Code of Research Integrity

2012

camh
Centre for Addiction and Mental Health
Centre de toxicomanie et de santé mentale

Research Program

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Table of Contents

i. Introduction

Purpose

This code is a formal statement of the standards and expectations for conducting research with integrity at the Centre for Addiction and Mental Health (CAMH).

The policies provided herein and the associated procedures enable CAMH to comply, in part, with requirements regarding the conduct of research incurred by agreements with other organizations, in particular:

1. The agreement between the Governing Council of the University of Toronto and the Centre for Addiction and Mental Health known as "The Affiliation Agreement"
2. The Memorandum of Understanding (MOU) on the Roles and Responsibilities in the Management of Federal Grants and Awards, in particular the "Tri-Agency Framework: Responsible Conduct of Research" attached thereunto.
3. U.S. Public Health Service (PHS) Policies on Research Misconduct and Financial Conflict of Interest, 42 CFR Parts 50 and 93, and 45 CFR Part 94.

Scope

This code provides guidance on research conduct and augments the professional conduct requirements given in the CAMH Code of Conduct. If there is a conflict between the Code of Research Integrity and the CAMH Code of Conduct, or with any other professional code to which you may be required to adhere, the expectation is that you will follow the Code that is more rigorous.

Individual units (for example labs, sections, departments, and programs) may provide protocols and operating procedures (for example Standard Operating Procedures) which provide further clarification on expectations for conduct. Failure to follow the protocols and procedures implemented at the unit level constitutes a breach of research integrity and may constitute research misconduct. If there is a conflict between the Code of Research Integrity, including the associated procedures, and protocols and procedures implemented at the unit level, the expectation is that you will follow the protocol or procedure that is more rigorous.

This code is not intended to provide guidance on the ethical review of research involving human subjects, which is addressed in a separate policy. However, incompliance with ethical review processes and/or the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans during the conduct of research activity constitutes a breach of research integrity and may constitute misconduct.

This code is not intended to provide guidance on the ethical review of research involving animals, which is addressed under other policies and procedures. However, incompliance with requirements regarding animal research during the course of research constitutes a breach of research integrity and may constitute misconduct.

This code is not intended to provide guidance on financial integrity in the use of research funds, which is addressed in the CAMH Financial Accountability Policy as well as the policies and requirements of external sponsors to which you may be bound by virtue of agreements with those sponsors. However, incompliance with requirements regarding financial integrity in the use of research funds during the course of research activity may constitute misconduct under this or another policy.

Further clarifications on scope are found in the specific policies below.

1. Policy on Research Integrity

Statement: The research community, funding agencies, and the public at large, must be confident that research results and the process leading to them are honest and reliable. There is an expectation for research to be conducted with integrity.

I. *General Principles*

A. It is the responsibility of all people conducting research under the auspices of the Centre for Addiction and Mental Health to uphold the following principles:
   1) Use scholarly and scientific rigor and integrity in obtaining, recording and analyzing data, and in reporting and publishing results;
   2) Recognize the substantive contributions of collaborators and trainees including students and postdoctoral fellows;
   3) Only use unpublished work of others with appropriate permission and with due acknowledgement;
   4) Use archival material in accordance with the rules of the archival source;
   5) Obtain appropriate permission before using new information, concepts, or data originally obtained through access to confidential documents as a result of being a peer reviewer or a referee;
   6) Ensure that authorship of published work includes all those who have materially contributed to, and share responsibility for, the contents of the publication, and only those people;
   7) Reveal to sponsors, universities, journals or funding agencies, any material conflict of interest, financial or other, that might influence their decisions on whether the individual should be asked to review manuscripts or applications, test products or be permitted to undertake work sponsored from outside sources;
   8) Reveal to sponsors, universities, journals or funding agencies, any material conflict of interest, financial or other that might influence or be perceived to influence their interpretation of research findings when such findings are submitted for publication or presentation or otherwise made public.

II. *Specific Principles*

A. CAMH is a University of Toronto affiliated hospital and a specific objective of this code is to foster a research climate that will promote both research integrity and research creativity resulting in the generation of research of the highest quality and prevention of misconduct in research. In addition to the above general principles all CAMH researchers are expected to:
   1) Respect and support an environment of research integrity and research creativity by role-modelling high-quality and honest scholarship;
   2) Conduct research with the highest of ethical standards and comply with the policies, procedures and directions of the Research Ethics Board, Animal Care Committee, Bio-safety Committee and funding agencies;
   3) Reveal to CAMH any conflict of interest they may have when making an allegation of research misconduct or when asked to comment or review a case concerning research misconduct;
   4) Ensure that those reporting alleged research misconduct who do so in good faith do not become subjected to retaliation of any kind;
   5) Create a research climate that fosters self-regulation as a mechanism to protect the public and the interests of the research program and its members by making good-faith efforts to assist CAMH and/or the University of Toronto in identifying cases of research misconduct and in conducting an objective and thorough inquiry and, if appropriate, investigation, into these matters.
   6) Comply with CAMH and University of Toronto policies and procedures and with laws and regulations;
   7) Comply with contracts and agreements with external parties and with collaborators which are in concordance with these principles and responsibilities regarding the conduct of research;
   8) Not enter into contracts and agreements with external parties or with collaborators when the terms and

conditions are not in keeping with the principles and responsibilities given in this Code.

9) Recognise the importance of publishing work in a timely fashion and ensure that they do not contribute to long and unjustifiable delays in preparing, submitting, or revising a manuscript for publication

III. *Responsibilities of Researchers*

A. As a University of Toronto affiliated hospital, researchers are expected to adhere to the highest standards of research and scholarly integrity. The following provides additional guidance on responsibilities of researchers in the context of specific situations:

1) Selecting of Students, Postdoctoral Fellows, Other Associates and Staff: The **#1 Procedure for Selecting Students, Postdoctoral Fellows, Other Associates and Staff with Integrity** should be followed.
2) Educating Students, Postdoctoral Fellows, Other Associates and Staff: The **#2 Procedure for Providing Education on Research Integrity to Trainees and Staff** should be followed.
3) Monitoring of the work of students and postdoctoral fellows: Any researcher supervising a student or postdoctoral fellow shares responsibility at all times for the work done under her/his mentorship. The **#3 Procedure for Monitoring the Work of Research Trainees** should be followed.
4) Monitoring the Work of Research Staff: Supervising researchers should monitor the research procedures and results of research staff and should follow the **#4 Procedures for Monitoring the Work of Research Staff**.
5) Multi-Investigator Teams: During the conduct of research wherein more than one researcher has responsibility for the collection of data, the **#5 Procedure for Cross-Checking Raw Data** should be used.
6) Handling of data: please see **4. Policy on Data/Research Resources, Authorship, and Publication**
7) Collaboration - authorship, attribution and acknowledgment: please see **4. Policy on Data/Research Resources, Authorship, and Publication** and the **#6 Procedure for Managing Relationships with Collaborators**.
8) Media Contacts: please see **4. Policy on Data/Research Resources, Authorship, and Publication** and the CAMH Media Policy
9) Relationships between researchers and industry: please see **5. Policy**.

IV. *Institutional Responsibility*

A. The CAMH Research Program is committed to:

1) Promoting integrity in research and scholarship;
2) Fostering a research environment that promotes the responsible conduct of research, research training, and activities related to that research or research training;
3) Discouraging research misconduct; and
4) Dealing promptly with allegations or evidence of possible research misconduct.
5) Managing conflicts of interest to prevent bias or the appearance of bias in research.

2. Policy on Research Misconduct

Definitions are found at the end of this policy, in section IX.

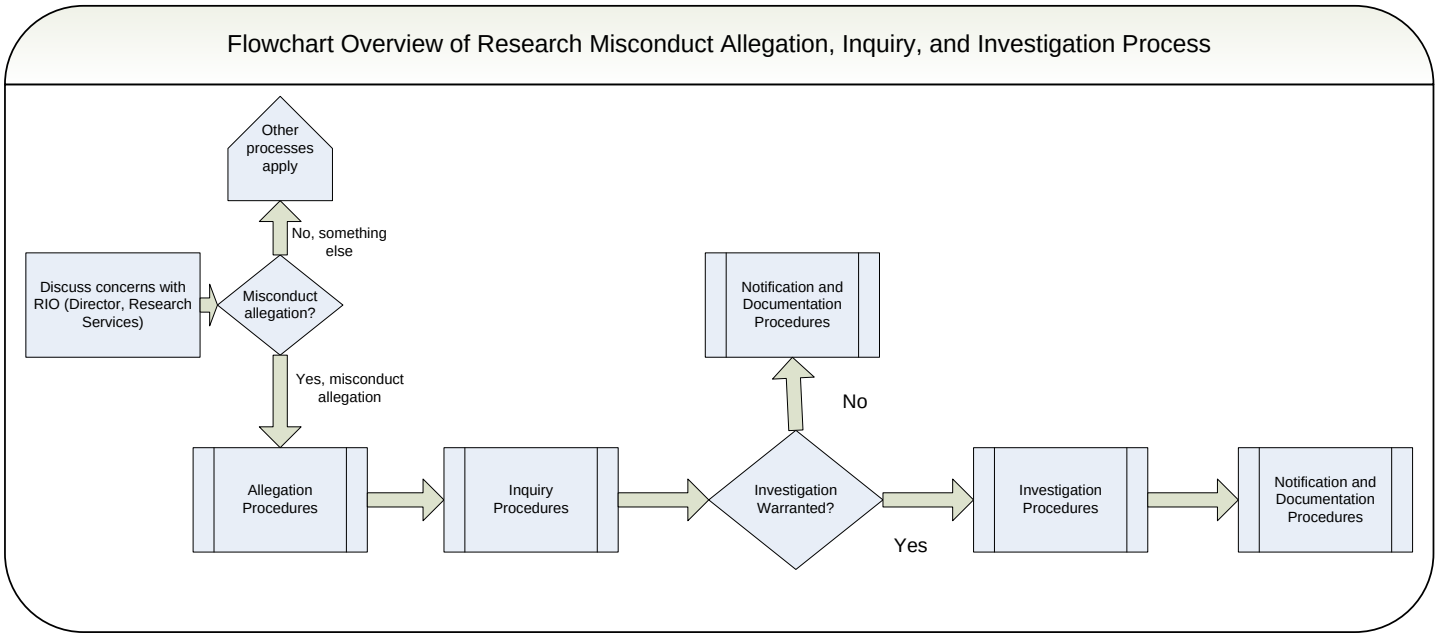


Figure 2.1

I. *Introduction*

A. Scope

1) Any action during the conduct of research which is inconsistent with the principles of integrity provided in 1. Policy on Research Integrity constitutes **a breach of research integrity** and may constitute **research misconduct**. The principles listed in 1. Policy on Research Integrity should be interpreted with the understanding that research can involve honest error, conflicting data or valid differences in experimental design or in interpretation or judgment of information. This policy does not apply to **assertions of a breach of research integrity** which do not constitute, specifically, an **allegation of research misconduct**. All claims of fabrication, falsification or plagiarism constitute an **allegation of research misconduct** and are subject to this policy.

2) This policy applies only to allegations of research misconduct that occurred within six years of the date the Centre for Addiction and Mental Health, a sponsor, or a regulating agency received the allegation. The six-year limitation does not apply in the following instances:

   (i) *Subsequent use exception:* The respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, republication or other use for the potential benefit of the respondent of the research record that is alleged to have been fabricated, falsified, or plagiarized.
   (ii) *Health or safety of the public exception:* If CAMH, a sponsor, or regulating agency determines that the alleged misconduct, if it occurred, would possibly have a substantial adverse effect on the health and safety of the public.

3) This policy applies to allegations of research misconduct, including fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results, involving:
   (i) A person who, at the time of the alleged research misconduct, was employed by, was an agent of, or was affiliated by contract or agreement with CAMH; and
   (ii) Research, research training or activities related to that research training, such as the operation of tissue and data banks and the dissemination of research information conducted under the auspices of CAMH,
   (iii) Applications or proposals for support for research, research training or activities related to that research or research training made through CAMH, or
   (iv) Plagiarism of research records produced in the course of research, research training or activities related to that research or research training conducted under the auspices of CAMH.

   This includes any research proposed, performed, reviewed, or reported, or any research record generated from that research.

B. Jurisdiction

1) In the case of complaints made against persons who conduct research under the auspices of either or both CAMH and the University of Toronto (including its other affiliates), **#8 Procedures for Inter-Institutional Notification Regarding Research Misconduct and Determining Jurisdiction with the University of Toronto** will be followed.

2) *Non-duplication and Institutional Administrative Actions:* Neither the University of Toronto (and/or its Affiliates) or CAMH will pursue the same or substantially similar allegation determined under **#8 Procedures for Inter-Institutional Notification Regarding Research Misconduct and Determining Jurisdiction with the University of Toronto** to be under the jurisdiction of the other party, unless new and compelling information becomes available that was not reasonably available at the time of the original complaint. In such case, the matter will be treated as a new complaint and will be subject to the jurisdictional determinations of **#8 Procedures for Inter-Institutional Notification Regarding Research Misconduct and Determining Jurisdiction with the University of Toronto.** Notwithstanding that the University of Toronto or affiliate did not participate in or have jurisdiction to conduct an inquiry or investigation in connection with a complaint, nothing in this policy prevents either the University of Toronto or its affiliate (including CAMH) from imposing the same or comparable institutional administrative actions in connection with the complaint based on the conclusions reached in the inquiry or investigation.

C. Examples

1) Specifically, the following acts are generally considered instances of research misconduct, although research misconduct is not necessarily limited to these:
   (i) Fabrication of recording or reporting and other falsification of data, results, or source materials (fraud);
   (ii) Falsely claiming someone else's written words or ideas as one's own with an intent to deceive (plagiarism);
   (iii) Failure to honour the confidentiality that the researcher promised or was contracted to as a way to gain valuable information from a party internal or external to CAMH;
   (iv) Deliberate misuse of funds acquired for support of research, including (but not limited to) failure to comply with the terms and conditions of grants and contracts; misuse of CAMH resources, facilities and equipment; failure to identify correctly the source of research funds (financial misconduct); see also the CAMH Code of Conduct and the CAMH Financial Accountability Policy.
   (v) Deliberate destruction of one's own research data or records to avoid the detection of wrong doing or the deliberate destruction of someone else's data or records without authorization;

(vi) Retaliation against a person who acted in good faith and reported or provided information about alleged research misconduct;
(vii) Material failure to comply with relevant federal, provincial, or other statutes or regulations applicable to the conduct and reporting of research;
(viii) Failure to comply with a direction of the CAMH Research Ethics Board upon which an approval to proceed with the research was granted or failing to notify the Research Ethics Board of significant protocol changes that may affect its prior decision to approve the research proceeding;
(ix) Failure to comply with a direction of the Animal Care Committee or Bio-safety Committee upon which an approval to proceed with the research was granted or failing to notify the officer/committee of significant protocol changes that may affect its prior decision to approve the research proceedings;
(x) Failure to provide relevant materials to CAMH's Research Ethics Board (or Animal Care Committee, or Bio-safety Committee) required by the institution or which the research or academic community considers to be materials relevant to decision-making;
(xi) Failure to reveal material conflicts of interest to CAMH, sponsors, colleagues or journal editors when submitting a grant, protocol, or manuscript or when asked to undertake a review of research grant applications, manuscripts or to test or distribute products;
(xii) Making false or misleading statements that are contrary to good faith reporting of alleged research misconduct or failing to declare any conflicts of interest when reporting alleged research misconduct;
(xiii) Misleading publication; for example –
1. Failing to appropriately include as authors other collaborators who prepared his or her contribution with the understanding and intention that it would be a "joint" publication;
2. Failing to provide collaborators with an opportunity to contribute as an author in a "joint publication" when they contributed to the research with the understanding and intention that they would be offered this opportunity;
3. Falsely claiming someone else's data as his or her own;
4. Preventing access to research data to a legitimate collaborator who contributed to the research with the explicit understanding and intention that the data was their own or would be appropriately shared;
5. Giving or receiving honorary authorship or inventorship;
6. Denying legitimate inventorship;
7. Knowingly agreeing to publish as a co-author without reviewing the work including reviewing the final draft of the manuscript;
8. Failing to obtain consent from a co-author before naming him or her as such in the work;
9. Portraying of one's own work as original or novel without acknowledgement of prior publication or publication of data for a second time without reference to the first.

(xiv) Wilfully misrepresenting and misinterpreting (for any reason) of findings resulting from conducting research activities;
(xv) Condoning or not reporting the performance by another CAMH member any of the acts noted above.
(xvi) Encouraging or facilitating another researcher to carry out scholarly misconduct (e.g. a supervisor telling his graduate student to falsify data); or otherwise creating an environment that promotes misconduct by another.

II. *Rights and Responsibilities*

A. Research Integrity Officer (RIO)

1) The Vice-President of Research will appoint the RIO who will have primary responsibility for implementation of the CAMH research program policies and procedures on research misconduct. Details of the responsibilities and duties of the RIO related to research misconduct proceedings are also found in the

procedures. The Research Integrity Officer at CAMH is the Director, Research Services.

B. Complainant

1) The complainant is responsible for making allegations in good faith, declaring conflicts of interest, maintaining confidentiality, and cooperating with the inquiry and investigation. As a matter of good practice, the complainant should be interviewed at the inquiry stage and given the transcript or recording of the interview for correction. The complainant must be interviewed during an investigation, and be given the transcript or recording of the interview for correction.

C. Respondent

1) The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry and investigation. The respondent is entitled to:
   (i) A good faith effort from the RIO to notify the respondent in writing at the time of or before beginning an inquiry;
   (ii) An opportunity to comment on the inquiry report and have his/her comments attached to the report;
   (iii) Be notified of the outcome of the inquiry, and receive a copy of the inquiry report that includes a copy of, or refers to CAMH's policies and procedures on research misconduct and any other rules or regulations that apply to the research activity, including 42 CFR Part 93 in the case of research relating to the U.S. DHHS;
   (iv) Be notified in writing of the allegations to be investigated within a reasonable time after the determination that an investigation is warranted, but before the investigation begins (within 30 days after the institution decides to begin an investigation), and be notified in writing of any new allegations, not addressed in the inquiry or in the initial notice of investigation, within a reasonable time after the determination to pursue those allegations;
   (v) Be interviewed during the investigation, have the opportunity to correct the recording or transcript, and have the corrected recording or transcript included in the record of the investigation;
   (vi) Have interviewed during the investigation any witness who has been reasonably identified by the respondent as having information on relevant aspects of the investigation, have the recording or transcript provided to the witness for correction, and have the corrected recording or transcript included in the record of investigation; and
   (vii) Receive a copy of the draft investigation report and, concurrently, a copy of, or supervised access to the evidence on which the report is based, and be notified that any comments must be submitted within 30 days of the date on which the copy was received and that the comments will be considered by the institution and addressed in the final report.

2) The respondent should be given the opportunity to admit that research misconduct occurred and that he/she committed the research misconduct. With the advice of the RIO and/or other CAMH officials, the Deciding Official (Vice-President of Research) may terminate CAMH's review of an allegation that has been admitted, if CAMH's acceptance of the admission and any proposed settlement is approved by any funding or other body related to the research activity, in the case of research related to the US DHHS, the Office of Research Integrity.

D. Deciding Official (Vice-President of Research)

1) The Deciding Official (Vice-President of Research) will receive the inquiry report and after consulting with the RIO and/or other institutional officials, decide whether an investigation is warranted under the criteria detailed in **#16 Procedure: Criteria for Evaluating Whether an Investigation into Research Conduct is Warranted**.

2) The Deciding Official (Vice-President of Research) will receive the investigation report and, after consulting

with the RIO and/or other institutional officials, decide the extent to which CAMH accepts the findings of the investigation and, if research misconduct is found, decide what, if any, institutional administrative actions are appropriate.

3) The Deciding Official (Vice-President of Research) will also ensure that the final investigation report, the findings of the Deciding Official (Vice-President of Research) and a description of any pending or completed administrative actions are provided to any external agency as may be required by any regulation or agreement with an agency.

III. *General*

A. Responsibility to Report Misconduct

1) All institutional members will report observed, suspected, or apparent research misconduct to the RIO. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may meet with or contact the RIO (Director, Research Services, at sam_tischler@camh.net, phone extension 4785) to discuss the suspected research misconduct informally, which may include discussing it anonymously and/or hypothetically. If the circumstances described by the individual do not meet the definition of research misconduct, the RIO will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

2) At any time, an institutional member may have confidential discussions and consultations about concerns of possible misconduct with the RIO and will be counselled about appropriate procedures for reporting allegations, namely **#7 Procedure for Reporting Alleged Research Misconduct**.

B. Cooperation with Research Misconduct Proceedings

1) Institutional members will cooperate with the RIO and other institutional officials in the review of allegations and the conduct of inquiries and investigations. Institutional members, including respondents, have an obligation to provide evidence relevant to research misconduct allegations to the RIO or other institutional officials.

C. Confidentiality

1) The RIO shall:

(i) limit disclosure of the identity of respondents and complainants to those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding; and
(ii) except as otherwise prescribed by law, limit the disclosure of any records or evidence from which research subjects might be identified to those who need to know in order to carry out a research misconduct proceeding. The RIO should use written confidentiality agreements or other mechanisms to ensure that the recipient does not make any further disclosure of identifying information.

D. Protecting complainants and witnesses

1) Institutional members may not retaliate in any way against complainants and witnesses. Institutional

members should immediately report any alleged or apparent retaliation against complainants and witnesses to the RIO, who shall review the matter and, as necessary, make all reasonable and practical efforts to counter any potential or actual retaliation and protect and restore the position and reputation of the person against whom the retaliation is directed.

E. Protecting the Respondent

1) As requested and as appropriate, the RIO and other institutional officials shall make all reasonable and practical efforts to protect or restore the reputation of persons alleged to have engaged in research misconduct, but against whom no finding of research misconduct is made.

F. Interim Administrative Actions

1) Throughout the research misconduct proceeding, the RIO will review the situation to determine if there is any threat of harm to public health, research funding and research infrastructure, or the integrity of the research process and in the event of such a threat implement the **#10 Procedure for Interim Administrative Actions Regarding Research Misconduct**.

IV. *Conducting the Assessment and Inquiry*

A. Upon receiving an allegation of research misconduct, the RIO will immediately assess the allegation using the **#9 Procedure for the Assessment of Research Misconduct Allegations** to determine whether it is sufficiently credible and specific so that potential evidence of research misconduct may be identified, whether it is within the jurisdiction of this policy, and whether the allegation falls within the scope of research misconduct given in this code. An inquiry must be conducted if these criteria are met.

B. The procedures for conducting an inquiry are provided in the:

- **#11 Procedure for Initiating a Research Misconduct Inquiry**,
- **#12 Procedure for Notifying the Respondent and Sequestering Research Records Pursuant to a Research Misconduct Inquiry**,
- **#13 Procedure for Conducting the Research Misconduct Inquiry Process**,
- **#14 Procedure for Preparing the Final Research Misconduct Inquiry Report**
- **#15 Procedure for Notifying the Respondent of the Research Misconduct Inquiry Findings and Providing Opportunity to Comment,**
- **#17 Procedure for Institutional Decision on the Research Misconduct Inquiry Findings** (includes provision for notification of external agencies), and
- **#18 Procedure for Documenting a Decision Not to Investigate Research Conduct**

V. *Conducting the Investigation*

A. The investigation must begin within 30 calendar days after the determination by the Deciding Official (Vice-President of Research) that an investigation is warranted. The purpose of the investigation is to develop a factual record by exploring the allegations in detail and examining the evidence in depth, leading to recommended findings on whether research misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible research misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the

alleged research misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice. The findings of the investigation must be set forth in an investigation report.

B. The procedures for conducting an investigation are provided in:
   - **#19 Procedure for Notifying Parties and Sequestering Records Pursuant to an Investigation**
   - **#20 Procedure for Appointment of the Research Misconduct Investigation Committee**
   - **#21 Procedure for Writing the Charge to the Research Misconduct Investigation Committee and Holding the First Meeting**
   - **#22 Procedure for Conducting the Research Misconduct Investigation Process**
   - **#23 Procedure for Preparing the Misconduct Investigation Report**
   - **#24 Procedure for Institutional Decision, Notification**
   - **#25 Procedure for Managing the Records of the Research Misconduct Investigation**

VI. *Completion of Cases*

A. Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently. However, a case may close at the inquiry or investigation stage for such reasons as the respondent has admitted guilt or a settlement with the respondent has been reached. The **#26 Procedure for the Closure of a Research Misconduct Case at the Inquiry or Investigation Stage** must be followed.

B. In cases involving research related to the US PHS, the RIO must notify the Office of Research Integrity in advance if there are plans to close a case at the inquiry or investigation stage except when closing of a case at the inquiry stage on the basis that an investigation is not warranted or a finding of no misconduct is made at the investigation stage, which must be reported to the Office of Research Integrity as prescribed in **#24 Procedure for Institutional Decision, Notification** .

VII. *Institutional Administrative Actions*

A. If the DO determines that research misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consultation with the RIO. The administrative actions may include:
   1) Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found;
   2) Removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment or appointment;
   3) Restitution of funds to the grantor agency as appropriate; and
   4) Other actions appropriate to research misconduct.

VIII. *Other Considerations*

A. Termination or Resignation Prior to Completing Inquiry or Investigation

   1) The termination of the respondent's institutional employment, by resignation or otherwise, before or after

an allegation of possible research misconduct has been reported, will not preclude or terminate the research misconduct proceedings or otherwise limit any of CAMH's responsibilities under law or agreements with other parties.

2) If the respondent, without admitting to the misconduct, elects to resign his or her position after the institution receives an allegation of research misconduct, the assessment of the allegation will proceed, as well as the inquiry and investigation, as appropriate based on the outcome of the preceding steps. If the respondent refuses to participate in the process after resignation, the RIO and any inquiry or investigation committee will use their best efforts to reach a conclusion concerning the allegations, noting in the report the respondent's failure to cooperate and its effect on the evidence.

B. Restoration of the Respondent's Reputation

1) Following a final finding of no research misconduct, including concurrence from other parties as may be required by law or under agreements pertaining to the research, the RIO must, at the request of the respondent, undertake all reasonable and practical efforts to restore the respondent's reputation. Depending on the particular circumstances and the views of the respondent, the RIO should consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in any forum in which the allegation of research misconduct was previously publicized, and expunging all reference to the research misconduct allegation from the respondent's personnel file(s). Any institutional actions to restore the respondent's reputation should first be approved by the DO.

C. Protection of the Complainant and Witnesses

1) During the research misconduct proceeding and upon its completion, regardless of whether a determination is made that research misconduct occurred, the RIO must undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any complainant who made allegations of research misconduct in good faith and of any witnesses and committee members who cooperate in good faith with the research misconduct proceeding. The DO will determine, after consulting with the RIO, and with the complainant, witnesses, or committee members, respectively, what steps, if any, are needed to restore their respective positions or reputations or to counter potential or actual retaliation against them. The RIO is responsible for implementing any steps the DO approves.

D. Protection of the Investigation Committee

1) Individuals serving as members of the Investigation Committee and who are acting in good faith shall be indemnified by CAMH.

E. Allegations Not Made in Good Faith

1) If relevant, the DO will determine whether the complainant's allegations of research misconduct were made in good faith, or whether a witness or committee member acted in good faith. If the DO determines that there was an absence of good faith he/she will determine whether any administrative action should be taken against the person who failed to act in good faith.

IX. *Definitions*

In the case of research related to the United States Department of Health and Human Services (DHHS), terms used in this policy have the same meaning as given them in the Public Health Service Policies on Research Misconduct, 42 CFR Part 93, Subpart B--Definitions. For reference, the DHHS includes the following agencies (amongst others):

- Agency for Healthcare Research and Quality (AHRQ)
- Centers for Disease Control and Prevention (CDC)
- Food and Drug Administration (FDA)
- National Institutes of Health (NIH)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

In the case of research not related to the DHHS, terms are defined more generally, as follows:

Administrative action: Means—
(a) An action by CAMH or an external agency in response to a research misconduct proceeding taken to protect the health and safety of the public, to promote the integrity of research, research training, or activities related to that research or research training and to conserve funds; or
(b) An action by CAMH or an external agency in response either to a breach of a material provision of a settlement agreement in a research misconduct proceeding or to a breach of any debarment or suspension.

Allegation: Means a disclosure of possible research misconduct through any means of communication. The disclosure may be by written or oral statement or other communication to an institutional official.

Complainant: Means a person who in good faith makes an allegation of research misconduct.

Debarment or suspension: Means:
(a) exclusion, whether temporary or for a set term, of a person from eligibility for grants, contracts, and cooperative agreements or
(b) exclusion, whether temporary or for a set term, from eligibility to conduct research under the auspices of CAMH.

(In the case of research related to the DHHS, debarment or suspension means the U.S. Government wide exclusion, whether temporary or for a set term, of a person from eligibility for Federal grants, contracts, and cooperative agreements under the DHHS regulations at 45 CFR part 76 (nonprocurement) and 48 CFR subparts 9.4 and 309.4 (procurement).)

Deciding official (DO): Means the CAMH official who makes final determinations on allegations of research misconduct and any institutional administrative actions; the CAMH DO is the Vice-President of Research. The Deciding Official will not be the same individual as the Research Integrity Officer and should have no direct prior involvement in the institution's inquiry, investigation, or allegation assessment. A DO's appointment of an individual to assess allegations of research misconduct, or to serve on an investigation committee, is not considered to be direct prior involvement.

Evidence: Means any document, tangible item, or testimony offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact.

Good faith: Good faith as applied to a complainant or witness, means having a belief in the truth of one's allegation or testimony that a reasonable person in the complainant's or witness's position could have based on the information known to the complainant or witness at the time. An allegation or cooperation with a research misconduct proceeding is not in good faith if made with knowing or reckless disregard for information that would negate the allegation or testimony. A complainant or witness does not act in good faith if their actions are influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct

proceeding. Good faith as applied to a committee member means cooperating with the research misconduct proceeding by carrying out the duties assigned impartially for the purpose of helping CAMH meet its responsibilities under this policy. A committee member does not act in good faith if his/her acts or omissions on the committee are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.

Inquiry: Means preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures of this policy.

Institutional member: Means a person who is employed by, is an agent of, or is affiliated by contract or agreement with the CAMH research program. Institutional members may include, but are not limited to, officials, teaching and support staff, researchers, research coordinators, clinical technicians, postdoctoral and other fellows, students, volunteers, agents, and contractors, subcontractors, and subawardees, and their employees.

Investigation: Means the formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation for a finding of research misconduct which may include a recommendation for other appropriate actions, including institutional or external administrative actions.

Notice: Means a written communication served in person, sent by mail or its equivalent to the last known street address, facsimile number or e-mail address of the addressee.

Person: Means any individual, corporation, partnership, institution, association, unit of government, or legal entity, however organized.

Preponderance of the evidence: Means proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.

Research: Means a systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research).

Research Integrity Officer (RIO): Means the institutional official responsible for:

(1) assessing allegations of research misconduct to determine if they fall within the definition of research misconduct, are covered by this policy, and warrant an inquiry on the basis that the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified;
(2) overseeing inquiries and investigations; and
(3) the other responsibilities described in this policy and associated procedures.

At CAMH, the Research Integrity Officer is the Director, Research Services.

Research misconduct proceeding: Means any actions related to alleged research misconduct taken under this policy, including but not limited to, allegation assessments, inquiries, investigations, oversight reviews, hearings, and administrative appeals.

Research record: Means the record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to an institutional official by a respondent in the course of the research misconduct proceeding.

Respondent: Means the person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

Retaliation: Retaliation for the purpose of this policy means an adverse action taken against a complainant, witness,

or committee member by an institution or one of its members in response to—
(a) A good faith allegation of research misconduct; or
(b) Good faith cooperation with a research misconduct proceeding.

Support. Means funding, or applications or proposals therefore, for research, research training, or activities related to that research or training, that may be provided through: grants, cooperative agreements, or contracts, or subgrants or subcontracts; or salary or other payments.

3. Policy on Research Project Role Eligibility

I. *Purpose*

A. Conducting research with integrity requires each researcher to have the knowledge, training, credentials, skills, experience, and resources appropriate to their role and level of responsibility on a particular research project.

B. This policy is intended to supplement existing policies on professional roles and responsibilities at the Centre for Addiction and Mental Health and to provide clarification on the conditions that must be met for a person intending to conduct research under the auspices of the CAMH research program to be designated with a particular role on a research project document (proposal, application, protocol, etc.) and to incur and assume the responsibilities **CAMH** or any **external partners** assign to project participants with the designated role during the conduct of said research project.

II. *Scope*

A. The scope of this policy does not extend to research project staff whose role designation on the project is no different than that indicated on their CAMH employment documents.

B. This policy does not apply to people who may be designated with a role on research project documents affixed with CAMH institutional signatures but who will be conducting project research either independently or under the auspices of another organization (i.e. external collaborators). Anyone submitting documentation for research projects including project work that will be conducted outside of the auspices of the CAMH research program is advised to comply with any external organization requirements that may apply regarding role designations.

III. *Eligibility*

A. Eligibility to be designated with a specific role on a research project document

1) A person intending to conduct research under the auspices of the CAMH Research Program is eligible to be designated with a particular role (i.e. “Principal Applicant”, “Project Director”, “Collaborator”, “Fellow”, etc.) on a specific research project document and to thereafter assume the responsibilities incurred as a consequence of being so designated, in so far as the following conditions are met:

(i) The person has a current appointment or engagement in the CAMH Research Program and the terms of the appointment or engagement are documented in a letter of appointment or engagement issued by the Research Program and on file in the Research Office at the time the person’s role is designated on the project, and

(ii) The terms of the appointment or engagement are consistent with the terms required for a person to be eligible to be so designated by all sponsors, stakeholders, and partners supporting the project and by any regulations which may apply to the project.

(iii) Each researcher must use the **#27 Procedure for Determining Research Project Role Eligibility** to evaluate whether the terms of their appointment meet the conditions above.

B. Eligibility to take on the responsibilities incurred by the role designation on a specific project

1) A person is eligible to take on the responsibilities incurred by a research project document role designation during the conduct of a research project in so far as:

(i) The person has an appointment or engagement in the CAMH Research Program and the terms of the appointment or engagement are documented in a letter of appointment or engagement issued by the Research Program and on file in the Research Office during the time the research is conducted, and

(ii) The terms of the appointment or engagement are consistent with the terms required for a person to be eligible to assume the responsibilities incurred by the role designation under the requirements of all sponsors, stakeholders, and partners supporting the project and by any regulations which may apply to the project during the conduct of the research, and

(iii) All sponsors, stakeholders, and partners have confirmed the person’s project role designation in writing

(including, but not limited to, approval of a proposal which details project roles with no conditions or comment on the project roles indicated in the proposal), and

(iv) The appointment or engagement in the CAMH Research Program has not been terminated or suspended, and

(v) The person's role and/or role designation on the project has not been suspended or terminated in writing by any sponsor, stakeholder, or partner supporting the project, or any regulatory body which may have jurisdiction over project activities.

4. Policy on Data/Research Resources, Authorship, and Publication

As a publicly funded organization that conducts research with integrity, CAMH has a fundamental interest in ensuring that the findings that result from the research it performs, including research publications and publication-related data, are available to the widest possible audience, and at the earliest possible opportunity.

I. *Data/Research Resources*

A. General

1) Researchers must comply with all rules and requirements associated with any data source.
2) Investigators conducting research, particularly biomedical research, frequently develop unique research resources. The sharing of such unique research resources (also called research tools) is an important means to enhance the value of sponsored research. Restricting the availability of unique resources can impede the advancement of further research. Therefore, after the research findings have been published it is important that they be made readily available for research purposes to qualified individuals within the scientific community. At the same time, the rights of researchers and research contractors to retain title to subject inventions must be respected.
3) In some cases data-sharing may be complicated or limited by other policies, ethical conduct considerations, and law. Data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

B. Collection/Recording

1) In general, raw data should be recorded in permanent media, data books or computer disks. Provisions for data back-up and security must be made. If research data will not be housed within standard CAMH systems (which have back-up and security provisions) unit-level back-up and security protocols must be devised, written down and followed. Specific procedures also apply:
   - **#2 Procedure for Providing Education on Research Integrity to Trainees and Staff**
   - **#3 Procedure for Monitoring the Work of Research Trainees**
   - **#4 Procedures for Monitoring the Work of Research Staff**
   - **#5 Procedure for Cross-Checking Raw Data**

C. Sharing

1) Data Sharing
   (i) As a general rule, all the key scientific members of the research team should have access to raw data unless there is some exceptional circumstance that warrants controlled access. Rights of access should be discussed in advance by team members. Rapid sharing of new data is essential among members of the team given their collective responsibilities. The **#5 Procedure for Cross-Checking Raw Data** applies.
   (ii) Researchers must also respect all data sharing requirements of external sponsors or regulatory agencies, or sharing plans indicated in research project documentation. For example, CIHR grantees must deposit bioinformatics and molecular coordinate data into the appropriate public database immediately upon publication of research results (e.g., deposition of nucleic acid sequences into GenBank).

2) Sharing Model Organisms
   (i) In the case of model organisms, including but not restricted to mammalian models such as rat and mouse, all specific plans for sharing and distributing unique model organism research resources provided for in research proposal documentation for approved and sponsored research must be respected.

D. Ownership
   1) CAMH will not enter research agreements that do not allow researchers to retain a copy of data gathered at a CAMH site pursuant to a sponsored study.

   2) Collaborators should work out issues of ownership of data at the time a collaborative project is being considered in accord with the **#6 Procedure for Managing Relationships with Collaborators**.

E. Retention
   1) Researchers must respect all data/records retention requirements of external sponsors or regulatory agencies. For example, data retention is mandated by CIHR. Grantees must retain original data sets arising from CIHR-funded research for a minimum of five years after the end of the grant. This applies to all data, whether published or not.
   2) The CAMH research program records management policy/guidelines apply and see specific guidance in the *Human Studies Research Records Management and Retention Policy* as well as the related policies:
      - *Departing CAMH Researcher Policy*
      - *Personal Health Information and Privacy Policy*

II. *Authorship, Publication, and Public Access*

A. General
   1) All CAMH researchers must respect the principles of research integrity provided in this code with regard to collaboration, authorship and publication and must also respect all public access ("open access") requirements to which their research may be subject. Open access enables researchers to make their research results freely accessible and useable for the international research community thereby enhancing the application of research results. CAMH strongly supports unrestricted access to research outputs, which promotes the principles of scientific openness and integrity.
   2) CAMH and the University of Toronto, with which CAMH is affiliated, are committed to the concept that review by scholarly peers is the cornerstone of excellence in research, and that researchers should have the right to publish or otherwise disseminate the results of their research.
   3) CAMH will not enter agreements that allow research sponsors to suppress or censor research results.

B. Relationship with Collaborators
   1) Multi-investigator teams are important vehicles for conducting high quality research as they allow individuals from different disciplines or sub-fields to perform specialised functions or to contribute in novel ways. However, they also provide challenges for the allocation of credit and responsibility. We expect CAMH researchers to abide by the rules of authorship that are commonly accepted standards or practices of the relevant research community including those from peer-reviewed journals, please see **#6 Procedure for Managing Relationships with Collaborators**.

C. Publication
   1) Results of research undertaken at CAMH shall be fully publishable with the following qualifications:
      (i) Where the sponsor has intellectual property rights arising from a research project for which it wishes to obtain statutory protection, an agreement with the sponsor may provide for a short delay for protection, provided that:
         1. normally, no delay will exceed 90 days from the date of submission of the manuscript or presentation to the sponsor;
         2. in no event will any delay exceed 6 months from the date of submission of the manuscript or presentation to the sponsor; and,
         3. publication of the thesis of a University of Toronto graduate student will not be delayed, unless

permitted by the regulations of the University of Toronto School of Graduate Studies.

2) CAMH may agree to receive information identified as "confidential" or "proprietary" from a sponsor if such information is essential to facilitate performance of research and maintaining such information in confidence would not preclude the publication of CAMH's research results.
3) If a sponsor is given the right to publish CAMH research results and there is any change in the sponsor's publication from the original report, the names of CAMH and the report's authors shall not be used in connection with the sponsor's publication without the written consent of CAMH and the authors.

D. Protection for Intellectual Freedom: Publication Rights and Right to Disclose

1) Researchers must retain the right to publish or present their findings as they interpret them, in accord with the **#28 Procedure for Retaining the Rights to Publish**.

2) **Retaining rights in agreements with sponsors**: In agreements with sponsors of health-related research, it is acceptable to agree to provide the sponsor with a manuscript or presentation for review prior to publication or presentation. Strenuous efforts should be made to limit the sponsor's delay of such publication or presentation to a maximum of 60 days, and in no case shall the allowable delay be more than 4 months from the submission of the publication or presentation to the sponsor, after which time, the researchers must be free to proceed with the publication or presentation.

3) **Retaining rights in agreements with publishers – addressing copyright and public access**: CAMH researchers must not enter agreements that would prevent the publication or presentation of research results in any publicly accessible format (for example, PubMed Central or PubMed Central Canada in the case of research sponsored by NIH or CIHR respectively) that may be required by the research sponsor, following the **#28 Procedure for Retaining the Rights to Publish**.

4) **Right to publish single-site results:** For large multi-site studies, a CAMH participating site might not be directly involved in the preparation and submission of a manuscript for publication, and therefore the interchanges with study sponsors might not be fully disclosed. To safeguard against the unlikely possibility that the study steering committee could be impeded in submitting a manuscript by a sponsor, the participating site at CAMH should retain the right to publish single-site results or make a single-site presentation and to submit such single-site publication or presentation to a sponsor within a maximum of 18 months after study completion. After submission to the sponsor, the review time-lines in subsection D paragraph 2 above apply. If the trial is sponsored solely by a public grant agency (or public granting agencies), a CAMH participating site may decide not to retain the right to publish single-site results or make single-site presentations under certain conditions. These conditions include there being a Steering Committee (and if relevant a Publication Committee) that retains the right to publish and which cannot be impeded from doing so by the sponsor.

5) **Right to disclose research results to subjects:** Agreements with sponsors for research involving human subjects must permit the disclosure of research results to study subjects and/or their lawful representatives, sponsors, study steering committee, Research Ethics Boards at CAMH and at other participating study sites, and regulators, if and when the investigator, institution and/or Research Ethics Board(s) deem disclosure necessary to protect the health of study participants. Provision for disclosure to study subjects and/or their lawful representatives must also be made so as to obtain and maintain informed consent.

E. Media Contacts

1) The traditional rule in presenting scientific results is to expose them first to appropriate scientific and professional peer groups for review and criticism before they are revealed to the public at large. If this is not possible because the data is used for the purposes of the courts or other proceedings, researchers are expected to disclose that the results have not yet undergone a peer-review mechanism. Even when this rule is observed there are ethical considerations in the way that researchers present their work and themselves to the public media. Dangerously false hopes may be raised by premature and unproven claims. Further, even when there are exciting preliminary results, researchers must be extremely cautious in interpreting

their findings and their own roles to the press and must constantly be aware of the very real risks of misleading patients and of depriving colleagues of deserved credit. This problem is compounded by interviewers and reporters not allowing researchers to review material before it is published or goes on the air.

2) The CAMH Media Policy also applies.

5. Policy on Conflict of Interest in Research

Definitions are found at the end of this policy. Figure 5.1: Flowchart Overview of Project-Specific Interest/Interaction Assessment, Disclosure, Review and Management Processes is found at the end of this policy and in **#29 Procedure for Assessing and Disclosing Interests/Interactions (Financial or Tobacco Industry)**.

I. Purpose

CAMH is dedicated to ensuring that there is no reasonable expectation that the design, conduct or reporting of research under its auspices is biased or appears to be biased by researcher conflict of interest.

This policy provides the framework whereby personal, professional, and financial conflicts of interest pertaining to research designed, conducted, and reported at CAMH are to be identified and **managed** or **mitigated**.

Tobacco Industry: CAMH, as a public institution within Canada, recognizes an international standard established by the 2003 WHO Framework Convention on Tobacco Control, Article 5.3 and the associated 2008 Guidelines for implementation of Article 5.3 of the WHO Framework Convention on Tobacco Control which requires "protect[ing] the formulation and implementation of public health policies for tobacco control from the tobacco industry to the greatest extent possible" (p. 2). Guiding principles of this treaty include:

- "Principle 1: There is a fundamental and irreconcilable conflict between the tobacco industry's interests and public health policy interests" (p. 2).
- "Principle 2: Parties, when dealing with the tobacco industry or those working to further its interests, should be accountable and transparent. 14. Parties should ensure that any interaction with the tobacco industry on matters related to tobacco control or public health is accountable and transparent" (p. 3).

Therefore, "the tobacco industry should not be partner in any initiative linked to setting or implementing public health policies, given that its interests are in direct conflict with the goals of public health" (p. 4). The Guidelines include a recommendation to "avoid conflicts of interest" (p. 3) and mandate a "policy on the disclosure and management of conflicts of interest that applies to all persons involved in setting and implementing public health policies with respect to tobacco control, including government officials, employees, consultants and contractors" (p. 5). Therefore, this policy and the associated procedures provide a means whereby any applicable researcher interactions with the tobacco industry can be made transparent and limited in accord with the above treaty and guidelines.

U.S. PHS: In the case of research relating to the U.S. Public Health Service, researchers need to be aware of the U.S. Federal regulation on Financial Conflict of Interest (FCOI), specifically Title 42 Code of Federal Regulations (CFR) Part 50 Subpart F (for grants and cooperative agreements) and Title 45 CFR Part 94 (for research contracts). For reference, the PHS includes the following agencies (amongst others):

- Agency for Healthcare Research and Quality (AHRQ)
- Centers for Disease Control and Prevention (CDC)
- Food and Drug Administration (FDA)
- National Institutes of Health (NIH)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

CIHR: Institutional conflict of interest policies and management are required under the Memorandum of Understanding (MOU) on the Roles and Responsibilities in the Management of Federal Grants and Awards, schedule 14.

II. Scope

This policy augments guidance on real, perceived or potential conflicts of interest provided elsewhere in this Code, in 1. Policy on Research Integrity, 2. Policy on Research Misconduct, as well as the CAMH Code of Conduct and any other professional code of conduct to which you may be required to adhere. If there is a conflict between this policy, including the associated procedures, and another policy/procedure, the expectation is that you will follow the

policy/procedure that is more rigorous.

III. *Responsibilities*

A. **Researchers.** All those who are responsible for the design, conduct, or reporting of research under the auspices of CAMH:
   1) are responsible for complying with this policy and associated procedures and for disclosing the required information to CAMH,
   2) are, in cases where they are the primary CAMH contact for a research activity, **responsible for taking reasonable steps to ensure that the secondary contacts identify their financial conflicts of interest if applicable** either through the **#29 Procedure for Assessing and Disclosing Interests/Interactions (Financial or Tobacco Industry)**, or through provision of assurances in cases where a researcher is conducting his or her part of the work under the auspices of an entity other than CAMH,
   3) have a responsibility to ensure trainees and staff are aware of and compliant with this policy and other conflict of interest requirements that may apply, and
   4) are responsible for determining any TI/FCOI assessment and disclosure requirements in addition to those provided for in this policy and associated procedures to which they may be subject by virtue of specific agreements with sponsors or agencies.

B. **Institution.** CAMH is responsible for:
   1) educating researchers on conflict of interest, this policy and procedures; researchers with NIH funding are advised to complete the NIH Office of Extramural Research Web-based FCOI tutorial: http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm
   2) ensuring that any necessary interaction with the tobacco industry should be carried out in such a way as to avoid the creation or any perception of a real or potential partnership or cooperation resulting from or on account of such interaction, and in the event the tobacco industry engages in any conduct that may create such a perception, to act to prevent or correct this perception,
   3) complying with policy and procedural requirements established under agreements with sponsors and partners or by laws and regulations,
   4) managing the **#29 Procedure for Assessing and Disclosing Interests/Interactions (Financial or Tobacco Industry),**
   5) determining which disclosures are Tobacco Industry/Financial Conflicts of Interest using the **#30 Procedure for Reviewing Interest/Interaction Disclosures**
   6) managing or mitigating financial conflicts of interest using the **#31 Procedure for Writing and Implementing a COI Management and/or Mitigation Plan** and
   7) reporting financial conflicts of interest as may be required under agreements and memoranda of understanding with sponsors and partners using the **#32 Procedure for Notification/Reporting of COI**.

IV. *Disclosure*

A. Researcher disclosure:
   1) Disclosures of real, perceived or potential **personal** or **professional** conflict of interest must be made:
      (i) to someone who is not themselves in conflict of interest,
      (ii) who can conduct a review of the disclosure or arrange for such a review to be conducted, and
      (iii) who can enact measures, or arrange for measures to be enacted, to manage or mitigate any identified personal or professional conflict of interest.
   2) Real, perceived, or potential **personal** or **professional** conflict of interest disclosure proceeds by:
      (i) means that are informal and initiated on an as-needed basis arising in circumstances where no formal procedure or standard practice is in place.
      (ii) means that are established by a standard practice used under specific circumstances (for example, potential committee members may be asked to declare a personal or professional conflict of interest to the Chair as part of the process of being appointed to an advisory committee) and initiated on timelines specific to the circumstance.

3) Real, perceived or potential **financial/tobacco industry** interest/interaction disclosure proceeds by:
   (i) the **#29 Procedure for Assessing and Disclosing Interests/Interactions (Financial or Tobacco Industry)** ***and by the annual performance review process***. The **#29 Procedure for Assessing and Disclosing Interests/Interactions (Financial or Tobacco Industry)** must be completed a minimum of 10 business days before a research proposal is submitted to any external sponsor. It includes provision for repeating or initiating the procedure under other timelines to accommodate circumstances in addition to proposal submission (for example, when a new Significant Financial Interest is obtained by a researcher or their spouse/spousal equivalent or dependent child(ren)).
   (ii) In order for a researcher's financial interest to bias the research, the researcher must be aware of the interest. Therefore, researchers are responsible for disclosing interests where a reasonable person would conclude that they ought to have known of the interest. For example, a researcher may have a blind trust and would be aware of the assets originally placed in the trust and therefore should disclose any such assets in accord with the **#29 Procedure for Assessing and Disclosing Interests/Interactions (Financial or Tobacco Industry)**. However, the researcher would not be aware of any new assets purchased with the proceeds from the original assets and could not disclose those interests.

V. Disclosure Review and Determination of Conflicts

A. **Personal** and **professional** disclosures:
   1) will be reviewed by either an informal process or a standard practice used to review such disclosures in specific circumstances. The review must constitute a reasonable attempt to determine whether a conflict exists.

B. **Financial/tobacco industry** interest/interaction disclosures:
   1) will be reviewed under the **#30 Procedure for Reviewing Interest/Interaction Disclosures** which constitutes a reasonable attempt to determine whether a tobacco industry/financial conflict of interest exists ***and will be reviewed as part of the annual review process.***

VI. Management or Mitigation Plan

A. Management Plan
   1) Generally, a management plan will be devised to reduce, eliminate, or otherwise manage the identified conflict of interest such that biased research or the appearance of biased research due to researcher conflict of interest is prevented.
   2) If a **personal** or **professional** conflict of interest is determined to exist under section V above, the management plan must be devised and implemented by someone:
      (i) Who is not themselves in conflict of interest
      (ii) Has the authority to devise and implement the required measures
   3) If a tobacco industry/financial conflict of interest is determined to exist under section V, the **#31 Procedure for Writing and Implementing a COI Management and/or Mitigation Plan** must be followed. Normally, a management plan is devised and implemented before the research design is finalized, and the research conducted or reported in order to prevent bias from affecting the research (see B below for mitigation plans).
      (i) In the case of research related to the U.S. National Institutes of Health, CAMH must not allow NIH funds to be expended if a management plan for a financial conflict of interest has not been devised and implemented (reporting requirements also apply) and for financial conflicts of interest identified subsequent to any initial report, CAMH has 60 days to devise and implement a financial conflict of interest management plan, at least on an interim basis.

B. Financial Conflict of Interest/Tobacco Industry Interaction (FCOI/TII) Mitigation Plan
   1) If it is determined that an FCOI/TII exists and it was not disclosed and reviewed prior to the design finalization, conduct or reporting of the affected research:
      (i) the Special Evaluation to Identify Bias clause of the **#30 Procedure for Reviewing Interest/Interaction Disclosures** applies and it must be determined whether the research was biased by the FCOI/TII, and
      (ii) a Mitigation Plan must be devised and implemented under the **#31 Procedure for Writing and Implementing a COI Management and/or Mitigation Plan** .

VII. Notifications and Reporting

A. Notifying the research ethics board
   1) If an FCOI/TII is identified, the CAMH REB will be notified under the **#32 Procedure for Notification/Reporting of COI**. The Management or Mitigation Plan devised under the above paragraph may be devised with input from the REB.

B. Notifying and reporting to sponsors or other external partners
   1) CAMH will notify or report to sponsors or other external partners in compliance with timelines and other requirements established in agreements with those sponsors or other external partners as required under the **#32 Procedure for Notification/Reporting of COI**. For example, in the case of grant research relating to NIH, CAMH will report to NIH:
      (i) An identified FCOI prior to expending any funds under an NIH award
      (ii) For any FCOI identified subsequent to the initial report under the award, within 60 days of that identification, and
      (iii) The report will be submitted through the eRA Commons FCOI Module and include the information required under that process.

C. Reporting: Public Disclosure
   1) Public reporting of identified FCOI or TII will comply with sponsor requirements.

VIII. Enforcement and Sanctions

A. A researcher's failure to comply with this policy and associated procedures may constitute misconduct under the CAMH Code of Conduct, research misconduct under this Code (in particular the *Policy on Research Misconduct* in chapter 2), or incur enforcement/administrative actions or sanctions under another policy or agreement.

IX. FCOI Records Management

A. CAMH records management guidelines apply; records of all financial disclosures and all actions taken by CAMH with respect to a FCOI must be maintained as follows:
   1) In the case of grants or cooperative agreements, for at least three years from the date of submission of the final expenditures report, or, where applicable, from other dates specified in agreements with sponsors
   2) In the case of research contracts, for three years after final payment or, where applicable from other dates specified in agreements with sponsors

X. Definitions

Primary CAMH Contact: the researcher (see definition below) who is entitled to be listed and is listed on the Research Assurances/Approvals Form used during the Procedure for Research Proposal Review and Approval (see also "secondary contacts", below)

Researcher: any person who is responsible for the design, conduct, or reporting of the research activity. Questions regarding the applicability of this policy and procedures to specific individuals should be directed to Susan Powell, Manager, Finance and Research Services, susan_powell@camh.net.

Secondary Contacts: The researchers involved in the design, conduct, or reporting of a research activity (including a proposed activity) who are not listed as the primary contact on the Research Assurances/Approvals Form used during the Procedure for Research Proposal Review and Approval of that activity.

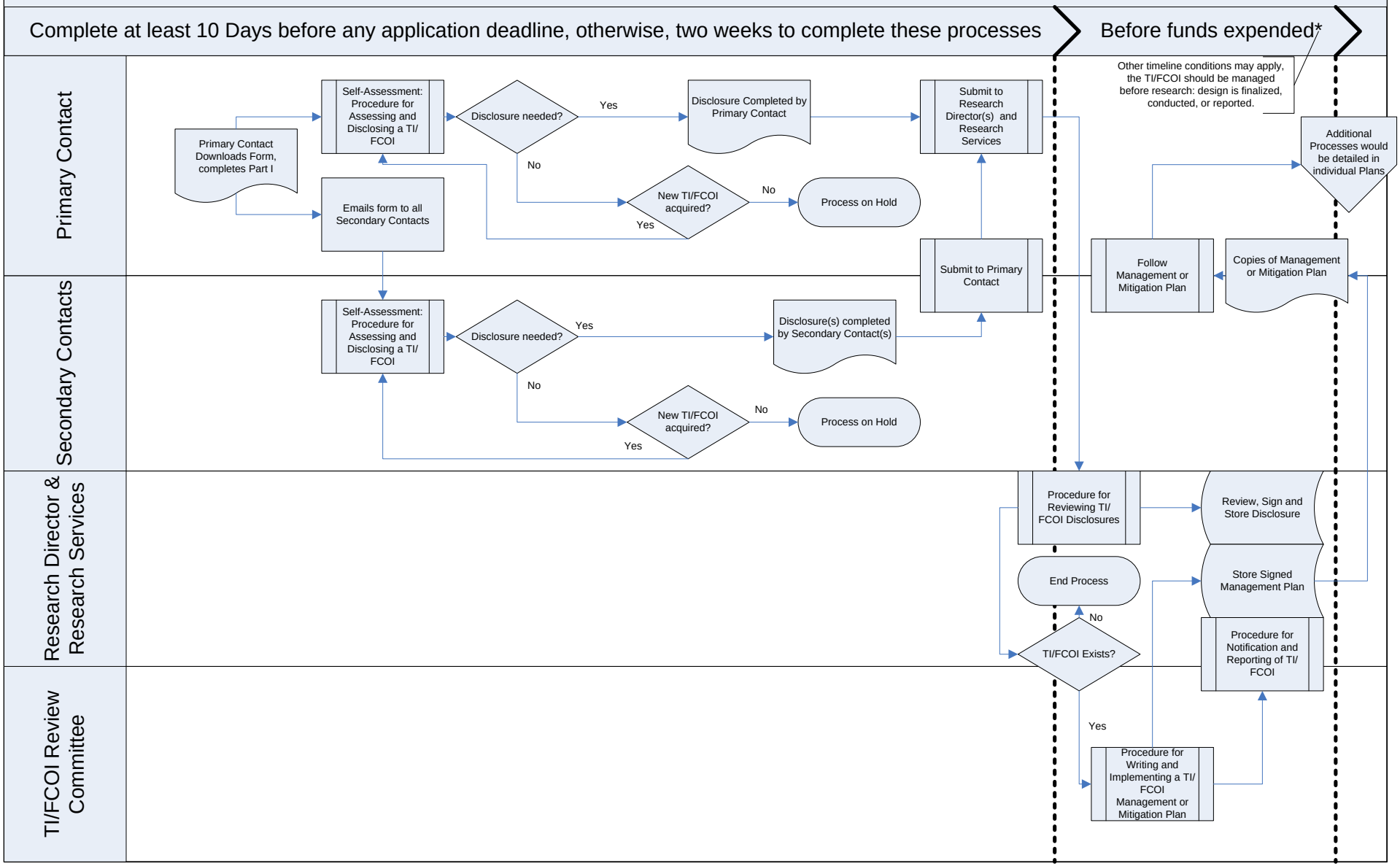
Significant Financial Interest:

1. A financial interest consisting of one or more of the following interests of the researcher, the researcher's spouse/spousal equivalent or dependent child(ren):

a. An interest in any publicly traded entity if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of the disclosure, when aggregated, exceeds $5,000 (in either Canadian or US dollars, whichever currency value yields the highest amount)
    i. Remuneration includes salary and any payment for services not otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship, travel reimbursement);
    ii. Equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
b. An interest in any non-publicly traded entity if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
c. Intellectual property rights (e.g. patents, copyrights), royalties from such rights, and agreements to share in royalties related to such rights, upon receipt of income related to such rights and interests

2. The term does not include the following types of financial interests:
    a. salary, royalties, or other remuneration paid by the Institution to the researcher if the researcher is currently employed or otherwise appointed or engaged by the institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights
    b. any ownership in the institution held by the researcher if the institution is a commercial or for-profit organization,
    c. income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
    d. income from seminars, lectures, or teaching engagements sponsored a government agency or an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education
    e. or income from service on advisory committees or review panels for a government agency or an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education

Flowchart Overview of Project Specific* Interest/Interaction Assessment Disclosure, COI Review, and Management Processes



* An annual review of significant financial interests related to each researcher's institutional responsibilities is conducted through the PRS process.

#1 Procedure for Selecting Students, Postdoctoral Fellows, Other Associates and Staff with Integrity

This procedure is associated with 1. Policy on Research Integrity and is also intended to meet policy and procedural responsibilities (in part) required under the agreement with U of T known as the "Affiliation Agreement."

When students, postdoctoral fellows, research associates, and research support staff are interviewed attention should be paid not only to their potential for becoming good scientists but also to their attitudes regarding truth, honesty and fairness. A focus on the responsibilities and virtues required of scientists will help establish the expectation of integrity from the start.

camh Centre for Addiction and Mental Health

#2 Procedure for Providing Education on Research Integrity to Trainees and Staff

This procedure is associated with 1. Policy on Research Integrity and is also intended to meet policy and procedural responsibilities (in part) required under the agreement with U of T known as the "Affiliation Agreement."

CAMH, as a University of Toronto affiliated hospital, has a unique and distinctive role in promoting an environment of scientific integrity because we supervise and train students, postdoctoral fellows, and other young researchers. By appropriate role modelling and mentoring, we can foster scientific integrity in future generations. Therefore, researchers, particularly University of Toronto faculty, must demonstrate integrity in how they collaborate with colleagues and in how they supervise and train students, postdoctoral fellows and other young researchers. An environment of honesty and integrity must be fostered through the training of junior members of the research community and by reinforcing the responsibilities of senior members through guidelines developed for these purposes.

Education

By analysing ethical and unethical research, including previous examples of fraud in research and problems inherent in the use of human and animal research subjects, students, postdoctoral fellows, research associates, and research staff will develop greater sensitivity to these issues. Morover, by becoming familiar with relevant codes of conduct and understanding the need for ethical principles, they will be better equipped to deal with new and challenging problems they may encounter. Students should also be encouraged to take a course on ethical problems in research. For example, the Institute of Medical Science (MSC 1051H; MSC 3004Y) offers relevant courses and The Collaborative Program in Bioethics has a listing of a number of relevant courses. The Joint Centre for Bioethics has information about bioethicists who are available for advice relating to research proposals. It is hoped that successful completion of a research ethics course will be required for all graduate students.

Responsibilities of Students, Postdoctoral Fellows, Research Associates, and Research Staff

Students, postdoctoral fellows, research associates, and research staff, have a responsibility for the ethical conduct of research by becoming knowledgeable about the norms of good research and by acting in accordance with them. These norms should be understood as applied to research in the basic, clinical sciences, and community health. In addition, the ethical considerations of research involving human and animal subjects are areas that need to be addressed. In particular, students, postdoctoral fellows, research associates and research staff must be familiar with relevant ethical codes and guidelines governing medical research (e.g. University of Toronto guidelines, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* and the *Canadian Council on Animal Care Guidelines* and the *Animals for Research Act of Ontario*).

#3 Procedure for Monitoring the Work of Research Trainees

This procedure is associated with 1. Policy on Research Integrity and is also intended to meet policy and procedural responsibilities (in part) required under the agreement with U of T known as the "Affiliation Agreement."

There is a graded and shared responsibility in any research team. The supervising researcher shares responsibility at all times for the work done under her/his mentorship, however, the degree of responsibility borne by the trainee increases steadily from the limited burden of a new graduate student to a very high degree of onus for full compliance that must be borne by a senior postdoctoral fellow. Unusual results and results that seem too-perfect-to-be-true should be independently duplicated using blinded methods as appropriate. Student's and postdoctoral fellows' data should be presented frequently for discussion at laboratory meetings and drafts of papers should be circulated for critical review to knowledgeable members of the department prior to publication. Supervising researchers should be sensitive to the circumstances of individual trainees, including students and postdoctoral fellows and give guidance, encouragement and critical evaluation of their work as appropriate.

#4 Procedures for Monitoring the Work of Research Staff

This procedure is associated with 1. Policy on Research Integrity and is also intended to meet policy and procedural responsibilities (in part) required under the agreement with U of T known as the "Affiliation Agreement."

Supervising researchers should monitor the research procedures and results of research support staff. This includes, but is not limited to, establishing a system when appropriate. Unusual results and results that seem too-perfect-to-be-true should be independently duplicated using blinded methods as appropriate. Staff's data should be presented frequently for discussion at laboratory meetings and drafts of papers should be circulated for critical review to knowledgeable members of the department prior to publication. Supervising researchers should be sensitive to the circumstances of individual staff and give guidance, encouragement and critical evaluation of their work as appropriate.

#5 Procedure for Cross-Checking Raw Data

This procedure is associated with 1. Policy on Research Integrity and is also intended to meet policy and procedural responsibilities (in part) required under the agreement with U of T known as the "Affiliation Agreement."

In programs involving several researchers who are considered principal investigators, attempts should be made to cross-check each other's raw data where appropriate.

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#6 Procedure for Managing Relationships with Collaborators

This procedure is associated with 1. Policy on Research Integrity and is also intended to meet policy and procedural responsibilities (in part) required under the agreement with U of T known as the "Affiliation Agreement."

Misunderstandings or differences of opinion ideally are discussed openly by members of research teams. These can often be resolved by frank discussion. Allegations of research misconduct can often be averted when open discussion within research teams is the norm. Parties should work out issues of principle investigator, authorship, ownership of data and other important issues at the time a collaborative project is being considered or as soon as the team starts to solidify. It is at this time that individuals are best able to articulate their interests and arrive at creative solutions that are tailored to their individual teams or fields. Creative solutions may involve the co-writing of a research agreement where rules are clearly stated and agreed to prior to the commencement of the work. There will be a dimension of uncertainty with respect to issues that may arise and collaborators need to be willing to discuss these as the collaboration unfolds or the research is underway in the hopes of reaching an agreement among the individuals.

#7 Procedure for Reporting Alleged Research Misconduct

This procedure is associated with 2. Policy on Research Misconduct and is also intended to ensure CAMH researchers meet policy and procedural responsibilities (in part) required under the agreement with U of T known as the Affiliation Agreement, particularly the "Framework to Address Allegations of Research Misconduct."

Preliminary step: Any individuals who have knowledge of a breach of research integrity, particularly observed, suspected, or apparent research misconduct, should begin by contacting the Research Integrity Officer, the Director, Research Services, sam_tischler@camh.net to obtain information on policies and procedures which may apply and to discuss the issue.

At a minimum:

Step #1	The complainant will be interviewed by the RIO.
Step #2	The complaint will be written down.
Step #3	The written complaint will be reviewed, corrected as needed, and signed and dated by the complainant.
Step #4	The RIO will sign and date the written complaint.
Step #5	The complaint will be securely filed in accord with CAMH records management guidelines.

- *Confidentiality agreements may also be put in place under this procedure.*

#8 Procedures for Inter-Institutional Notification Regarding Research Misconduct and Determining Jurisdiction with the University of Toronto

This procedure is associated with 2. Policy on Research Misconduct and is also intended to meet policy and procedural responsibilities (in part) required under the agreement with U of T known as the "Affiliation Agreement."

I. Definitions

a) "Affiliated institution" means a fully affiliated or community affiliated teaching hospital which is party to an affiliation agreement with the University signed by the authorized officers of the parties, and any other institution independent from the University which has agreed to be bound by the University of Toronto Framework to Address Allegations of Research Misconduct under an agreement signed by the authorized officers of the parties. For greater certainty, no federated college of the University shall be considered to be an Affiliated Institution for the purposes of these procedures.
b) "Responsible Officer" means (i) for the University of Toronto, the University's Vice-Provost, Relations with Healthcare Institutions and (ii) for an Affiliated Institution, the Affiliated Institution's Vice-President, Research (or equivalent), or delegate as communicated in writing to the other party's Responsible Officer. The Responsible Officer for CAMH is the Vice-President of Research.
c) "Status-Only Appointee" means a person who has a primary appointment at an Affiliated Institution and excludes Teaching Staff, employees, and students of the University of Toronto.
d) "Student" means a student enrolled in an academic program of the University of Toronto.
e) "Teaching Staff" means employees of the University, University College, the constituent colleges and the arts and science faculties of the federated universities of the University of Toronto who hold the academic rank of professor, associate professor, assistant professor, full-time lecturer or part-time lecturer, unless such part-time lecturer is registered as a student, or who hold any other rank created by the University of Toronto and designated by it as an academic rank under the *University of Toronto Act*.

II. Inter-Institutional Notification of Complaint

If CAMH receives a complaint against a member of the University of Toronto teaching staff, student body, or employee group or where the research that is the subject matter of the complaint was conducted, in whole or in part, at the University of Toronto, CAMH will notify the University of Toronto's Responsible Officer, the Vice-Provost, Relations with Healthcare Institutions.

If the University of Toronto receives a complaint against a University of Toronto status-only appointee with a CAMH appointment or a CAMH employee or where the research that is the subject matter of the complaint was conducted, in whole or in part, at CAMH, the University will notify the CAMH Responsible Officer, the

Vice-President of Research.

If either the University of Toronto or CAMH receives a complaint against an individual who is cross-appointed at the University and the Affiliated Institution but who is not listed above, the institution that received the complaint shall notify the other party's Responsible Officer and they shall jointly determine jurisdiction in accordance with the procedures below.

If a complaint is received against an individual who is cross-appointed at more than one affiliated institution, the Responsible Officers of the Affiliated Institutions may use the criteria below to determine jurisdiction.

Where, after jurisdiction has been assumed by either the University or an Affiliated Institution or jointly by more than one institution, it is subsequently determined that the complaint involves additional institution(s), the Responsible Officer of the institution that has taken jurisdiction shall notify the Responsible Officer of the additional institution(s) and they shall jointly re-determine jurisdiction in accordance with the Code of Research Integrity and the University of Toronto Framework to Address Allegations of Research Misconduct, including the Research Misconduct Framework Addendum and these procedures.

III. Determining Jurisdiction

a) For complaints against University of Toronto status-only appointees or CAMH employees, jurisdiction is presumed to be solely at CAMH unless the criteria below convince the CAMH Responsible Officer, the Vice-President of Research, otherwise.
b) For complaints against members of the University of Toronto Teaching Staff, Students or employees, jurisdiction is presumed to be solely at the University unless the criteria below convince the University of Toronto Responsible Officer, the Vice-Provost, Relations with Healthcare Institutions, otherwise.
c) For complaints against an individual not listed in (a) or (b) above who is cross-appointed at both the University of Toronto and CAMH, jurisdiction should not be presumed by either the University or CAMH and must be determined as outlined below.

Jurisdiction will be determined by establishing which institution has the stronger connection to the complainant, after making due consideration for responsibilities for handling the research misconduct that may have been incurred by each institution by virtue of pre-existing agreements (e.g. grant agreements). In general, the following factors shall be considered in determining jurisdiction:

i) Where was the research that is the subject matter of the complaint conducted (e.g. university or Affiliated Institution premises)? If the complaint involves several research studies or a body of research, the focus will be on where the research is primarily conducted.
ii) Where did supervision for the research occur?
iii) Which institution administered the research funding, if any?
iv) Which institution is party to the research contract with any third party?
v) Which institution's research ethics board, animal care committee or biosafety committee conducted the full board review of the research?
vi) Is the respondent a recipient of a support arrangement that is jointly administered by both the University and the Affiliated Institution (e.g., a Canada Research Chair)?

In some cases, it may be determined that both the University of Toronto (and/or its other Affiliate) and CAMH should have joint jurisdiction.

IV. Procedures of the Institution that has Jurisdiction

The institution that has jurisdiction as determined hereunder shall be responsible for all communications to the Complainant and Respondent. Where there is joint jurisdiction, the Responsible Officers of the University and the Affiliated Institution will jointly make decisions typically made by an institution with sole jurisdiction. Should the Responsible Officers be unable to reach a joint decision, the matter shall be referred to the applicable hospital CEO and the University Provost, in consultation with the University's Vice-President, Research, for resolution. Each party shall have the option of having at least one representative on the Investigation Committee.

Notice Requirements

In cases where sole jurisdiction lies with either the University of Toronto or an Affiliated Institution but circumstances warrant notice to the other institution, notice of the outcome of the Inquiry and/or Investigation shall also be made to the other institution.

Timelines

These procedures must be implemented in accord with timeframes and deadlines established elsewhere in the Code of Research Integrity and its associated procedures.

#9 Procedure for the Assessment of Research Misconduct Allegations

This procedure is associated with 2. Policy on Research Misconduct and is also intended to meet procedural requirements (in part) mandated by the U.S. department of Health and Human Services, as regulated under 42 CFR Parts 50 and 93, to which CAMH research sponsored by the DHHS (i.e. NIH) is subject.

As the DHHS agency that deals with research misconduct, the Office of Research Integrity, has extensive experience with effective procedures for handling allegations of misconduct, their sample policy and procedures have been modified to derive the following procedure, which applies to all allegations of research misconduct at CAMH, irrespective of whether it relates to the U.S. DHHS. Definitions for terms used herein can be found in 2. Policy on Research Misconduct and/or 42 CFR Parts 50 and 93.

Upon receiving an allegation of research misconduct, the RIO will immediately assess the allegation to determine whether it is sufficiently credible and specific so that potential evidence of research misconduct may be identified and whether it falls within the jurisdiction of 2. Policy on Research Misconduct. An inquiry must be conducted if these criteria are met (see **#11 Procedure for Initiating a Research Misconduct Inquiry**).

The assessment period should be brief, preferably concluded within a week. In conducting the assessment, the RIO need not interview the complainant, respondent, or other witnesses, or gather data beyond any that may be have been submitted with the allegation, except as necessary to determine whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified. The RIO shall, on or before the date on which the respondent is notified of the allegation, obtain custody of, inventory, and sequester all research records and evidence needed to conduct the research misconduct proceeding, as provided in 2. Policy on Research Misconduct (see **#12 Procedure for Notifying the Respondent and Sequestering Research Records Pursuant to a Research Misconduct Inquiry**).

#10 Procedure for Interim Administrative Actions Regarding Research Misconduct

This procedure is associated with 2. Policy on Research Misconduct and is also intended to meet procedural requirements (in part) mandated by the U.S. department of Health and Human Services, as regulated under 42 CFR Parts 50 and 93, to which CAMH research sponsored by the DHHS (i.e. NIH) is subject.

As the DHHS agency that deals with research misconduct, the Office of Research Integrity, has extensive experience with effective procedures for handling allegations of misconduct, their sample policy and procedures have been modified to derive the following procedure, which applies to all allegations of research misconduct at CAMH, irrespective of whether it relates to the U.S. DHHS. Definitions for terms used herein can be found in 2. Policy on Research Misconduct and/or 42 CFR Parts 50 and 93.

Throughout the research misconduct proceeding, the RIO will review the situation to determine if there is any threat of harm to public health, funding and equipment, or other threats to the integrity of the research process. In the event of such a threat, the RIO will, in consultation with other institutional officials (and, in the case of research related to the U.S. DHHS, the Office of Research Integrity), take appropriate interim action to protect against any such threat. Interim action might include additional monitoring of the research process and the handling of funds and equipment, reassignment of personnel or of the responsibility for handling funds and equipment, additional review of research data and results or delaying publication.

In the case of research related to the U.S. DHHS, the RIO shall, at any time during a research misconduct proceeding, notify the Office of Research Integrity immediately if he/she has reason to believe that any of the following conditions exist:

- Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
- DHHS resources or interests are threatened;
- Research activities should be suspended;
- There is a reasonable indication of possible violations of civil or criminal law;
- U.S. government action is required to protect the interests of those involved in the research misconduct proceeding;
- The research misconduct proceeding may be made public prematurely and DHHS action may be necessary to safeguard evidence and protect the rights of those involved; or
- The research community or public should be informed.

#11 Procedure for Initiating a Research Misconduct Inquiry

This procedure is associated with 2. Policy on Research Misconduct and is also intended to meet procedural requirements (in part) mandated by the U.S. department of Health and Human Services, as regulated under 42 CFR Parts 50 and 93, to which CAMH research sponsored by the DHHS (i.e. NIH) is subject.

As the DHHS agency that deals with research misconduct, the Office of Research Integrity, has extensive experience with effective procedures for handling allegations of misconduct, their sample policy and procedures have been modified to derive the following procedure, which applies to all allegations of research misconduct at CAMH, irrespective of whether it relates to the U.S. DHHS. Definitions for terms used herein can be found in 2. Policy on Research Misconduct and/or 42 CFR Parts 50 and 93.

If the RIO determines that the criteria for an inquiry are met, he or she will immediately initiate the inquiry process. The purpose of the inquiry is to conduct an initial review of the available evidence to determine whether to conduct an investigation. An inquiry does not require a full review of all the evidence related to the investigation. The following procedures apply to inquiries:

- **#12 Procedure for Notifying the Respondent and Sequestering Research Records Pursuant to a Research Misconduct Inquiry**
- **#13 Procedure for Conducting the Research Misconduct Inquiry Process**
- **#14 Procedure for Preparing the Final Research Misconduct Inquiry Report**
- **#15 Procedure for Notifying the Respondent of the Research Misconduct Inquiry Findings and Providing Opportunity to Comment**
- **#16 Procedure: Criteria for Evaluating Whether an Investigation into Research Conduct is Warranted**
- **#17 Procedure for Institutional Decision on the Research Misconduct Inquiry Findings**
- **#18 Procedure for Documenting a Decision Not to Investigate Research Conduct**

#12 Procedure for Notifying the Respondent and Sequestering Research Records Pursuant to a Research Misconduct Inquiry

This procedure is associated with 2. Policy on Research Misconduct and is also intended to meet procedural requirements (in part) mandated by the U.S. department of Health and Human Services, as regulated under 42 CFR Parts 50 and 93, to which CAMH research sponsored by the DHHS (i.e. NIH) is subject.

As the DHHS agency that deals with research misconduct, the Office of Research Integrity, has extensive experience with effective procedures for handling allegations of misconduct, their sample policy and procedures have been modified to derive the following procedure, which applies to all allegations of research misconduct at CAMH, irrespective of whether it relates to the U.S. DHHS. Definitions for terms used herein can be found in 2. Policy on Research Misconduct and/or 42 CFR Parts 50 and 93.

At the time of or before beginning an inquiry, the RIO must make a good faith effort to notify the respondent in writing, if the respondent is known. If the inquiry subsequently identifies additional respondents, they must be notified in writing.

On or before the date on which the respondent is notified, or the inquiry begins, whichever is earlier, the RIO must take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence and sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.

#13 Procedure for Conducting the Research Misconduct Inquiry Process

This procedure is associated with 2. Policy on Research Misconduct and is also intended to meet procedural requirements (in part) mandated by the U.S. department of Health and Human Services, as regulated under 42 CFR Parts 50 and 93, to which CAMH research sponsored by the DHHS (i.e. NIH) is subject.

As the DHHS agency that deals with research misconduct, the Office of Research Integrity, has extensive experience with effective procedures for handling allegations of misconduct, their sample policy and procedures have been modified to derive the following procedure, which applies to all allegations of research misconduct at CAMH, irrespective of whether it relates to the U.S. DHHS. Definitions for terms used herein can be found in 2. Policy on Research Misconduct and/or 42 CFR Parts 50 and 93.

Those conducting the inquiry will normally interview the complainant, the respondent, and key witnesses as well as examine relevant research records and materials. Then, those conducting the inquiry will evaluate the evidence, including the testimony obtained during the inquiry. After consultation with the RIO, those conducting the inquiry will decide whether an investigation is warranted based on the criteria in 2. Policy on Research Misconduct.

The scope of the inquiry is not required to and does not normally include deciding whether misconduct definitely occurred, determining definitely who committed the research misconduct or conducting exhaustive interview and analyses.

However, if a legally sufficient admission of research misconduct is made by the respondent, misconduct may be determined at the inquiry stage if all relevant issues are resolved. In that case and if the research relates to the U.S. DHHS, the Office of Research Integrity will be promptly consulted to determine the next steps that should be taken.

Timeline for Completion

The inquiry, including preparation of the final inquiry report (see **#14 Procedure for Preparing the Final Research Misconduct Inquiry Report** & **#15 Procedure for Notifying the Respondent of the Research Misconduct Inquiry Findings and Providing Opportunity to Comment**) and the decision of the DO on whether an investigation is warranted (see **#16 Procedure: Criteria for Evaluating Whether an Investigation into Research Conduct is Warranted**), must be completed with 60 calendar days of initiation of the inquiry, unless the RIO determines that circumstances clearly warrant a longer period. If the RIO approves an extension, the inquiry record must include documentation of the reasons for exceeding the 60-day period.

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#14 Procedure for Preparing the Final Research Misconduct Inquiry Report

This procedure is associated with 2. Policy on Research Misconduct and is also intended to meet procedural requirements (in part) mandated by the U.S. department of Health and Human Services, as regulated under 42 CFR Parts 50 and 93, to which CAMH research sponsored by the DHHS (i.e. NIH) is subject.

As the DHHS agency that deals with research misconduct, the Office of Research Integrity, has extensive experience with effective procedures for handling allegations of misconduct, their sample policy and procedures have been modified to derive the following procedure, which applies to all allegations of research misconduct at CAMH, irrespective of whether it relates to the U.S. DHHS. Definitions for terms used herein can be found in 2. Policy on Research Misconduct and/or 42 CFR Parts 50 and 93.

Elements of the Inquiry Report

A written inquiry report must be prepared that includes the following information:

- the name and position of the respondent;
- a description of the allegations of research misconduct;
- a listing of the funding supporting the research, including, for example, grant numbers, grant applications, contracts, and publications listing the support;
- the basis for recommending or not recommending that the allegations warrant an investigation;
- any comments on the draft report by the respondent or complainant (see **#15 Procedure for Notifying the Respondent of the Research Misconduct Inquiry Findings and Providing Opportunity to Comment**).

Institutional counsel should review the report for legal sufficiency. Modifications should be made as appropriate in consultation with the RIO and those who conducted the inquiry.

Timeline for Completion

The inquiry, including preparation of the final inquiry report must be completed with 60 calendar days of initiation of the inquiry, unless the RIO determines that circumstances clearly warrant a longer period. If the RIO approves an extension, the inquiry record must include documentation of the reasons for exceeding the 60-day period.

#15 Procedure for Notifying the Respondent of the Research Misconduct Inquiry Findings and Providing Opportunity to Comment

This procedure is associated with 2. Policy on Research Misconduct and is also intended to meet procedural requirements (in part) mandated by the U.S. department of Health and Human Services, as regulated under 42 CFR Parts 50 and 93, to which CAMH research sponsored by the DHHS (i.e. NIH) is subject.

As the DHHS agency that deals with research misconduct, the Office of Research Integrity, has extensive experience with effective procedures for handling allegations of misconduct, their sample policy and procedures have been modified to derive the following procedure, which applies to all allegations of research misconduct at CAMH, irrespective of whether it relates to the U.S. DHHS. Definitions for terms used herein can be found in 2. Policy on Research Misconduct and/or 42 CFR Parts 50 and 93.

The RIO shall notify the respondent whether the inquiry found an investigation to be warranted, and include a copy of the draft inquiry report for comment within 10 days, and include a copy of relevant CAMH and external policies, procedures, and regulations on research misconduct.

Any comments that are submitted by the respondent or complainant will be attached to the final inquiry report. Based on the comments, those who conduct the inquiry may revise the draft report as appropriate and prepare it in final form. Those who conduct the inquiry will deliver the final report to the RIO.

Timeline for Completion

The inquiry, including preparation of the final inquiry report must be completed with 60 calendar days of initiation of the inquiry, unless the RIO determines that circumstances clearly warrant a longer period. If the RIO approves an extension, the inquiry record must include documentation of the reasons for exceeding the 60-day period.

#16 Procedure: Criteria for Evaluating Whether an Investigation into Research Conduct is Warranted

This procedure is associated with 2. Policy on Research Misconduct and is also intended to meet procedural requirements (in part) mandated by the U.S. department of Health and Human Services, as regulated under 42 CFR Parts 50 and 93, to which CAMH research sponsored by the DHHS (i.e. NIH) is subject.

As the DHHS agency that deals with research misconduct, the Office of Research Integrity, has extensive experience with effective procedures for handling allegations of misconduct, their sample policy and procedures have been modified to derive the following procedure, which applies to all allegations of research misconduct at CAMH, irrespective of whether it relates to the U.S. DHHS. Definitions for terms used herein can be found in 2. Policy on Research Misconduct and/or 42 CFR Parts 50 and 93.

Purpose: This procedure is intended to provide guidance on evaluating whether an investigation is warranted during an inquiry into potential misconduct. This procedure is also intended, in cases of research related to the U.S. DHHS, to enable evaluation in a manner that is compliant by using the criteria indicated in 42 CFR § 93.307 (d).

An inquiry's purpose is to decide if an allegation warrants an investigation. An investigation is warranted if there is –

(1) A reasonable basis for concluding that the allegation falls within the definition of research misconduct under the policy, and
(2) Preliminary information-gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance.

Evaluation of these criteria is undertaken by the Deciding Official.

Any finding that an investigation is warranted must be made in writing by the DO and may need to be provided to a sponsoring or regulating agency. In the case of research related to the U.S. DHHS, the finding must be provided to the Office of Research Integrity, together with a copy of the inquiry report meeting the requirements of 42 CFR § 93.309, within 30 days of the finding.

If it is found that an investigation is not warranted, the DO and the RIO will ensure that detailed documentation of the inquiry is retained for at least 7 years after termination of the inquiry. In the case of research related to the U.S. DHHS, this will enable the Office of Research Integrity to assess the reasons why the institution decided not to conduct an investigation.

camh Centre for Addiction and Mental Health

#17 Procedure for Institutional Decision on the Research Misconduct Inquiry Findings

This procedure is associated with 2. Policy on Research Misconduct and is also intended to meet procedural requirements (in part) mandated by the U.S. department of Health and Human Services, as regulated under 42 CFR Parts 50 and 93, to which CAMH research sponsored by the DHHS (i.e. NIH) is subject.

As the DHHS agency that deals with research misconduct, the Office of Research Integrity, has extensive experience with effective procedures for handling allegations of misconduct, their sample policy and procedures have been modified to derive the following procedure, which applies to all allegations of research misconduct at CAMH, irrespective of whether it relates to the U.S. DHHS. Definitions for terms used herein can be found in 2. Policy on Research Misconduct and/or 42 CFR Parts 50 and 93.

Decision by Deciding Official

The RIO will transmit the final inquiry report and any comments to the DO, who will determine in writing whether an investigation is warranted. The inquiry is completed when the DO makes this determination.

Timeline for Completion

The inquiry, including preparation of the final inquiry report must be completed with 60 calendar days of initiation of the inquiry, unless the RIO determines that circumstances clearly warrant a longer period. If the RIO approves an extension, the inquiry record must include documentation of the reasons for exceeding the 60-day period.

If the research relates to the U.S. DHHS, within 30 calendar days of the DO's decision that an investigation is warranted, the RIO will provide the Office of Research Integrity with the DO's written decision and a copy of the inquiry report. The RIO will also notify those institutional officials who need to know of the DO's decision. The RIO must provide the following information to the Office of Research Integrity upon request: (1) the institutional policies and procedures under which the inquiry was conducted; (2) the research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and (3) the charges to be considered in the investigation.

#18 Procedure for Documenting a Decision Not to Investigate Research Conduct

This procedure is associated with 2. Policy on Research Misconduct and is also intended to meet procedural requirements (in part) mandated by the U.S. department of Health and Human Services, as regulated under 42 CFR Parts 50 and 93, to which CAMH research sponsored by the DHHS (i.e. NIH) is subject.

As the DHHS agency that deals with research misconduct, the Office of Research Integrity, has extensive experience with effective procedures for handling allegations of misconduct, their sample policy and procedures have been modified to derive the following procedure, which applies to all allegations of research misconduct at CAMH, irrespective of whether it relates to the U.S. DHHS. Definitions for terms used herein can be found in 2. Policy on Research Misconduct and/or 42 CFR Parts 50 and 93.

If the DO decides that an investigation is not warranted, the RIO shall secure and maintain for 7 years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment but any external agency with jurisdiction (such as the Office of Research Integrity in the case of research related to the U.S. DHHS) of the reasons why an investigation was not conducted. These documents must be provided to the external agency with jurisdiction upon request.

#19 Procedure for Notifying Parties and Sequestering Records Pursuant to an Investigation

This procedure is associated with 2. Policy on Research Misconduct and is also intended to meet procedural requirements (in part) mandated by the U.S. department of Health and Human Services, as regulated under 42 CFR Parts 50 and 93, to which CAMH research sponsored by the DHHS (i.e. NIH) is subject.

As the DHHS agency that deals with research misconduct, the Office of Research Integrity, has extensive experience with effective procedures for handling allegations of misconduct, their sample policy and procedures have been modified to derive the following procedure, which applies to all allegations of research misconduct at CAMH, irrespective of whether it relates to the U.S. DHHS. Definitions for terms used herein can be found in 2. Policy on Research Misconduct and/or 42 CFR Parts 50 and 93.

On or before the date on which the investigation begins, the RIO must: (1) notify any external agency with a right to be notified, in the case of research related to the U.S. DHHS, the Office of Research Integrity Director, of the decision to begin the investigation and provide said agency with a copy of the inquiry report; and (2) notify the respondent in writing of the allegations to be investigated.

The RIO must also give the respondent written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the inquiry or in the initial notice of the investigation.

The RIO will, prior to notifying respondent of the allegations, take all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the research misconduct proceeding that were not previously sequestered during the inquiry. The need for additional sequestration of records for the investigation may occur for any number of reasons, including the institution's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during an inquiry (see **#12 Procedure for Notifying the Respondent and Sequestering Research Records Pursuant to a Research Misconduct Inquiry**).

#20 Procedure for Appointment of the Research Misconduct Investigation Committee

This procedure is associated with 2. Policy on Research Misconduct and is also intended to meet procedural requirements (in part) mandated by the U.S. department of Health and Human Services, as regulated under 42 CFR Parts 50 and 93, to which CAMH research sponsored by the DHHS (i.e. NIH) is subject.

As the DHHS agency that deals with research misconduct, the Office of Research Integrity, has extensive experience with effective procedures for handling allegations of misconduct, their sample policy and procedures have been modified to derive the following procedure, which applies to all allegations of research misconduct at CAMH, irrespective of whether it relates to the U.S. DHHS. Definitions for terms used herein can be found in 2. Policy on Research Misconduct and/or 42 CFR Parts 50 and 93.

The RIO, in consultation with other institutional officials as appropriate, will appoint an investigation committee and the committee chair as soon after the beginning of the investigation as is practical. The **#8 Procedures for Inter-Institutional Notification Regarding Research Misconduct and Determining Jurisdiction with the University of Toronto** also applies to the appointment of an investigation committee as University of Toronto representation may be required. The investigation committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the investigation and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the respondent and complainant and conduct the investigation.

When necessary to secure the necessary expertise or to avoid conflicts of interest, the RIO may select committee members from outside CAMH.

CAMH may notify the respondent of the proposed committee membership to give the respondent an opportunity to object to a proposed member based upon personal, professional, or financial conflict of interest and the respondent has no more than 10 calendar days to submit objections to the RIO. CAMH will make the final determination of whether a conflict exists.

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#21 Procedure for Writing the Charge to the Research Misconduct Investigation Committee and Holding the First Meeting

This procedure is associated with 2. Policy on Research Misconduct and is also intended to meet procedural requirements (in part) mandated by the U.S. department of Health and Human Services, as regulated under 42 CFR Parts 50 and 93, to which CAMH research sponsored by the DHHS (i.e. NIH) is subject.

As the DHHS agency that deals with research misconduct, the Office of Research Integrity, has extensive experience with effective procedures for handling allegations of misconduct, their sample policy and procedures have been modified to derive the following procedure, which applies to all allegations of research misconduct at CAMH, irrespective of whether it relates to the U.S. DHHS. Definitions for terms used herein can be found in 2. Policy on Research Misconduct and/or 42 CFR Parts 50 and 93.

Charge to the Committee

The RIO will define the subject matter of the investigation in a written charge to the committee that:

- Describes the allegations and related issues identified during the inquiry;
- Identifies the respondent;
- Informs the committee that it must conduct the investigation as prescribed in **#22 Procedure for Conducting the Research Misconduct Investigation Process**;
- Defines research misconduct;
- Informs the committee that it must evaluate the evidence and testimony to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, the type and extent of it and who was responsible;
- Informs the committee that in order to determine that the respondent committed research misconduct it must find that a preponderance of the evidence establishes that:
  (1) Research misconduct, as defined in 2. Policy on Research Misconduct, occurred (respondent has the burden of proving by a preponderance of the evidence any affirmative defences raised, including honest error or a difference of opinion);
  (2) The research misconduct is a significant departure from accepted practices of the relevant research community; and
  (3) The respondent committed the research misconduct intentionally, knowingly, or recklessly; and
- Informs the committee that it must prepare or direct the preparation of a written investigation report that meets the requirements of this policy. In the case of research related to the U.S. DHHS, the report must meet the requirements of this policy and 42 CFR § 93.313.

First Meeting

The RIO will convene the first meeting of the investigation committee to review the charge, the inquiry report, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality and for developing a specific investigation plan. The investigation committee will be provided with a copy of this statement of policy and procedures and, in the case of research related to the U.S. DHHS, 42 CFR part 93. The RIO will be present or available throughout the investigation to advise the committee as needed.

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#22 Procedure for Conducting the Research Misconduct Investigation Process

This procedure is associated with 2. Policy on Research Misconduct and is also intended to meet procedural requirements (in part) mandated by the U.S. department of Health and Human Services, as regulated under 42 CFR Parts 50 and 93, to which CAMH research sponsored by the DHHS (i.e. NIH) is subject.

As the DHHS agency that deals with research misconduct, the Office of Research Integrity, has extensive experience with effective procedures for handling allegations of misconduct, their sample policy and procedures have been modified to derive the following procedure, which applies to all allegations of research misconduct at CAMH, irrespective of whether it relates to the U.S. DHHS. Definitions for terms used herein can be found in 2. Policy on Research Misconduct and/or 42 CFR Parts 50 and 93.

The investigation must begin within 30 calendar days after the determination by the DO that an investigation is warranted.

The investigation committee and the RIO must:

- Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of each allegation;
- Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;
- Interview each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent, and record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of the investigation; and
- Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of any additional instances of possible research misconduct, and continue the investigation to completion.

Time for Completion

The investigation is to be completed within 120 days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft report for comment and sending the final report to any external agency which has a right to receive it, in the case of research related to the U.S. DHHS, the Office of Research Integrity.

However, in the case of research related to the U.S. DHHS, if the RIO determines that the investigation will not be completed within this 120-day period, he/she will submit to the Office of Research integrity a written request for an extension, setting forth the reasons for the delay. The RIO will ensure that periodic progress reports are filed with the Office of Research Integrity, if the Office of Research Integrity grants the request for an extension and directs the filing of such reports.

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#23 Procedure for Preparing the Misconduct Investigation Report

This procedure is associated with 2. Policy on Research Misconduct and is also intended to meet procedural requirements (in part) mandated by the U.S. department of Health and Human Services, as regulated under 42 CFR Parts 50 and 93, to which CAMH research sponsored by the DHHS (i.e. NIH) is subject.

As the DHHS agency that deals with research misconduct, the Office of Research Integrity, has extensive experience with effective procedures for handling allegations of misconduct, their sample policy and procedures have been modified to derive the following procedure, which applies to all allegations of research misconduct at CAMH, irrespective of whether it relates to the U.S. DHHS. Definitions for terms used herein can be found in 2. Policy on Research Misconduct and/or 42 CFR Parts 50 and 93.

A. Elements of the Investigation Report

The investigation committee and the RIO are responsible for preparing a written draft report of the investigation that:

- Describes the nature of the allegation of research misconduct, including identification of the respondent.
- Describes and documents the funding in support of the research, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing support;
- Describes the specific allegations of research misconduct considered in the investigation;
- Includes the institutional policies and procedures under which the investigation was conducted;
- Identifies and summarizes the research records and evidence reviewed and identifies any evidence taken into custody but not reviewed; and
- Includes a statement of findings for each allegation of research misconduct identified during the investigation. Each statement of findings must:
  (1) identify whether the research misconduct was falsification, fabrication, or plagiarism (in the case of research related to the U.S. DHHS) or another breach of research integrity constituting research misconduct, and whether it was committed intentionally, knowingly, or recklessly;
  (2) summarize the facts and the analysis that support the conclusion and consider the merits of any reasonable explanation by the respondent, including any effort by respondent to establish by a preponderance of the evidence that he or she did not engage in research misconduct because of honest error or a difference of opinion;
  (3) identify the specific funding supporting the research;
  (4) identify whether any publications need correction or retraction;
  (5) identify the person(s) responsible for the misconduct; and
  (6) list any current support or known applications or proposals for support that the respondent has pending with any agency.

B. Comments on the Draft Report and Access to Evidence

1. Respondent

The RIO must give the respondent a copy of the draft investigation report for comment and, concurrently, a copy of, or supervised access to the evidence on which the report is based. The respondent will be allowed 30 days from the date he/she received the draft report to submit comments to the RIO. The respondent's comments must be included and considered in the final report.

2. Confidentiality

In distributing the draft report, or portions thereof, to the respondent, the RIO will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. For example, the RIO may require that the recipient sign a confidentiality agreement.

#24 Procedure for Institutional Decision, Notification and Appeal

This procedure is associated with 2. Policy on Research Misconduct and is also intended to meet procedural requirements (in part) mandated by the U.S. department of Health and Human Services, as regulated under 42 CFR Parts 50 and 93, to which CAMH research sponsored by the DHHS (i.e. NIH) is subject.

As the DHHS agency that deals with research misconduct, the Office of Research Integrity, has extensive experience with effective procedures for handling allegations of misconduct, their sample policy and procedures have been modified to derive the following procedure, which applies to all allegations of research misconduct at CAMH, irrespective of whether it relates to the U.S. DHHS. Definitions for terms used herein can be found in 2. Policy on Research Misconduct and/or 42 CFR Parts 50 and 93.

The RIO will assist the investigation committee in finalizing the draft investigation report, including ensuring that the respondent's comments are included and considered, and transmit the final investigation report to the DO, who will determine in writing:

(1) whether the institution accepts the investigation report, its findings, and the recommended institutional actions; and
(2) the appropriate institutional actions in response to the accepted findings of research misconduct.

If this determination varies from the findings of the investigation committee, the DO will, as part of his/her written determination, explain in detail the basis for rendering a decision different from the findings of the investigation committee. Alternatively, the DO may return the report to the investigation committee with a request for further fact-finding or analysis.

When a final decision on the case has been reached, the RIO will normally notify both the respondent and the complainant in writing. The respondent has 5 days from the receipt of notification to file an appeal.

Sub Procedure for Appeals

1. Within five days of receipt of the notification of decision the respondent has the right to appeal the decision by submitting a petition for review of the investigation and decision to the President/CEO of CAMH.
2. On receipt of an appeal, the President/CEO of CAMH or a designate other than the DO or members of the investigation committee will review the records of the inquiry and investigation and the investigation report and either confirm the decision or issue a revised decision to the RIO who will once again notify the respondent and complainant in writing. This will occur within 120 days of receipt of the appeal.

On the sixth day after the RIO notifies the respondent and the complainant provided no appeal has been filed, or immediately after the respondent and complainant have been notified of the outcome of an appeal, and

after informing any other agency which may have a right to be informed (in the case of research relating to the U.S. DHHS, the Office of Research Integrity), the DO will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case.

The RIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies. For example, in the case of research relating to the U.S. DHHS, unless an extension has been granted, the RIO must, within the 120-day period for completing the investigation, submit the following to the Office of Research Integrity:

(1) a copy of the final investigation report with attachments;
(2) a statement of whether the institution accepts the findings of the investigation report;
(3) a statement of whether the institution found misconduct and, if so, who committed the misconduct; and
(4) a description of any pending or completed administrative actions against the respondent.

#25 Procedure for Managing the Records of the Research Misconduct Investigation

This procedure is associated with 2. Policy on Research Misconduct and is also intended to meet procedural requirements (in part) mandated by the U.S. department of Health and Human Services, as regulated under 42 CFR Parts 50 and 93, to which CAMH research sponsored by the DHHS (i.e. NIH) is subject.

As the DHHS agency that deals with research misconduct, the Office of Research Integrity, has extensive experience with effective procedures for handling allegations of misconduct, their sample policy and procedures have been modified to derive the following procedure, which applies to all allegations of research misconduct at CAMH, irrespective of whether it relates to the U.S. DHHS. Definitions for terms used herein can be found in 2. Policy on Research Misconduct and/or 42 CFR Parts 50 and 93.

The RIO must maintain records of research misconduct proceedings, which include:

(1) The records that the institution secures for the proceedings, except to the extent the institution subsequently determines and documents that those records are not relevant to the proceeding or that the records duplicate other records that are being retained;
(2) The documentation of the determination of irrelevant or duplicate records;
(3) The inquiry report and final documents (not drafts) produced in the course of preparing that report, including the documentation of any decision not to investigate as required.
(4) The investigation report and all records (other than drafts of the report) in support of that report, including the recordings or transcriptions of each interview conducted;
(5) And, in the case of research relating to the U.S. DHHS, provide these to the Office of Research Integrity on request.

Records of research misconduct proceedings must be maintained in a secure manner for 7 years after completion of the proceeding. In the case of research involving the U.S. DHHS, 7 years after the completion of any PHS proceeding involving the research misconduct allegation and the RIO is also responsible for providing any information, documentation, research records, evidence or clarification requested by the Office of Research Integrity to carry out its review of an allegation of research misconduct or of the institution's handling of such an allegation.

#26 Procedure for the Closure of a Research Misconduct Case at the Inquiry or Investigation Stage

This procedure is associated with 2. Policy on Research Misconduct and is also intended to meet procedural requirements (in part) mandated by the U.S. department of Health and Human Services, as regulated under 42 CFR Parts 50 and 93, to which CAMH research sponsored by the DHHS (i.e. NIH) is subject.

As the DHHS agency that deals with research misconduct, the Office of Research Integrity, has extensive experience with effective procedures for handling allegations of misconduct, their sample policy and procedures have been modified to derive the following procedure, which applies to all allegations of research misconduct at CAMH, irrespective of whether it relates to the U.S. DHHS. Definitions for terms used herein can be found in 2. Policy on Research Misconduct and/or 42 CFR Parts 50 and 93.

In the case of research relating to the U.S. DHHS, the RIO must notify the Office of Research Integrity in advance if there are plans to close a case at the inquiry, investigation, or appeal stage on the basis that respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except: (1) closing of a case at the inquiry stage on the basis that an investigation is not warranted; or (2) a finding of no misconduct at the investigation stage, which must be reported to the Office of Research Integrity, as prescribed in the Policy on Allegations of Research Misconduct and U.S. 42 CFR § 93.315.

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#27 Procedure for Determining Research Project Role Eligibility

This procedure is associated with 3. Policy on Research Project Role Eligibility.

This procedure should be used by all CAMH researchers with the following exception: CAMH employees whose project role designation on a research proposal document does not differ from their CAMH employment documents.

In the case of research teams, the primary CAMH research contact must ask the secondary contacts (i.e. other CAMH researchers) to follow this procedure to confirm their eligibility.

Step #1 Locate your most recent active letter of appointment to the CAMH Research Program.

Step #2 Review the sponsor's call for proposals document (or equivalent, such as the "funding opportunity announcement" or "request for proposals" etc.) and locate any sponsor requirements regarding researcher/project role eligibility for the specific funding opportunity

Step #3 Review the sponsor's general funding program or agency policies and locate any sponsor requirements provided therein regarding researcher/project role eligibility (in particular, citizenship, jurisdiction or institutional affiliation requirements).

Step #4 Review any other sponsor document which pertains to researcher/project role eligibility and identify any other requirements, these are typically found in program guidelines and post-award administration requirements (in particular financial management responsibilities).

Step #5 Check the sponsor requirements. If the sponsor requires researchers with specific project roles:

(a) To have certain credentials or experience, do your credentials and experience match the requirements?

(b) To be at a certain career stage, such as independent researcher, are you at this career stage and is this confirmed in your appointment letter?

(c) To have not exceeded a certain career stage, is your CV consistent with this limitation and is there nothing in your appointment letter which indicates that you are at a later career stage?

(d) To have access to specific kinds of resources by virtue of your appointment,

i. for example, specific institutional research infrastructure which is under your direction, such as work space, or

ii. time which is yours to direct to the research work which will be funded by the sponsor, and

iii. are the appropriate and required resources under your control to the extent required?

(e) To have certain rights and responsibilities regarding the training and supervision of project staff, and do you have these rights?

(f) To be entitled to financial management responsibilities at CAMH, are you able to hold an account?

Step #6 If you can answer yes to all the questions in step 5, you should be eligible to assume the project role on proposal documents and to assume that role during the conduct of the research insofar as your continued ability to answer yes to those questions does not change.

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#28 Procedure for Retaining the Rights to Publish

This procedure is associated with 4. Policy on Data/Research Resources, Authorship, and Publication and is also intended to meet policy and procedural responsibilities (in part) required under the agreement with U of T known as the "Affiliation Agreement."

Procedure: All research contracts will be negotiated, reviewed and approved using standard contract review practices and in such a manner that they will be compliant with 4. Policy on Data/Research Resources, Authorship, and Publication and/or the University of Toronto Affiliation Agreement.

Special procedure for researchers supported by NIH funding:

1. Researchers review and become familiar with the NIH "Public Access" policy requirements, currently provided here: http://publicaccess.nih.gov/
2. Researchers comply with the requirements.

Special procedure for researchers supported by CIHR funding:

1. Researchers review and become familiar with the CIHR "Policy on Access to Research Outputs", currently provided here: http://www.cihr-irsc.gc.ca/e/32005.html
    a. Including the Resources:
        i. Flowchart for open access publications: http://www.cihr-irsc.gc.ca/e/35677.html
2. Researchers comply with the requirements.

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#29 Procedure for Assessing and Disclosing Interests/Interactions (Financial or Tobacco Industry)

This procedure is associated with 5. Policy and is also intended to meet procedural requirements (in part) mandated by the U.S. department of Health and Human Services, as regulated under 42 CFR Part 50 Subpart F, to which CAMH research sponsored by the PHS (i.e. NIH) is subject. This procedure also recognizes recommendations of the 2003 WHO Framework Convention on Tobacco Control as per the 2008 Guidelines for implementation of article 5.3 of the WHO Framework Convention on Tobacco Control.

A flowchart overview of the process is provided on the next page.

Step #1. The person who will be listed as the "Primary Contact" for the project in line 1.1 of the RAAF downloads a TI/FCOI assessment tool and enters the details of the project into Part I (and saves the file).

Step #2. The Primary Contact then sends that file, in an email, to anyone else who is responsible for the design, conduct, or reporting of the research (these are "Secondary Contacts"), and asks each person to read Part I and Part II and perform the assessment in Part III no later than 2 weeks before a proposal submission deadline or no later than 2 weeks before the start of research, whichever event is earliest.

Step #3. The Primary and Secondary Contacts ask themselves the questions in Part III and read the instructions in bold at the bottom of Part III.

- If a given person answers "No" to every question, that person does not have to complete and submit the form at this time.
- If a given person answers "Yes" to any question, they must make a disclosure by completing Part IV of the form and then submitting it as indicated in Part V.

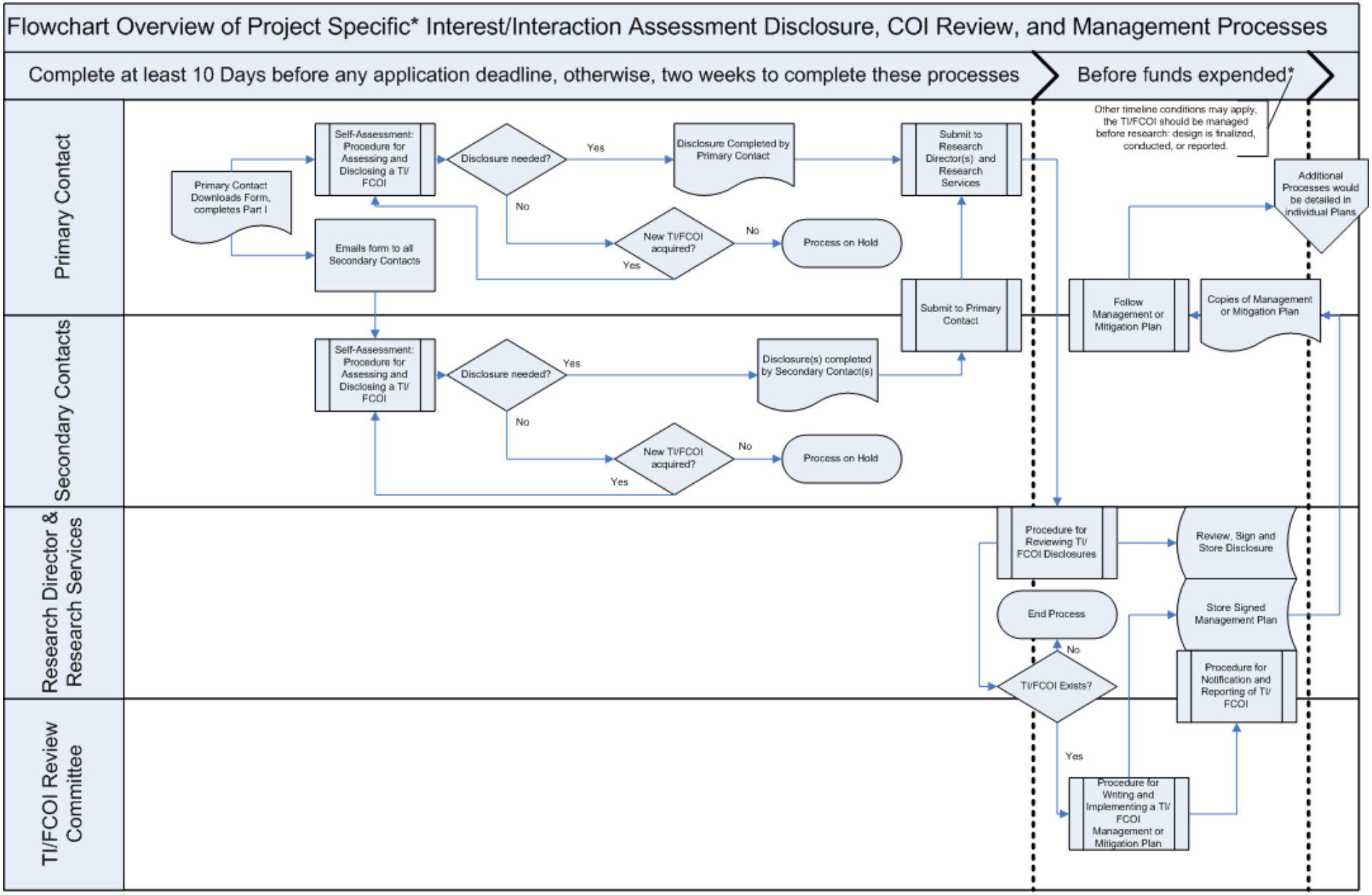
Step #4. The Primary Contact completes a RAAF for the project and indicates in line 9.7 if any disclosures were submitted to date and, by signing the RAAF, confirms that this procedure has been followed.

Provision is made on the form for repetition of this process, for example in the event that a researcher, a researcher's spouse/spousal equivalent or dependent child(ren) obtain a new Significant Financial Interest after the most recent disclosure.

Researchers are reminded that even non-funded research must be reviewed and approved under the Procedure for Research Proposal Review and Approval and that procedure requires compliance with 5. Policy.

Researchers will also use this process and the form in cases where tobacco industry/significant financial interests for research already designed, conducted or reported are being disclosed.

A sponsor or other agency may require additional assessment and disclosure and researchers should check TI/FCOI disclosure requirements to which they may be subject by virtue of agreements with sponsors or agencies before entering into such agreements.



* An annual review of significant financial interests related to each researcher's institutional responsibilities is conducted through the PRS process.

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Interest/Interaction

Assessment Tool and Disclosure Form
Ver. 2012

Date Received:			Office Use
Date Reviewed:			
TI/FCOI: YES NO	Tier: NA 1 2	BIAS: NA YES NO	
Reviewer:	Signature:		

As outlined in the Conflict of Interest in Research Policy in the Code of Research Integrity, the Research Program is committed to ensuring that there is no reasonable expectation that the design, conduct, or reporting of research with integrity was/is/will be compromised by real, apparent or potential financial conflict of interest or interactions with the tobacco industry. As a public hospital which also competes for public grant funding, CAMH is also committed to ensuring that reporting processes required under Canadian and U.S. regulations (Title 42 Code of Federal Regulations (CFR) Part 50 Subpart F for grants or cooperative agreements and Title 45 CFR Part 94 for research contracts) are in place to maintain the public trust.

*Please complete this assessment and submit any resulting disclosures **at least 10 business days before any pending funding application deadline** or within two weeks of receiving this form if no deadline is pending**.***
*Provision for repeating this process is also made below**.***

This form will help each researcher participating in the research activity listed below to:

1. Assess whether his/her participation in the research activity constitutes a potential conflict of interest and, if so,
2. To disclose the interest(s)/interaction for review by the appropriate official(s) to determine whether a conflict of interest exists and how it will be managed.
3. Directs all people involved in the design, conduct or reporting of PHS funded research to complete the tutorial before PHS funding flows to the project and at least once every four years : http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm

Part I: Research Activity Details

Activity Title					
Sites					
Primary CAMH Contact		Contact's Role		Contact's email	
Funding Source(s)				Application date(s)	
If the research activity involves human subjects, indicate the REB review status and/or REB approval number:					

Part II: Definition

Significant Financial Interest:

1. A financial interest consisting of one or more of the following interests of the researcher, the researcher's spouse/spousal equivalent or dependent child(ren):
   a. An interest in any publicly traded entity if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of the disclosure, when aggregated, exceeds $5,000 (in either Canadian or US dollars, whichever currency value yields the highest amount)
      i. Remuneration includes salary and any payment for services not otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship, travel reimbursement);
      ii. Equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
   b. An interest in any non-publicly traded entity if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
   c. Intellectual property rights (e.g. patents, copyrights), royalties from such rights, and agreements to share in royalties related to such rights, upon receipt of income related to such rights and interests.
2. The term does not include the following types of financial interests:
   a. salary, royalties, or other remuneration paid by the Institution to the researcher if the researcher is currently employed or otherwise appointed or engaged by the institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
   b. any ownership in the institution held by the researcher if the institution is a commercial or for-profit organization,
   c. income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
   d. income from seminars, lectures, or teaching engagements sponsored a government agency or an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education
   e. or income from service on advisory committees or review panels for a government agency or an institution of higher education an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education

Part III: Investigator's Assessment of Potential Conflict of Interest

A. Considering the research activity indicated in Part I:		
1. Do you, your spouse/spousal equivalent or dependent child(ren) hold a position of management, such as board member, director, officer, partner trustee, employee or consultant with a private or for-profit entity related to the research activity?	Yes	No
2. Do you, your spouse/spousal equivalent or dependent child(ren) have a Significant Financial Interest in any:		
• private or for-profit entity related to the research activity?	Yes	No
• private or for-profit entity that will manufacture or commercialize any drug, vaccine, device, product, procedure, or process that is associated with or that will predictably result from the research activity?	Yes	No
• private or for-profit entity that can reasonably be expected to benefit directly and significantly from the design, conduct, or reporting of the research activity?	Yes	No
• entity that can reasonably be expected to compete with the product or procedure that will predictably result from the research work?	Yes	No
3. Have you, your spouse/spousal equivalent or dependent child(ren) assigned to any private or for-profit entity related to the research activity rights to a disclosed intellectual property, pending patent application or an issued patent to any invention(s), or copyright for software?	Yes	No
4. Is it reasonable to anticipate that you, your spouse's/spousal equivalent's or dependent child(ren)s' financial interest could be directly and significantly affected by the design, conduct, or reporting of the research activity?	Yes	No
B. Are you/were you/will you be involved in setting and implementing public health policies with respect to tobacco control, in any capacity, including as a consultant or contractor, <u>and</u> have you/do you/will you have an interaction with the tobacco industry involving the offer and/or receipt of: • payments, gifts and services, monetary or in-kind, or • research funding, or • an occupational activity within the tobacco industry, whether gainful or not (such as a board membership), or • a direct interest (for example, an investment)?	Yes	No
If you answered "No" to all of the questions above, no further action is required at this time.		
If you answered "Yes" to any of the questions listed above, please complete Part IV and submit this disclosure (see Part V).		
If at any time during the design, conduct, or reporting of the research activity listed in Part I you, your spouse/spousal equivalent or dependent child(ren) obtain a new Significant Financial Interest, please repeat this process.		
If at any time during the design, conduct, or reporting of the research activity listed in Part I, your tobacco industry interest expands beyond that disclosed herein (as applicable), please repeat this process.		

Part IV: Disclosure of Potential Conflict of Interest

Your Name		Your Role		Your email	
Date		Date(s) of previous disclosures related to this research activity			

As applicable, in the box below, describe any management positions held by you, your spouse/spousal equivalent or dependent child(ren) with any private or for-profit entity related to the research activity. Be specific and detailed, including full company names and individual titles held, and take as much space as needed.

As applicable, in the box below, describe any Significant Financial Interests held by you, your spouse/spousal equivalent or dependent child(ren) with any private or for-profit entity related to the research activity. Be specific and detailed and take as much space as needed.

As applicable, in the box below, describe any Significant Financial Interests held by you, your spouse/spousal equivalent or dependent child(ren) in any private or for-profit entity that will manufacture or commercialize any drug, vaccine, device, product, procedure, or process that is associated with or that will predictably result from the research activity. Be specific and detailed and take as much space as needed.

As applicable, in the box below, describe any Significant Financial Interests held by you, your spouse/spousal equivalent or dependent child(ren) in any private or for-profit entity that can reasonably be expected to benefit directly and significantly from the design, conduct, or reporting of the research activity. Be specific and detailed and take as much space as needed.

As applicable, in the box below, describe any Significant Financial Interests held by you, your spouse/spousal equivalent or dependent child(ren) in any entity that can reasonably be expected to compete with the product or procedure that will predictably result from the research work. Be specific and detailed and take as much space as needed.

As applicable, in the box below, describe any instances whereby you, your spouse/spousal equivalent or dependent child(ren) assigned to any private or for-profit entity related to the research activity rights to a disclosed intellectual property, pending patent application or an issued patent to any invention(s), or copyright for software. Be specific and detailed and take as much space as needed.

As applicable, in the box below, describe how it is reasonable to anticipate that you, your spouse's/spousal equivalent's or dependent child(ren)s' financial interest could be directly and significantly affected by the design, conduct, or reporting of the research activity. Be specific and detailed and take as much space as needed.

As applicable, in the box below, describe your interactions with the tobacco industry. Be specific and detailed and take as much space as needed.

I hereby certify that the information I provide above is true, accurate and complete regarding this disclosure of a potential conflict of interest. I will repeat the assessment process and disclose any potential financial conflicts of interest thereby identified if new tobacco industry interests are obtained or if I, my spouse/spousal equivalent or dependent child(ren) obtain a new Significant Financial Interest.	Sign and date x

Part V: Submission Instructions

- If you are not the Primary CAMH Contact listed in Part I, please email the completed disclosure to the Primary CAMH Contact listed in Part I.
- If you are the Primary CAMH Contact listed in Part I and are receiving a disclosure on this form from a secondary contact (other researcher), please email the disclosure and a copy of the current research plan to the Director of research for your department (Clinical, Neuroscience, PET Centre or SER) and to Encar_tiglao@camh.net.
- If you are the Primary CAMH Contact listed in Part I and are making a disclosure on this form, please email it with the current research plan to the Director of research for your department and to Encar_tiglao@camh.net .

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#30 Procedure for Reviewing Interest/Interaction Disclosures

This procedure is associated with 5. Policy and is also intended to meet procedural requirements (in part) mandated by the U.S. department of Health and Human Services, as regulated under 42 CFR Part 50 Subpart F, to which CAMH research sponsored by the PHS (i.e. NIH) is subject. This procedure also recognizes recommendations of the 2003 WHO Framework Convention on Tobacco Control as per the 2008 Guidelines for implementation of article 5.3 of the WHO Framework Convention on Tobacco Control.

Under **#29 Procedure for Assessing and Disclosing Interests/Interactions (Financial or Tobacco Industry)**, researchers will submit disclosures using the ***TI/FCOI Research Financial Conflict of Interest Assessment and Disclosure form*** as follows:

- If the researcher is not the Primary CAMH Contact listed in Part I, he or she will email the completed disclosure to the Primary CAMH Contact listed in Part I.
- If the researcher is the Primary CAMH Contact listed in Part I and is receiving a disclosure on this form from a secondary contact (other researcher), he or she will email the disclosure and a copy of the current research plan to the Director of research for his or her department (Clinical, Neuroscience, PET Centre or SER) and to Encar_tiglao@camh.net .
- If the researcher is the Primary CAMH Contact listed in Part I and is making a disclosure he or she will email it with a copy of the current research plan to the Director of research for his or her department and to Encar_tiglao@camh.net

Step #1 On receipt of a disclosure:

(a) the research director should review the disclosure in conjunction with the research plan/RAAF for the associated research activity (the disclosure may affect the Director's decision to sign the RAAF)

(b) the Finance Clerk should print out and date stamp the disclosure and provide it, within a day, to the Manager, Finance and Research Services or an alternate in the event that the Manager, Finance and Research Services is not available.

(c) if the research involves human subjects, the Manager, Finance and Research Services or alternate will also inform the CAMH REB of the disclosure by completing and submitting a modified Protocol Deviation Form to the REB with a copy of the completed disclosure form.

Step #2 Within five days:

(a) The Manager, Finance and Research Services (or alternate) will review the disclosure and current research plan in consultation with the Research Director (or a more senior alternate if the Research Director or Vice- President of Research is disclosing) to make a determination as to whether a real, apparent, or potential tobacco industry/financial conflict of interest does or does not exist.

(b) ***Special Evaluation to Identify Bias:*** If the disclosure is regarding research activity which was already designed, already conducted, or already reported and was made in conjunction with a tobacco industry interaction established or Significant Financial Interest obtained more than 10 business days before the date the researcher signed the disclosure, the Manager, Finance and Research Services or an alternate, and the Director (or alternate) must review the disclosure and the research plan and make a determination as to whether it is possible bias affected the research. Further

information (research results, etc.) may be requested from the Primary contact or secondary contact(s) to assess possible bias and an additional ten business days may be taken to reach this determination.

(c) In the event that the Director (or alternate) and Manager, Finance and Research Services (or alternate) cannot agree on a determination, the disclosure, research plan (and other documents collected during the review) and opinions of the Director and Manager will be provided to the Vice-President of Research (or more senior alternate), who will make a final determination as to whether the disclosure provided identifies a real, apparent, or potential tobacco industry or financial conflict of interest and, as applicable, whether it is possible bias affected the research. An additional five business days may be required to reach this determination.

Step #3 As applicable, the determination will be classified by the Manager, Finance and Research Services as either a **tier 1** TI/FCOI or a **tier 2** TI/FCOI:

(a) A tier 1TI/ FCOI is any TI/FCOI disclosed by a member of the REC or any disclosed TI/FCOI that, in the opinion of the Manager, Finance and Research Services is a major financial interest/major risk to reputation which should be managed with additional oversight from the CAMH General Counsel/Director of Finance/Director of Risk Management.

(b) A tier 2 TI/FCOI is any TI/FCOI that does not meet the definition of a tier 1 TI/FCOI.

Step #4 Once the determination regarding the TI/FCOI status of a disclosure is made:

(a) The submitted ***TI/FCOI: Research Financial Conflict of Interest Assessment and Disclosure form*** review date box will be stamped to reflect the determination date.

(b) "Yes" or "No" will be circled in the FCOI box to reflect "Yes" a real, apparent, or potential financial conflict of interest exists or "No" it does not and the person who made the determination (normally the Manager, Finance and Research Services or alternate) will write their name and sign in the space provided.

(c) If the FCOI box indicates "Yes", the tier classification of the FCOI disclosure will also be indicated in the appropriate box.

(d) The Bias box on the disclosure will be completed:

i. In cases where the disclosure was submitted before the final design, conduct or reporting of the research activity or submitted in conjunction with a new Significant Financial Interest disclosed no more than 10 business days after it was obtained, "NA" (not applicable) will be selected.

ii. If the disclosure was regarding research activity already designed, already conducted, or already reported and was made in conjunction with a Significant Financial Interest obtained more than 10 business days before the date the researcher signed the disclosure, either "Yes" or "No" must be selected to reflect the determination that yes, the financial conflict of interest may have introduced bias that affected the research, or no, it is not possible the financial conflict of interest introduced bias that affected the research, respectively.

(e) A copy of the signed and reviewed disclosure will be attached to the RAAF associated with the project activity.

(f) The original disclosure will be filed in accord with CAMH records management requirements.

If the determination is that a tobacco industry/ financial conflict of interest exists, commence the **#31 Procedure for Writing and Implementing a COI Management and/or Mitigation Plan**.

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#31 Procedure for Writing and Implementing a COI Management and/or Mitigation Plan

This procedure is associated with 5. Policy and is also intended to meet procedural requirements (in part) mandated by the U.S. department of Health and Human Services, as regulated under 42 CFR Part 50 Subpart F, to which CAMH research sponsored by the PHS (i.e. NIH) is subject. This procedure also recognizes recommendations of the 2003 WHO Framework Convention on Tobacco Control as per the 2008 Guidelines for implementation of article 5.3 of the WHO Framework Convention on Tobacco Control.

Step #1 If it is determined that there is a real, apparent, or potential tobacco industry/financial conflict of interest (TI/FCOI), the Manager, Finance and Research Services or alternate will, within five days of that determination:

(a) Review the policies, procedures, and agreements made between CAMH and any external sponsor or agency relevant to the research activity identified in the disclosure and determine any requirements for notification and reporting. The Manager, Finance and Research Services or alternate will create a plan to comply with these notification and reporting requirements, which may affect the following timelines and processes.

(b) Confirm the composition of a tobacco industry/financial conflict of interest (TI/FCOI) review committee which will be charged with determining the nature of the financial conflict of interest, and then writing and implementing a management/mitigation plan for the TI/FCOI.

i. Normally, for tier 2 TI/FCOI disclosures, the composition of the review committee is the Director, Research Services, the Vice-President of Research and the Research Director(s) of the researcher making the disclosure (or of the primary contact in cases where the disclosure is submitted by a secondary research at another institution). However:

1. In informal consultation with the above, it may be determined that the review committee requires the addition of other scientific experts.
2. If the research involves human subjects, the committee may include the Chair of the Ethics Committee and/or the Manager, Research Ethics, or an alternate.
3. The Manager, Finance and Research Services or alternate should ask the proposed committee members to disclose any personal or professional, or potential financial, conflicts of interest and members with disclosures determined by the Manager, Finance and Research Services (or alternate) as real, perceived, or potential conflicts must be excused. The Manager may consult with the Director, Research Services or a senior alternate to make this determination.

ii. Normally, in the case of tier 1 disclosures, the above conditions apply with the following exceptions and additions:

1. If the person disclosing would normally be a member of the review committee under point i. above, they are automatically excluded from the TI/FCOI review committee.
2. At least one of: the CAMH General Counsel, the CAMH Director of Finance, and the CAMH Director of Risk Management should be a voting member on the TI/FCOI review committee.

Step #2 The Manager, Finance and Research Services or alternate will inform the Director, Research Services that a date for review by the committee must be set in accord with the conditions identified in 1(a) above and within 1 month of the review date on the ***TI/FCOI Research Financial Conflict of Interest Assessment and Disclosure form***. The Manager, Finance and Research Services or alternate will provide the Director, Research Services with the committee names, disclosure, and current research plan as well as other documents collected for the case under **#30 Procedure for Reviewing Interest/Interaction Disclosures**

Step #3 The Director, Research Services will:

i. Convene the review process. The quorum for the TI/FCOI review committee is three voting review committee members; remote attendance will suffice,
ii. Provide the committee with the disclosure, and current research plan as well as other documents collected for the case under **#30 Procedure for Reviewing Interest/Interaction Disclosures,**
iii. Provide the committee with this procedure, and
iv. Request that the committee members provide, via email, no later than two days before the review deadline date established in Step #2:
    1. his or her determination regarding how the tobacco industry interaction/significant financial interest is in real, apparent, or potential conflict with designing, conducting or reporting the research activity with integrity (see Part III of the template below), and
    2. suggested clauses for the Management/Mitigation Plan (see sample clauses in Part IV of the template below).

(b) The Director, Research Services will arrange for the responses provided by the committee to be assembled into a draft TI/FCOI Management Plan using the template (below) and the day before the review, the Director, Research Services will provide to the committee the draft TI/FCOI Management Plan, reflecting the comments provided to date.

(c) During the review, the Director, Research Services, will, at a minimum hold a vote to confirm the determination(s) and the detailed management/mitigation plan. Discussion may also occur and additions or modifications made to the detailed management/mitigation plan. The determinations or detailed management/mitigation plan clauses may be voted on individually or in groups. If a majority of the TI/FCOI review committee votes to confirm a determination(s) or a clause(s), the determination(s) is considered made and the clause(s) a required component of the detailed management/mitigation plan.

(d) On completion of the above, the committee will vote to approve the entire TI/FCOI Management or Mitigation Plan, and if the majority of the TI/FCOI review committee votes to approve the plan, it is considered approved.

i. The TI/FCOI review committee will then sign the plan (members who did not vote to approve the plan are not required to sign the plan but are encouraged to do so and members attending remotely can sign at a later date or arrange for facsimile or electronic signature).

Step #4 The Director of the person making the disclosure (or more senior alternate as applicable), or the Director of the primary contact in the case where the secondary contact making the disclosure is not associated with CAMH, will then arrange to meet with the researcher (or primary contact if the researcher is not associated with CAMH) who made the disclosure to present the plan and go over the determinations and clauses of the detailed management/mitigation plan. TI/FCOI review committee members may be in attendance at this meeting.

(a) The Director (or more senior alternate) will ask the researcher to agree to the detailed management/mitigation plan and to sign below it. The researcher is not entitled to agree or disagree with the determinations of the financial conflict of interest review committee (Part III).

(b) If the researcher refuses to agree to the plan, they will be asked to prepare a rebuttal of the clause(s) of the detailed management/mitigation plan with which they disagree and the Director (or more senior alternate) will provide the rebuttal to the committee members via email. Depending on the complexity of the rebuttal, another review may need to be held (Step #3 above) or the matter

resolved with the committee via email. If a plan agreeable to the researcher and the committee is found, the committee and the researcher will sign the plan.

(c) If a plan agreeable to both the committee and the researcher cannot be found, the matter will be referred to the Vice President of Research (or a more senior alternate), who may take administrative actions as provided for under the Code of Research Integrity or another policy, agreement, law or regulation.

Step #5 Once a plan has been signed, copies will be provided to, at a minimum, the researcher, the researcher's Director, and to other parties as may be indicated in the plan itself, with all due respect for any applicable confidentiality considerations. The original signed plan will be filed with the original disclosure.

COI Management/Mitigation Plan - template[1]

Parts I and II are taken directly from the submitted disclosure.

Part I: Research Activity Details

Activity Title					
Sites					
Primary CAMH Contact		Contact's Role		Contact's email	
Funding Source(s)				Application date(s)	
If the research activity involves human subjects, indicate the REB review status and/or REB approval number:					

Part II: Significant Financial Interest Disclosed

Your Name		Your Role		Your email	
Date		Date(s) of previous disclosures related to this research activity			

As applicable, in the box below, describe any management positions held by you, your spouse/spousal equivalent or dependent child(ren) with any private or for-profit entity related to the research activity. Be specific and detailed, including full company names and individual titles held, and take as much space as needed.

As applicable, in the box below, describe any Significant Financial Interests held by you, your spouse/spousal equivalent or dependent child(ren) with any private or for-profit entity related to the research activity. Be specific and detailed and take as much space as needed.

As applicable, in the box below, describe any Significant Financial Interests held by you, your spouse/spousal equivalent or dependent child(ren) in any private or for-profit entity that will manufacture or commercialize any drug, vaccine, device, product, procedure, or process that is associated with or that will predictably result from the research activity. Be specific and detailed and take as much space as needed.

As applicable, in the box below, describe any Significant Financial Interests held by you, your spouse/spousal equivalent or dependent child(ren) in any private or for-profit entity that can reasonably be expected to benefit directly and significantly from the design, conduct, or reporting of the research activity. Be specific and detailed and take as much space as needed.

As applicable, in the box below, describe any Significant Financial Interests held by you, your spouse/spousal equivalent or dependent child(ren) in any entity that can reasonably be expected to compete with the product or procedure that will predictably result from the research work. Be specific and detailed and take as much space as needed.

As applicable, in the box below, describe any instances whereby you, your spouse/spousal equivalent or dependent child(ren) assigned to any private or for-profit entity related to the research activity rights to a disclosed intellectual property, pending patent application or an issued patent to any invention(s), or copyright for software. Be specific and detailed and take as much space as needed.

As applicable, in the box below, describe how it is reasonable to anticipate that you, your spouse's/spousal equivalent's or dependent child(ren)s' financial interest could be directly and significantly affected by the design, conduct, or reporting of the research activity. Be specific and detailed and take as much space as needed.

As applicable, in the box below, describe your interactions with the tobacco industry. Be specific and detailed and take as much space as needed.

Part III: Review Committee Determination

[1] This template was prepared using related templates from the Universities of Colorado, Mississippi, and Pittsburgh

The Review Committee has determined that the above interest(s) is in real, apparent, or potential conflict with designing, conducting or reporting the research activity listed in Part I with integrity. Specifically:

Research Design:

Data integrity and confidentiality:

Data analysis:

Results reporting:

Other:

The Review Committee has determined that the above interest(s) biased the research activity listed in Part I. Specifically:

Part IV: Detailed Management/Mitigation Plan

Regarding the research activity listed in Part I:

Prohibitions:

Potential Clause:	You cannot be a principal investigator/co-investigator/qualified investigator/director/chair/key personnel/consultant/board member.
Potential Clause:	You cannot be involved in the recruitment of subjects.
Potential Clause:	You cannot recruit subjects but may refer patients to [name] for information and possible enrollment.
Potential Clause:	You cannot be involved in the recording of research data.
Potential Clause:	You cannot be involved in clinical assessments of eligibility criteria and intervention outcomes.
Potential Clause:	You cannot participate in data and safety monitoring activities.
Potential Clause:	You cannot interpret results.
Potential Clause:	You cannot interpret results unless you are a member of a committee evaluating results and final decisions of appropriate interpretations of research results cannot rest with you.
Potential Clause:	Your financial conflict of interest may not place restrictions on the researchers working on the research activity and cannot inhibit their right to receive, analyze, or interpret any data generated.
Potential Clause:	You may not be paid by [name of company involved in the disclosure] as a consequence of obtaining a particular research result.
Potential Clause:	You may not be paid by [name of company involved in the disclosure] for subject enrollment or for the referral of patients unless this is approved by the CAMH REB.
Potential Clause:	You, your spouse/spousal equivalent or dependent child(ren) may not receive any personal incentives, such as payments, research support, or fellowships, directly related to any study sponsored by [name].
Potential Clause:	You are prohibited from making procurement decisions involving the purchase of items from [company name]

Potential Clause:	You must recuse yourself from [company] board decisions which involve the research.
Potential Clause:	If you, your spouse/spousal equivalent or dependent child[ren] were divested of your equity interest in [company], this would eliminate the conflict of interest [relating to…]
Required Disclosures:	
Potential Clause:	You must disclose your financial conflict of interest to all researchers working on the research activity listed in Part I by providing them with a copy of this management plan, and they are hereby informed that they are entitled, at any point during the design, conduct or reporting of the research to bring any concerns about the FCOI to the attention of the FCOI review committee by contacting [name].
Potential Clause:	You must disclose your financial conflict of interest to all reviewers by informing them in a proposal text or in a covering letter. Sample: "[Name] has [a financial interest in] company that may be affected by the research proposed herein. S/He has disclosed those interests fully to CAMH and has in place an approved plan for managing any potential conflicts arising from that involvement."
Potential Clause:	You must disclose your financial conflict of interest to all journals to which the research is submitted by informing those to whom you are submitting, in a letter/email: "[description]."
Potential Clause:	You must disclose your financial conflict of interest to all sponsors of the research by informing them in a letter/email: "[description]."
Potential Clause:	You must disclose your financial conflict of interest in all publications and presentations of the results by including a note that for the publication: "[description]."
Potential Clause:	The REB-approved Informed Consent Form(s) for this research activity [will/may] be modified to include information about your financial conflict of interest, which will be required for research subjects to provide informed consent. The REB will issue a revised protocol approval.
Potential Clause:	You will repeat the **#29 Procedure for Assessing and Disclosing Interests/Interactions (Financial or Tobacco Industry)** as required under the Code of Research Integrity and make additional disclosures as appropriate. In particular, if you should obtain a new Significant Financial Interest relating to this research activity [or any new Significant Financial Interest] be aware that you have 10 days to disclose the interest under the **#29 Procedure for Assessing and Disclosing Interests/Interactions (Financial or Tobacco Industry).**
Potential Clause:	[Invention disclosure to the Technology Transfer Office.]
Required agreements:	
Potential Clause:	You will not transfer any materials or proprietary information prior to the establishments of confidential disclosure agreement/sponsored research agreement/license agreement/facilities use agreement.
Potential Clause:	An outside activities agreement needs will be established by [date].
Research design revision requirements:	
Potential Clause:	The principal investigator of this research activity should be changed to [name]
Potential Clause:	Concurrent replication at another site where researchers do not have a conflict will ….
Monitoring:	
Potential Clause:	Independent review is required. [Insert specifics – names, etc.]
Potential Clause:	Annual review is required. [Insert specifics – names, etc.]
Potential Clause:	As indicated above, the research team is entitled, at any point during the design, conduct or reporting of the research to bring any concerns about the FCOI to the

	attention of the FCOI review committee by contacting [name].
Required notifications and reporting:	
Potential Clause:	We will inform NIH of this FCOI on [date].
Financial Measures:	
Potential Clause:	It is the opinion of the committee that [specific agreements/policies] require the [return of grant funds to a sponsor. The Manager, Finance and Research Services will …]
Mitigation Measures:	
Potential Clause:	The following publications need to be retracted…
Additional requirements:	
Potential Clause:	The committee finds that the disclosed financial conflict of interest applies beyond the scope of the research activity listed in Part I. Therefore:
Summary statement:	
Potential Clause:	In summary, the disclosed financial conflict of interest requires the implementation of this management plan in order to [manage, reduce, eliminate, or mitigate] the affect of this conflict on the integrity of the research listed in Part I [and other research under invocation of the additional requirements clause above]. Therefore, we ask you to accept this management plan and to confirm that you will comply with this management plan by signing below.
Potential Clause:	This management plan may be terminated upon execution of a superseding Management/Mitigation Plan or at such time as the financial conflict of interest review committee determines that no further Management/Mitigation Plan is required under the Code of Research Integrity. If you fail to comply with the terms of this plan, you can no longer claim that “CAMH [has] approved a plan for managing any potential conflicts arising from that involvement”. …
Review Committee Signatures	
Signature of Researcher	

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#32 Procedure for Notification/Reporting of COI

This procedure is associated with 5. Policy and is also intended to meet procedural requirements (in part) mandated by the U.S. department of Health and Human Services, as regulated under 42 CFR Part 50 Subpart F, to which CAMH research sponsored by the PHS (i.e. NIH) is subject. This procedure also recognizes recommendations of the 2003 WHO Framework Convention on Tobacco Control as per the 2008 Guidelines for implementation of article 5.3 of the WHO Framework Convention on Tobacco Control.

Step #1 As indicated in Step 1(a) of the **#31 Procedure for Writing and Implementing a COI Management and/or Mitigation Plan**, the Manager, Finance and Research Services, will, with five days of receipt of a disclosure, review the policies, procedures, and agreements made between CAMH and any external sponsor or agency relevant to the research activity identified in the disclosure and determine any requirements for notification and reporting.

(a) Specifically it will be determined who is entitled to be notified/receive a report, and by what dates, regarding:
   i. Disclosures
   ii. Determinations of conflicts
   iii. Management/Mitigation Plans

For example,

(b) If the research involves human subjects, the Manager, Finance and Research Services will also inform the CAMH REB of the disclosure by completing and submitting a modified Protocol Deviation Form to the REB with a copy of the completed disclosure form on receipt of a disclosure for review.

Step #2 Having determined the requirements, the Manager, Finance and Research Services will complete and submit notifications/reports as required. For example, in the case of grant research relating to NIH, CAMH will notify NIH:

(a) Of an identified FCOI prior to expending any funds under an NIH award

(b) For any FCOI identified subsequent to the initial report under the award, within 60 days of that identification, and

(c) The notification will be submitted through the eRA Commons FCOI Module and include the information required under that process.

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#33 Procedure for Research Program Appointments and Engagements

This procedure is associated with 3. Policy on Research Project Role Eligibility in the Code of Research Integrity and applies only to academic-type research appointments (i.e. research trainees, project scientists, independent scientists, senior scientists, clinician scientists, clinician researchers, clinician research collaborators, affiliate scientists).

All those who are/will be involved in the design, conduct, or reporting of research under the auspices of CAMH must be registered in the Research Program appointments system as indicated in the sub-procedures on the following pages. There are separate sections for:

1. Engagements (trainees and affiliates)
2. Appointments (all others)

1. Engagements

Sub-Procedure for Engaging Research Trainees
Initiating and maintaining trainee engagements

Trainees who will be involved in the design, conduct, or reporting of research under the auspices of CAMH must be registered in the appointments system. This applies irrespective of the funding arrangements supporting their training. Shortly after registration, a formal letter of engagement and a package of information, including program policies and procedures, will be generated for the supervisor to provide to the trainee. Registration in the system also supports analysis and reporting.

Undergraduate Student Trainees, Master's Student Trainees, and Doctoral Student Trainees must be currently enrolled in a program of study at a university. Postdoctoral fellows (PDFs) must have completed at least one terminal degree (MSW in the case of Social Work). Post-MDs returning to complete master or doctoral degrees can be listed as PDFs or as student trainees, whichever is deemed more appropriate by the supervisor.

Step #1 The primary CAMH supervisor copies the following table into an email and addresses it to both ResearchTraining@camh.ca as well as their research program director. If a trainee has more than one research program engagement (i.e. two separate projects), one table needs to be completed for each engagement. Co-supervisions for a single appointment can be supported in one table (only one supervisor needs to send the email).

Supervisor(s):	By default the person submitting the email will be listed as a supervisor, if there is more than one supervisor, list them here. Provide a rough percentage of supervision responsibility for each.
Trainee type	Select one of: Undergraduate Student Trainee, Master's Student Trainee, Doctoral Student Trainee, Postdoctoral Fellow
First Name	
Last Name	
Contact information (Mailing Address)	
Engagement Start Date	This will be the effective date of the appointment, format mm/dd/yyyy:
Engagement End Date	Include a termination date if known or an estimated end date or review date, format mm/dd/yyyy:
Note	You can indicate whether the engagement is "funded" or "un-funded" or provide additional characterization about the engagement here. In the engagement letter, this note will appear in brackets after the trainee type designation. Limit of 50 characters.
Research department	Indicate the primary research department for the engagement covered in this table, one of: Clinical research, Neuroscience, Research imaging centre, or Social and epidemiological.
FTE	Indicate the percentage of a Full Time Equivalent training position that is represented by this engagement (i.e. if this is the trainee's sole engagement and is 100% funded by a training grant held at CAMH, you would list 100%):
Research subunit section	Indicate the section within the department that houses the trainee:
Supervisor	
Contingent engagement	Provide narrative describing any conditions upon which the engagement is contingent, including compensation arrangements based on core budget availability or external funding. This will appear as a paragraph in the engagement letter. Maximum 255 characters:
Funding contingency	If the appointment is contingent on a funding proposal which is in the process of being submitted or which has been submitted/funded (i.e. contingent on funding continuation), indicate, if possible, the RAAF number or accounting unit of the proposal, or: • the primary contact for the proposal (as indicated on line 1.1 of the RAAF); • title of the proposal, • agency, • funding program, and • date of submission. This allows us to link to the proposal tracking system. This information will appear as a paragraph in the letter of engagement
Responsibilities	Describe the nature of the services to be provided in point form, maximum 255 characters per point.
Program of study	Indicate the degree the trainee is in the process of obtaining and provide the core department (we do not have the capacity to track all academic programs, so attempt to indicate the department most affiliated with their program of study), faculty, and

	university at which the trainee is enrolled.
Other position	Some trainees are also employees at CAMH. If the person does have a staff position along with the training engagement, indicate their job title and CAMH department.
Compensation amounts/rate/pay schedule	This will appear in a separate compensation document provided with the letter and this information will be provided only to those entitled to access it.

Step #2 Obtain a copy of the proposed trainee's last degree (certificate or transcript) scan it and attach it, along with a copy of the learning plan for the trainee (a draft is sufficient), to the email.

Step #3 After submitting the email in steps 1 and 2, a letter of engagement and policies will be generated using those details and sent to the supervisor, the supervisor provides the letter and policies to the trainee.

Step #4 The letter is receipt of inclusion in the system and will, under normal circumstances, be provided to the supervisor within two weeks. In the event of an unexpected delay exceeding two weeks, the supervisor can follow-up by contacting Dimple.Patel@camh,ca.

Step #5 Research Services will prompt supervisors to review their trainee engagements once annually. Obsolete engagements will be retired at that time and continuing ones renewed.

Sub-Procedure for Initiating and Maintaining Affiliate Scientist Engagements

A person currently holding a Research Program appointment (not an engagement) can recommend to their research department director and the Vice President of research that a researcher with a primary appointment at another institution be affiliated with the Research Program. On approval by the Director and the Vice-President of this affiliation a letter of engagement will be issued to the affiliated scientist along with an information package. The steps for recommending an affiliate are:

Step #1 The person making the recommendation copies the following table/enters the following section headings into an email, provides the information required under each heading, and addresses it to their research program director (if more than one person is making the recommendation, only one person needs to submit the email):

Affiliate Scientist Recommendation	
On the recommendation of:	By default the person submitting the email. If more than one person is recommending, provide their names here.
Affiliate First Name	
Affiliate Last Name	
Email	
Address	List the best contact address for the proposed affiliate:
Primary affiliation	Indicate the person's primary affiliation department, faculty/unit, and organization:

Job title	Indicate the person's job title at the primary affiliation.
Engagement Start Date	This will be the effective date of the appointment, format mm/dd/yyyy:
Engagement End Date	Include a termination date if known or an estimated end date or review date(normally, 1, 2, or 3 years), format mm/dd/yyyy:
Note	You can indicate what the nature of the affiliation is here. Limit of 50 characters.
Research department	Indicate the primary research department for the engagement covered in this table, one of: Clinical research, Neuroscience, Research imaging centre, or Social and epidemiological.
Contingent engagement	Describe any conditions upon which the engagement is contingent. This will appear as a paragraph in the engagement letter. Maximum 255 characters:

Step #2 Attach a CV to the email with the above table and include a brief introduction/justification and send the email to your director.

Step #3 The director reviews the request and if approved, forwards the email to the Administrative Assistant of the Vice-President Research (linda.burford-mason@camh.ca) and the request is reviewed by the Vice-President of Research.

Step #4 If approved, an electronic engagement letter and information package is sent to the affiliate, cc'ing the person recommending the affiliate and the director.

Step #5 Research Services will prompt review of the affiliate recommendation as the engagement end date approaches.

Sub-Procedure for terminating an engagement prematurely

With all due respect for the requirements of other policies and procedures, engagements can be terminated prematurely as follows:

Trainees

The supervisor can inform the trainee that the appointment is terminated, indicating the effective date of the termination, in an email to researchtraining@camh.ca. Or, if the trainee has instigated the termination, the supervisor can simply include that fact in an email to researchtraining@camh.ca, indicating the effective date.

Affiliates

The director should either inform the Administrative Assistant of the Vice-President Research of the effective termination date in cases where the affiliate has terminated the engagement or contact the Vice-President and request a termination of engagement letter be issued, providing a reason. The Vice-President will, if the request is approved, direct that a letter of termination be issued and sent to the affiliate.

2. Appointments

Sub-Procedure for initiating, changing, and terminating appointments

Clinical research appointments (not trainees, not affiliates)

Clinical research program appointments are provided under the following scenarios:

	Performance Review	CAMH Funded Research Resources (Time/Space)	Clinical Appointment	University Status (Professoriate)	University Status, Lecturer (Not independent)	External Funding
Clinician Scientist	Yes	Yes	Yes	Yes	No	Normally
Clinician Investigator	No	No	Yes	Yes	No	No
Project Scientist	Yes	Maybe	Yes	Maybe	Maybe	Yes
Clinician research collaborator	No	No	Yes	No	Yes	No

Initiating a new appointment

During or shortly after hiring or assigning clinical privileges to a person not previously at CAMH, the Academic Chief/Chief of Clinical Research director will complete the following table/using the following headings and provide the required information for each (1 table per appointment in the case of cross-appointed people. The Chief of Clinical Research will send it to the Administrative Assistant of the Vice President Research (linda.burford-mason@camh.ca). The data will be used to generate the research program appointment appropriate to their clinical and university appointments and current research resource arrangements (time or space for research).

First Name	
Last Name	
Contact information	Should be CAMH address
Start Date	This will be the effective date of the appointment, format mm/dd/yyyy:
End Date	Include a termination date if known or an estimated end date or review date, format mm/dd/yyyy:
Note	Use to provide additional characterization of the appointment (i.e. “Part-time”), maximum 50 characters.
FTE	Indicate salary or stipend support in the form of a percentage of a full-time equivalent (time for the purposes of research).
Resources	If the person has reached an agreement for resources dedicated to research (space, equipment, support staff) in addition to time, describe them:
Clinical	Indicate the person’s appointment in the clinical program (Medical Staff –Physician,

Program appointment	Psychologist, Manager, Consultant, etc.). If the person is listed as 'Medical Staff – Physician' this must match the status in the database maintained by the Manager, Medical Services.
Subunit section	Indicate the research subunit within clinical research – this normally corresponds with the person's Clinical Program unit.
Other appointments	Indicate the person's appointment(s) at U of T (include department and faculty), including status as: lecturer, assistant professor, associate professor, or professor. Indicate other appointments/board memberships if known.

Once the letter of appointment and information package are generated, they will be sent via e/mail to the appointee with request for sign-back acknowledging read and receipt (and acceptance of terms).

Maintaining research program appointments

Once annually, the Chief of Clinical Research will be provided with a list of all existing Clinical Research Appointees, their current Research Program appointment as well as their recorded university appointment(s) and other selected appointment(s). The Chief of Clinical Research will also be provided with sub-lists for each clinical section.

The Chief of Clinical Research will oversee review of the lists as well as collection of new appointments to be initiated during the annual review process. The Chief of Clinical Research will arrange for changes, amendments, and termination of appointments details to be provided to the Administrative Assistant of the Vice-President Research (linda.burford-mason@camh.ca) on a timeline to be established by the Vice-President of Research.

Once a year the reviewed appointments will be reissued, along with key communications from the Vice-President's office.

Non-Clinical research appointments (not trainees, not affiliates)

For project scientist, independent scientist, and senior scientist appointments outside of clinical research, the appointment will be initiated as follows:

During or shortly after hiring, the director will provide the following table/use the following section headings and provide information needed for each to the Administrative Assistant of the Vice-President Research (Linda.burford-mason@camh.ca) in an email:

First Name	
Last Name	
Job Title	
Section and Department and CAMH address (room code)	
Start Date	This will be the effective date of the appointment, format mm/dd/yyyy:

End Date	Include a termination date if known or an estimated end date or review date, format mm/dd/yyyy:
Note	Use to provide additional characterization of the appointment (i.e. “Part-time”), maximum 50 characters.
FTE	Indicate salary or stipend support in the form of a percentage of a full-time equivalent (time for research).
Resources	If the person has reached an agreement for resources dedicated to research (space, equipment, support staff) in addition to time, describe them:
Other appointments	Indicate the person’s appointment(s) at U of T (include department and faculty), including status as: lecturer, assistant professor, associate professor, or professor. Indicate other appointments/board memberships if known.

Once annually, the director will be provided with a list of all existing Appointees, their current Research Program appointment as well as their recorded university appointment(s) and other selected appointment(s).

The director will oversee review of the list as well as collection of new appointments to be initiated during the annual review process. The director will arrange for changes, amendments, and termination of appointments details to be provided to the Administrative Assistant of the Vice President Research (linda.burford-mason@camh.ca) on a timeline to be established by the Vice-President of Research.

Once a year the reviewed appointments will be reissued, along with key communications from the Vice-President’s office.

Terminating an appointment during its term

Appointments are terminated during term will all due respect for the requirements of other policies and procedures and the termination clause included in the original letter of appointment. Directors are responsible for ensuring that the Research Service system is updated by informing the Administrative Assistant of the Vice-President Research of appointment terminations within 2 days of the effective date of the termination. Issuance of letters of termination will proceed on the advice of the Vice-President Research and the Director.