ADMINISTRATIVE MANUAL
Policy/Protocol

TITLE:	Responsible Conduct of Research	**NUMBER:**	335
Sponsor**:**	Director, Research Operations	Page:	1 of 34
Approved by:	Vice President, Research and Innovation	Approval Date: Effective Date:	March 28, 2022 March 29, 2022
Applies To:	Anyone conducting research and/or any research related activities on behalf of the IWK Health		

TABLE OF CONTENTS

PREAMBLE

This policy establishes expectations for the Responsible Conduct of Research at the IWK and outlines processes for handling allegations of research misconduct. It applies to all research conducted with the support of the IWK, with the use of IWK resources or under the jurisdiction of the IWK Research Ethics Board (REB) and all persons involved in the research enterprise at the IWK in any capacity whatsoever including, but not limited to, past and present employees (including seconded employees), privileged physicians, learners, committees, officials and agents.

Notes:

1. **This policy in no way limits the IWK Research Ethics Board's authority to review, approve, monitor or restrict research under its jurisdiction.**
2. **For allegations of research misconduct involving research funds from the United States Public Health Service, please see Appendix C.**

POLICY STATEMENTS

1 Responsible Conduct of Research

1.1 Research at the IWK must be conducted in accordance with the highest scientific and ethical standards. These include, but are not limited to:

1.1.1 Legal requirements including, but not limited to, privacy legislation and Canada's Food and Drugs Act,
1.1.2 Professional standards and codes of conduct,
1.1.3 Tri-Agency requirements, including the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, The Tri-Agency Framework: Responsible Conduct of Research* ("RCR Framework"), and any amendments, interpretations or successor statements that may be made from time to time,
1.1.4 IWK policies, procedures and bylaws,

1.1.5 Dalhousie University's Scholarly Misconduct Policy (for persons who have an appointment with Dalhousie University or who are conducting research under the jurisdiction of the Dalhousie University research ethics board).

1.2 All persons involved in research must behave in a manner that is competent, honest and respectful of others. Resources (including funding, space, equipment and personnel) are to be managed responsibly and ethically.

1.3 All persons involved in research are responsible for familiarizing themselves with principles of Responsible Conduct of Research and for the application of these principles to foster a positive and constructive research-working environment. Persons involved in research with oversight roles should provide appropriate supervision of, and training to, their trainees and research personnel in Responsible Conduct of Research.

1.4 All persons involved in research must avoid (wherever possible) and manage actual, potential and perceived conflicts of interest in accordance with the IWK's Conflict of Interest policy #135.0, bylaws, rules and regulations, and professional standards and codes of conduct.

1.5 Research publications must be prepared in accordance with ethical considerations outlined in the RCR Framework and the International Committee of Medical Journal Editors' *Uniform Requirements for Manuscripts Submitted to Biomedical Journals*.

1.5.1 Learners must be given appropriate recognition for authorship or collection of data in any publication.

1.5.2 One or more authors must be designated as 'guarantor' with responsibility for the integrity of the work as a whole and final approval of the version to be published.

2 Responsibilities to Report Allegations of Research Misconduct

2.1 All persons (including but not limited to IWK employees, seconded employees, privileged physicians, learners, committees, officials and agents) who, acting in good faith, have reasonable grounds to suspect research misconduct, have a responsibility to report or address their concerns promptly as set out in this Policy.

2.2 Where persons who have reasonable grounds to suspect research misconduct do not report their concerns, or do not act upon reported concerns in accordance with this policy, there exists the possibility that they may be viewed as being involved with or complicit in the suspected misconduct.

2.3 There must not be harassment or retaliation against any persons who make allegations in good faith, or who express intention to make an allegation, or who

aid in relation to an allegation under this policy. Harassing or retaliatory behaviour will be dealt with in accordance with IWK policy and applicable disciplinary procedures (see Related Documents section).

2.4 An allegation made in bad faith (with a conscious design to mislead or deceive, or with a malicious or fraudulent intent) may provide grounds for corrective action in accordance with IWK policy and applicable disciplinary procedures (see Related Documents section).

3 Review and Investigation of Allegations of Research Misconduct

3.1 Review and investigation of allegations must be conducted in a fair, objective, and timely manner and are to be well documented.

3.2 Allegations of research misconduct vary greatly with their respect to urgency, seriousness, and complexity. The VP Research will exercise their discretion in determining the appropriate timelines for commencing, conducting, and reporting on investigations, provided that where agreements with, or policies of, sponsors of the research that is the subject of the allegations require reporting within prescribed timelines, all reasonable efforts will be made to meet those requirements. Normally, the following timelines will apply:

- The VP Research will appoint an Investigator/Investigation Committee within 15 business days of determining an Investigation should be conducted.
- The Investigation Committee will convene within 15 business days of its appointment or as soon thereafter as is reasonably possible.
- The Investigation Committee will complete its investigation and initial findings within 60 business days of the first meeting of the Investigation Committee or the commencement of the Investigation by the Investigator.
- The final report of the Investigator/Investigation Committee will be delivered to the VP Research within 45 business days after the completion of the Investigation.

If these deadlines cannot reasonably be met, the Investigator/Investigation Committee will submit a procedural report citing the reasons for the delay and progress to date to the VP Research, with copies to the Complainant and Respondent. The VP Research, at their discretion, may share this report with other appropriate individuals.

For matters involving research funded by the Tri-Agencies, Inquiries should be conducted and concluded with a report to the Secretariat on Responsible Conduct of Research (SRCR) within two months of receiving an allegation. Investigations should be conducted and concluded with a report to the SRCR within five months following

review of an Inquiry. If circumstances warrant, these timelines may be extended with appropriate justification provided to the SRCR.

3.3 The VP Research (or the President & CEO where applicable) may impound and retain research-related materials at any time following an allegation of research misconduct.

3.4 At any point during an investigation, the VP Research may offer the Complainant and Respondent mediation services to enable the resolution of matters arising from the investigation. However, mediation cannot replace adjudication of a matter involving Tri-Agency funding.

3.5 The burden of proof for establishing a finding of research misconduct rests with the IWK to find, based on a balance of probabilities on a preponderance of the evidence (meaning it was more likely to have happened than not based on the majority and/or quality of the evidence), that misconduct occurred. The Respondent has the burden of proof, based on a balance of probabilities on a preponderance of the evidence, to show an honest error or difference of opinion occurred.

3.6 Determinations of research misconduct, once made by the VP Research (or the President & CEO where applicable), are binding on the IWK and on all persons involved in research at the IWK.

3.7 All parties must cooperate fully with the processes outlined in this document, with any other applicable IWK policies and procedures, and with any related requirements stipulated by IWK committees, officials and agents.

3.8 All persons involved with reviewing an allegation must ensure that they are impartial and have no relationship to the persons or matter under review that may present actual or perceived conflict of interest. Any potential for conflict of interest is to be disclosed to the VP Research (or the President & CEO where applicable). Affected persons are to remove themselves from the review process and replacements are to be designated as required.

3.8.1 Where the VP Research is unable to discharge their responsibilities under this policy in relation to a particular allegation due to a conflict of interest, their responsibilities under this policy are to be assumed by the President & CEO or designate.

3.9 The privacy of the Respondent(s), the person(s) making the allegation(s), and others (e.g., witnesses) is to be protected as far as is possible given the need for due process and any legal requirements. An allegation cannot be fully confidential as information must be given to those responsible for the review and investigation of the matter, to witnesses and to the Respondents to permit a fair and full process of review. The highest degree of confidentiality reasonably possible in the circumstances is to be maintained by all persons involved in the process. Allegations and information arising

from the review process will not be shared with personnel who are not directly involved except as required by law, this policy or an existing legal agreement. Complainants and witnesses may request that information be kept confidential and persons involved in the review will make their best efforts to respect those requests, however, confidentiality cannot be assured.

3.10 The IWK and researchers must not enter into confidentiality agreements or other agreements that may prevent the IWK from reporting to the Tri-Agencies or other parties as described in this policy.

3.11 Records related to allegations, investigations and decisions under this policy must be kept in confidential files with restricted access and must be retained in accordance with IWK requirements for investigative reviews.

3.11.1 These files must be maintained by the office of the VP Research (or the President & CEO where applicable) using physically and/or electronically secure location(s).

3.11.2 The VP Research and the President & CEO may authorize supervised access to approved parties upon receipt of a written request. Such requests must also be authorized by the IWK's General Counsel or their legal services designate.

3.12 In cases of confirmed research misconduct, IWK committees and officials have authority to impose appropriate sanctions. Sanctions are to be consistent with the nature and severity of the misconduct, including a Serious Breach, and may include, but are not restricted to, prohibitions in relation to research activity at the IWK and/or referral of the matter for disciplinary action in accordance with applicable policies, procedures, bylaws, collective agreements and Respondent's professional association as required.

3.13 Nothing in this Policy precludes the VP Research from taking appropriate steps to protect patients, the public, staff, research participants, or other researchers, such as notifying medical leadership of patient care issues, notifying the police of criminal activities or restricting or suspending the Respondent's activities pending the outcome of the investigation.

3.14 Where an allegation is determined to be unfounded, the IWK will make all reasonable efforts to protect or restore the reputation of those subjected to an unfounded allegation.

GUIDING PRINCIPLES AND VALUES

1 The IWK affirms its unconditional commitment to the Responsible Conduct of Research. Adherence to the highest scientific and ethical principles ensures that research results are true and meaningful, that researchers receive appropriate recognition for their work, and that the rights, safety, and well-being of research participants are always safeguarded.

2 Expectations for research conduct are outlined in policies, procedures, standards, guidelines, and regulations issued by various provincial, national, and international organizations (see References and Related Documents for a partial list). The Research Services Office (RSO) and the Research Ethics Board (REB) provide guidance and training regarding these expectations and assist researchers to interpret and apply them to their practice.

3 To assure integrity, allegations of research misconduct must be received, investigated and followed-up in a fair, transparent, timely and respectful manner, consistent with procedural and legal requirements. The process must protect the reputations of individuals and the IWK while ensuring that scientific integrity is preserved, and research participants are protected.

PROCESS

1 Making an Allegation of Research Misconduct

1.1 If uncertain whether an activity constitutes research misconduct, contact the VP Research (or the President & CEO if the activity relates to the VP Research or their staff) to discuss the matter on a confidential basis.

1.2 Submit any allegations of research misconduct to the VP Research (or the President & CEO if the allegation relates to the VP Research or their staff) as promptly as possible upon becoming aware of the alleged misconduct.

1.3 Allegations should include contact information and supporting documentation from the Complainant. Allegations sent anonymously or via a third party will be considered and reviewed by the VP Research (or the President & CEO where applicable) to the extent relevant facts are independently verifiable through reasonable efforts.

1.4 Where the Allegation involves research funded by the Tri-Agencies, a Complainant should review the RCR Framework *Tri-Agency Framework: Responsible Conduct of Research (2021)* and may send a copy of the Allegation directly to the Secretariat on Responsible Conduct of Research (SRCR).

2 Receipt and Initial Inquiry

Upon receipt of an allegation, the VP Research (or the President & CEO where applicable) must conduct an initial inquiry to determine whether there is a responsible allegation and an appropriate course of action:

2.1 The VP Research (or the President & CEO where applicable) and/or their agents:

2.1.1 Records receipt of the allegation.

2.1.2 In the case of verbal allegations where it is not practicable or appropriate to request the Complainant make the complaint in writing, documents the reported facts and asks the Complainant to verify that this constitutes an accurate representation of the complaint they wish the IWK to pursue.

2.1.3 Verifies whether complaints pertain to alleged research misconduct as defined in this policy.

Note: Complaints pertaining to other matters do not fall within the scope of this policy and will be handled through other mechanisms.

2.1.4 Places written allegations of research misconduct in confidential files with restricted access and discloses the names of the parties involved only on a strict "need to know" basis or as otherwise required by law.

2.1.5 Immediately notifies the SRCR if the allegation relates to activities funded by the Tri-Agencies and may involve significant financial, health and safety, or risk to others.

2.1.6 Considers whether research-related materials should be impounded and, if so, arranges to obtain these materials as quickly as possible.

2.1.7 Independently, or at the request of a Tri-Agency in exceptional circumstances, decides whether immediate action should be taken to protect the administration of research funds and, if so, notifies the Director Research Operations and the principal investigators (PIs) and any supervising investigators (SIs) of affected studies. Immediate actions could include freezing research accounts, requiring an additional authorized signature from an institutional representative on all expenses charged to research accounts, or other measures, as appropriate.

2.1.8 After notification of Respondent, if the Respondent is also associated with another institution (e.g., university, college), contacts the relevant other entity to discuss whether, in the circumstances, the complaint would be best handled by the IWK or the other entity or whether it may be necessary for more than one institution to pursue the complaint. The VP Research will provide the other institution with the least amount of information reasonably necessary to determine the appropriate involvement of the other institutions which may include the name of the Respondent and nature of the allegations.

2.1.9 Within 5 business days of receiving the allegation:

2.1.9.1 Issues an acknowledgement of receipt to the Complainant and provides them with a copy of this policy.

2.1.9.2 Contacts the Complainant to obtain further information, if required;

2.1.9.3 Notifies any Complainants who wish to remain anonymous that the institution's ability to proceed may be limited and will be based on whether relevant facts are independently verifiable or publicly available.

2.1.10 Within 10 business days of receiving the allegation:

2.1.10.1 Notifies the Chair(s) of the IWK Research Ethics Board (REB) and Research Services that an allegation of research misconduct has been received and provides general details (e.g., alleged mismanagement of research funds);

2.1.10.2 If the Respondent has a Dalhousie University affiliation, notifies Dalhousie University's scholarly integrity officer if the scholarly integrity of Dalhousie students or faculty members has been called into question.

2.1.10.3 Notifies the Respondent that an allegation of research misconduct has been received and provides a summary of the allegation and a copy of this policy;

2.1.10.4 Provides the Respondent with an opportunity to respond to the allegation within a further 15 business days.

2.1.11 Within 20 business days of receiving the Respondent's response or the time for providing a response expiring, reviews the allegation (and the Respondent's response, if received) and decides to:

2.1.11.1 Not pursue the allegation any further (if it is reasonably believed that it is without merit, or if it cannot be pursued without further information which cannot be obtained); or

2.1.11.2 Refer the Complainant to another party (if the matter is deemed to fall within the jurisdiction of that party); and/or

2.1.11.3 Investigate the allegation.

2.1.12 In circumstances where the nature of the Allegation makes it clear that an investigation will be required, the VP Research in their sole discretion may forego the requirements of sections 2.1.9-2.1.11 and proceed directly to Section 4 of Process.

2.1.13 If the VP Research determines at the inquiry stage that a breach is substantiated and the Respondent accepts responsibility and further investigation would not uncover any new information pertinent to the matter, the VP Research may make a finding of research misconduct at the inquiry stage and not proceed with further investigation.

2.2 Inquiries should be conducted and concluded, or a determination made to refer the Allegation for an investigation, within two months of receipt of an Allegation. The VP Research will provide a report to the SRCR if the SRCR was copied on the Allegation or notified as per section 2.1.5, within 2 months of receiving the Allegation or advise the SRCR if more time is needed.

2.3 The VP Research may, in their discretion, obtain the assistance of other qualified individuals to assess at the inquiry stage whether it is a responsible allegation and should proceed to investigation. The individual(s) assessing an inquiry should be without conflict of interest, whether real, potential or perceived, and may not participate as an Investigator or on an Investigation Committee in relation to that allegation if it is referred for investigation.

3 Decision Not to Proceed/Referral of an Allegation

3.1 When a decision has been made not to proceed further with the matter and/or to refer the allegation to another party, the VP Research (or the President & CEO where applicable) and/or their agents:

3.1.1 Documents the decision and the basis for that decision.

3.1.2 Within 10 business days of the decision, provides written notification to the REB Chair, Research Services, the Respondent, the Complainant and, if the SRCR was copied on the allegation or notified as per section 2.1.5, the SRCR.

3.1.3 Where applicable, refers the Complainant to another organization that may be in a better position to investigate or otherwise assist with the matter.

3.1.4 Notifies the appropriate authorities if illegal activity is suspected.

3.1.5 If it appears that the allegation was made in bad faith, considers whether there are grounds for corrective action and proceeds accordingly (see Policy Statement 2.4).

3.1.6 Retains records relating to the allegation and the decision in confidential files as outlined in Policy Statement 3.11.

4 Investigation of an Allegation

4.1 Within 15 business days of deciding that an investigation is warranted, the VP Research (or the President & CEO where applicable) and/or their agents:

4.1.1 Documents the decision and the basis for that decision.

4.1.2 Notifies the following parties of the decision to initiate an investigation:

- The REB Chair(s),
- Research Services,
- The Respondent,

- The Respondent's supervisor,
- The Complainant,
- The director (if the Respondent is an employee) or the chief (in the case of physicians) of the Respondent's IWK department/division/program/service,
- PIs (and any SIs) of affected studies,
- The SRCR, if the SRCR was copied on the allegation or notified as per section 2.1.5, and
- The Respondent's associated institution(s) as required.

4.1.3 The notification to the Complainant and Respondent should:

- identify the research in question and the specific allegations.
- provide a copy of this policy.
- list the names of the members of the Investigation Committee or the Investigator, as well as any experts expected to participate. If the Investigation Committee have not yet been appointed, advise of the anticipated timeline for appointment and the process for advising of the appointments.
- explain the opportunity to challenge the appointment of a member of the Investigation Committee or expert for bias or conflict of interest.
- describe this policy in regards to protection against retaliation, and
- describe the need to maintain confidentiality of proceedings.

4.1.3.1 The notification to the Respondent should also include:

- a copy of the allegations.
- advise of the right to counsel.
- request to retain all materials relevant to the allegation.
- explain the Respondent's opportunity to be interviewed and present evidence to the Investigation Committee and to comment on the draft investigation findings;
- advise the Respondent of their obligation to cooperate; and
- advise the Respondent that as an individual who is the subject of an Investigation, they must temporarily withdraw from participation in any Tri-Agency review process and, if applicable, should immediately inform the relevant Agency's staff of their temporary unavailability to participate in the review process. Individuals who are the subject of an Investigation may continue to request and hold Tri-Agency funding.

4.1.4 Decides whether immediate action should be taken to protect the administration of research funds and, if so, notifies Research Services, and the PIs (and any SIs) of affected studies.

4.1.5 Designates an Investigation Committee or appoints an Investigator. In cases involving Tri-Agency funding, the VP Research will designate an Investigation Committee.

4.2 The REB Management Committee decides whether any research activities should be restricted pending the result of the investigation and, if so, notifies the VP Research (or the President & CEO where applicable), Research Services and the PIs (and any SIs) of affected studies.

Investigator/Investigation Committee

4.3 Given the nature of the Allegation, the VP Research may appoint an Investigator or designate an Investigation Committee, and appoint its members, to investigate the Allegation. The VP Research will make best efforts to confirm the appointments to the Investigation Committee within 15 business days of the decision to proceed with an investigation of the Allegation. In the case of an Allegation involving research with Tri-Agency funding, the VP Research shall appoint an Investigation Committee.

4.4 An Investigation Committee shall normally include three persons and include at least one external member who has not been affiliated with the IWK for at least a period of 6 years. The Investigation Committee members or Investigator shall have the necessary expertise and shall not have any conflict of interest, whether real or apparent. The members of the Investigation Committee will select one member to act as a Chair. No member of a department in which a Respondent, or Complainant (if applicable), holds membership will be appointed to the Investigation Committee or as the Investigator.

4.5 A staff member of the Research Services Office (RSO) designated by the VP Research may act as liaison with the Investigation Committee/Investigator to provide administrative support and direction. The liaison person may attend any meetings or interviews of the Investigator or Investigation Committee at the request of the Chair. Where appropriate, and it is recommended in the circumstances that any of the parties are represented by legal counsel, the Chair or RSO liaison may also seek the support and involvement of IWK Legal Services.

4.6 The Respondent and Complainant will have the opportunity to review the membership of the Investigation Committee and to comment on any members who may have a conflict of interest. Any objection to the composition of the Investigation Committee shall be made in writing to the VP Research within 5 business days of being informed of the composition. Any objection will be reasonably considered by the VP Research, however the decision as to composition is in the sole discretion of the VP Research and final.

4.7 The Investigator/Investigation Committee will conduct the investigation in a timely manner. Where the Investigation and initial findings cannot be completed within 60 business days of the first Investigation Committee meeting or the Investigator's

starting date, the Investigator/Investigation Committee will notify the VP Research, the Respondent and Complainant of the reasons for delay and advise them of the expected completion date. Where the Complainant or Respondent has representation, the representative will also be notified.

4.8 The Investigator/Investigation Committee shall collect and review evidence and interview witnesses, including the Complainant and Respondent, to the degree necessary to decide as to whether or not a breach of this Policy has occurred. The Investigator/Investigation Committee may determine its own process in conducting the investigation, providing it is consistent with relevant IWK policies and the principles of natural justice. Additional guidance to support Investigators/ Investigation Committees is found in Appendix B to the Policy.

4.9 The Investigator/Investigation Committee will:

4.9.1 Review pertinent research records and any other evidence relevant to the allegation.
4.9.2 Interview relevant persons, including the Respondent, the Complainant and any witnesses.
4.9.3 Advise interviewees regarding the importance of maintaining confidentiality with respect to these processes.
4.9.4 Provide the Respondent with an opportunity to respond to the Allegation which may be in person or in writing.
4.9.5 Maintain records of interviews and document the process and findings of the investigation.

4.10 Based on the available evidence, the Investigator/Investigation Committee will make an initial determination as to the relevant facts and whether those facts support a finding of research misconduct. The Investigator/Investigation Committee:

4.10.1 Within 10 business days of making this determination, provides the Respondent with a copy of its initial investigation findings and the basis of those findings in a form determined by the Investigator/Investigation Committee

Note: Any concerns regarding the provision of an unredacted report are to be referred to IWK's General Counsel and/or their designated legal services contact person.

4.10.2 Provides the Respondent with 10 business days in which to respond in writing to the initial findings in order to clarify or correct inaccuracies. This response period begins on the date the investigation report was provided to the Respondent.

4.10.3 Within 15 business days after the end of the response period, and after reviewing any response received from the Respondent, determines whether, in their opinion, research misconduct has occurred.

4.11 Within 5 business days of making its determination under Policy 4.10.3, the Investigator/Investigation Committee:

4.11.1 Provides the VP Research (or the President & CEO where applicable) with a written report of the Investigator/Committee's determination, including pertinent facts of the complaint, applicable evidence received and the basis for the decision reached and any response from the Respondent received under 4.10.2 if applicable.

4.11.2 Returns all investigation-related documents and files to the VP Research (or the President & CEO where applicable) for retention as per Policy Statement 3.12.

4.12 Within 10 business days of receiving the Investigator/Investigation Committee's written report, the VP Research (or the President & CEO where applicable) reviews the information provided by the Investigator/Investigation Committee and determines whether they are in agreement with the determination.

5 Unfounded/Unverifiable Allegations

5.1 If, after reviewing the Investigator/Investigation Committee's written account, the VP Research (or the President & CEO where applicable) determines that there is no basis for a finding of research misconduct, they and/or their agents:

5.1.1 Within 10 business days of this determination, notifies the following parties that it has been determined that there is no basis for a finding of research misconduct:

- The REB Chair(s),
- Research Services,
- The Complainant,
- The Respondent,
- The Respondent's supervisor,
- The director (if the Respondent is an employee) or the chief (in the case of physicians) of the Respondent's department/division/program/service,
- PIs (and any Sis) of affected studies,
- The SRCR, if the SRCR was copied on the allegation or notified as per section 2.1.5, and
- The Respondent's associated institution(s) as required.

5.1.2 Returns any materials that were impounded.

5.1.3 Asks the REB Management Committee to reinstate any research activities that were restricted pending the result of the investigation.

5.1.4 Directs Research Services to rescind any restrictions on the administration of research funds (if applicable).

5.1.5 Makes efforts to protect and/or restore the reputation of the Respondent as warranted. This includes retrieving investigation-related documents and files and destroying surplus copies.

5.1.6 If it appears that the allegation was made in bad faith, considers whether there are grounds for corrective action and proceeds accordingly (see Policy Statement 2.4).

5.1.7 Retains records relating to the allegation, investigation and decision in confidential files as outlined in Policy Statement 3.11.

5.2 If the research received Tri-Agency funding and, after reviewing the Investigation Committee's written account, the VP Research determines that there was a breach of Tri-Agency policies, requirements or agreements that did not constitute Research Misconduct, the VP Research will ensure that any reporting required under the RCR Framework or applicable Agency agreement is made to SCRC and the funding Agency occurs.

6 Determination of Research Misconduct

6.1 If, after reviewing the Investigator/Investigation Committee's written account, the VP Research (or the President & CEO where applicable) determines that research misconduct has occurred, they and/or their agents:

6.1.1 Within 10 business days of this determination, informs the Respondent in writing that a determination of research misconduct has been made and advises the Respondent of their right to file a written request for review on the grounds that there was a substantive procedural error in the application of this policy and provides a copy of this notification to the President & CEO.

6.1.2 Retains records relating to the allegation, investigation and determination in confidential files as outlined in Policy Statement 3.11.

7 Review of a Determination of Research Misconduct

7.1 Respondents may request a review of a determination of research misconduct on the grounds that there was a substantive procedural error in the application of this Policy.

7.1.1 Written notice of this request (including details of the asserted procedural error) must be submitted to the President & CEO (or, if the the finding is of research misconduct by the VP Research or their staff) the Chair of the Research Ethics Board).

7.1.2 The President & CEO (or the Chair of the Research Ethics Board where applicable) is to base their decision on the written submission of the Respondent and the VP Research.

7.2 To request a review of the determination of research misconduct pursuant to Process section 6.1.1, the Respondent submits a written request to the President & CEO (or, if the complaint related to the VP Research or their staff, the Chair of the REB Management Committee). The request for review is to be submitted within 10 business days of the delivery of the determination to the Respondent.

7.3 The Respondent's request for review must establish the existence of one or more of the following substantive grounds for appeal:

- evidence of substantive procedural error made by the Investigation Committee/Investigator in reaching their decision.
- evidence of bias or other unfairness on the part of the Investigation Committee/Investigator in reaching their decision; or
- significant new information about the case that was not accessible by reasonable effort prior to the Investigation Committee's/Investigator's decision.

If the request does not meet this threshold, the CEO will advise the Respondent in writing within ten (10) business days that the request is rejected for failure to establish the necessary grounds of appeal.

7.4 After determining there are substantive grounds to proceed with the request for review, with 10 business days the President & CEO (or the Chair of the Research Ethics Board where applicable) :

7.4.1 Notifies the VP Research (or the President & CEO where applicable) that a review has been requested and will proceed.

7.4.2 Notifies the Respondent and Complainant that a review will proceed.

7.4.3 Notifies the REB Management Committee, which then decides whether any research activities should be modified during the review process and, if so, notifies the VP Research (or the President & CEO where applicable), Research Services and the PIs (and any Sis) of affected studies.

7.4.4 Notifies the VP Research (or the President & CEO where applicable), the REB Chair(s) and the Respondent of the result of the review.

7.5 If the review proceeds, the President & CEO (or the Chair of the Research Ethics Board where applicable) may in their discretion assign a "Reviewer" external to the IWK to review the grounds of appeal. The Reviewer shall have full access to all evidence considered by the VP Research and the Investigator/Investigation Committee as well as the Investigator/Investigation Committee's final report and Respondent's appeal letter.

7.6 The Reviewer will submit a report to the President & CEO (or the Chair of the Research Ethics Board where applicable) within 20 business days of assignment considering the appeal and providing an opinion on whether the IWK should uphold, overturn, or vary the Investigator/Investigation Committee's findings and VP Research decision.

7.7 Within 10 business days of receiving and reviewing the Reviewer's report or determining that no Reviewer will be appointed, the President & CEO (or the Chair of the Research Management Committee where applicable) shall inform in writing the Respondent, the Complainant and the VP Research of their decision including any further appropriate course of action, with reasons for the decision, concerning the review. The decision of the President & CEO (or the Chair of the Research Management Committee – Ethics where applicable) is final.

8 Actions and Sanctions Following a Determination of Research Misconduct

8.1 If a review is not initiated or a review is conducted, and it has been determined that there were no substantive procedural errors in the application of this Policy:

8.1.1 The VP Research (or the President and CEO, where applicable) and/or their agents notifies the following parties in writing that a determination of research misconduct has been made:

- The REB Chair(s),
- Research Services,
- The Complainant,
- The Respondent,
- The Respondent's supervisor,
- The director (if the Respondent is an employee) or the chief (in the case of physicians) of the Respondent's IWK department/division/program/service,
- PIs (and any SIs) of affected studies,
- The SRCR, if the SRCR was copied on the allegation or notified as per section 2.1.5
- The Respondent's associated institution(s) as required.

If there is more than one Respondent or Complainant, reasonable efforts will be made to provide each with only the findings that are pertinent to them. Subject to applicable IWK policies and privacy legislation, the VP Research may in their discretion provide any of the notified parties with a copy or portions of any report or findings of the Investigator/Investigation

Committee, ensuring that the Complainant generally receives no less disclosure than the other parties subject to any privacy concerns. Information disclosed should provide information on any improvements to IWK processes and procedures that will be made as a result of the information, however, information related to sanctions or recourse against a Respondent will only be shared with the Respondent, or those who are authorized to have such information.

8.1.2 The VP Research (or the President & CEO where applicable) determines whether any impounded materials should be returned or retained and makes the appropriate arrangements.

8.1.3 The REB Management Committee - Ethics and/or the VP Research implements appropriate actions and/or sanctions of approved research involving the Respondent. This may include, but is not restricted to, suspension or termination of approval of current research activities, notifying research participants, requiring additional training before further projects will be considered, and requiring close oversight (including mandatory internal audits) of current and future studies.

8.1.4 The VP Research (or the President & CEO, where applicable) and/or their agents notifies any other parties who have a legitimate right to be informed of the determination of research misconduct. The VP Research, may in their discretion, provide a summary of any information or reports to these parties as appropriate. These parties may include:

- IWK committees and officials (e.g., Research Management Committee – Ethics, VP Medicine, Medical Advisory Committee, Director's Council),
- IWK departments and services (e.g., Financial Services, Professional Practice, Risk Management and General Counsel),
- Academic institutions (e.g., Dalhousie University), when the Respondent is a faculty member or learner at that institution,
- Affiliated health care institutions (e.g., Nova Scotia Health),
- Sponsors and/or funders associated with the research,
- Publishers,
- Professional licensing bodies, and/or
- Law enforcement agencies, if illegal activity is suspected.

8.1.5 The VP Medicine and/or the VP Research will ensure any required reporting occurs to applicable regulatory authorities of the determination of research misconduct and any actions taken and/or sanctions invoked.

8.1.6 The VP Research (or the President & CEO where applicable) and the IWK committees and officials referred to in the previous section:

8.1.6.1 May conduct further review and/or implement additional actions and/or sanctions (e.g., freezing research accounts, altering privileges, taking corrective action) in accordance with applicable policies, procedures, bylaws and collective agreements.

8.1.6.2 Inform the VP Research (or the President & CEO where applicable), Research Services, the REB, the Respondent and/or other parties, as appropriate, regarding the progress and outcome of any additional review, actions and/or sanctions.

9 Reporting to Tri-Agencies via the Secretariat on Responsible Conduct of Research

Within two months of receipt of an Allegation and within five months of commencing an Investigation, the VP Research (or the President & CEO where applicable) and/or their agents provides the SRCR with a report on each inquiry and investigation concerning Tri-Agency-funded activities or pertaining to funding applications submitted to Tri-Agencies.

Note: To request an extension of this timeline, consult with the SRCR and provide periodic updates until the processes described within this Policy are complete. The frequency of the periodic updates should be determined jointly by the Institution and the SRCR.

9.2 Subject to any applicable laws, including privacy laws, reports are to include the following information:

- The specific allegation(s), a summary of the finding(s) and reasons for the finding(s),
- The process and timelines followed for the inquiry and investigation,
- The Respondent's response to the allegation, investigation and findings, and any measures taken to rectify the breach,
- Determinations made by the VP Research, the President & CEO and the Chair, Research Management Committee – Ethics (as applicable),
- Actions taken by the Institution.

9.3 The report should not include:

- Information that is not related specifically to Agency funding and policies, or
- Personal information about the Respondent, Complainant, researcher, or any other person, including study participants, that is not material to the findings and the report to the SRCR.

10 Reporting to the REB Management Committee

10.1 The VP Research and/or their agents submits an annual report to the Research Management Committee – Ethics summarizing any allegations of research misconduct that were:

- Received, and the general nature of these allegations,
- Dismissed, and the reasons why,
- Referred to other parties, and the reasons why,
- Investigated,

- Resolved, with a brief categorization of the outcomes, and
- Unresolved and/or outstanding at the end of the reporting period.

11 Promoting Awareness and Education

11.1 The Institution is responsible for:

11.1.1. Promoting awareness of responsible conduct of research, including Agency requirements.

11.1.2. Communicating its policy within the Institution and posting, annually, on its website confirmed findings of breaches subject to applicable laws, including privacy laws.

11.1.3. Reporting annually to the SRCR the total number of allegations received involving Agency funds, number of confirmed breaches and the nature of those breaches, subject to applicable laws, including privacy laws.

11.1.4. Communicating the central point of contact responsible for receiving confidential enquiries, allegations and information related to allegations of breaches of Agency policies

REFERENCES

Canadian Institutes of Health Research, http://www.cihr-irsc.gc.ca/ and Natural Sciences and Engineering Research Council of Canada, http://www.nserc-crsng.gc.ca/ and Social Sciences and Humanities Research Council of Canada http://www.sshrc-crsh.gc.ca/ policies and guidelines, including:

- *Tri-Agency Framework: Responsible Conduct of Research, 2021* Tri-Agency Framework: Responsible Conduct of Research (2021)
- *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*., 2010 http://cpsa.ca/wp-content/uploads/2015/06/ethical-conduct-human-research.pdf

Canadian Medical Association https://www.cma.ca p olicies and guidelines, including:

- *Code of Ethics,(March 2018), www.cma.ca/En/Pages/code-of-ethics.aspx*
- *Guidelines for Physicians in Interactions with Industry*. (2007) http://policybase.cma.ca/dbtw-wpd/Policypdf/PD08-01.pdf

Canadian Nurses Association https://www.cna-aiic.ca/en policies and guidelines, including:

- *Code of Ethics for Registered Nurses*.(2017) https://I-aiic.ca/~/medIcna/page-content/pdf-en/code-of-ethics-2017-edition-secure-interactive.pdf?la=en

College of Physicians and Surgeons of Nova Scotia https://cpsns.ns.ca/ policies and guidelines, including:

- *Conflict of Interest Guidelines. (May 25th 2018) https://cpsns.ns.ca/wp-content/uploads/2017/11/Conflict-of-Interest-Standards.pdf*

Council for International Organizations of Medical Sciences (CIOMS) https://cioms.ch/ in collaboration with the World Health Organization (WHO), http://www.who.int/

- *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (2002).http://www.frqs.gouv.qc.ca/documents/10191/186011/CIOMS+ethics+guidelines.pdf/3a3307e9-65f7-4fb1-b7d8-b69c977df155

Council of Canadian Academies,

- *Honesty, Accountability and Trust: Fostering Research Integrity in Canada* (2010). http://scienceadvice.ca/en/assessments/completed/research-integrity.aspx

Dalhousie University https://www.dal.ca/ policies and guidelines, including:

- *Faculty of Medicine Institutional Guidelines for Good Research Conduct, https://medicine.dal.ca/departments/core-units/postgraduate/calendar/research/institutional-guidelines-research-conduct.html*
- *Scholarly Misconduct*. https://www.dal.ca/dept/research-services/responsible-conduct-/research-integrity/scholarly-misconduct-.html

Health Canada https://www.canada.ca/en/health-canada.html legislation and guidelines.

International Committee of Medical Journal Editor

- *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication 2008 . https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3142758/*

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, http://www.ich.org/home.html

- *ICH Harmonised Tripartite Guideline E6: Guideline for Good Clinical Practice* (1996; adopted by Health Canada in 1997). https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6R1_Guideline.pdf

Province of Nova Scotia https://novascotia.ca/ legislation and guidelines.

U.S. Department of Health and Human Services, Office of Research Integrity policies and guidelines.
https://healthfinder.gov/FindServices/Organizations/Organization.aspx?code=HR2971https://healthfinder.gov/FindServices/Organizations/Organization.aspx?code=HR2971

U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research,

- *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (1979). https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

RELATED DOCUMENTS

Policies

IWK 822 - Workplace Harassment and Bullying Program
IWK 116.0 – Discipline
IWK 129.0 – Intellectual Property
IWK 135.0 – Conflict of Interest Policy
IWK 150.0 – Disclosure of Wrongdoing

Other

IWK Research Ethics Board standard operating procedures
Medical Staff Bylaws, Part A General
IWK Medical, Dental and Scientific Staff General Bylaws Pursuant Section 6 of the *Hospital Act and* Section 24 of the *Health Authorities Act*
Research Accountability Statement (available from Research Services)

Appendices

APPENDIX A – Definitions

APPENDIX B – Investigation Guidelines

APPENDIX C – Statement on Dealing with Allegations of Research Misconduct Under United States Public Health Service (USPHS) Research-related Activities for Foreign Institutions

APPENDIX A – DEFINITIONS

Agency/Agencies or Tri-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 or orally to the effect that there has been, or continues to be, research misconduct.
Balance of Probabilities:	It is more likely to have happened than not based on the majority and/or quality of the evidence.
Breach:	A breach of the RCR Framework is a failure to comply with any Agency policy throughout the life cycle of a research project – from application for funding, the conduct of the research and the dissemination of the research results. It includes all activities related to the research, including the management of Agency funds.
Breach of Agency Policies or Ethical Requirements for Certain Types of Research:	Failure to comply with research funding agreements, all applicable Agency and IWK policy requirements, or to comply with relevant policies, laws or regulations, for the conduct of certain types of research activities, including, but not limited to, the following: a. Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans (TCPS 2); b. Canadian Council on Animal Care Policies and Guidelines. c. Agency policies related to the Canadian Environment Assessment Act. d. Licenses for research in the field. e. Canadian Biosafety Standards and Guidelines. f. Controlled Goods Program. g. Canadian Nuclear Safety Commission Regulations. h. Canada's Food and Drugs Act. i. Research funding agreements, Tri-Agency Financial Administration Guide and Agency grants and awards guides; relevant Provincial, Federal and International statutes or regulations for the conduct of research; and j. Failure to obtain appropriate approvals, permits or certifications before conducting research and scholarly activities.
Breach of Agency review processes:	Non-compliance with the Conflict of Interest and Confidentiality Policy of the Tri-Agencies when participating in Tri-Agency review processes or, participating in Tri-Agency review processes while under investigation for a breach of research integrity.

Complainant: The person who makes an allegation of research misconduct.

Conflict of interest: A situation in which someone in a position of trust and in the discharge of one's duties and responsibilities has competing business, financial or personal interests. Such competing interests can make it difficult to fulfill their duties impartially. Even if there is no evidence of improper actions, a conflict of interest can create an appearance of impropriety that can undermine confidence in the ability of that person to act properly or objectively in their position. For further information on identifying and reporting Conflicts of Interests, see IWK 135.0 – Conflict of Interest Policy.

Destruction of research records: The destruction of one's own or another's research data or records or in contravention of the applicable funding agreement, institutional policy and/or laws, regulations and professional or disciplinary standards. This also includes the destruction of data or records to avoid the detection of wrongdoing.

Fabrication: Making up data, source material, methodologies or findings, including graphs and images.

Falsification: Manipulating, changing, or omitting data, source material, methodologies or findings, including graphs and images, without appropriate acknowledgement, such that the research record is not accurately represented.

Financial mismanagement: May include but is not limited to: misleading budget requests; misleading information provided for contractual purposes; failure to comply with the terms and conditions of grants and contracts; failure to correctly identify the source of research funds; and/or misappropriation or misuse of institutional resources, facilities, or equipment.

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

Inquiry: The process of reviewing an allegation of research misconduct to determine whether an investigation is warranted.

Invalid authorship: Inaccurate attribution of authorship, including attribution of authorship to persons other than those who have made a substantial contribution and who accept responsibility for the content of a publication or document.

Investigation: A systematic process of examining an allegation of research misconduct, collecting and examining the evidence related to the allegation, and making a decision as to whether research misconduct has occurred.

Investigator:	For the purposes of this policy, "investigator" refers to a person appointed by the VP Research under section Process 4.3 of this Policy to investigate an allegation of research misconduct. A person appointed as an Investigator may not be an employee, physician, or have an appointment with the IWK unless the Investigator is approved by the Complainant and Respondent.
Investigation Committee:	Committee appointed by VP Research under section Process 4.3 of this Policy to investigate an allegation of research misconduct.
Mismanagement of conflict of interest:	Failure to appropriately manage any real, potential or perceived conflict of interest in accordance with applicable policies and standards.
Misrepresenting Information:	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; providing incomplete, inaccurate or false information in a submission or response to the IWK REB or Research Services; applying for and/or holding a Tri-Agency award when deemed ineligible by the Tri-Agencies or any other research funding organization world-wide for reasons of breach of responsible conduct of research policies such as ethics, integrity or financial management policies; and listing of co-applicants, collaborators or partners without their agreement.
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.
Principal Investigator (PI):	The person responsible for the conduct of a research study at the IWK.
Redundant publications:	The re-publishing of one's own previously published work or part thereof, or data, in the same or another language, without adequate acknowledgement of the source, or justification.
Regulatory Authorities:	Health Canada, the U.S. Department of Health and Human Services, the U.S. Food and Drug Administration and other bodies having the power to regulate pharmaceuticals, devices, medical procedures, or other areas of research.
Research:	An undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.
Researcher:	Anyone who conducts research activities falling under the jurisdiction of the IWK Research Ethics Board.

Research Ethics Board (REB): A body of researchers, community members, lawyers, and others with specific expertise (e.g., in ethics, relevant research disciplines) established by the IWK to review the ethical acceptability of all research involving humans conducted within its jurisdiction or under its auspices.

Research integrity: Intentional and consistent adherence with the highest principles and standards for research.

Research Misconduct: Includes but is not limited to:

- Breach of Agency or IWK Policies or Ethical Requirements for Certain Types of Research
- Breach of Agency Review Processes
- Deception,
- Fabrication,
- Falsification,
- Destruction of Research Records,
- Plagiarism,
- Redundant Publications,
- Invalid Authorship,
- Inadequate Acknowledgement,
- Mismanagement of Conflict of Interest,
- Misrepresenting Information,
- Financial Mismanagement,
- Material failure to comply with relevant laws or regulations, agreements, or published policies of the IWK or sponsor that are applicable to the conduct and reporting of the research.
- Failure to comply with a direction of the IWK REB upon which an approval to proceed was granted or failing to notify the IWK REB of material changes to the protocol or research approval as per IWK REB policies.
- Material breach of confidentiality including but not limited to breaches of a duty to protect personal information (including but not limited to personal health information); breaches of a duty of confidentiality owed to a colleague;); breaches of a duty of confidentiality owed to under a contract; deliberate destruction of another person’s data or records without authorization; or breach of confidentiality due to an investigation under this Policy.
- Failure to obtain appropriate approvals, permits, or certification for the conduct of the research.
- Willfully misrepresenting and misinterpreting (for any reason) of research findings.
- Condoning or not reporting research misconduct by another IWK employee, physician, scientist or student.
- Encouraging or facilitating another researcher to carry out Research Misconduct or otherwise creating an environment that promotes Research Misconduct by another.
- Making an allegation under this Policy in bad faith.

- Retaliation against a person who acted in good faith and reported or provided information about alleged Research Misconduct.

A finding of Research Misconduct requires all three of the following to be present:

- a serious deviation from commonly accepted ethics and integrity standards or practices for proposing, conducting or reporting the relevant research
- an intentional, knowing, or reckless act meaning without due consideration to the circumstances (i.e., not seeking critical information or not being informed of relevant research protocols) and
- proof by a preponderance of evidence.

Research misconduct does not include honest error when due consideration is exercised, honest difference of opinion or honest difference in research methodologies.

Responsible Allegation

An allegation: 1) that is based on facts which have not been the subject of a previous investigation; 2) that involves possible research misconduct; and 3) which would, if proven, have constituted research misconduct at the time the alleged breach occurred.

Responsible Conduct of Research

Responsible Conduct of Research is the behavior expected of anyone who conducts or supports research activities throughout the life cycle of a research project (i.e., from the formulation of the research question, through the design, conduct, collection of data, and analysis of the research, to its reporting, publication and dissemination, as well as the management of research funds). It involves the awareness and application of established professional norms, as well as values and ethical principles that are essential in the performance of all activities related to research. These values include honesty, fairness, trust, accountability, and openness.

Respondent:

The person against whom an allegation of research misconduct is made, or who may be implicated in an allegation, or who becomes the subject of an investigation.

Secretariat on Responsible Conduct of Research (SRCR)

The body responsible for administering policies of the Tri-Agencies.

Serious Breach

Research Misconduct that jeopardizes the safety of an individual, 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; using animals in a study with significant risks or harms without appropriate animal care committee approval, or not following approved protocols; deliberate misuse of research grant funds for personal benefit not related to research; knowingly publishing research results based on fabricated data; obtaining grant/award funds from an Agency by misrepresenting one's credentials, qualifications and/or research contributions in an application.
Sponsor:	The individual, company, institution, or organization that takes responsibility for the initiation, management and regulatory compliance (if applicable) of a research study. There may be only one sponsor per study.
Supervising Investigator (SI):	An IWK staff member who accepts overall clinical and supervisory responsibility during the conduct of a research study at the IWK, as specified in the Ethics Approval Submission Form. Applies only to non-interventional studies where the principal investigator is a trainee and/or is not an IWK staff member. *Previously referred to as the "site investigator".*
Supervisor:	For the purposes of this policy, "supervisor" refers to the person to whom the Respondent directly reports at IWK. In most cases this will be the Respondent's department or division chief, manager, director or principal investigator.
Tri-Agencies:	Canada's three federal granting agencies: the Canadian Institutes of Health Research (CIHR); the Natural Sciences and Engineering Research Council (NSERC); and the Social Sciences and Humanities Research Council (SSHRC).
VP Research and Innovation:	Refers to the vice president with responsibility for the research portfolio at the IWK.
Witnesses:	Persons who have personal knowledge of an incident or who may have information related to an investigation of research misconduct.

Many of these definitions have been taken from, or are based upon, definitions listed in the 2nd Edition of the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans (TCPS 2), the Tri-Agency Framework: Responsible Conduct of Research, and ICH Guidance E6: Guideline for Good Clinical Practice.

APPENDIX B – Investigation Guidelines for Investigator or Investigation Committee

The following are guidelines provided for the support of Investigators and Investigation Committees, but compliance is not strictly required by the Policy. If there is any conflict between these guidelines and the Policy, the Policy prevails.

Investigation Conduct:

The Investigator or Investigation Committee will review the Allegation, any response(s) from the Respondent and any evidence or materials submitted or collected. At any stage of the investigation, the Investigator or Investigative Committee may request additional records to be obtained in order to complete the investigation.

The Investigator or Investigation Committee should give the opportunity to the Complainant to provide any supplementary written materials in addition to the Allegation that the Complainant wishes to provide.

The Investigator or Investigation Committee should take steps to provide to the Respondent reasonable access to relevant documents in its possession so as to provide the Respondent with a fair opportunity to respond to relevant material. The Investigator or Investigation Committee may provide access to particular documents to the Complainant in special cases where it is believed that a response from the Complainant is required to help in determining the facts of the investigation. The Respondent and if applicable, the Complainant, may be required to sign a confidentiality agreement before materials are provided.

The Respondent should be given reasonable access to all materials received from the Complainant concerning the Allegation. If there is a concern with respect to sharing of certain information regarding the Complainant with the Respondent, the Investigator or Investigation Committee may reasonably redact or withhold such information, but will advise the Respondent of the general nature of the information that has been redacted or withheld.

The Respondent should generally have the opportunity to comment, in writing, and provide any supplementary written materials in response to the Allegations.

An Investigator or Investigation Committee is not to conduct a hearing and is only obliged to conduct a fair and objective investigation. They may in their discretion, request an interview with any or all of the Complainant, the Respondent, or other relevant people. Written summaries of interviews (but generally not verbatim text or audio recordings) should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigation file.

For investigations conducted by an Investigation Committee, such interviews may be conducted by one member or a sub-group of the Investigation Committee. The individuals conducting interviews on behalf of an Investigation Committee should remain consistent if possible.

When applicable, the Investigator or Investigation Committee should invite the Respondent and the Complainant to appear separately to be heard and to provide evidence. The

Respondent and the Complainant should have the right to have one person of their choosing, including legal counsel, attend the meeting/interview with the Committee as an advisor. The name and position of the person should be provided to the Investigation Committee Chair at least 3 working days prior to any meeting. Requests for additional persons to attend with the Complainant or the Respondent as advisors will be at the discretion of the Investigator or Investigation Committee Chair, however such requests should not be unreasonably denied. An advisor may not appear as a witness or provide evidence to the Investigator or Investigation Committee.

At any point during witness interviews, including if the Complainant or Respondent's legal counsel attends, the Investigation Committee Chair may ask IWK Legal Counsel to be present as well.

Where an Investigator or Investigative Committee gathers evidence from witnesses, the Investigator or Investigative Committee should consider whether the evidence is sufficiently critical to prepare a report of testimony and provide this to the Respondent for review and comment. The Respondent should be provided with a reasonable amount of time upon receipt of such a report to respond to the report either orally or in writing.

An Investigator or Investigation Committee may seek impartial expert opinions (from outside the Institution if required), as necessary and appropriate, to ensure that the investigation is thorough and authoritative provided that the Chair advises the VP Research and obtains approval before incurring any expenses associated with obtaining an opinion. The Respondent may challenge the appointment of any expert for bias or conflict of interest. The validity of a challenge shall be determined by the VP Research whose determination shall be final.

An Investigator or an Investigation Committee may set reasonable deadlines by which responses must be made and evidence must be submitted in order to ensure compliance with the Policy. No response or evidence will be accepted after the deadline except where the Investigator or Investigation Committee Chair has agreed to an extension and no significant prejudice would result to a party as a result of the delay.

All involved parties who are associated with the Institution will be expected to cooperate with the investigation in a timely manner. This includes providing documentation and information and appearing before the Investigator or Investigation Committee if requested. If a witness, Committee member, or party to the Investigation fails to reasonably cooperate with the conduct of the Investigation, the Investigator or Investigative Committee Chair may report the behaviour to the VP Research.

<u>Investigation Records:</u>

The Investigator or Investigation Committee Chair will ensure a record is made of all relevant documentation and evidence collected and reviewed as part of the investigation and that such records are managed and delivered in keeping with the Policy.

After an Investigation Committee delivers its report, the Chair should notify all members of the Investigation Committee to return all documentation to the Chair or VP Research or VP Research agent and not to keep any copies of materials related to the investigation.

New Allegations

If, during the course of the investigation, information gathered discloses a new related instance of possible Research Misconduct that was not part of the original Allegation or which suggests additional Respondents, the Investigator or Investigation Committee may expand the investigation, provided that the VP Research, Complainant and Respondent are notified and the Respondent is allowed to respond to the new instances of possible Research Misconduct. If the expanded investigation involves new Respondents, they will be provided with notice and shall for the purpose of this Policy, be treated as Respondents.

Interim Findings:

If there are interim findings that the Investigator or Investigation Committee believes ought to be reported in order to protect the public good and the interests of other researchers or the Institution, the Investigator or Investigation Committee Chair may make a written interim report to the VP Research setting out the findings, the reason for the report, and a recommendation regarding appropriate administrative action. Any interim report should be in writing and copied to all members of the Investigation Committee, to the Complainant and the Respondent**.**

Investigation Reports:

The investigation report might include the following elements where determined appropriate by the Investigator or Investigation Committee:

- the Allegation
- list of the Committee members and their credentials
- Outline of the process and timelines followed for the inquiry and/or investigation, including any agreed upon changes to timelines
- summary of relevant evidence including sources and a list of those who were interviewed as witnesses
- respondent's response to the allegation, investigation and findings, and any measures the respondent has taken to rectify the breach
- finding of whether Research Misconduct occurred and if so, its extent and seriousness
- any mitigating factors related to the Research Misconduct
- recommendations to the VP Research on remedial action to be taken and/or recommendations of changes to procedures or practices to avoid similar situation
- identification of any reporting requirements or additional affected parties for consideration by VP Research resulting from Research Misconduct finding
- whether a serious scientific error has been made which does not constitute Research Misconduct.

Investigation reports should generally not contain the following:

- Personal information that is not relevant to the Allegation or finding (i.e. full CVs, identifiable personal health information)
- Legal advice provided to any party, witness, Investigator or Investigation Committee, the Institution or its representatives

Investigators or Investigation Committees may wish to consult IWK Legal Services if there are any questions in relation to information that should not be contained in an investigation report.

Once delivered to the VP Research, the report of the Investigator or Investigation Committee is final and not subject to revision except for factual error or honest mistake.

Investigation Recommendations:

Recommendations of the Investigative Committee or Investigator may include recommendations on any remedial action to be taken to correct the scientific or scholarly record in the matter in question and/or recommendations of changes to procedures or practices to avoid similar situations in the future, which may include, without limitation:

- Withdrawing all pending relevant publications;
- Notifying publications in which the involved research was reported;
- Ensuring the groups or clinical units involved are informed of appropriate practices for promoting the proper conduct of research; and,
- Informing any sponsor or outside funding entity of the research that is the subject of the Complaint of the results of the inquiry and of actions to be taken;

Recommendations of the Investigator or Investigative Committee should generally not include recommendations with respect to disciplinary actions to be taken under applicable Institution policies or procedures or recommendations for changes to the Institution's funding and policies that do not pertain to the Allegation. If an Investigator or Investigation Committee wishes to make recommendations of this nature, the Investigator or Investigation Committee Chair should discuss such a request with the VP Research and IWK Legal Counsel before proceeding.

APPENDIX C – Statement on Dealing with Allegations of Research Misconduct under United States Public Health Service (USPHS) Research-related Activities for Foreign Institutions

The Izaak Walton Killam Health Centre ("IWK") has incorporated into its policies and procedures the following approach for dealing with and reporting possible research misconduct when USPHS funds are involved.

1. The IWK will designate an official to receive allegations and develop procedures for use by research employees or others who wish to make an allegation of research misconduct involving USPHS funds. This designated official will notify the U.S. Office of Research Integrity (ORI) when an allegation of research misconduct involving USPHS funds is received. Phone: (240) 453-8800. Fax: (301) 594-0043. E-mail: askORI@osophs.dhhs.gov.

2. The IWK will then work with ORI or other appropriate offices of the U.S. Department of Health and Human Services (HHS) to develop and implement a process for responding to the research misconduct allegation that is consistent with U.S. Federal regulation, 42 CFR Parts 50 and 93.

3. The IWK will submit appropriate reports (in English) to ORI that describe the process followed in conducting the investigation, the evidence on which the conclusions of the investigation are based, and if a finding of research misconduct is made, the administrative actions that are taken against the Respondent.

4. The IWK will inform research employees about the official who is designated to receive allegations and the procedures for the employee or other individuals to make an allegation of research misconduct involving USPHS supported research. This information will also be posted on the organization's web site.

5. The IWK certifies that this statement will be a permanent amendment to the institution's procedures for responding to allegations of research misconduct.

6. The IWK will submit the "Annual Report on Possible Research Misconduct" to ORI by March 1 of each year. The report is submitted electronically through the ORI web site at http://ori.hhs.gov.

* * *

District Health Authority/IWK Policies Being Replaced

Version History

(To Be Completed by the Policy Office)

Major Revisions (e.g. Standard 4 year review)	Minor Revisions (e.g. spelling correction, wording changes, etc.)
2018	
2022	