Holland Bloorview Kids Rehabilitation Hospital	Manual Corporate	Cluster Bloorview Research Institute
	Theme Research Conduct	Number 00084

Responsible Conduct of Research

Preamble

Holland Bloorview Kids Rehabilitation Hospital is committed to the promotion of research through its ongoing support of scientific inquiry that fosters intellectual honesty, integrity and vigilance regarding the conduct of research.

Researchers at Holland Bloorview shall strive to follow best practices and conduct research honestly, accountably, openly and fairly in the search for and dissemination of knowledge. Researchers are required to follow the requirements of institutional policies and professional or disciplinary standards and shall comply with applicable laws and regulations. Researchers in breach of the policy should be proactive in rectifying the breach.

The Tri-Council officially launched the new Tri-Agency Framework: Responsible Conduct of Research in December 2011. The Framework describes the Tri-Council policies and requirements related to applying for and managing Tri-Council funds, performing research and disseminating results. This policy is based on this Framework and compliant with the requirements of the Tri-Agencies (Canadian Institutes of Health Research (CIHR), Natural Sciences and Engineering Research Council (NSERC), or Social Sciences & Humanities Research Council of Canada (SSHRC) [also referred to as Tri-Agency(ies)] and other granting agencies. This policy applies to all individuals conducting research under the auspices and jurisdiction of Holland Bloorview Kids Rehabilitation Hospital, here on out referred to as researchers.

PROMOTING AWARENESS OF THIS POLICY

Holland Bloorview shall make the policy available through its website, in regular communications with all Bloorview Research Institute staff, and through annual training workshops. Holland Bloorview makes its annual reports public and shall include a section regarding confirmed findings of breaches of the policy and actions taken within the report.

Policy Statement

This policy outlines the requirements that all researchers involved in the conduct of research, specifically the management of grant funds, performing research, and disseminating results of that research at Holland Bloorview must adhere to the processes that must be followed in the event of an allegation of a breach of Institutional policy. All research conducted under the auspices or jurisdiction of Holland Bloorview must adhere to this policy.

This policy should be reviewed in conjunction with the Holland Bloorview Conflict of Interest Policy. The objectives of this policy are to ensure funding decisions are based on accurate and reliable information; to use public funds for research are used responsibly and in accordance with funding agreements; to promote and protect the quality, accuracy, and reliability of research; and to promote fairness in the conduct of research.

Procedure:

To be in compliance with this policy all researchers conducting research under the auspices or jurisdiction of Holland Bloorview are responsible for the following:

a. Using a high level of rigor in proposing and performing research; in recording, analyzing, and interpreting data; and in reporting and publishing data and findings.

b. Keeping complete and accurate records of data, methodologies and findings, including graphs and images, in accordance with the applicable funding agreement, institutional policies and/or laws, regulations, and professional or disciplinary standards in a manner that will allow verification or replication of the work by others.

c. Referencing and, where applicable, obtaining permission for the use of all published and unpublished work, including data, source material, methodologies, findings, graphs and images.

d. Including as authors, with their consent, all those and only those who have materially or conceptually contributed to, and share responsibility for, the contents of the publication or document, in a manner consistent with their respective contributions, and authorship policies of relevant publications.

e. Acknowledging, in addition to authors, all contributors and contributions to research, including writers, funders and sponsors.

f. Appropriately managing any real, potential or perceived conflict of interest, per Holland Bloorview Conflict of Interest Policy.

To be in compliance with this policy while applying for and holding funding

a. Applicants and holders of 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. Principal funding applicants must ensure that others listed on the application have agreed to be included.

b. For Tri-Agency grants, applicants certify that they are not currently ineligible to apply for, and/or hold, funds from NSERC, SSHRC, CIHR 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.

BREACHES OF POLICY

1. Researchers and research personnel must ensure they do not breach the policy in the following ways:

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 wrong doing 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*: The re-publication of one's own previously published work or part thereof, or 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 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.

g. *Inadequate acknowledgement*: Failure to appropriately recognize contributions of others in a manner consistent with their respective contributions and authorship policies of relevant publications.

h. *Mismanagement of Conflict of Interest:* Failure to appropriately manage any real, potential or perceived conflict of interest, in accordance with Holland Bloorview's Conflict of Interest policy, preventing one or more of the objectives of the policy from being met.

2. In the Management of Grant and Award funds applicants and holders of funding must ensure that the following does not occur:

   a. *Misrepresentations in an Application or related Document which includes:*
      - 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.
      - Applying for and/or holding an award when deemed ineligible by a Tri-Agency (NSERC, SSHRC, CIHR) 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.
- Listing of co-applicants, collaborators or partners without their agreement.

b. Mismanagement of Grant or Awards Funds which includes:
- Using grant or award funds for purposes inconsistent with the policies of the Tri-Agencies or any other research or research funding or organization; misappropriating grants and award funds; contravening Tri-Agency (namely the *Tri-Agency Financial Administration Guide,* Agency grants and awards guides) and/or any other funding organization financial policies; or providing incomplete, inaccurate or false information on documentation for expenditures from grant or award accounts.

3. In the Management of certain types of research, researchers must ensure that the following does not occur:

a. Failing to meet Tri-Agency policy requirements or, to comply with relevant policies, laws or regulations, for the conduct of certain types of research activities; failing to obtain appropriate approvals, permits or certifications before conducting these activities will be deemed a breach.

ADDRESSING ALLEGATIONS OF POLICY BREACH

Reporting an Allegation

Responsible allegations, or information related to responsible allegations, must be sent directly to the Vice-President, Research (VPR), in writing. A higher institutional authority at Holland Bloorview, the President and CEO, will receive this information if the VPR has a conflict of interest that may unduly influence decision making or is involved directly in the allegations of misconduct.

Individuals are expected to report in good faith any information pertaining to possible breaches of funder policies to the VPR where the researcher involved is currently employed, enrolled as a student or has a formal association with Holland Bloorview.

Individuals involved in an inquiry or investigation must follow Holland Bloorview's policy and process as a complainant, a respondent or a third party, as appropriate.

If an anonymous allegation is received, it will be considered, but there will be limits on how far the allegations can be meaningfully investigated depending on the detail of the information provided. Complaints that are submitted without identifying the complaining individual make it difficult, if not impossible, for the VPR to adequately investigate, respond

or take appropriate action. Individuals with complaints are strongly encouraged to contact the VPR directly if there are specific concerns about filing a complaint.

Institutional Responsibility on Receiving Allegations
The VPR will receive confidential enquiries, allegations of breaches of policies, and information pertinent to the allegations.

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

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

The VPR will maintain the highest possible degree of confidentiality will be maintained regarding all allegations of suspected misconduct, inquiries and investigations, subject to any disclosure that might be required by law. However, at no point during this process may VPR and the researcher enter into confidentiality agreements or other agreements related to an inquiry or investigation that prevent Holland Bloorview from reporting to the funding organization including the Tri-Agencies.

The VPR will to protect, to the best of his/her ability, the complainant from reprisals.

The VPR may independently, or in specific cases, at Tri-Agency's request in exceptional circumstances, take immediate action to protect the administration of Tri-agency or any other research funds. Immediate actions may 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.

The VPR shall advise the relevant funding agency as required of any allegations related to activities that involve significant financial, health or safety or other risks. In the case of activities funded by the Tri Agencies, the VPR is required to immediately advise the Agency or Secretariat on Responsible Conduct of Research (SRCR) immediately upon receiving any allegation.

Institutional Responsibility on Investigating Allegations
Steps followed in the Investigation of an Allegation:

Step 1 – Inquiry

The VPR will initiate an inquiry into the allegation to ascertain whether there are reasonable grounds to proceed to an investigation, not to determine whether misconduct has occurred. The inquiry also provides an opportunity to determine whether it is appropriate to offer the complainant and the respondent an alternative dispute resolution process. During the inquiry the VPR or delegate will be vigilant not to permit personal conflicts between colleagues to obscure the facts and divert attention from the substance of the allegation.

Inquiry process:

i. The VPR will meet with the complainant independently to review the written allegation, decide whether the allegation constitutes possible misconduct and merits further inquiry. If merited, the VPR will meet with the respondent independently to discuss the concern that has been raised.

The VPR may consult with an individual with expertise in the area relating to the alleged policy breach to inform his/her decision.

The VPR or delegate will make a decision as to whether an investigation is warranted based on the following

- Is the complaint outside Holland Bloorview'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?

Where it is decided that a formal investigation be undertaken, the VPR or delegate will provide written notice of its decision to the respondent and the complainant.

If an investigation is warranted the VPR will inform the chairs of the Research Advisory Committee (RAC), Senior Management and Communications and Public Affairs.

Where it is decided not to proceed with an investigation, the VPR or delegate 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 VPR or delegate has reasonable grounds to believe that the complainant did not act in good faith, he/she will write the complainant and the respondent to summarize these grounds and inform him/her that the matter is being referred to appropriate Holland Bloorview Senior Management to be assessed in accordance with the relevant code of conduct.

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

The respondent may appeal the application of this policy to the President and Chief Executive Officer (CEO) with respect to the inquiry.

Within 2 months of the initial disclosure of the allegation the VPR or delegate shall write a letter to the relevant funding agency, as required, confirming whether or not the Institution is proceeding with an investigation. In the case of activities funded by the Tri-Agencies, the VPR or delegate is required to send a letter to the Agency or the SRCR once a decision has been reached.

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

Step 2 – Investigation

If an investigation is recommended, the VPR will seek to establish an investigation committee and name the chair of this committee. The VPR may not act as the chair of the committee. The investigation committee will be made up of at least three individuals who have the necessary expertise and who are without conflict of interest, whether real or apparent, and will include at least one external member who has no current affiliation with the Institution.

All potential committee members will be polled to see whether they have a real, potential or perceived 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 VPR 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.

If there is a finding of misconduct, the VPR, in conjunction with other appropriate Holland Bloorview Senior Management team will determine the sanctions/consequences.

Complaints of research misconduct may vary greatly with respect to urgency, seriousness and complexity. The VPR will exercise his/her discretion in determining the appropriate timelines for commencing, conducting and reporting on investigations. If, during the course of the investigation, the respondent resigns from Holland Bloorview, 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.

a. Investigation committee:

i. The 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 Holland Bloorview, as required.
ii. Consults confidentially with anyone who comes forward with information regarding the complaint.
iii. Maintains confidentiality during the entire course of the investigation in order to protect the rights of all parties involved.
iv. Is vigilant not to permit personal conflicts between colleagues to obscure the facts and divert attention from the substance of the allegation.
v. Maintains appropriate documentation of the investigation, including summaries of interviews and all original submissions and correspondence.
vi. 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

b. The respondent has the following rights:

i. To know the identity of the complainant.
ii. The opportunity to present his/her case to the investigation committee at the initial and final stages of the investigation.

Access to supporting documents provided by the investigation committee.

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.

c. Investigation outcome

In cases where **no research misconduct** has been found:

i. The Chair of the investigative committee will submit a written report to the VPR (see below for details)
ii. The VPR will ensure that a letter confirming the finding of no misconduct is sent to the respondent, the complainant, the CEO and President, any

appropriate Holland Bloorview Senior Management Team, and the Chair of the RAC.

iii. The VPR and Holland Bloorview will make every effort to protect and restore the reputation of all those wrongly subjected to the allegation.

iv. 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 VPR will discuss 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.

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

In cases where **<u>research misconduct has been found:</u>**

i. Chair of the investigative committee will submit a written report to the VPR (see below for details).

If there are no further procedural requirements under Holland Bloorview policies, the VPR, in conjunction with Holland Bloorview Senior Management Team may impose sanctions.

In consolation with Communication and Public Affairs, the VPR may communicate the outcome of the investigation, as required, directly, or to the Holland Bloorview Senior Management Team, the chairs of the RAC, MAC and the REB, and parties external to Holland Bloorview including the participants of the research study in which the misconduct occurred.

d. **Investigation report**:

i. The Chair of the investigational committee will submit a written report to the VPR (within 6 months of the initial receipt of allegation), summarizing the process, findings and conclusions, including its final decision of the investigation.

ii. The report shall include:

- 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.
- original and/or certified copies as appropriate, of all documents examined during the investigation and summaries of all interviews conducted.

iii. The Investigation report should not include

- information that is not related specifically to Tri-Agency; or personal information about the researcher
- any other person, that is not material to Holland Bloorview's findings and its report to the SRCR or funding organization.

The VPR will provide a copy of the report to the respondent and other appropriate Holland Bloorview Senior Management Team and the Chair of the RAC.

In cases where the research in question is funded by the Tri Agencies, the VPR shall submit the investigation reports to the SRCR or funding organizations within seven months, of receipt of the allegation by Holland Bloorview. These timelines may be extended in consultation with the SRCR (or funding organization) if circumstances warrant, and with monthly updates provided to the Tri-Agency or funding organization until the investigation is complete.

e. **Appeal Process**

i. The scientist/investigator will write a notice of appeal the application of this policy and appropriateness of any disciplinary sanction to the President and CEO or, in the case of a respondent covered by the Medical Staff By-Laws, following procedures outlined in the Medical Staff By-Laws.

ii. If the President and CEO judges that the appeal provides new information that is pertinent to the investigation, findings and report of the Investigative Committee and merits further review, then a new committee may be formed with a different membership.

iii. The aforementioned investigation procedures will apply. If there is a discrepancy between the initial and subsequent Investigation Committees' decisions, the VPR will make the final decision in consultation with the President and CEO of Holland Bloorview Kids Rehabilitation Hospital.

iv. In the case that the finding of misconduct is reversed, the VPR will provide a copy of the new report to the respondent and other appropriate Holland Bloorview Senior Management Team and the Chair of the RAC.

v. In cases where the research in question is funded by the Tri Agencies, the VPR shall submit the new investigation report to the SRCR or the relevant funding organizations

RECOURSE IN THE CASE OF A BREACH OF POLICY

Based on the Investigation Committee's report, appropriate interim and/or administrative actions shall be taken against individuals found to have engaged in research misconduct. If the Committee's report indicates that research misconduct has occurred, the VPR, in conjunction with appropriate Holland Bloorview Senior Management Team, such as the Vice-President, Medicine and Academic Affairs, where a respondent is covered by the Medical Staff By-Laws, the Research Ethics Board chair and/or the Research Advisory Board

Chair will consider what remedial action, appropriate to the circumstances, should be taken in accordance with applicable procedural. The recourse will be proportionate to the misconduct. The plan for recourse will be signed by the VPR, the respondent and a third party (REB chair, Holland Bloorview Senior Management Team or RAC member) who was part of the decision making process.

DEFINITIONS

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

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.
(http://www.rcr.ethics.gc.ca/eng/policy-politique/framework-cadre/ -footnoteplus#footnoteplus)

Inquiry –The process of reviewing an allegation to determine whether the allegation is responsible, 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 – The formal process to make a determination of 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. See Section on **Breaches of Policy**.

Research Personnel - All personnel paid by Holland Bloorview or other sources, involved in the conduct of research at Holland Bloorview. 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 misconduct or an allegation of misconduct.

REFERENCES

1. The Tri-Agency Framework: Responsible Conduct of Research (2011).
2. Tri-Agency Agreement on the Administration of Agency Grants and Awards by Research Institutions -the revised Memorandum of Understanding (MOU) on the Roles and Responsibilities in the Management of Federal Grants and Awards (2012).

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Policy Lead	Issued Date
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Committee Chair	**Review Date**
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Committee Member(s)	**Review Date**
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