

Manual	Research Manual	POLICY
Section	Research	
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Approved by	RESEARCH EXECUTIVE COMMITTEE	
Date	O: 06/26/2024	3
	R:	Reference #: 10960
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RESPONSIBLE CONDUCT OF RESEARCH- POLICY

Policy Statement

The Responsible Conduct of Research (“RCR”) policy is set to:

- Outline the processes for receiving, inquiring, investigating, addressing, and reporting allegations of research misconduct for all Staff, Physicians, Trainees and Volunteers (known as “Researchers”) engaged in research activities and/or conducts research at or under the auspices of Humber River Health (“HRH”).
- State the responsibilities of researchers at HRH.
- Outline how education and awareness of RCR will be promoted at HRH.

Policy

It is essential to maintain a positive research environment to promote research integrity; HRH is committed to fostering an environment that promotes RCR of anyone engaged in research activities and/or conducts research at or under the auspices of HRH. HRH encourages researchers to act fairly, honestly, accountably, and openly and will strive to create an environment that promotes this behaviour. HRH is also committed in fulfilling the requirements of the tri-agencies (Canadian Institutes of Health Research (CIHR), Social Sciences and Humanities Research Council (SSHRC), and Natural Sciences and Engineering Research Council of Canada (NSERC)) to promote RCR. This RCR policy has been developed to comply with the requirements set out in the Tri-Agency Framework: Responsible Conduct of Research 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 HRH. Additional information on the Tri-Agencies’ policies and procedures can be found on the official online Tri-Agency Framework: Responsible Conduct of Research document at <https://rcr.ethics.gc.ca/eng/framework-cadre-2021.html#a4-2>.

HRH expects its Researchers to hold the highest standards of ethical conduct in the conduction of research. The RCR policy sets out the responsibilities of researchers engaged in research activities. Any Researcher conducting research activities at or under the auspices of HRH must comply at minimum with this RCR policy, any professional or disciplinary standards as part of their professions, and requirements from the Tri-Agency Framework: Responsible Conduct of Research. At a minimum, researchers are responsible for the following: rigour, record keeping, accurate referencing, authorship, acknowledgement, and conflict of interest management. Researchers must comply with all applicable legislation, guidelines, policies and Agency requirements for the conduct of research.

Research Manual	Version #: 3
Responsible Conduct of Research- Policy	Reference #: 10960

Procedures for Allegations of Research Misconduct

Prior Assessment

Before making an allegation:

1. The Complainant is encouraged to first informally address the issues raised with the potential Respondent, especially if the issue may be a potential misunderstanding or minor in nature.
2. The Complainant is encouraged to reach out to the Responsible Officer to discuss the concern, if they are unsure as to whether an allegation is needed. The Responsible Officer shall not inform the Respondent in this scenario, as these discussions do not constitute an allegation of research misconduct.

Receiving Allegations

1. All allegations of research misconduct involving research activities at or under the auspices of HRH must be sent to the Responsible Officer either directly or through the Research Integrity Office at ResearchIntegrityOffice@hrh.ca. The Responsible Officer is the central point of contact who will receive all confidential inquiries, allegations of research misconduct, and information related to allegations of research misconduct.
2. Any allegation received by another individual shall be submitted promptly to the Responsible Officer.
3. When there is an allegation involving a physician, the Responsible Officer will notify HRH's Chief of Staff.
4. Any allegation that involves activities of the Responsible Officer must be submitted to the President & CEO.
5. When the Responsible Officer has a real, perceived, or potential conflict of interest, the allegation shall be referred through the Office of the President & CEO, to the President & CEO who will act as the Responsible Officer.
6. Contents of the allegation document are as follows:
 - a. Written by Complainant
 - b. Contains all relevant information to the allegation
 - c. State reasonable grounds on which allegation is based
 - d. Includes supporting evidence if available
 - e. Declaration of conflict of interest (real, perceived, or potential) from the Complainant
 - f. Signed
 - g. Dated
 - h. Name of Complainant included
7. Allegations must not be frivolous in nature, malicious, or based on rumour.

Research Manual	Version #: 3
Responsible Conduct of Research- Policy	Reference #: 10960

8. Allegations must be based on facts that have not been the subject of a previous investigation process.
9. At times there may be similar notices of allegations by the Complainant received multiple times by the Responsible Officer; the Responsible Officer at their discretion may determine if these allegations are warranted or if there is a possibility for vexatious allegations. If the allegations are seen to be vexatious in nature, then the Responsible Officer may enact appropriate disciplinary action.
10. Any anonymous allegation will be considered if there is enough credible information initially provided by the Complainant, with which an assessment of both the allegation and credibility of associated facts and evidence, can move forward.
11. If a Complainant has indicated that they do not want to be identified, then they will be treated as anonymous.
12. If a Complainant is anonymous, they will not receive communications on status updates or outcomes of the research misconduct allegation process.
13. When notified of an allegation involving Agency funding, HRH may as needed, or at the Agency's request, take immediate action (e.g., freezing grant accounts) to protect administration of Agency funds.
14. Any individual making an allegation in good faith or providing information related to an allegation, will be protected to the extent possible as per HRH privacy and confidentiality policies from any reprisals.
15. For an allegation that occurred at another institution, the institution receiving the allegation will: (1) contact the other institution via their pre-designated point of contact, as well as determine which institution will conduct the allegation inquiry and investigation (if needed), and (2) will communicate this decision to the Complainant. The pre-designated point of contact at HRH is the Responsible Officer.
16. When there is an allegation involving a Researcher affiliated with the University of Toronto, the Responsible Officer will notify the pre-designated point of contact at the University of Toronto.
17. When there is an allegation involving a Researcher affiliated with another organization or University other than the University of Toronto, the Responsible Officer will notify that organization's (1) pre-designated point of contact, or (2) their Responsible Officer if a pre- designated point of contact does not exist.

Two-Step Process

The research misconduct allegation process is generally divided into two (2) steps:

1. The inquiry process which determines whether there an allegation of research misconduct is warranted.
2. The investigation process which determines if an act of research misconduct has been committed.

Research Manual	Version #: 3
Responsible Conduct of Research- Policy	Reference #: 10960

Inquiry

An inquiry will be initiated to determine whether an allegation is warranted and if a subsequent formal investigation is needed. Individuals involved in said inquiry should have no real, potential, or perceived conflict of interest.

The process for an inquiry is listed below. Any exceptions to the timelines below should be explained and documented accordingly by HRH.

1. Once the Responsible Officer receives an allegation that meets the criteria listed in Receiving Allegations, the Responsible Officer will appoint one or more individual(s) without real, potential, or perceived conflict of interest, to conduct the inquiry (“Administrator”).
2. If the Administrator discloses a conflict of interest then the Responsible Officer will appoint once disclosed, a different individual(s) to conduct the inquiry.
3. The allegation will be sent to the designated Administrator.
4. Both the Complainant and Respondent will be sent separate packages which will include this policy, an outline of the process, and will be advised to maintain confidentiality throughout the process.
5. The Administrator may ask for supplementary materials to be provided in writing if the allegation as written does not contain sufficient information for an assessment.
6. The Administrator will reach out to the Respondent to discuss said allegation.
7. The Administrator may consult confidentially within HRH, or externally if required, to assist in determining whether an allegation is warranted.
8. Based on the information obtained by the Administrator, the Administrator will make a decision on whether an allegation is warranted. This decision will be made regardless of the cooperation of other individuals with this inquiry.
9. The Administrator will in writing notify the Responsible Officer on whether an investigation is warranted or not for said allegation and the reasons why.
10. The Administrator will also notify the Complainant and Respondent in writing on whether an investigation is warranted or not for said allegation and a summary of the reasons why for this decision.
11. The final inquiry report will be submitted by the Administrator to the Responsible Officer within two (2) months of receipt the allegation by the Responsible Officer. The report will be kept by HRH for a period for seven (7) years from receipt by the Responsible Officer for record-keeping.

Investigation

If the outcome of the inquiry warrants an investigation, then a subsequent committee to perform the investigation (“Investigation Committee”) will be appointed by the Responsible Officer with the authority to determine if a breach has occurred. At minimum the Investigation Committee will include three (3) members with at least one independent member which no current affiliation with

Research Manual	Version #: 3
Responsible Conduct of Research- Policy	Reference #: 10960

HRH or the University of Toronto. The Administrator for the inquiry, and the Responsible Officer, shall not be members of this committee.

Members of this committee will have the necessary expertise needed to investigate the breach and will not have a conflict of interest (real, potential, or perceived).

The Responsible Officer will appoint a Chair of the Investigation Committee (“Chair”), who must be a senior member of HRH. This Chair cannot be the Administrator of the inquiry nor the Responsible Officer.

This Investigation Committee will sit as an official committee at HRH and will be covered under HRH’s insurance provider.

The Responsible Officer will assign administrative support to the Investigation Committee. The Responsible Officer will also ensure that the Investigation Committee’s members are all informed of the process, understand the importance of a thorough and careful investigation, vigilance and protecting the reputations of both the Complainant and the Respondent.

The process for an investigation is listed below. Any exceptions to the timelines below should be explained and documented accordingly by HRH.

1. The Chair will notify both the Complainant and Respondent in writing of the appointment of an Investigation Committee and their respective obligations.
2. The formal investigation will begin thirty (30) calendar days after completion of the inquiry and after written notice of the appointment of the Investigation Committee has been provided to the Complainant and the Respondent.
3. The start of the investigation is considered to be the date when the first assembled meeting of the Investigation Committee is held. 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.
4. Both the Complainant and Respondent will have an opportunity to be heard as part the investigation process for determining the validity of the allegation.
5. The investigation will include, but not limited to, a thorough examination of all relevant information provided. Some examples include research data, proposals, correspondence, letters, publications, as well as other sources.
6. Interviews may be conducted as part of the investigation process with the Complainant, Respondent, and witnesses. These interviews will be documented in writing and kept as part of the investigation’s file.
7. The Respondent and Complainant may choose to have legal counsel or a representative present when meeting with the Investigation Committee.
8. The Chair of the Investigation Committee at any point may also ask HRH legal counsel to be present when the Investigation Committee is meeting with the Respondent and/or Complainant.
9. The Investigation Committee will prepare a written report which outlines at

Research Manual	Version #: 3
Responsible Conduct of Research- Policy	Reference #: 10960

minimum the following:

- a. Findings
 - b. Recommendations
 - c. Decision on whether there is or not a case of research misconduct
10. The Investigation Committee must agree to release the written report based on majority rule.
 11. The written report will then be delivered to the Responsible Officer.
 12. The Responsible Officer will provide a summary of the written report to the Respondent. It is up to the discretion of the Responsible Officer as to how much information in the report is to be disclosed and to whom. This includes disclosure of information to the Complainant.
 13. Even though the written report is final and is not subject to revision, the Respondent will have up to fifteen (15) working days from the receipt of the report summary to make a submission to the Responsible Officer regarding the contents of this report.
 14. If a breach of policy is confirmed, the Respondent will have an opportunity to appeal.
 15. Following this 15-day period for the respondent to make a submission to the Responsible Officer, the Responsible Officer will make the final decision on accepting the report and its recommendations.
 16. When there is a finding of research misconduct involving a physician, the Chief of Staff will be notified to determine reporting to the College of Physicians and Surgeons of Ontario (CPSO).
 17. When applicable, HRH will inform University of Toronto's office of Research Oversight and Compliance of the outcome.
 18. In an event of individuals being subjected to an allegation(s) that was determined to be unfounded by the Investigation Committee, all reasonable efforts will be made by HRH to protect or restore the reputation of these individuals.
 19. The Responsible Officer will ensure that all affected parties are informed in a timely manner of the decision reached by the Investigation Committee and any remedial actions that are to be taken by HRH, in accordance with applicable privacy laws and regulations.
 20. The final written report will be kept by HRH for a period of seven (7) years for record-keeping.

Remedial Action

The Responsible Officer will determine what types of remedial actions will be taken by HRH. The Responsible Officer may consult with other senior team members when making a decision. Any recourse against a Respondent will only be shared with (a) the Respondent or (b) individuals authorized to receive this information. The timeframe and specific measures taken for remedial action will be based on the nature and severity of the breach outlined in the written report, and intent may be taken into consideration as well.

Some examples of remedial action include:

- Verbal warning
- Special monitoring of work
- Verbal warning with a letter temporarily on file in the appropriate office
- Letter of reprimand on the Researcher's personnel file

Research Manual	Version #: 3
Responsible Conduct of Research- Policy	Reference #: 10960

- Modifications to publications
- Withdrawal of publications
- Removal of specific responsibilities
- Suspension
- Steps to terminate

Reporting to Relevant Agency Through the Secretariat on Responsible Conduct of Research

All allegations related to: (1) funding applications submitted to an Agency, or (2) activities funded by the Agency, will be communicated by Responsible Officer to the relevant Agency or the SRCR as per HRH's privacy and confidentiality policies, if said allegation may involve significant risks.

HRH and the researcher must not enter into any confidentiality or other types of agreements which may inhibit HRH's ability to report to the Tri-Agencies through the SRCR.

Where applicable, HRH 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 HRH.

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

U.S. Regulated Studies

Any allegations of research misconduct which are related to research activities funded by a US Department of Health and Human Services public health services unit, will be managed and reported in accordance with the regulations and requirements provide by U.S. government requirements.

Conflicts of Interest

Any real, perceived, or potential conflicts of interest must be declared by all individuals involved in the allegation of research misconduct process. Researchers should at minimum adhere and

Research Manual	Version #: 3
Responsible Conduct of Research- Policy	Reference #: 10960

refer to the Conflicts of Interest Hospital Wide policy and procedure (Ref#: 3175) for HRH to review what potential conflicts of interest can be.

If there is a conflict of interest with the Responsible Officer, then the Responsible Officer must engage with the Office of the President & CEO to find an appropriate delegate in senior administration to act as the Responsible Officer.

The Complainant (the individual submitting the allegation of research misconduct) is expected to declare any conflicts of interest (whether real, potential or perceived), at the time of making the allegation.

If there is a conflict of interest (whether real, potential, or perceived), with the individual(s) conducting the inquiry or Investigation Committee, these individuals are expected to declare these conflicts of interest and the Responsible Officer will subsequently find an appropriate delegate(s) to conduct their tasks.

Confidentiality

Any individual making an allegation in good faith or providing information related to an allegation, as well as the privacy of the Complainant and Respondent, will be protected to the best extent possible by HRH. Individuals involved in the inquiry process or Investigation Committee will be expected to conduct their duties in a confidential manner to ensure that the privacy of the Complainant and Respondent are protected.

All confidential enquiries, allegations of breaches of policies, and information related to allegations will be submitted to the Responsible Officer to ensure that information related to the allegation and subsequent activities remain confidential.

Promoting Education and Awareness on the Importance of RCR

All HRH Researchers will receive communication and training of general HRH research procedures at the time of hire and during their first few months of being involved at HRH. Researchers will be directed and encouraged to review this Responsible Conduct of Research Policy and the Research Training Requirements guidelines (Ref #10896), to encourage from the HRH and Tri-Agency viewpoints, an understanding on the responsible conduct of research, the application of responsible conduct of research to help create a positive research environment at HRH, to ensure a clear understanding of the process for allegations of research misconduct, and to be made aware of consequences of not meeting the requirements of responsible conduct of research. A researcher who acts as a supervisor or who has oversight roles should also provide the appropriate supervision and training to all research Researchers in regard responsible conduct of research.

Research Manual	Version #: 3
Responsible Conduct of Research- Policy	Reference #: 10960

Researchers will be aware of the key point of contact at HRH (Responsible Officer) for all confidential inquiries, allegations of research misconduct, and information related to allegations of research misconduct including breaches of Agency policies. They will be aware of the process for addressing allegations at HRH and when there is cross-appointment or inclusion of the University of Toronto in this process.

HRH will make public annual reports with statistics on confirmed findings of breaches (for example the number and general nature of the breaches), subject to applicable laws, including the privacy laws.

In regard to cases of research misconduct, HRH will have a report outlining measures taken as a result of the inquiry and/or subsequent investigation. Training (if warranted) for staff may be implemented and recorded as part of the documentation on measures taken as a result of the inquiry and/or investigation.

Accountability / Responsibility

The Responsible Officer will, take into account any applicable privacy laws and regulations, inform all affected parties a timely manner, of the decision reached by the Investigation Committee on an allegation of research misconduct, and of any remedial actions that will be taken by HRH.

If allegations of research misconduct are determined to be unfounded, then HRH will take every effort to protect or restore the reputation of individuals wrongly subjected to an allegation.

Researchers conducting research at or under the auspices of HRH are required to read through this HRH RCR policy to promote a positive research environment. Researchers are also required to complete all Learning Information Management Environment (LIME) modules, research-specific training requirements outlined in the Research Training Requirements guidelines (Ref #10896), study-specific policies/guidelines which will be communicated to them by their respective Research Manager, as well as orientation days 1 and 2 (as applicable) prior to conducting research activities.

Definitions

Please note that some of the definitions for some of the following terms are pulled from the [Tri-Agency Framework: Responsible Conduct of Research](#). For the most up-to-date information on these definitions, please consult the official online version of the Tri-Agency Framework at <https://rcr.ethics.gc.ca/eng/framework-cadre-2021.html>.

Research Manual	Version #: 3
Responsible Conduct of Research- Policy	Reference #: 10960

Administrator

The individual(s) that the Responsible Officer has assigned to conduct the inquiry for an allegation of research misconduct.

Agencies

Canada's three federal granting agencies: the Canadian Institutes of Health Research (CIHR); the Natural Sciences and Engineering Research Council of Canada (NSERC); and the Social Sciences and Humanities Research Council of Canada (SSHRC).

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 of one or more Agency, Institutional, and applicable Regulatory policies, the validity of which has not been established.

Applicant (including co-applicant)

An individual who has submitted an application, individually or as part of a group or team, for funding from the Agency or the Institution.

Breach

A breach of the RCR Framework is the failure to comply with any Agency, Institutional, and applicable Regulatory policies throughout the life cycle of a research project – from application for funding, to the conduct of the 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, Institutional, and applicable Regulatory policy or related document; mismanagement of grants or award funds; breach of

Research Manual	Version #: 3
Responsible Conduct of Research- Policy	Reference #: 10960

Agency policies or requirements for certain types of research; and breach of agency review processes.

Serious breach: In determining whether a breach is serious, HRH 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);
- 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, Institutional, or Regulatory policy.

Conflict of Interest

A conflict of interest may arise when activities or situations place an individual in a real, potential or perceived conflict between the duties or responsibilities related to research, and personal, institutional or other interests. These interests include, but are not limited to, business, commercial or financial interests pertaining to the individual, their family members, friends, or their former, current or prospective professional associates.

Research Manual	Version #: 3
Responsible Conduct of Research- Policy	Reference #: 10960

Inquiry

The process of reviewing an allegation to determine whether the particular policy or policies that may have been breached, and whether an investigation is warranted based on the information provided in the allegation.

Investigation Committee

At minimum a group of three (3) individuals, of which at least one person is not currently affiliated with HRH or the University of Toronto, that have been assigned by the Responsible Officer to perform an investigation to determine if a breach has occurred.

Research

An undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.

Researcher

Anyone who conducts research activities.

Respondent

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

Responsible Conduct of Research

The expected behaviour of an individual involved in any aspect of a research activity.

Responsible Officer

The Responsible Officer at HRH is the Vice President, Research & Innovation. This individual along with the Research Integrity Office will be responsible for overseeing the research misconduct allegation process and will act as the main point of contact to whom all allegations will be submitted.

Documentation

All documentation pertaining to allegations of research misconduct, including the initial allegation letter or other communications, inquiry and/or investigation materials/interviews/correspondence/written reports/other, as well as any remedial actions, will be maintained by HRH in a confidential and secure manner for seven (7) years after the final report is received by the Responsible Officer. Any documentation distributed to individuals involved in the initial inquiry process or as part of the investigation shall either be (1) returned to the Responsible Officer, or (2) shredded or securely deleted in accordance with HRH policies.

Research Manual	Version #: 3
Responsible Conduct of Research- Policy	Reference #: 10960

Infection Prevention and Control Considerations

All patients will be cared for using Infection Prevention and Control Routine Practices and Additional Precautions as outlined in **Provincial Infectious Diseases Advisory Committee (PIDAC): Routine Practices and Additional Precautions**, Ministry of Health and Long-term Care, as per HRH policy. All staff will perform Hand Hygiene as per HRH guideline.

Acknowledgement

We would like to acknowledge the usefulness of the Sunnybrook Health Sciences Centre RCR policy to help write this RCR policy.

References

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