University Health Network
Policy & Procedure Manual
Research: Responsible Conduct of Research

Policy

In keeping with its commitment to maintaining public confidence in research, University Health Network (UHN) addresses requirements that relate specifically to the conduct of research. UHN is committed to the promotion of research integrity through its ongoing education, training programs and centres and, therefore, all research at UHN will be conducted with the highest degree of integrity.

Research activity at UHN depends on freedom of inquiry, thought, expression and publication since these are the cornerstones of scientific progress. Each member of the research community has a responsibility to foster intellectual honesty and integrity, and to be vigilant regarding the conduct of research, whether their own or other's. It is essential that research personnel maintain the highest standard of public trust and integrity.

All concerns raised regarding failures to comply with regulations, potential misconduct, or allegations of misconduct should be made in good faith. They will be investigated in an impartial, timely, fair, and transparent manner while maintaining the greatest level of confidentiality.

Consistent with relevant laws, rules and regulations, UHN is committed to the protection of the privacy and/or confidentiality of respondents, complainants, and research subjects identifiable from research records or evidence.

This policy should be reviewed in conjunction with the following applicable UHN policies:

- Academic Authorship & Public Access of Publications policy 40.60.001
- Conflict of Interest of Research Personnel policy 40.90.002
- Reporting & Investigation of Suspected Fraud policy 1.30.006
- Fostering Respect in the Workplace policy 2.50.005
- Violence & Domestic Violence in the Workplace policy 6.30.004

Further, this policy is intended to be consistent with the University of Toronto's Policy on Ethical Conduct in Research; the Tri-Agency Framework: Responsible Conduct of Research containing the requirements of the Tri-Agencies (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council, and Social Sciences & Humanities Research Council of Canada); and the contractual obligations and/or requirements of other granting agencies such as the United States Department of Defense, and operating divisions of the United States Public Health Service (PHS), for example the National Institutes of Health.

This policy applies to anyone who is involved in the conduct of research at or under the auspices of UHN and covers:

- misconduct in research
- concerns that fall outside the scope of research misconduct
- response to concerns regarding research integrity
- responsibilities
- complaints process
  a. step 1: inquiry
     i. timing of inquiry
     ii. inquiry process
     iii. appeal
  b. step 2: investigation
     i. investigation committee
     ii. conduct of investigation
     iii. investigation report
     iv. investigation outcome
     v. appeal
  c. indemnification
- definitions

Misconduct in Research

Research misconduct at UHN includes the following behaviors:

- falsification
- fabrication
- plagiarism
- material non-compliance with accepted standards and regulations

Due latitude is given for honest errors, honest differences in methodology, interpretation or judgment, or divergent paradigms in science; what is at issue are genuine breaches of the integrity of the research process.

Depending upon the severity and magnitude, the following examples may be construed as research misconduct:

- fabrication of recording or reporting and other falsification of data or results (fraud)
- the use of someone else's written words or ideas without giving appropriate credit (plagiarism)
- material failure to use scholarly and scientific rigour and integrity in obtaining, recording, and analyzing data, and in reporting and publishing results
- deliberately failing to appropriately include, as authors, other collaborators who prepared their contribution with the understanding and intention that it would be

a “joint” publication
- inaccurate attribution of authorship, including attribution of authorship to persons other than those who have contributed sufficiently to take responsibility for the intellectual content, or agreeing to be listed as author to a publication for which one made little or no material contribution
- deliberately failing to provide collaborators with an opportunity to contribute as an author in a “joint publication” when they contributed to the research with the understanding and intention that they would be offered this opportunity
- falsely claiming someone else’s data as their own
- preventing access to research data to a legitimate collaborator who contributed to the research with the explicit understanding and intention that the data was their own or would be appropriately shared
- giving or receiving honourary authorship or inventorship
- denying legitimate inventorship
- knowingly agreeing to publish as a co-author without reviewing the work including reviewing the final draft of the manuscript
- failing to obtain consent from a co-author before naming them as such in the work
- portraying one’s own work as original or novel without acknowledgement of prior publication or publication of data for a second time without reference to the first
- willfully misrepresenting (for any reason) findings resulting from conducting research activities
- actively condoning or not reporting direct knowledge of the performance by another researcher of any of the acts noted above
- taking retribution or retaliating against a whistleblower or individual who is acting in good faith through reporting or providing information about alleged misconduct
- encouraging or facilitating another researcher to carry out scholarly research misconduct (e.g. a supervisor telling their graduate student to falsify data); or otherwise creating an environment that promotes research misconduct by another
- failure to honour the confidentiality that the researcher promised or was contracted to as a way to gain valuable information from a party internal or external to UHN
- deliberate destruction of one’s own research data or records to avoid the detection of wrong doing or the deliberate destruction of someone else’s data or records
- material failure to comply with relevant federal or provincial statues or regulations applicable to the conduct and reporting of research
- failure to comply with a direction of UHN's Research Ethics Board upon which an approval to proceed with the research was granted, or failing to notify the Research Ethics Board of significant protocol changes that may affect its prior decision to approve the research proceeding
- failure to adhere to reporting requirements of regulators, sponsors, or funding agencies (e.g. adverse event reporting)

- failure to obtain consent from research subjects
- failure to comply with a direction of UHN's Animal Care Committee or Biosafety Committee upon which an approval to proceed with the research was granted, or failing to notify the committee of significant protocol changes that may affect its prior decision to approve the research proceedings
- failure to provide relevant materials to UHN's Research Ethics Board (or to the Animal Care Committee or Biosafety Committee) required by UHN or which the research or academic community considers to be materials relevant to decision-making
- failure to reveal material conflicts of interest to UHN, sponsors, colleagues, or journal editors when submitting a grant, protocol, or manuscript, or when asked to undertake a review of research grant applications, manuscripts, or to test or distribute products
- making false or misleading statements that are contrary to good faith reporting of alleged research misconduct or failing to declare any conflicts of interest when reporting alleged research misconduct

Concerns that Fall Outside the Scope of Research Misconduct

This policy does not address concerns that reflect professional misconduct that fall outside of the scope of research misconduct. Concerns that fall outside of the scope of research misconduct must be directed to the appropriate UHN leadership and will be managed according to the relevant policies and/or processes. Examples of this include:

- conduct described as incivility, bullying, harassment, sexual harassment, or discrimination will be referred to People & Culture (see Fostering Respect in the Workplace policy 2.50.005)
- review of alleged violence directed toward staff and patients will be referred to UHN Safety Services and People & Culture (see Violence & Domestic Violence in the Workplace policy 6.30.004)
- activities that might reasonably be characterized as fraud will be referred to general counsel (see Reporting & Investigation of Suspected Fraud policy 1.30.006)

Response to Concerns Regarding Research Integrity

Any member of the research community is obligated to report concerns regarding suspected research misconduct to the appropriate leadership who will communicate these concerns to the executive vice-president, Science & Research (EVPSR).

To the extent possible, an individual making an allegation in good faith or providing information related to an allegation, will be protected from reprisal in a manner consistent with relevant legislation.

Concerns may also be identified as a result of routine administrative processes by the Institution, or third parties, in the course of standard audits, or other reviews that, upon initial fact finding, may be flagged as possible research misconduct. These concerns, when identified, will be initiated as an inquiry, in accordance with this policy, and follow the processes thereafter as further outlined below, recognizing that such processes will be adjusted, as needed, for the fact that no complainant will be designated.

Responsibilities

Complainant

- Discuss concerns with EVPSR and other appropriate UHN leadership.
- Report concerns in good faith.
- Fully cooperate with all parties conducting the inquiry or investigation.

Respondent

- Meet with the EVPSR and other appropriate UHN leadership to discuss the raised concern and participate in inquiry and investigation processes, as required.
- Fully cooperate with all parties conducting the inquiry or investigation.
- Provide written responses, as required.

Executive Vice-president, Science & Research

- Manage research integrity concerns raised at UHN.
- Establish the inquiry panel.
- Establish the investigation committee.
- Consult with and engage appropriate UHN leadership throughout inquiries and investigations; this may include taking immediate action to protect the administration of the funds of any of the tri-agencies or other granting agencies. Immediate actions could include freezing grant accounts, requiring a second authorized signature from an appropriate UHN representative on all expenses charged to a respondent's grant accounts, or other measures, as appropriate.
- Subject to any applicable laws, including privacy laws, advise the Secretariat on Responsible Conduct of Research immediately of any allegations related to activities funded by the agency that may involve significant financial, health and safety, or other risks.

- Determine sanctions in conjunction with appropriate UHN leadership.

  Note: For the purpose of inquiry and investigation, UHN leadership will exclude the chief executive officer (CEO).

- Notify respondents and complainants of the appeal process to the CEO.

Complaints Process

The processing of complaints of research misconduct must be carried out carefully, thoroughly, objectively, fairly and as promptly as possible, to resolve all questions regarding the integrity of the research.

Individuals responsible for carrying out any part of the research misconduct proceeding may not have unresolved personal, professional, or financial conflicts of interest with the complainant or respondent.

All persons involved, those making allegations, those who are the subject of the allegations of research misconduct, and those who assist in the inquiry and investigation, will be treated with respect, fairness and with due sensitivity.

All proceedings will be conducted in a timely manner and will be documented appropriately.

The highest possible degree of confidentiality will be maintained regarding all allegations of suspected research misconduct, inquiries and investigations, subject to any disclosure that might be required by law.

Anonymous allegations will be considered if accompanied by sufficient information to enable the assessment of the allegation and the credibility of the facts and evidence on which the allegation is based, without the need for further information from the complainant.

Any person who makes an anonymous allegation will be encouraged to identify themselves properly and to express their concerns in good faith. If a person wishes to remain anonymous, reasonable efforts will be made to gather relevant information relating to the concerns and to protect their confidentiality to the extent permitted.

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.

Two-step Approach

There are potentially two steps in the procedure to address and manage a complaint: an inquiry step to determine if an investigation of an allegation is warranted, and an investigation step to determine if there is sufficient evidence to support a finding of research misconduct.

Step 1: Inquiry

An inquiry is initiated to ascertain whether there are reasonable grounds to proceed to an investigation, not to determine whether research misconduct has occurred.

The inquiry is a preliminary process where the following threshold assessments are made:

- Is the complaint outside UHN's jurisdiction?
- Is it clearly mistaken or unjustified?
- Does it involve allegations that, even if proven, would not constitute research misconduct?
- Is it frivolous, vexatious or made in bad faith?

and if not any of the foregoing:

- Is there a reasonable prospect that a further investigation will materially enhance the integrity of the scientific process?

The inquiry also provides an opportunity to determine whether it is appropriate to offer the complainant and the respondent an alternative dispute resolution process.

The inquiry team will be vigilant not to permit personal conflicts between colleagues to obscure the facts and divert attention from the substance of the allegation.

Timing of inquiry:

Every effort will be made to ensure that an inquiry is completed in a timely manner, and within requirements of granting and oversight bodies.

Prior to commencing the inquiry:

- The EVPSR will meet with the complainant to discuss the concern that has been raised and review the inquiry/investigation process.
- The EVPSR will meet with the respondent to discuss the concern that has been raised and review the inquiry/ investigation process.

- The EVPSR will establish an inquiry panel.

Inquiry process:

- All potential inquiry team members will be polled to see whether they have a potential conflict of interest. No person with a direct interest in the research or a personal connection with the complainant or respondent will serve on the inquiry panel.

- The inquiry panel will consult as necessary and make a decision and recommendations to the EVPSR as to whether an investigation is warranted.

- Where the inquiry panel decides to recommend that a formal investigation be undertaken, it will provide written notice of its decision to the respondent and the complainant. The respondent may provide written comments on the inquiry report.

- Where the inquiry team decides not to proceed with an investigation, it will provide written notice of its decision to the respondent and the complainant. The notice will include a brief written summary of the reasons for such a determination.

- If the inquiry panel has reasonable grounds to believe that the complainant did not act in good faith, it will write to the complainant and respondent to summarize these grounds and inform them that the matter is being referred to appropriate leadership to be assessed in accordance with the relevant code of conduct.

- The highest level of confidentiality possible will be maintained throughout the inquiry process.

- If an investigation is warranted and if deemed appropriate, the EVPSR will inform, as appropriate, internal UHN leadership (e.g. Medical Advisory Committee chair, Research Ethics Board chair).

- The respondent may **appeal** the application of this policy to the CEO with respect to the inquiry.

- Consistent with relevant laws, rules and regulations, the EVPSR will cooperate with relevant governmental authorities, for example the United States Office of Research Integrity (ORI), in matters involving PHS funding.

Step 2: Investigation

If an investigation is recommended, the EVPSR will seek to establish an investigation committee and name the chair of this committee. The investigation committee will include at least one external member who has no current affiliation with UHN. The EVPSR may not participate on the committee.

All potential committee members will be polled to see whether they have a potential conflict of interest. No person with a direct interest in the research or a personal connection with the complainant or respondent will serve on the committee.

The purpose of the investigation is to examine the allegations and to weigh the evidence to determine whether or not research misconduct has occurred, and, if so, whom the involved parties are.

The EVPSR will provide the respondent with written documentation of the allegation, notification of investigation, an outline of the investigative process, and the names of the members of the investigation committee.

The EVPSR will notify internal and external authorities, as appropriate, (e.g. funder, University of Toronto, Secretariat on Responsible Conduct of Research, US Office of Research Integrity) of the initiation of the investigation and, subsequently, will report the results of the investigation. In matters involving PHS funding, the EVPSR will provide written notice to the ORI of any decision to open an investigation on or before the date on which the investigation begins. Consistent with relevant laws, rules and regulations, the EVPSR will provide to ORI notice of any facts that may be relevant to protect public health, PHS funds, and the integrity of the PHS funded research process.

If there is a finding of research misconduct, the EVPSR, in conjunction with other appropriate UHN leadership, determines sanctions/consequences.

Complaints of research misconduct may vary greatly with respect to urgency, seriousness and complexity. The EVPSR will exercise their discretion in determining the appropriate timelines for commencing, conducting and reporting on investigation.

The **investigation committee:**

- Has the authority to interview persons whose evidence is thought to be helpful, to examine relevant documents and data records, and to consult with experts both within and outside UHN, as required.

- Consults confidentially with anyone who comes forward with information regarding the complaint.

- Maintains confidentiality during the entire course of the investigation in order to protect the rights of all parties involved.

- Is vigilant not to permit personal conflicts between colleagues to obscure the facts and divert attention from the substance of the allegation.

- Maintains appropriate documentation of the investigation, including summaries of interviews and all original submissions and correspondence.

The **chair of the investigation committee** will ensure that the members of the committee are informed of the:

- investigative process
- requirements to conduct the investigation carefully and thoroughly and to endeavour to address all questions raised by the complaint regarding the integrity of the research
- responsibility to be vigilant and not to permit personal conflicts between the complainant and the respondent to obscure the facts and divert attention from the substance of the allegation
- importance of protecting the reputations of the complainant and respondent throughout the investigation
- requirement that proceedings be kept strictly confidential and documents be kept confidential and obtainable only by those who are entitled to them in order to protect the rights of all parties involved, subject to any legal requirements

Conduct of investigation: The respondent has the following rights:

- to know the identity of the complainant
- the opportunity to present their case to the investigation committee at the initial and final stages of the investigation
- access to supporting documents provided by the investigation committee and that have been made anonymous
- to be informed whenever significant new directions are taken if, in the course of the investigation, additional information emerges that broadens the scope of the investigation beyond that of the inquiry

Any involved parties are to be informed that they will be required to cooperate with the proceedings of the investigation in a timely manner.

If, **during** the course of the investigation, the respondent leaves UHN, the investigation will be continued to its full conclusion.

If the complainant decides not to proceed with the allegations after the investigation has been initiated, the investigation committee may decide to proceed with the investigation even without the further participation of the complainant.

Investigation report and documents:

- Within 60 days from the making of a final decision by the investigation committee, the chair will submit a written report to the EVPSR, summarizing the process, findings and conclusions of the investigation.

- The report may include recommendations on any remedial actions to be taken in the circumstances and/or recommendations of changes to procedures or practices to avoid similar situations in the future.

- The EVPSR, in conjunction with the appropriate area VP, such as the executive vice-president and chief medical officer (EVP/CMO), where a respondent is covered by the Medical Staff By-laws, will decide on implementation of any recommendations contained in the report.

- The originals and/or certified copies as appropriate, of all documents examined during the investigation and summaries of all interviews conducted will be kept by the EVPSR's Operations department for document control purposes.

- The respondent will have an opportunity to provide written comments on the draft report of the investigation, and the investigation committee will have an opportunity to consider and address the comments before issuing the final report.

- The EVPSR, in conjunction with the appropriate area VP, will provide a copy of the final report to the respondent and other appropriate UHN leadership.

Investigation outcome:

- In cases where no research misconduct has been found:

    a. The EVPSR, in conjunction with the appropriate area VP, will ensure that a letter confirming the finding of no research misconduct is sent to the respondent, the complainant, and any appropriate UHN leadership.

    b. To the extent possible, the EVPSR, in conjunction with the appropriate area VP, will make reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputation of persons alleged to have engaged in research misconduct but against whom no findings of research misconduct is made.

    c. To the extent possible, the EVPSR, in conjunction with the appropriate area VP, will make reasonable and practical efforts to protect or restore the position and reputation of any complainant, or committee member, and to counter potential or actual retaliation against these complainant and committee members.

d. In the case where the investigation may disclose evidence of serious scientific error that requires further action, even when no research misconduct is found, the EVPSR will discuss this case with the chair of the investigation committee and the respondent, will consider the respondent's submissions, if any, and will decide what action to take.

e. No disciplinary measures will be taken against the complainant if the complaint was made in good faith.

- In cases where research misconduct has been found:

  a. The EVPSR, in conjunction with the appropriate area VP, such as the EVP/CMO, where a respondent is covered by the Medical Staff By-laws, will consider what remedial action, appropriate to the circumstances, should be taken in accordance with applicable procedural requirements, such as those outlined in the above mentioned By-laws and other relevant policies.

  b. The decision with respect to any remedial action will be made within 15 working days from the date of the EVPSR's receipt of the Respondent's written response to the findings. If there are no further procedural requirements under UHN policies, the EVPSR, in conjunction with the appropriate area VP, may sanction disciplinary measures.

  c. Any remedial action is subject to any applicable UHN policies.

- The EVPSR may communicate the outcome of the investigation, as required, directly, or through other UHN leadership, to parties within UHN, such as the chairs of the Medical Advisory Committee and the Research Ethics Board, or external to UHN.

- The respondent may **appeal** the application of this policy and appropriateness of any disciplinary sanction to the CEO or, in the case of a respondent covered by the Medical Staff By-laws, following procedures outlined in the Medical Staff By-laws.

Indemnification

Individuals serving as members of the investigation committee, ad hoc advisors, participants in the process who are acting in good faith, etc., will be indemnified by UHN.

Definitions

Complainant: An individual who raises a concern about potential misconduct in research or who makes an allegation of research misconduct.

Good faith: As applied to a complainant, good faith means having a belief in the truth of one's allegation or concern that a reasonable person in the complainant's position could have, based on the information known to the complainant at the time. A complainant's allegation or concern is not in good faith if made with knowing or reckless disregard for information that would negate the allegation or concern. Good faith as applied to a committee member means carrying out the duties assigned impartially for the purpose of helping UHN meet its responsibilities under the applicable laws, rules, regulations and agency requirements regarding the responsible conduct of research. A committee member does not act in good faith if their acts or omissions on the committee are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the matter under inquiry or investigation.

Inquiry: The informal process to determine whether a formal investigation of research misconduct allegations should be conducted.

Investigation: The formal process to make a determination of research misconduct in response to allegations.

Research misconduct: Any research practice that deviates materially from the commonly accepted ethics/integrity standards or practices of the relevant research community and includes, but is not limited to, intentional fabrication, falsification, plagiarism, and material non-compliance with accepted standards and regulations.

- **Fabrication:** Making up data, source material, methodologies, findings or results, including graphs and images, and recording or reporting them.

- **Falsification:** Manipulating, changing or omitting research materials, equipment, processes, data or results, including graphs and images, without proper acknowledgement such that the research is not accurately represented in the research findings, conclusions or records.

- **Plagiarism:** The appropriation of another person's ideas, processes, results, or words without giving appropriate credit; or the re-use of one's own work, ideas, processes, results, or words without proper acknowledgement of the previous use or without the permission of any person who may have acquired copyright or intellectual property rights by virtue of such previous use.

- **Material non-compliance with accepted standards and regulations** is the:

    a. Material failure to correct non-compliance with relevant federal or provincial statutes or regulations for the protection of researchers, human subjects, or the public or for the welfare of laboratory animals.

    b. Material failure to correct non-compliance with other legal or UHN requirements that relate to the conduct of research.

    c. Material failure to conform with accepted professional and academic

standards and practices with respect to scientific rigour, accountability, honesty, fairness and professional integrity.

Research personnel: All personnel paid by UHN or other sources involved in the conduct of research at UHN. This includes, but is not limited to, those personnel working in laboratory, administrative, clinical or support areas.

Respondent: An individual who is the subject of a concern regarding research misconduct or an allegation of research misconduct.

References

1. Tri-Agency Framework: Responsible Conduct of Research (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council, and Social Sciences & Humanities Research Council of Canada).

2. U.S. Department of Health and Human Services (2005). 42 CFR – Code of Federal Regulations, Parts 50 and 93, Public Health Service Policies on Research Misconduct.