

Title:	Policy and procedure for managing allegations of breach of responsible conduct of research at CIUSSS du Centre-Ouest-de-l'Île-de-Montréal	
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SUMMARY

The policy and procedure for managing allegations of breach of responsible conduct of research applies to all actors at the Centre intégré universitaire en santé et services sociaux du Centre-Ouest-de-l'Île-de-Montréal (CCOMTL) involved in research activities carried out under the auspices or under the responsibility of the institution.

The CCOMTL is required to promote the responsible conduct of research and to establish a procedure for handling allegations of breach of responsible conduct of research. As such, this policy and procedure for managing allegations of breach of responsible conduct of research at the CCOMTL is governed by the Ministère de la Santé et des Services sociaux's (MSSS) Ministerial Reference Framework for Research Involving Human Participants (MSSS 2020), the Fonds de recherche du Québec's Policy for the Responsible Conduct of Research (FRQ 2014), and the Tri-Agency Framework: Responsible Conduct of Research (Social Sciences and Humanities Research Council, Natural Sciences and Engineering Research Council, and Canadian Institutes of Health Research) (2016).

This policy and procedure first sets out what constitutes responsible conduct of research, as well as the behaviour expected of the various actors targeted by the policy in the conduct of research activities. This expected behaviour is based on values such as honesty, reliability and rigour, objectivity, fairness and independence, justice (especially in recognizing the contributions of others), trust, accountability and benevolence, openness and transparency. It then presents the breaches of responsible conduct of research as described in the FRQ's Policy for the Responsible Conduct of Research.

This policy and procedure governs the management of allegations of breach of responsible conduct of research that are reported to the designated authority and that relate to research activities. It outlines the role of the Responsible Conduct of Research Officer (RCRO) as the person designated by the CCOMTL to perform the preliminary assessment of admissibility of the allegation, the examination of the allegation, and the convening of a complaint review committee, if necessary. It describes the guiding principles of the examination of allegations, the various steps, and the roles and responsibilities of each actor at each step.

1. SCOPE

This policy and procedure applies to all actors involved in Research activities that, regardless of the type of research or funding:

- are conducted in whole or in part at the CCOMTL or for which the CCOMTL is responsible;
- involve users or their loved ones, employees or physicians of the CCOMTL;
- use information contained in user records held by the institution;
- use human biological material stored at or obtained from the CCOMTL, or information derived from it;
- use the human, material, or financial resources of the CCOMTL;
- include the creation or use of a database or biobank created for research purposes.

In particular, it targets the managers and staff (despite each one having different roles and responsibilities) in all the clinical and administrative departments of the CCOMTL who supervise, support, or participate in Research projects, namely Investigators, physicians, pharmacists and dentists, Research staff, students, postdoctoral fellows, managers of research funds, Research Review Office staff, members of research ethics boards, staff from the Academic Affairs and Research Ethics Directorate and the Lady Davis Institute (LDI) who assist the Investigators with submitting research projects, and the Responsible Conduct of Research Officer (RCRO) at the CCOMTL.

Under Section 4 of the *Act to modify the organization and governance of the health and social services network, in particular by abolishing the regional agencies* (R.S.Q., c. O-7.2), the CCOMTL is the institution responsible for implementing the policy and procedure for managing allegations of breach of responsible conduct of research.

2. GENERAL FRAMEWORK

In accordance with the Ministère de la Santé et des Services sociaux's (MSSS) Framework for Research Involving Human Participants (MSSS 2020), the Fonds de recherche du Québec's Policy for the Responsible Conduct of Research (FRQ 2014), and the Tri-Agency Framework: Responsible Conduct of Research (Social Sciences and Humanities Research Council, Natural Sciences and Engineering Research Council, and Canadian Institutes of Health Research) (2016), the Institution is required to promote the responsible conduct of research and to establish a procedure for handling allegations of breach of responsible conduct of research. Any institution that receives funding from the Fonds de recherche du Québec (FRQ), that is a trustee of such funds, or that hosts FRQ fellows shall have a policy on the responsible conduct of research and a procedure for managing allegations of breach of responsible conduct of research that meets the requirements of the FRQ. In terms of responsible conduct of research, the MSSS's reference framework adheres to the standards and policy of the FRQ. The institution's procedure must therefore meet the minimum requirements of the FRQ, as set out in Standard 9 of the Ministerial Reference Framework. The Ministerial Reference Framework states, however, that the "standard in no way impacts the prerogatives of the institution's local service quality and complaints commissioner (LSQCC) and the medical examiner with respect to a research participant's right to file a complaint and the authority of the commissioner and the medical examiner to conduct a review."

3. DESCRIPTION OF THE POLICY AND PROCEDURE

3.1. Subject

This policy and procedure provides a framework for managing allegations of breach of responsible conduct of research that are reported to the designated authority and that concern research activities as defined in Section 1. It sets out the steps involved, as well as the roles and responsibilities of the various actors at each of these steps.

3.2. Definitions

The definitions retained for the following terms are those proposed or inspired by the Fonds de recherche du Québec, with the necessary adaptations as required.

Allegation of breach of responsible conduct of research: An assertion or statement relating to facts whose existence remains to be confirmed by the preponderance of evidence on a balance of probabilities. An allegation handled by the LSQCC or the medical examiner in accordance with Section 34, paragraph 2 of the *Act respecting health services and social services* (R.S.Q., c. S-4.2) is a complaint for the application of this policy and procedure.

Board of Directors: The CCOMTL's Board of Directors, as defined by sections 9 and 10 of the *Act to modify the organization and governance of the health and social services network, in particular by abolishing the regional agencies* (R.S.Q., c. O-7.2).

Complainant: Any person, whether or not an employee of the institution (manager, clinician, physician, research personnel, student, REB member, user, etc.), who is directly or indirectly informed of a breach of responsible conduct of research and who reports the facts thereof to the RCRO or files a complaint with the LSQCC.

Conflict of interest: Circumstance of a person or organization in a real, perceived, or potential conflict between their duties or responsibilities related to the Research Activities and their personal, institutional or other interests.

Funding: Financial support granted by a public or private funding agency in the form of a scholarship or a grant.

Infrastructure: Major facility or research centre supported by the Fonds de recherche du Québec through their various funding programs.

Institution: An institution is a legal entity with legal capacities and responsibilities that is licensed by the Ministère de la Santé et des Services sociaux (MSSS). According to Section 94 of the AHSSS, an institution is any person or partnership carrying on activities inherent to the mission of one or more of the following centres: residential and long-term care centre (CHSLD), local community service centre (CLSC), child and youth protection centre (CPEJ), rehabilitation centre (CR), and hospital centre (CH). An institution has a Board of Directors and is covered by the liability insurance plan of the Direction des assurances du RSSS (DARSSS).

LDI: Lady Davis Institute for Medical Research.

Multiple-status person: When filing an Allegation, any person for whom both the University and the institution can be considered their employer under the *Act respecting labour standards* (CQLR, c. N-1.1), or any person with a current University appointment who is not considered a University staff member.

Research activities: All steps included in the life cycle of knowledge creation through rigorous methodologies that are—or are in the process of becoming—recognized by peers, spanning from the initial project proposal to the dissemination of results, including applications for research funding and peer review. These steps also include activities related to research management.

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Research ethics: All Research activities must be conducted in accordance with a set of ethical standards for research, such as those set out in the Tri-Council Policy Statement, the ethics standards of the FRQ (Fonds de recherche du Québec), or the *Politique d'éthique et d'intégrité scientifique* of the FRQNT (Fonds de recherche du Québec - Nature et technologie). These standards are primarily concerned with the deontological approach governing the behaviour of researchers, students and research personnel regarding the respect and protection of human participants and animals used in research. In Québec, research ethics boards (REB) and animal protection committees ensure that all research involving human participants or animals (respectively) complies with these ethical standards.

Research Ethics Board: A group of individuals with specific expertise (e.g., in ethics or relevant research disciplines) formed by an organization to review the ethical acceptability of any research involving human participants conducted under the organization's jurisdiction or under its auspices, in accordance with applicable standards and laws.

Research integrity: The coherent and consistent application of values and principles essential to encouraging and achieving excellence in the search for, and dissemination of, knowledge. These values include honesty, fairness, trust, accountability, and openness (Council of Canadian Academies' Expert Panel on Research Integrity).

Research participant: An individual who directly participates in research, whose data, biological material, responses to interventions, stimuli, or questions by a Researcher are relevant to answering a research question; Also referred to as "human participant" or, in other policies/guidelines, as "subject" or "research subject."

Research personnel: Person employed by the CCOMTL or an academic institution to take part in research activities. This person may be a research professional or a support staff for the research activities being conducted at the CCOMTL. Employees may also include postdoctoral fellows or students in certain contexts.

Research Review Office of the CCOMTL: Office comprised of staff that coordinate and support the institutional suitability and ethics review of research projects conducted at the CIUSSS du Centre-Ouest-de-l'Île-de-Montréal and at the facilities and sites it administers, or that involve users of its care and services, under the authority of the person formally mandated to authorize the research.

Researcher: A person to whom the CCOMTL has awarded research privileges, excluding research personnel or students (see respective definitions for these terms).

Respondent: Person who is the subject of an allegation of breach of responsible conduct of research, in an assertion or statement of fact that remains to be validated and that implies non-compliance with the policy on the responsible conduct of research.

Responsible Conduct of Research Officer (RCRO): Person mandated by the institution to oversee the dissemination and application of the institutional policy on the responsible conduct of research.

Responsible conduct of research: The behaviour expected of researchers, students, research personnel, and fund managers in the conduct of research activities, in accordance with the criteria specified in the Policy for the Responsible Conduct of Research (2014) and presented in the CCOMTL's Policy and procedure for managing allegations of breach of responsible conduct of research.

Student: A person registered at an academic institution for the purpose of obtaining a degree, diploma or other academic recognition requiring that they engage in research activities. A student may be a college student, an undergraduate, graduate or postgraduate university student or, in certain contexts, a postdoctoral fellow.

3.3. Responsible conduct of research

As described in more detail in the FRQ's Policy for the Responsible Conduct of Research, responsible conduct of research refers to the behaviour expected of the various actors targeted by the policy in the conduct of research activities. This expected behaviour is based on values such as honesty, reliability and rigour, objectivity, fairness and independence, justice (especially in recognizing the contributions of others), trust, accountability and benevolence, openness and transparency.

The expected elements of responsible conduct of research, detailed in the policy, are as follows:

- a) Conduct research in an honest search for knowledge;
- b) Foster an environment of research integrity, accountability and public trust;
- c) Maintain an appropriate level of knowledge and expertise, and act accordingly;
- d) Review the work of others with integrity;
- e) Avoid conflicts of interest, or if they cannot be avoided, address them in an ethical manner;
- f) Be transparent and honest in applying for and managing public funds;
- g) Use research funds and resources responsibly and provide accountability;
- h) Report on research in a responsible and timely fashion;
- i) Treat data with scholarly rigour;
- j) Acknowledge all contributors and contributions in research;
- k) Treat all research participants fairly and with respect and consider the environmental impact of research;
- l) Define the responsibilities of partners in the responsible conduct of research;
- m) Promote the responsible conduct of research and remain up to date with the development of best practices.

3.4. Breaches of responsible conduct of research

The CCOMTL adheres to the definitions of breach of responsible conduct of research as described in the FRQ's Policy for the Responsible Conduct of Research. They are as follows:

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 acknowledgement and which results in inaccurate findings or conclusions.

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

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.

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.

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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.

Inadequate acknowledgement: Failure to appropriately recognize contributions of others in a manner consistent with their respective contributions and authorship policies of relevant publications. Inadequate acknowledgement also includes failure to mention the source of funding of the research activities, as required by the funding agencies.

Mismanagement of conflict of interest: Failure to appropriately manage any real, potential or perceived conflict of interest, in accordance with the institution's policies and procedures on conflict of interest and the REB's standard operating procedures on conflict of interest.

Misrepresentation in an agency application or related document:

- a) Providing incomplete, inaccurate or false information in a grant or award application or related document, such as a letter of support or a progress report.
- b) Applying for and/or holding funds from an agency when deemed ineligible to apply for or hold funds from such agency for reasons of breach of responsible conduct of research policies, such as ethics, integrity, or financial management policies.
- c) Listing of collaborators or partners without their consent.

Mismanagement of grants or award funds: Using grants or award funds for purposes inconsistent with the policies of the funding agency; misappropriating grants and award funds; contravening the institution's financial policies; destroying relevant documents in an untimely manner or providing incomplete, inaccurate or false information on documentation for expenditures from grant or award accounts.

Breaches of policies or requirements for certain types of research: Failing to meet agency policy requirements or to comply with relevant policies, laws or regulations providing clear and compulsory directives for the conduct of certain types of research activities; failing to obtain appropriate approvals, permits or certifications before conducting these research activities; failing to respect confidentiality agreements.

Infringement of the integrity of a scientific peer review process and the awarding of funding: Collusion; failure to appropriately manage conflict of interest; appropriating the work of another following a scientific assessment; or failure to respect confidentiality.

False or misleading allegations: Making malicious or knowingly false allegations of research misconduct or accusing a person of such a breach.

3.5. Responsible Conduct of Research Officer (RCRO) at the CCOMTL

As stated in the MSSS's Reference Framework for Research Involving Human Participants, research misconduct cases must be handled separately from the research itself. The institution must designate a Responsible Conduct of Research Officer (RCRO). This Officer must hold a position with a sufficient level of independence and decision-making autonomy, namely to appropriately address any conflicts of interest associated with the management of allegations of breach of responsible conduct of research. At the CCOMTL, the Associate Executive Director is designated as the RCRO and ensures that the institution promotes the responsible conduct of research, in particular through training for its community members. They are supported by the personnel in the institution's Research Review Office. The RCRO oversees the allegations management process for the CCOMTL.

The RCRO receives and processes allegations of breach of responsible conduct of research according to the procedures set out in sections 4 and 5 of this document and summarized in the process diagram in Appendix 1. They may hire staff to assist them in this role. At the initial review stage, they may also work with another manager at the CCOMTL or the University, chosen based on the grounds or nature of the allegation.

3.6. Guidelines for the review of allegations of breach of responsible conduct of research

Confidentiality

The institution and anyone involved in the allegation management process have the responsibility to protect the confidentiality of sensitive information concerning all parties involved, in accordance with applicable laws. The communication of personal information is limited to the individuals responsible for managing the review, making the decision, and applying the disciplinary measures. As long as there is no proven breach, reviews shall be reported in accordance with the requirements of the funding agencies, and confidentiality and anonymity must be maintained at all steps. The annual report submitted by the RCRO to the institution's Board of Directors shall contain only information on the number and nature of allegations of breach of responsible conduct of research.

As such, the communication of personal information is limited to that which is strictly necessary for the preliminary assessment of the allegation and, if necessary, its review, and to the smallest number of people possible.

Other guidelines

The persons involved in the management of allegations of breach of responsible conduct of research shall agree to follow these guidelines and sign an undertaking to that effect:

- a) demonstrate the highest standards of transparency in any situation of conflict of interest, real or apparent, and manage these situations appropriately;
- b) be impartial;
- c) show discretion and respect the confidentiality of sensitive information;
- d) comply with the principles of procedural fairness and natural justice when managing a breach of responsible conduct of research allegation. If pertinent, they will seek advice from the institution's Legal Affairs office.

4. ALLEGATIONS REVIEW PROCESS

4.1. Information and support prior to filing an allegation

Prior to filing an allegation, any person may contact the RCRO or their support staff for assistance in determining whether a fact or event constitutes a possible breach of responsible conduct of research and to discuss the most appropriate body for handling the allegation, depending on the grounds or nature of the allegation.

4.2. Receiving an allegation and reviewing the grounds

The RCRO shall receive all allegations and is responsible for carrying out a preliminary assessment of the complaint's admissibility. Allegations of research misconduct may sometimes be addressed to the Local Service Quality and Complaints Commissioner (LSQCC), when a user or a research participant chooses this route, as permitted by the *Act respecting health services and social services* (the "AHSS") (Section 34, paragraph 2).

In fact, a research participant who files a complaint regarding care or services received, or that should have been received, during a research project, or regarding a medical, dental, or pharmaceutical act or the behaviour of a

person conducting the research project, would request a review by the LSQCC or the medical examiner rather than by the RCRO.

As such, when a complaint or an allegation of breach related to a research project is received, it is important to examine the grounds to ensure the complainant is referred to the right place.

Filing an allegation with the RCRO:

Any person may file an allegation of a breach of responsible conduct of research.

A form is available on the CCOMTL website for filing an allegation, under the University Mission tab (see Appendix 2). Any person may also file an allegation by contacting the RCRO in writing or by telephone. Whether using the form or another means, the complainant is required to provide the following information:

- The grounds or nature of the breach (see Section 3.4);
- A description of the facts and context, including information about the research project and the link between the breach and the institution;
- The date on which the breach was allegedly made and observed;
- Name(s) and position(s) of the person(s) concerned by the allegation;
- The perceived degree of urgency to intervene;
- Any other information required to understand the allegation.

The allegation can be filed by a research participant or their representative, a personnel member, an REB member, an investigator or a member of their team, or any other person. Upon review of the grounds by the RCRO, if the allegation concerns a complaint related to a medical, dental or pharmaceutical act, or to care or services received, or that should have been received, or to the behaviour of a staff member of the CIUSSS, a physician or a dentist toward the research participant, the RCRO will refer the complainant to the LSQCC, who will forward the complaint to the medical examiner if it involves a physician, dentist or resident.

For any other grounds for a misconduct allegation, the RCRO can carry out the preliminary assessment with another manager (see 4.3 Preliminary assessment).

Filing a complaint with the LSQCS regarding a research project

Research participants have the same rights as other users receiving health and social services, in particular with respect to the complaints process. Any person, whether or not a user, who participates in research may make a complaint to the LSQCC concerning the research (Section 34, AHSSS). The LSQCC will review the complaint in accordance with their role and the *By-law respecting the complaint examination procedure*. If the complaint relates to a medical or dental act received as part of a research protocol, and involves a physician, dentist or medical resident, the LSQCC transfers the complaint to the medical examiner, in accordance with the AHSSS and the institution's *By-law respecting the complaint examination procedure*. If the complaint relates to an administrative or organizational issue associated with care or services received, or that should have been received, by a research participant as part of a research project, or relates to a professional act other than medical or dental, the complaint is examined by the LSQCC in accordance with the AHSSS and the institution's *By-law respecting the complaint examination procedure*. For any other grounds for an allegation of breach of responsible conduct of research, the LSQCC transfers the complaint to the RCRO, who will review the allegation.

The application of the policy shall not have the effect of interfering with the duties and functions of the LSQCC, or of preventing the LSQCC or the medical examiner from exercising the jurisdiction granted to them in accordance with the AHSSS and the institution's *By-law respecting the complaint examination procedure*.

4.3. Preliminary assessment of admissibility of the allegation

The institution reviews the admissibility of all allegations received. Its personnel compile all information on the grounds for the allegations, to determine the need for information and training related to the responsible conduct of research, whether or not the allegations are founded.

The purpose of the preliminary assessment of admissibility is to determine whether there are sufficient facts or information indicating a possible breach of responsible conduct of research requiring further investigation.

During the preliminary assessment, the RCRO may work with another **manager** at the institution to assess the admissibility of the allegation. This manager will be chosen based on the grounds for the allegation.

Good review practices for allegations of breach of responsible conduct of research include the right to be heard for the respondent. The complainant will be contacted for more information, if necessary.

Information and consultation with the REB, RRO or other managers

As needed, the RCRO may consult with the chairs of the research ethics boards of the CCOMTL, in the event the allegation concerns non-compliance with conditions related to ethics certification. All research involving human participants shall be assessed and approved by an REB prior to the start of any research-related activities, whether the reviewing REB is that of the CCOMTL or another institution, in the case of a multicentre research project. Moreover, as stated in Standard 1 of the Ministerial Framework for Research Involving Human Participants (MSSS 2020), for all research conducted under the auspices of an institution in the health and social services network (HSSN), the ethics review shall be conducted by an REB within the HSSN or by the MSSS's Comité central d'éthique de la recherche. A researcher who has not obtained this approval from an appropriate REB, prior to the start of research activities, would thus be in breach of responsible conduct of research. The RCRO may need to verify with the REB whether approval was properly obtained according to the rules. Furthermore, as described in the standard operating procedures *Ongoing REB Review Activities* (REB-SOP 405A.001) and *Suspension or Termination of REB Approval* (REB-SOP 407.001), certain measures may need to be taken by the REB.

If necessary, the RCRO may also consult with a manager in the RRO, the LDI, or the Financial Resources Directorate to obtain any relevant documentation related to a research protocol, contract or award, while ensuring the guidelines in Section 3.6 are respected.

Information and consultation with the University

When the allegations involve a University student, a University personnel member, or a multiple-status individual, the CCOMTL's RCRO is required to inform and consult with the University.

University affiliation contracts (Section 4.4. Obligations of the Parties) stipulate that the institution and its affiliated universities shall inform each other of any information concerning complaints or allegations of breach of responsible conduct of research policies, related to the behaviour of a student, a researcher or a research staff member, or a faculty member carrying out their academic activities at the institution. The contracts state that the institution and its affiliated universities shall also agree on the procedure for handling complaints or allegations of breach of responsible conduct of research by drafting a specific agreement.

The CCOMTL's RCRO shall inform and consult with the University's RCRO when the respondent falls into one of these categories:

- 1) A member of the University's personnel, i.e., an employee whose sole employment relationship is with the University, within the meaning of the *Act respecting labour standards* (whether or not subject to a collective agreement), or a student at the University, i.e., a person registered for a training program at the University whose activities are part of their training program;

- 2) A multi-status person, any person for whom both the University and the institution can be considered their employer under the *Act respecting labour standards* (CQLR, c. N-1.1), or any person with a current University title or appointment who is not considered a University staff member, e.g., clinical instructor, associate professor, practical training instructor, visiting professor.

The CCOMTL's RCRO and the University's RCRO will jointly conduct the admissibility assessment for any University staff member who has an employment relationship with the University, or for any student. For persons with an appointment but no employment relationship with the University, the institution will conduct the admissibility assessment with or without the University, as agreed by the parties, depending on the grounds. The terms and conditions are subject to agreement, depending on the University concerned. In the case of a joint admissibility assessment with the University, both RCROs will agree on the best person in a management position at the University or the CCOMTL to assist with this preliminary assessment.

If the CCOMTL's RCRO carries out the admissibility assessment, they will keep the University's RCRO apprised of the facts, the admissibility decisions, and, in the event of an investigation, the findings. The CCOMTL's RCRO may also include, on its review committee, a person designated by the University, if the allegation is deemed admissible and a review takes place (see Section 5).

Similarly, if the University's RCRO receives an allegation related to a personnel member of the institution (CCOMTL), they will inform the CCOMTL's RCRO and refer the allegation to the latter.

4.4. Decision regarding admissibility of the allegation

The CCOMTL's RCRO shall render a decision on the admissibility of the allegation within a maximum of two months following receipt of the allegation. However, depending on the level of urgency, the institution shall aim for a maximum of one month and shall implement interim preventive measures. The RCRO shall inform the FRQ's Director of Ethics and Legal Affairs or the Tri-Agency Secretariat whether or not it intends to conduct a review of the allegation, according to the required information described in appendices 3 and 4.

Allegation deemed inadmissible

Following the preliminary assessment, if the allegation is deemed inadmissible, the RCRO will send a letter to the agencies containing the required information described in appendices 3 and 4 and that does not contain any information that directly or indirectly identifies the complainant or the respondent. The RCRO ensures that the file is closed and that any copies given out during the preliminary admissibility assessment are destroyed, if applicable.

Allegation deemed admissible

Following the preliminary assessment, if the allegation is deemed admissible, the RCRO shall form a review committee (see Section 5). They shall then inform the respondent and the complainant that there will be a review of the allegation of breach of responsible conduct of research. In addition, they shall inform:

- 1) The institution's Professional Services Directorate when the respondent is a physician or dentist member of the institution's CPDP; or
- 2) Administration at the LDI when the allegation is related to research activities conducted as part of research privileges awarded by the Director of the LDI; or
- 3) The scientific directorate of one of the research infrastructures of the Fonds de recherche du Québec-Société et Culture integrated with the CCOMTL, when the allegation is related to research activities conducted as part of research privileges awarded by the Director of Academic Affairs and Research Ethics; or

- 4) The institution's Director of Human Resources, Communications and Legal Affairs, if the allegation involves a staff member from the institution.

At this stage, it is possible that the facts may be clear and acknowledged by the respondent. The RCRO may then decide that a review committee would not yield any new elements and is therefore not necessary. In these exceptional cases, the FRQ would request that the RCRO and the manager involved in the preliminary assessment, if applicable, draft an allegation review report that includes the required information listed in Appendix 3.

Interim measures, if necessary

Depending on the grounds, the RCRO may decide to implement interim measures, if necessary (administrative, ethical, or other). In order to protect, for example, research participants or the administration of grants from funding agencies, the RCRO may inform the appropriate persons or authorities, who, depending on the situation, may be the chairs of the research ethics boards or the Director of Finance, or any other manager concerned. The RCRO may decide to initiate rapid interventions, in which case they will need to inform the latter of the identity of the respondent.

5. ALLEGATION REVIEW AND FORMATION OF A REVIEW COMMITTEE

Review committee

The review committee shall be comprised of individuals who collectively have the necessary expertise to arrive at an informed decision regarding the allegation. This committee must include:

- One member from outside the institution. This external member must be free of any conflict of interest while examining the allegation.
- An expert from the research discipline of the respondent, or of comparable professional competence, thereby considered to be a peer. This person must have sufficient technical or methodological expertise to properly assess the case or that is pertinent to the nature of the allegation.

It may be necessary to add a member with the necessary ethical and deontological knowledge to assess the file. The review committee must have access to and be able to analyze all available information relating to the allegation. It may request further details from the institution in order to validate the information provided. The committee may be guided by an individual with expertise regarding compliance and integrity of the process. It may also call on *ad hoc* experts if required for a proper understanding of the situation. The complainant shall be invited to present their observations, and the respondent shall be given an opportunity to present their version of the facts.

Timeline for reviewing the allegation

The maximum timeline prescribed by the FRQ for reviewing the allegation is five months following the transmission of the letter of admissibility to the FRQ.

5.1. Review findings

Upon completion of the allegation review process, the RCRO shall notify the respondent and the complainant and shall report the findings of the investigation in the prescribed formats (appendices 3 and 4):

In the event of an **unfounded allegation** of breach of responsible conduct of research:

- The RCRO shall transmit a letter to the agencies concerned if the allegation is unfounded. This letter shall not name the respondent, but shall contain information about the committee members, the review process, the conclusion, and the grounds for dismissing the allegation.

- The agencies and RCRO shall then close the file.

In the event of a **founded allegation** of breach of responsible conduct of research:

- The RCRO shall transmit a full and complete report to the agencies containing the required information listed in appendices 3 and 4. The identity of the parties involved in the matter shall be known. This report shall include, in addition to details about the committee, the timeline of the review process and justification for the conclusion, any interim interventions or measures requested pending the conclusion, any comments expressed by the complainant and the respondent, an assessment of the impact of the breach, and recommendations for sanctions and actions aimed at remedying any harm or correcting the scientific record, if appropriate.
- The RCRO informs the respondent and the complainant of the conclusion, as well as the individuals who were notified of the allegation's admissibility (see Section 4.4). It may also inform any other person who, having made the allegation, may be affected (e.g., in the event of a breach of confidentiality).

5.2. Appropriate interventions and sanctions

The RCRO and the review committee are generally tasked with recommending appropriate interventions and sanctions to the relevant authorities, which will be responsible for imposing them. The interventions and sanctions must be appropriate, i.e., take into account the intentionality and severity of the breach of conduct; its consequences on participants, scientific knowledge and credibility, and public confidence; and its repetitive nature. They can lead, for example, to the loss of research privileges, exclusion from a research infrastructure, compensation for wrongdoing or rectification of scientific facts, financial sanctions in connection with an award, temporary suspension or permanent termination of the research project, or suspension or dismissal, in the case of an employee. It may also be necessary to consider measures to minimize the negative impact on the individuals or institutions concerned, where possible. These sanctions are separate from any sanctions that may be imposed by a professional order, or from criminal prosecution in cases where the facts reported suggest a criminal offence.

Following the review of the detailed report, the FRQ may also decide to make recommendations to the director or scientific authority of the FRQ infrastructure concerned. FRQ decisions and sanctions are described in their Policy for the Responsible Conduct of Research (p. 29).

Appeal

Following receipt of the full and complete report of a substantiated breach and prior to transmitting it to the funding agency concerned, the respondent has 10 days to appeal the decision.

In the event of an appeal, the RCRO shall form a review committee made up of new members. The RCRO shall be replaced by a person with a sufficient level of independence and decision-making autonomy to appropriately address the appeal, or by an RCRO from another institution or university. This committee shall render its decision, which shall be final, within 90 days.

6. REFERENCES

Cadre de référence ministériel pour la recherche avec des participants humains, Direction de l'éthique et de la qualité, Direction de la recherche et de la coordination interne, Ministère de la Santé et des Services sociaux, October 2020.

Tri-Agency Framework: Responsible Conduct of Research, Government of Canada, Social Sciences and Humanities Research Council of Canada, Natural Sciences and Engineering Research Council of Canada, Canadian Institutes of Health Research, 2016.

Policy and procedure for managing allegations of breach of responsible conduct of research at CIUSSS du Centre-Ouest-de-l'Île-de-Montréal – 1100_02_01_F14

Act respecting health services and social services.

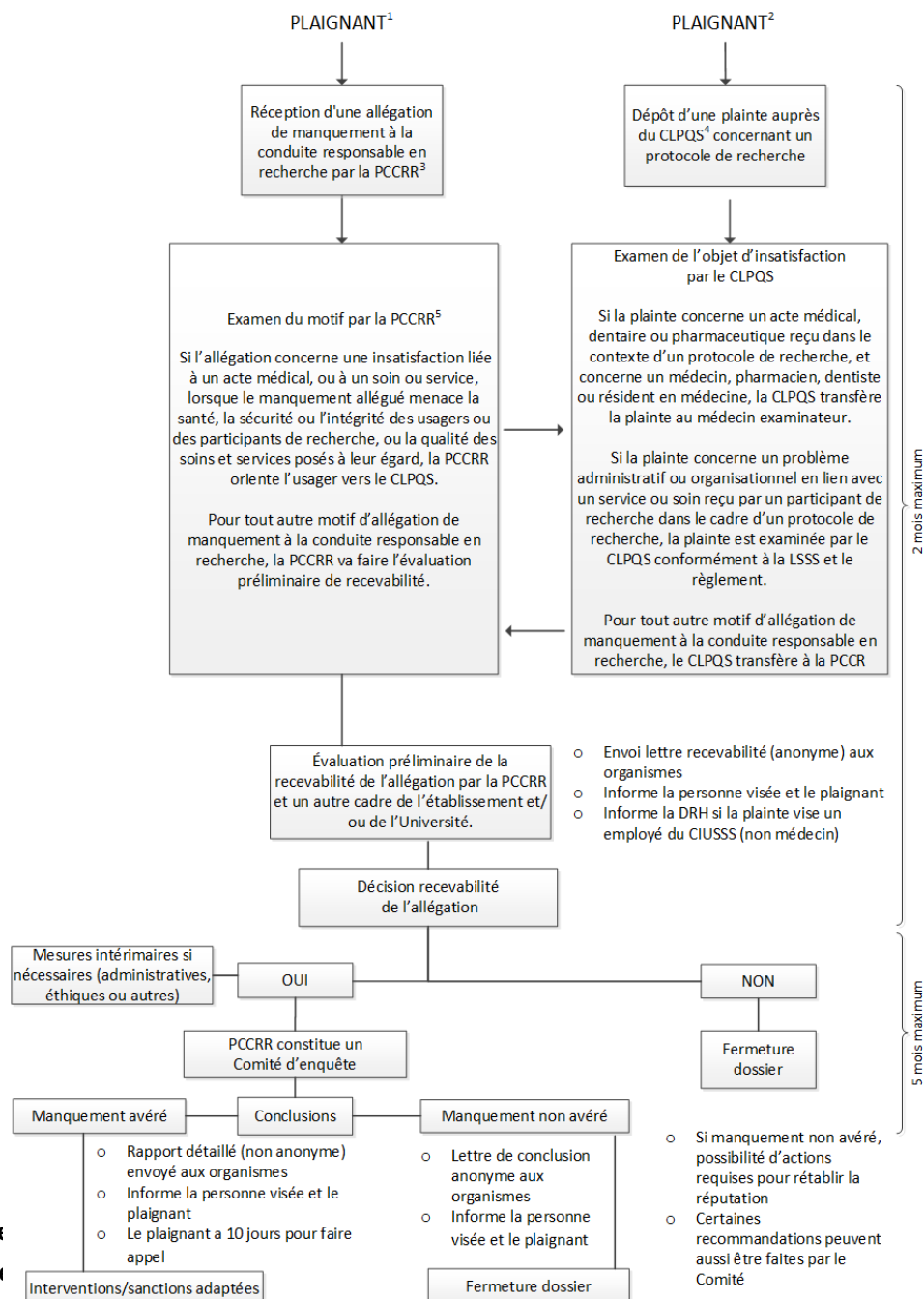
Policy for the Responsible Conduct of Research, Gouvernement du Québec, Fonds de recherche du Québec, 2014.

By-law respecting the complaint examination procedure. Centre intégré universitaire de santé et services sociaux du Centre-Ouest-de-l'Île-de-Montréal (CCOMTL), adopted by the members of the CCOMTL Board of Directors on December 1, 2016.

Standard operating procedures of the Research Ethics Board of the CIUSSS du Centre-Ouest-de-l'Île-de-Montréal, approved by the members of the CCOMTL Board of Directors on September 30, 2021.

7. APPENDICES

APPENDIX 1 - Procedure for managing allegations of breach of responsible conduct of research



Policy and proce
Centre-Ouest-di

CIUSSS du

¹ Toute personne ayant déposé une plainte visant un manquement à la conduite responsable en recherche. La plainte est considérée une allégation de manquement à l'intégrité ou conduite responsable en recherche. Elle peut être déposée par un participant à la recherche ou son représentant, un membre du personnel, un membre du CER, un chercheur ou un membre de son équipe, ou toute autre personne.

APPENDIX 2 - Form for filing an allegation of breach of responsible conduct of research

Centre intégré
universitaire de santé
et de services sociaux
du Centre-Ouest-
de-l'Île-de-Montréal



Form for filing an allegation of breach of responsible conduct of research

Once completed, this form must be returned to the RCRO, by mail or by email to PCCRR.RCRO.CCOMTL@SSSS.gouv.qc.ca.

Responsible Conduct of Research Officer
CIUSSS du Centre-Ouest-de-l'Île-de-Montréal
Jewish General Hospital
3755 Côte-Sainte-Catherine Road, A-903
Montréal, Québec, H3T 1E2

You may be asked to provide additional information to ensure the allegation is handled fairly and impartially. That's why the allegation cannot be filed anonymously. However, rest assured that the information in this form will remain confidential.

Once the file is complete, the preliminary assessment of admissibility will begin, and the respondent will be informed that an allegation has been filed against them; they will be informed of the type of alleged breach and that a preliminary assessment of admissibility is underway.

1) Respondent¹

- a. Last name, first name:
- b. Status at CCOMTL:
 - Researcher
 - Student
 - Employee
 - Physician, dentist or pharmacist
 - Other (specify): _____
- c. Contact information (if known):

2) Type of alleged breach (add an appendix of definitions of types of breaches):

- Fabrication
- Falsification

¹ If the respondent is an employee of another institution or university, for example, a university researcher, the Responsible Conduct of Research Officer shall inform the RCRO from the other institution or university upon receipt of the allegation and shall ensure that they are involved in handling the allegation, in accordance with recognized and applicable confidentiality rules.

- Destruction of research records
- Plagiarism
- Redundant publications
- Invalid authorship
- Inadequate acknowledgement
- Mismanagement of conflict of interest
- Misrepresentation in an agency's application or related document
- Mismanagement of grants or award funds
- Breach of policies or requirements for certain types of research
- Infringement of the integrity of a scientific peer review process and the awarding of funding
- Making false or misleading allegations

3) Date breach occurred:

4) Date breach observed:

5) Factual description of alleged breach (clearly indicate the link between the alleged breach and the CCOMTL's activities):

6) Perceived degree of urgency to intervene and justification:

7) Other factual information relevant to understanding the allegation:

I attest that I filed this allegation of breach of responsible conduct of research in good faith. I agree to be contacted by the Responsible Conduct of Research Officer to provide additional information to ensure the allegation is handled fairly and impartially.

Last name, first name:

Contact information:

Signature:

Date:

APPENDIX 3 - Reporting information to the FRQ (excerpts from the policy, pages 24-26)

Allegations concerning research activities to which FRQ funding is tied must be taken up and reported by the institution according to the measures described herein. The Institution's Responsible Conduct of Research Officer shall report to the FRQ, within the timelines described in sections 7.2.2 and 7.2.3, according to the parameters described below.

Letter of admissibility

Once the preliminary assessment of admissibility has been completed, the institution shall send a letter to the FRQ containing no personal information by which to identify the respondent or the complainant and indicating:

- a) the unique file identification number;
- b) the nature of the allegation, based on the categories in section 3.4;
- c) the date the complaint was received;
- d) the status of the parties involved in the complaint (researcher, student, research personnel, fund manager, participant in a research project, REB, etc.);
- e) the need for immediate intervention, if appropriate (to avoid harm, risk to participants, etc.);
- f) the admissibility of the allegation and the initiation of an allegation's review or the inadmissibility of the allegation and the grounds for dismissing the allegation;
- g) the complaint review committee composition, if necessary;
- h) the justifications for adopting an accelerated process to review the complaint (7.2.3.a) and its appropriateness under the circumstances, when applicable.

The institution shall retain the unique file number transmitted to the FRQ at least until every step of the process has been completed (including any possible appeal process).

Letter of findings following the complaint's review in the case of unfounded allegations

At the conclusion of a complaint's review that finds that no breach of responsible conduct has occurred, the institution shall send a letter to the FRQ indicating:

- a) the unique file identification number (8.1.a);
- b) the names of the committee members and their area of expertise, justifying their appointment and allowing validation of the adequacy of the committee (expertise, function or status);
- c) the timeline of the process as well as any feature demonstrating that the internal process as prescribed by the institutional policy was followed;
- d) the findings following the complaint's review, specifying the grounds for dismissal of the allegation.

The FRQ shall then consider the matter closed (without learning the identity of the respondent). However, the FRQ reserve the right to request further details from the institution within a period of 60 clear days.

Final report following the complaint's review in the case of substantiated allegations

At the conclusion of a complaint's review that confirms a breach of responsible conduct of research, the Fonds to which funding is tied must be informed forthwith. The institution shall transmit a full copy of the committee's report to the FRQ's Director of Ethical and Legal Affairs and inform the FRQ-funded researcher, awardee, research personnel or fund manager of this communication. The FRQ shall be apprised of the identity of the respondents involved in the matter.

A full and complete report shall be relayed to the FRQ specifying:

- a) the unique file identification number (8.1.a);
- b) the name of the respondent;
- c) the names of the committee members and their area of expertise, justifying their appointment and allowing validation of the adequacy of the committee (expertise, function or status);
- d) the timeline of the process as well as any feature demonstrating that the internal process as prescribed by the institutional policy was followed;
- e) any interventions requested by the institution pending the conclusion of the complaint's review;
- f) any comments expressed by the respondent;
- g) any comments expressed by the complainant;
- h) the findings following the complaint's review, clearly stating that a breach of responsible conduct did occur;
- i) an assessment of the impact of the breach, if applicable, making it possible to judge its seriousness. This assessment could include impacts on:
 - research participants, animals or the environment;
 - scientific knowledge in the discipline in question;
 - the research teams, students, colleagues, partners and institutions;
 - public trust in the scientific research activity or the scientific community;
 - the credibility of Québec's scientific community.
- j) recommendations (or a final decision, as per institutional policy) for sanctions and actions aimed at remedying any harm caused or correcting the scientific record, if appropriate.

If the institution does not produce a final report, if the timeline is extended unreasonably, if there was a procedural flaw in regards to FRQ requirements or institutional policy, or if the report appears unsatisfactory on the face of it, the FRQ shall request further details. Ultimately, the FRQ could ask the institution to proceed according to specifications and reserve the right to take measures aimed at inciting the institution to correct the situation and see the process through.

APPENDIX 4 - Tri-Agency Secretariat on Responsible Conduct of Research (SRCR) reporting requirements²

- Subject to any applicable laws, including privacy laws, the institution shall advise the relevant agency or the SRCR immediately of any allegations related to activities funded by the agency that may involve significant financial, health and safety, or other risks.
- The institution shall write a letter to the SRCR confirming whether or not the institution is proceeding with an investigation where the SRCR was copied on the allegation or advised as per Article 4.4.a. If a breach is confirmed at the inquiry stage, reporting requirements outlined in Article 4.4.c apply.
- The institution shall prepare a report for the SRCR on each investigation it conducts in response to an allegation of policy breaches related to a funding application submitted to an agency or to an activity funded by an agency. Subject to any applicable laws, including privacy laws, each report shall include the following information:
 - o the specific allegation(s), a summary of the finding(s) and reasons for the finding(s);
 - o the process and timelines followed for the inquiry and/or investigation;
 - o the researcher's response to the allegation, investigation and findings, and any measures the researcher has taken to rectify the breach; and
 - o the institutional investigation committee's decisions and recommendations, and actions taken by the institution.
- The institution's report should not include:
 - o information that is not related specifically to agency funding and policies; or
 - o personal information about the researcher, or any other person, that is not material to the institution's findings and its report to the SRCR.
- The institution should submit inquiry letters or inquiry reports to the SRCR within two months of receipt of an allegation. If an investigation is warranted, the institution has an additional five months following the end of the inquiry to conduct an investigation and submit its report to the SRCR. The institution therefore has a total of seven months from the date of receipt of an allegation that results in an investigation to report to the SRCR. These timelines may be extended in consultation with the SRCR if circumstances warrant, and with periodic updates provided to the SRCR until the investigation is complete.
- The frequency of the periodic updates will be determined jointly by the SRCR and the institution.
- The institution and the researcher may not enter into confidentiality agreements or other agreements related to an inquiry or investigation that prevents the institution from reporting to the agencies through the SRCR.
- In cases where the source of funding is unclear, the SRCR reserves the right to request information and reports from the institution.

² Excerpts, Social Sciences and Humanities Research Council of Canada (SSHRC), Natural Sciences and Engineering Research Council of Canada (NSERC), and Canadian Institutes of Health Research (CIHR), <https://rcr.ethics.gc.ca/eng/framework-cadre.html#a1>