that may have or may be perceived to have personal benefit, or may or may be perceived to differ from the interests of the organization for which they are making (or helping to make) a decision.

- a) Applicants and holders of HEART & STROKE grants and awards shall provide true, complete and accurate information in their funding applications and related documents and represent themselves, their research and their accomplishments in a manner consistent with the norms of the relevant field.
- b) Applicants certify that they are not currently ineligible to apply for, and/or hold, funds from Heart & Stroke or any other research or research funding organization world-wide for reasons of breach of responsible conduct of research policies such as ethics, integrity or financial management policies.
- c) Principal Investigator (PI) applicants must ensure that others listed on the application – co-applicants, collaborators, partners - have agreed to be included. A PI maintains overall oversight of all individuals associated with a project.

2.3 Management of HEART & STROKE Grant and Award Funds

Researchers are responsible for using grant or award funds in accordance with Heart & Stroke policy and Heart & Stroke Award Agreement; and for providing true, complete and accurate information on documentation for expenditures from grant or award accounts.

2.4 Significant Changes to Grant Objectives

Notwithstanding standard reporting requirements, changes that **significantly alter the objectives/ direction of HEART & STROKE-funded research** must be reported immediately to HEART & STROKE. Projects with changes to their objectives will be reviewed by HEART & STROKE scientific advisors and are subject to conditions being applied, up to and including termination if deemed to deviate significantly from the original peer-reviewed and approved proposal. In the event of the termination, the PI may re-apply with a new proposal.

2.5 HEART & STROKE Requirements for Research

Researchers must comply with all applicable requirements and legislation for the conduct of research, including, but not limited to:

- [2nd edition of Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans \(TCPS 2\)](#);
- [Good Clinical Practice \(GCP\)](#);
- [Good Laboratory Practice \(GLP\)](#);
- [Canadian Council on Animal Care Policies and Guidelines](#);
- [Public Health Agency/Canadian Food Inspection Agency's Canadian Biosafety Standards and Guidelines](#)
- Any research involving human pluripotent stem cells must adhere to [the CIHR Guidelines for Human Pluripotent Stem Cell Research](#). The institution must notify HEART & STROKE as to the results of the review by the CIHR's Stem Cell Oversight Committee.

2.6 Rectifying a Breach of HEART & STROKE Policy

Researchers in breach of an HEART & STROKE research funding policy are expected to be proactive in rectifying a breach, for example, by correcting the research record, providing a letter of apology to those impacted by the breach, repaying funds, or taking other action as may be dictated by the situation.

2.7 Participation in HEART & STROKE Review Processes

- a) Participants in HEART & STROKE review processes must comply with Heart & Stroke Code of Professional Ethics and Heart & Stroke Conflict of Interest Rules.
- b) Participants in HEART & STROKE review processes confirm that they are not currently under investigation for an alleged breach of the Framework or any other responsible conduct of research policies such as ethics, integrity or financial management policies.
- c) If participants find themselves under investigation, they must temporarily withdraw themselves from participation in any HEART & STROKE review process until the investigation is complete and a determination is made by HEART & STROKE whether they can resume their participation.

3. BREACHES OF HEART & STROKE POLICIES BY RESEARCHERS

HEART & STROKE funded researchers must comply with HEART & STROKE research funding policies. By signing an application for a grant or an award, and by accepting a grant or an award, a researcher agrees to comply with Heart & Stroke's policies.

3.1 Breaches of HEART & STROKE Policies

A breach of the Framework is the failure to comply with any HEART & STROKE policy throughout the life cycle of a research project – from application for funding, to the conduct of the research and the dissemination of research results. In determining whether an individual has breached an HEART & STROKE policy, it is not relevant to consider whether a breach was intentional or a result of honest error. However, intent is a consideration in deciding on the severity of the recourse that may be imposed. Breaches of HEART & STROKE policies include, but are not limited to, the following:

3.1.1 Breaches of HEART & STROKE Research Integrity Policy

- 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 and/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 publications or self-plagiarism*: The re-publication of one's own previously published work or part thereof, including data, in the same or

another 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 Framework (Section 1.3) from being met.

3.1.2 Misrepresentation in an HEART & STROKE 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 and/or holding an HEART & STROKE award when deemed ineligible by HEART & STROKE or any other research or 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.

3.1.3 Mismanagement of Grants or Award Funds

Using grant or award funds for purposes inconsistent with the policies of Heart & Stroke; misappropriating grants and award funds; contravening HEART & STROKE financial policies/grants and awards guides, (ie. Heart & Stroke Award Agreement and Heart & Stroke Grant Management Guidelines); or providing incomplete, inaccurate or false information on documentation for expenditures from grant or award accounts.

3.1.4 Breaches of HEART & STROKE Policies or Requirements for Research

Failing to meet HEART & STROKE policy requirements or, to comply with relevant policies, laws or regulations, for the conduct of research activities; failing to obtain appropriate approvals, permits or certifications before conducting these activities.

3.1.5 Breaches of HEART & STROKE Review Process

- a. Non-compliance with Heart & Stroke Code of Professional Ethics and Heart & Stroke Conflict Of Interest Rules
- b. Participating in an HEART & STROKE review process while under investigation

3.2 Roles of Individuals in Addressing Allegations of Policy Breaches

Researchers and others play important roles in the process for addressing allegations of policy breaches and in helping to ensure that allegations are addressed appropriately and in a timely manner. The following are guidelines for those making or involved in an allegation:

- a) Individuals are expected to report in good faith and confidentially any information pertaining to possible breaches of HEART & STROKE policies to the institution where the researcher involved is currently employed, enrolled as a student or has a formal association.

This information should be sent directly to the institution's designated point of contact, in writing, with an exact copy sent to HEART & STROKE Research Department in Ottawa.

- b) Individuals involved in an inquiry or investigation must follow the institution's policy and process as a complainant, a respondent or a third party, as appropriate.

4. RESPONSIBILITIES OF INSTITUTIONS

4.1 Agreement on the Administration of HEART & STROKE Grants and Awards by Research Institutions

Heart & Stroke Award Agreement and Heart & Stroke Grant Management Guidelines sets out the minimum roles, responsibilities and requirements that institutions must meet as a condition of eligibility to apply for and hold, HEART & STROKE funding.

4.2 Promoting Responsible Conduct of Research

Institutions shall strive to provide an environment that supports the best research and that fosters researchers' abilities to act honestly, accountably, openly and fairly in the search for, and dissemination of, knowledge. Institutions shall do so by:

- a) Establishing and applying responsible research conduct policy(ies) and procedures that meet the requirements of this Framework (Section 4.3);
- b) Promoting education on, and awareness of, the importance of the responsible conduct of research (Section 4.5).
- c) Reporting requirements to HEART & STROKE as per Section 4.4

4.3 Institutional Policy Requirements for Addressing Allegations of Policy Breaches

Institutions play important roles in addressing allegations of all types of policy breaches by researchers (as described in Section 3) and in ensuring that such allegations are handled appropriately and in a timely manner. Institutions shall develop and administer a policy(ies) that applies to all research conducted under the auspices or jurisdiction of the institution to address allegations of policy breaches by researchers that includes, at a minimum, the following sections:

4.3.1 Definitions

The definitions of researchers' responsibilities and breaches of policies as set out in Sections 2 and 3 of this Framework.

4.3.2 Confidentiality

A statement of principle to protect the privacy of the complainant(s) and respondent(s) as far as is possible.

4.3.3 Allegations Involving HEART & STROKE Peer Review

A statement indicating that, if an allegation received involves HEART & STROKE peer review, the institution will cede leadership of the investigation to HEART & STROKE, which will keep the institution(s) informed of progress and outcomes.

4.3.4 Receiving Allegations

- a) A central point of contact at a senior administrative level, to receive all confidential enquiries, allegations of breaches of policies, and information related to allegations.
- b) A statement that it will consider an anonymous allegation if accompanied by sufficient information to enable the assessment of the allegation and the credibility of the facts and evidence in which the allegation is based, without the need for further information from the complainant.
- c) A statement on how anonymous allegations will be addressed
- d) A statement of principle to protect, to the extent possible, the individual making an allegation in good faith or providing information related to an allegation from reprisals in a manner consistent with relevant legislation.
- e) A statement indicating that the institution may independently, or at Heart & Stroke's request in exceptional circumstances, take immediate action to protect the administration of HEART & STROKE funds. Immediate actions could include freezing grant accounts, requiring a second authorized signature from an institutional representative on all expenses charged to the researcher's grant accounts, or other measures, as appropriate.
- f) A statement indicating that, where the allegation related to conduct that occurred at another institution (whether as an employee, a student or in some other capacity), the institution that receives the allegation will contact the other institution and determine with that institution's designated point of contact which institution is best placed to conduct the inquiry and investigation, if warranted. The institution that received the allegation must communicate to the complainant which institution will be the point of contact for the allegation.

4.3.5 Investigating Allegations

- a) An initial inquiry process to establish whether an allegation is responsible and if an investigation is required.
- b) An investigation process for determining the validity of an allegation that provides the complainant and respondent with an opportunity to be heard as part of an investigation, and that allows for the respondent to appeal if a breach of policy is confirmed.
- c) An investigation committee, appointed with the authority to decide whether a breach occurred. The investigation committee shall include members who have the necessary expertise and who are without conflict of interest, whether real or apparent, and at least one external member who has no current affiliation with the institution.
- d) Reasonable timelines for completing an inquiry, completing an investigation, reporting the findings, making a decision on what action should be taken, and communicating with the parties involved. The timelines must be within the reporting timeframes outlined in Section 4.4.

4.3.6 Recourse

- a) A provision that the investigation committee's report, including its final decision, is provided to the Institution's central point of contact within a timeframe specified in the Institution's policy.
- b) A process for determining what kinds of recourse can be taken by the Institution, taking into account the severity of the breach.

4.3.7 Accountability

- a) A procedure, which takes into account applicable privacy laws and regulations, to inform all affected parties, in a timely manner, of the decision reached by the investigation committee and of any recourse to be taken by the Institution.
- b) A provision for allegations determined to be unfounded that every effort will be made by the Institution to protect or restore the reputation of those wrongly subjected to an allegation.

4.4 Reporting Requirements

- a) Subject to any applicable laws, including privacy laws, the institution shall advise HEART & STROKE immediately of any allegations related to activities funded by Heart & Stroke that may involve significant financial, health and safety, or other risks.
- b) The institution shall write a letter to Heart & Stroke confirming whether or not the institution is proceeding with an investigation where Heart & Stroke was copied on the allegation or advised as per Section 4.4a. If a breach is confirmed at the inquiry stage, reporting requirements outlined in Section 4.4c apply.
- c) The institution shall prepare a report for Heart & Stroke on each investigation it conducts in response to an allegation of policy breaches related to a funding application submitted to HEART & STROKE or to an activity funded by HEART & STROKE. Subject to any applicable laws, including privacy laws, each report shall include the following information:
 - the specific allegation(s), a summary of the finding(s) and reasons for the finding(s);
 - the process and time lines 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; and
 - the institutional investigation committee's decisions and recommendations and actions taken by the Institution.
 - The institution's report should not include:
 - information that is not related specifically to HEART & STROKE funding and policies; or
 - personal information about the researcher, or any other person, that is not material to the institution's findings and its report to Heart & Stroke.
- d) Inquiry letters and investigation reports should be submitted to Heart & Stroke within two and seven months, respectively, of receipt of the allegation by the institution. These timelines may be extended in consultation with Heart & Stroke

if circumstances warrant, and with monthly updates provided to Heart & Stroke until the investigation is complete.

- e) The institution and the researcher may not enter into confidentiality agreements or other agreements related to an inquiry or investigation that prevents the institution from reporting to Heart & Stroke.
- f) In cases where the source of funding is unclear, Heart & Stroke reserves the right to request information and reports from the institution.

4.5 Promoting Awareness and Education

An Institution is responsible for:

- a) Promoting awareness of what constitutes the responsible conduct of research, including HEART & STROKE requirements as set out in the institution's policies, the consequences of failing to meet them, as well as the process for addressing allegations, to all those engaged in research activities at the Institution.
- b) Communicating its policy on the responsible conduct of research within the institution, and making public statistical annual reports on confirmed findings of breaches of that policy and actions taken, subject to applicable laws, including the privacy laws.
- c) Communicating within the institution, the central point of contact responsible for receiving confidential enquiries, allegations and information related to allegations of breaches of Heart & Stroke policies.

5. BREACHES OF HEART & STROKE POLICIES BY INSTITUTIONS

Heart & Stroke requires that each institution complies with HEART & STROKE policies as one condition of eligibility to administer HEART & STROKE funds.

6. RESPONSIBILITIES OF HEART & STROKE

In striving to meet the objectives of this Framework, Heart & Stroke is responsible for:

- a) communicating this Framework, including the contact information for those responsible for its administration;
- b) responding promptly to enquiries regarding this Framework;
- c) helping to promote the responsible conduct of research and to assist individuals and institutions with the interpretation or implementation of this Framework;
- d) reviewing and updating this Framework at least every five years, aligning to the extent practicable with the Tri-Agency Framework; and
- e) responding to allegations of breaches of HEART & STROKE policies.

6.1 HEART & STROKE Process for Addressing Allegations of Policy Breaches by Researchers

HEART & STROKE plays an important role in addressing allegations of breaches of its policies and in ensuring that such allegations are addressed appropriately and in a timely manner. At any time after an allegation is made, Heart & Stroke may request information from the individual and institution involved. When an allegation involves HEART & STROKE Peer Review, HEART & STROKE will assume the leadership role in investigating the allegation; keep the institution(s) informed of progress and outcomes.

6.1.1 Receiving Allegations

- a) If Heart & Stroke receives an allegation directly from a complainant, it will ask the complainant to provide the information in writing HEART & STROKE will initially review the allegation to determine whether an investigation is warranted. If it is felt that an investigation is required, HEART & STROKE may request that this be conducted by the host institution where the researcher involved is currently employed, enrolled as a student or has a formal association. Following receipt of an allegation, if the matter involves HEART & STROKE funding and an alleged breach of an HEART & STROKE policy, Heart & Stroke will follow-up as needed with the complainant, the institution and other parties, subject to applicable laws, including the *Privacy Act*.
- b) Heart & Stroke may submit its own allegations directly to an institution, for example, as a result of information obtained through institutional monitoring reviews or its peer review activities.

6.1.2 Review of Institutional Reports

- a) Heart & Stroke may follow-up with the institution as needed to obtain updates on the status of the investigation.
- b) Heart & Stroke will review the institution's report to determine whether it meets HEART & STROKE requirements, as outlined in Section 4.4, and whether there has been a breach of HEART & STROKE policies and/or a funding agreement. Heart & Stroke may follow-up with the institution for clarification.

6.1.3 Recourse

- a) If Heart & Stroke determines that there has been a breach of an HEART & STROKE policy, it will exercise the recourse it considers appropriate, commensurate with the severity of the breach. When making its decision, Heart & Stroke will take into consideration the institution's findings, the severity of the breach and any actions taken by the institution and researcher involved to remedy the breach.
- b) Such recourse can include, but is not limited to:
 - issuing a letter of concern to the researcher;
 - requesting that the researcher correct the research record and provide proof that the research record has been corrected;
 - advising the researcher that Heart & Stroke will not accept applications for future funding from him/her for a defined time period or indefinitely;
 - terminating remaining installment payments of the grant or award;
 - seeking a refund within a defined time frame of all or part of the funds already paid;
 - advising the researcher that Heart & Stroke will not consider him/her to serve on HEART & STROKE committees (e.g. peer review, advisory boards); and/or

- such other recourse available by law.

In exercising the appropriate recourse, Heart & Stroke will give consideration to affected research personnel including students, post-doctoral fellows and research support staff.

6.1.4 Accountability and Reporting

- a) Heart & Stroke will inform the researcher subject to the decision, and his/her institution, of Heart & Stroke's decision, where applicable. The content of this communication will be subject to any applicable laws, including privacy laws.
- b) Heart & Stroke will notify the appropriate authorities if at any time it becomes aware of possible fraud or other unlawful activity.
- c) In cases of a serious breach of HEART & STROKE policy, as determined by Heart & Stroke with appropriate consultation and advice, Heart & Stroke may publicly disclose the name of the researcher subject to the decision, the nature of the breach, the institution where the researcher was employed at the time of the breach and the institution where the researcher is currently employed. In determining whether a breach is serious, Heart & Stroke will consider the extent to which the breach jeopardizes the safety of the public or would bring the conduct of research into disrepute.

6.1.5 Measures for Exceptional Circumstances

In exceptional circumstances, taking into account the severity and urgency of the alleged breach, its possible consequences and the potential financial, health, safety or other risks involved, Heart & Stroke reserves the right to take special measures, including the following:

6.1.5.1 Immediate Action

Heart & Stroke may take immediate action (as set out in Section 4.3.4 (e)), or may require the institution to do so. Heart & Stroke will consult with the institution and will consider any actions already taken by the institution and/or the researcher when deciding on whether further action is required.

6.1.5.2 Review or Compliance Audit

Heart & Stroke may conduct its own review or compliance audit, or require the institution to conduct an independent review/audit. Heart & Stroke will consult with the institution and will consider the investigation already planned, underway or completed by the institution, and its findings.