Inflammation and Electroconvulsive Therapy

Study Information and Consent Form (Depressed Participant)

Investigators: Drs. Jeffrey H. Meyer, Z. Jeff Daskalakis, Sylvain Houle, Alan Wilson, Elaine Setiawan, Benoit Mulsant

Study Background and Purpose

Clinical depression affects a large number of individuals worldwide. Electroconvulsive therapy or ECT is the best treatment currently available for severe depression. We think that ECT works by stimulating the brain to make new brain cells and raising levels of mood supporting chemicals. However, after ECT there is a high risk of recurrence, though anti-depressant medications can sometimes help prevent this. We think that although ECT has proven benefits, there might be some side effects that lead to the problem of later recurrence of illness. One possible side effect is that ECT causes an irritation in the brain, called inflammation. No one has ever examined inflammation in the brain following ECT.

We are a team of psychiatrist practitioners and researchers working at the Centre for Addiction and Mental Health (CAMH), College Site and the CAMH Research Imaging Centre, an affiliated teaching hospital of the University of Toronto. We have a new technology developed here at CAMH that is excellent for looking at inflammation using brain imaging. In this study we will use Positron Emission Tomography (PET) imaging to measure translocator protein (TSPO), which is a marker of inflammation, before and after ECT in people with clinical depression.

We hope that our study will help improve ECT and the understanding of clinical depression. If we find increased inflammation, we may be able to use existing drugs to reduce this side effect of ECT.

In total, this study will have 30 participants.

If you agree to participate, you will have two Positron Emission Tomography (PET) imaging scans and two magnetic resonance imaging (MRI) scans. PET imaging measures brain chemicals and MRI imaging looks at certain chemicals and the shape and structure of the brain. You will also complete some questionnaires, memory tasks and provide urine and blood samples.

Preliminary Screening

You will have a visit with a research staff member to ensure that you meet the requirements to take part in the study. In this visit we will ask you about your medical and psychiatric history. To ensure that it is safe for you to participate in this trial, we will ask you for a urine sample, which is a standard requirement in the neuroimaging research studies. This visit will last approximately 2 hours.
Medications

To participate in this study, you may continue taking any anti-depressant medications that have been prescribed by your physician for the duration of the study.

You may continue to take lorazepam (Ativan) and clonazepam (Rivotril) as prescribed your physician and/or the ECT psychiatrist for the duration of the study.

You are asked not to use other benzodiazepines, eg. diazepam (Valium) within the month prior to the first PET scan and for the duration of the study. This is because these medications may interfere with our PET measure. If you need to take these medications you should not continue to participate in this study.

You are asked not to take any anti-inflammatory medications (examples: acetylsalicylic acid (Asprin), ibuprofen (Advil) and inhaled or oral corticosteroids (Flovent, Pulmicort, Deltasone)) for at least a month before the first PET scan and for the duration of the study. If you need to take these medications on a regular basis you should not continue to participate in this study.

The PET Brain Imaging Day

PET uses emissions from radiotracers injected in the bloodstream that go to the brain in order to measure brain function. Prior to PET scanning, one catheter will be placed in one of your radial arteries to allow us to obtain blood samples during the scan. Blood samples will be obtained during the scan to measure the amount of tracer in your blood. The measurement of the amount of tracer in your blood is used in combination with the brain scan to measure the TSPO in your brain. One blood sample will be used to obtain information about the level of certain proteins that may play a role in the inflammatory process.

A second catheter will be placed in one of your veins and will be used to inject the radiotracer. Altogether, a total of 170 ml of blood will be collected (about 40% of a blood donation).

To start, you will receive a small amount of radiation from a brief transmission scan to measure how much radiation is absorbed by your brain and the bones of your skull. For the PET imaging scan we will inject a small quantity of a radioactive substance, called $[^{18}\text{F}]\text{FEPPA}$, through a tiny needle into your forearm. $[^{18}\text{F}]\text{FEPPA}$ binds to TSPO. This scan takes two hours. Each PET scanning session will require about 4-6 hours of your time. About 90 minutes of this time is spent completing questionnaires and memory tasks. Please note that $[^{18}\text{F}]\text{FEPPA}$ is an investigational compound used for research purposes and not yet marketed in Canada.

Risks Involved With the PET Scanning Procedure

The radiation dose from this study is less than 6 mSv for both $[^{18}\text{F}]\text{FEPPA}$ PET scans, well within the guidelines for this type of study (20mSv). The amount of radiation that you receive from natural sources during one year is about (3 mSv). The potential long-term risk from the radiation dose you will receive is uncertain but these doses have never been associated with any definite adverse effects. Thus the risk to you, if any, is estimated to be slight.
There will be a slight discomfort from the insertion of the intravenous line as well as the possibility of bruising. It is quite possible that you will have some temporary bruising from the arterial line. You will likely experience some discomfort from the insertion of the arterial line. More serious complications are rare but include aneurysm formation (local ballooning of the artery) or local thrombosis (blockage) of the artery, which may require surgical intervention to correct. Most subjects feel that arterial line placement is no more uncomfortable than voluntary blood donation. A physician who routinely puts in arterial lines will put in your arterial line.

**Women Please Note:** It is advised that pregnant women avoid all radiation to minimize any risk to the unborn child. You should not participate in this study if you are, could be, or plan to become pregnant during the study. A standard pregnancy test will be performed at each visit to our centre. If you change your mind about becoming pregnant during the study, please notify us immediately.

**Risks Involved With the MRI Scanning Procedure**

To help us localize various structures in your brain, we will also ask you to undergo a magnetic resonance (MRI) scan at CAMH and another at The Toronto General Hospital. New methods in magnetic resonance imaging are available at CAMH which give improved measurement of the structure of the brain and allow us to measure brain chemicals that are affected in clinical depression, such as n-acetyl aspartate. We still need the older MRI done at the Toronto General Hospital so that our PET imaging method is compatible with our earlier studies but the new MRI method will allow us to look at the relationship between the chemicals found with the MRI and the results found with the PET scanning. There is no known risk associated with this procedure unless you have metal implants. If you have metal implants (including metal fragments in your eye, pacemaker, surgical staples), you should not have an MRI. Metal braces for teeth and tooth fillings are compatible with receiving an MRI. Also, it is the policy of the hospital that you should not be pregnant at the time of the MRI scan. Before the MRI you will be asked to fill out a questionnaire with the research staff to ensure that it is safe for you to have an MRI. The major discomfort with MRI scanning is a knocking sound that the machine makes; earplugs will be available for you to decrease the noise. Some people may find the close space of the MRI scanner uncomfortable. It is not advisable for you to involve yourself in this study if you have a fear of closed spaces. About one hour will be required for each MRI scan. **As the MRI scanner uses a magnetic field to generate the images, it is absolutely necessary that you do not have any mental implants in your body or a cardiac pacemaker.**

**Risks Involved with ECT**

The most troublesome side effect of ECT is memory loss. Recovery from that memory loss begins a few weeks after treatment and is usually complete within six to nine months. There may be a permanent loss of memory for details of some events, particularly those which occurred some time before and during the weeks the treatment is given. Also, there may be some difficulty learning and remembering new information for a short period after ECT. However, the ability to acquire new memories recovers completely usually a few months after treatment. Thus, the treatment does not cause a permanent loss of the ability to learn and remember events following the treatment. A very small number of patients report severe problems with memory that remain for months or years. Some patients experience a brief period of confusion after waking from the
anaesthetic. Some also experience muscle aches and headaches, but these are usually not severe and recover after a few hours.

ECT is given under general anaesthesia. Therefore, as with any treatment given this way, there is a risk of death but this is now rare, between two and four deaths being reported for every 100,000 treatments. The risk may be higher for patients who have other physical illnesses. The effect on any patient’s physical illnesses on the treatment risk will be discussed with the patient. Also, very rare are bone fractures and broken teeth or other dental injury. Spontaneous seizures may occur some time after the treatment, but are rare.

Because of the time to recover fully from the general anaesthetic, patients must not operate a motor vehicle or any potentially dangerous equipment/machinery/tools until the day after each treatment.

These risks are identical to those found in the ECT Information for Clients/Patients form given to you during the consent process to receive ECT.

Confidentiality

All information about you collected during this study will be kept confidential and your identity will not be revealed when the results of this study are reported in presentations and publications. To protect your confidentiality we will label (“code”) your sample and your medical information with your initials and a number, not your name. This number will be how researchers keep track of samples and information. Your name will not be in any publications or reports about this research. The samples will be kept for a period of not longer than 20 years after approval of the study.

By agreeing to take part in this research, you will allow your medical information and results to be audited by people who check that the research was done in accordance with the laws and regulations governing scientific research. As part of the Research Services Quality Assurance role, studies may be audited by the Manager of Quality Assurance. Your research records and CAMH records may be reviewed during which confidentiality will be maintained as per CAMH policies and to the extent permitted by law.

Reimbursement

You will be paid a total of $645 in recognition of your time involved for the entire study. Each PET scan with the arterial line is reimbursed at $210, each MRI scan at $50, genetic sample at $20. Hourly rate for questionnaires, memory tests and pencil paper tests done on the screening day and on the brain imaging day are reimbursed at $15/hour and this total time is estimated at 7 hours. Hourly rate for the scan day is $15/hour. The total time commitment required for the study is a maximum of 16 hours.

There will be no direct benefit to you from this study. You will help increase the knowledge of how the inflammatory process and its mechanisms may influence our understanding of major depressive disorder, electroconvulsive therapy, other related diseases and treatments. In the
future this knowledge may help diagnose such diseases and help to find new treatments that can be used earlier. In some cases, disease might be prevented.

If you agree, we may contact you in the future to invite you to participate in other studies. If you would not prefer to be contacted this will not affect your participation in this study.

Voluntary Participation

Your participation in this study is voluntary. You may choose to withdraw from the study at any time. In addition, the investigators or their staff responsible for this study may, at their discretion, end your participation at any time. If your participation ends early for whatever reason, you will be compensated on a pro-rated basis as described above. Your choice to not participate, your choice to withdraw, or your dismissal by us will not affect any treatment needs that you might have at the Centre for Addiction and Mental Health now or in the future.

Conclusion

If you agree to take part in the study, please sign this Informed Consent Form. Thank you in advance for considering this study. The study staff will be more than happy to answer any questions about research. Their contact details are given below:

Contact Dr. Jeffrey Meyer the principle investigator at telephone number (416) 535-8501 ext 4007 at any time if you have questions about this study or wish to withdraw from this research. If you have any questions about your rights as a research participant, contact Dr. Padaig Darby, Co-Chair, Research Ethics Board, Centre for Addiction and Mental Health, at (416) 535-8501 ext. 6876.

A copy of this Consent Form (signed and dated) will be given to you.
CONSENT

I
have read the above information and have been given the opportunity to ask further questions
about this study. The study risks have been explained to me and my questions answered by

I consent to participate in this research project to investigate TSPO in ECT. I understand that I
will not benefit directly from this study. I understand that I may withdraw from this study at any
time. I also understand that these PET scans are for research purposes only and that they are not
part of any medical treatment. If I am a woman of childbearing age, it has been explained to me
that I should not volunteer for this study if there is any possibility that I might be pregnant at the
time of the study. If at any time during this study, there is a possibility that I could have become
pregnant, I will inform the investigator and will not undergo further PET scanning.

At Toronto, on __________________________________

________________________________
Your signature

________________________________
Witness

Should there be additional information that I could provide to help with this study, I am
agreeable to being re-contacted in the future.

________________________________
Your signature

Subject Initials ________ 6
UNIVERSITY OF TORONTO
OISE | ONTARIO INSTITUTE
FOR STUDIES IN EDUCATION

Dr. Bonnie Burstow, Ph.D., Department of Leadership, Higher, and Adult Education.
Ontario Institute for Studies in Education
252 Bloor St. West,
Toronto, Ontario, M5S 1V6

August 14, 2012.

Executive Director
Secretariat on Responsibility in Research

Dear Dr. Susan Zimmerman

I am writing you about what I consider a departure from research ethics. What makes this particular complaint especially pressing, what is at issue here is not that the researchers have done anything not permitted by the research ethics board by which they are governed. While the research is still in the recruitment stage, indeed, I have no reason to believe that the researchers are departing from or will be departing from the protocol that has been duly approved. What is at issue rather is the serious ethical problems attending what has been approved. As such, I am requesting that you not only look into this piece of research but also the Board that approved it.

To introduce myself, I am Dr. Bonnie Burstow. I am a faculty member in the Adult Education and Community Development program at Ontario Institute for Studies in Education at University of Toronto. Among other things, I teach graduate research approaches at OISE, including how to conduct research ethically, with special attention paid to ethics and the ethical review process. I have also sat on the education REB at University of Toronto. I am also someone who has conducted research into ECT. As such, I have some knowledge which brings me to seriously question the ethicality of a piece of ECT research which is currently advertising for participants.

I initially stumbled upon the research a couple of days ago, when concerned psychiatric survivors drew my attention to a call for research participants posted on Craigslist (see ad). Opening the website link, I discovered that under the column “Etcetera Jobs”, CAMH (Centre for Addiction and Mental Health) was advertising for participants for a research study, which would involve giving depressed people who agreed to be
participants ECT (electroconvulsive therapy). It was advertised under the category “Etcetera Job” because of the intention to pay people for this “work”. The advertisement was pulled from Craigslist on August 12 because enough people protested it. The study, not surprisingly, is continuing nonetheless.

I proceeded to get information about the study (not even the name of the study was on the initial ad) by calling the CAMH number provided and requesting and receiving further information. What I have found in no way assures me about the ethicality of this research.

What little background information I have, almost all of which you can glean from the other attached documents, the study is a CAMH study. It is called “Inflammation and Electroconvulsive Study”, with the principal investigator being Dr. Jeffrey Meyer. It recruits people who identify as depressed who live in the community and for whom psychiatric drugs have failed. It consists of subjecting “depressed participants” to ECT and various imaging procedures and types of apparatus. The object of the study is to discover the difference in brain inflammation pre and post ECT.

It is hard to know where to begin in the attempt to shed light on the ethical problems attendant on this research. To begin on a purely factual level, a basic responsibility which falls on all researchers is to provide perspective participants with the information needed to make an informed choice. This study fails on two counts—the facts quoted are woefully inaccurate; and facts which participants need to know are missing. For example, the advertisement blatantly states that “ECT works by telling the brain to create new cells”. The consent letter contains the similar but more moderate claim “we think that ECT works by stimulating the brain to produce new brain cells.” There is no evidence whatsoever of “new brain cells” in any ECT research literature. In other words this a made-up fact, and one significantly, geared to interest people who are unhappy with the current functioning of their brain. The consent letter also states that:

- Recovery from that memory loss begins a few weeks after treatment and is usually complete within six to nine months. There maybe a permanent loss of memory for details of some events, particularly those which occurred some time before and during the weeks the treatment is given. Also, there may be some difficulty learning and remembering new information for a short period after ECT. However, the ability to acquire new memories recovers completely usually a few months after treatment.

Again, this is not what the literature indicates. What the most carefully constructed research suggests is that long term and extensive memory loss is common, especially where recipients are women. See, for the largest ECT study in ECT history—Sackeim et al. (The Cognitive Effects of Electroconvulsive Therapy in Community Setting”, Neuropsychology, 2007). By the same token, the consent letter states that “Electroconvulsive therapy or ECT is the best treatment currently available for severe depression.” By contrast, literature which critically evaluate effectiveness studies clearly demonstrates that ECT has not been proven to be any more effective than placebo in addressing depression (See, for example, Colin Ross, The Sham ECT Literature, Ethical Human Psychology and Psychiatry, 2006).
What is more serious given that these participants are being recruited to be given ECT is the bewildering lack of mention of studies that indicate that ECT can cause brain damage. (Again, see Sackeim, 2007). Indeed, from the early 1950s with Hartelius’s animal studies (Hartelius, H.1952, Cerebral changes following electrically induced convulsions. Acta Psychiatr Neurol Scand) through to Sackeim, we have ample indications of brain damage. Not only do the researchers not see fit to mention such literature even in passing, they have invented a completely opposite claim for which there is no proof whatever—that ECT creates new brain cells.

A dilemma which, I am aware, presents itself to the Secretariat in this regard is the statement in the consent form that the risks described in this form “are identical to those found in the ECT Information for Clients/Patients given to you during the consent process to receive ECT.” Obviously, uniformity seems necessary and this fit sounds reassuring. The point is, however, that fits do not guarantee the quality of information. They do not render information which is otherwise incorrect and inadequate correct and adequate. And the fact remains that the statements providing to the perspective participants respecting risk are incorrect and inadequate, moreover, in ways that are not trite but serious.

The ethical problems presented by the study do not stop here. How can it be ethical to expose participants to brain damage even if they were informed of it? How can it be ethical to interfere with memory function for research purposes even if participants are informed of it? We might ask the same of one of the types of potential damage that the consent form acknowledges and indeed which constitutes the focus of the study—brain inflammation. The purpose of the study—and this is not clear in the initial advertisement but is found in the consent letter—is to look at brain inflammation caused by ECT with the intention of ameliorating this problem. How can it be acceptable to expose participants to inflammation of the brain for research purposes? The researchers suggest that they may be able to treat the inflammation by drugs. That statement minimally introduces the possibility that they might not be able to.

What we have with this study is participants being subjected to one of the most controversial treatments in the current psychiatric repertoire with little indication of the problems identified in the literature and with erroneous and otherwise misleading descriptions provided about ECT itself. The participants are not in a position to make an informed decision on the basis of these statements. Indeed, the reality of ECT is constantly obscured. One has to read the consent form very carefully even to be aware that ECT is happening for the focus is on the imaging. It is almost as if ECT were a minor part of the research. Moreover, in the advertisement, the patient is assured that the ECT procedure lasts only 5 or 10 minutes—a statement which intentionally draws the perspective participant’s attention away from the reality of the long term impact—something frequently mentioned in the ECT literature.

Besides contravening the principles of informed consent, exposing the most vulnerable of our citizens—people who are severely depressed—to cognitive and other impairment in the mere hope of gleaning useful knowledge would appear also to fail to achieve the
positive benefits/harm ratio required for research to be ethical. Its likewise violates principles of fundamental justice. In the knowledge-making process, why are the most vulnerable among us—the highly depressed—being singled out for extra risk?

This brings me to the issue of inducement. While the investigators make no such claims on an overt level, if you read the advertisement carefully, it is clear that the research team is playing on people’s hope that ECT will alleviate their depression. Please note in this regard that the advertisement is expressly directed at people who have not been able to alleviate their depression and it makes such statements as “Do you know that 50% to 80% of people achieve remission after ECT” (another misleading figure)? Claims of effectiveness that are equally problematic are found in the consent form.

What compounds this problem of inducement is the enormous amount of money being offered—something blatantly in violation of research ethics. A seriously depressed person who has unsuccessfully tried one product after another to alleviate their depression may hardly be able to drag themselves out of bed, may not be able to hold down a job, may have trouble making ends meet. Offering such a person six hundred and forty-five dollars clearly constitutes an inducement. Indeed, that the researchers in question were well aware that potential participants might engage in this research simply for monetary reasons is blatantly obvious from their choice to advertise under the category “Etcetera Jobs” in Craigist.

We are speaking of a vulnerable population here. It is an accepted principle in research ethics that extra care be taken with vulnerable populations. Now this research would have have been problematic even were the participants not vulnerable. But they are. Moreover, such vulnerability is being counted on. In the final analysis, that is offensive.

I can indeed see ways of making this study less offensive. The researchers could be asked to put in some qualifications, for example, or get rid of some of the misrepresentation, or withdraw what would appear to amount to a bribe, or include a statement in the consent form which promises help to people if they find themselves struggling with memory problems as a result of participating. However, I see no way of making the study acceptable. While we all know that there are research situations where a degree of misleading and even downright deception would be in order, we should not be misleading participants in situations such as this. We should not be exposing participants to appreciable risk—risks to their own mental and physical integrity—in the hope of gleaning knowledge. We should not be targeting the most vulnerable for damage. We should not be bribing. We should not be preying on people’s desperation and vulnerability. This piece of research does all of the foregoing. I accordingly ask the Secretariat to seriously consider ordering it stopped. Given the egregiousness of what is happening here and the fact that it has been authorized by a duly ordained body, I am likewise asking for a more general investigation into the working of the Research and Ethics Board of the Centre for Addiction and Mental Health. While I realize that there is only so far that the Secretariat is likely to want to go here, the Secretariat might consider examining samples of the protocols that this Board has approved in the recent past (advertisements for many of them not coincidentally have appeared under “Etcetera
Jobs." in Craigslist). There may be trends here that need to be addressed.

I have confidence that the Secretariat wants to preserve the integrity of research and would be especially sensitive to the question of vulnerable populations and the larger power issues involved here. It is because of those sensitivities and your commitment to research integrity over any particular institution that I have chosen you as the place to lodge this complaint.

I thank you in advance for your consideration. I ask you to act quickly, for we are talking about real harm to real human beings here, and time is of the essence. And I look forward to hearing from you.

Sincerely,

Dr. Bonnie Burstow

Dr. Bonnie Burstow
I have a piece of research that I am asking be inquired into for I have extremely serious concerns with it. I sent a letter of objection to the Secretariat. As you will see below, the Secretariat asked that the objection be sent to the appropriate people at the two institutions involved, University of Toronto, and CAMH, and more specifically to the Vice President of Research, Dr. Paul Young, at Simcoe Hall and to the vice-president of research at CAMH—Dr. Bruce Pollock, hence my writing to you. Attached please find 4 pieces of information, a) the initial letter to Dr. Susan Zimmerman, at the secretariat. At the Secretariat’s suggestion, I have not changed the letter to insert your name and institution, but nonetheless now ask that you and your institution be considered as the people to whom I am sending this objection; b) the letter of consent attached to the project; c) the brochure on the study; and d) one of the advertisements for the project. As this is matter of some urgency and seriousness, I ask you to read my letter and the accompanying material and look into this issue as soon as you possibly can.

Good afternoon Dr. Burstow,

This email is to follow up from our telephone conversation this morning.

Thank you for your email dated August 14, 2012 to the Secretariat on Responsible Conduct of Research, concerning a research project called “Inflammation and Electroconvulsive Therapy.” The Secretariat on Responsible Conduct of Research is responsible for matters related to research misconduct on behalf of Canada’s research granting Agencies (the Natural Sciences and Engineering Research Council, the Canadian Institutes of Health Research and the Social Sciences and Humanities Council of Canada), under the terms of the new Tri-Agency Framework: Responsible Conduct of Research (http://www.rcr.ethics.gc.ca/eng/policy-politique/framework-cadre/).

Section 3.2 of the new Framework requires that all allegations be sent to the institution: “responsible allegations, or information related to responsible allegations, should be sent directly to the Institution’s designated point of contact, in writing, with an exact copy sent to the [Secretariat]”. “Individuals are expected to report in good faith any information pertaining to possible breaches of Agency policies to the Institution where the researcher involved is currently employed, enrolled as a student or has a formal association.”
We would therefore ask that you send your allegation to the institution where the individuals who are the subject of your allegation are currently employed, with an exact copy to the Secretariat (I have copied the Secretariat email). Once received, the Secretariat will follow-up with the institution. It appears from the brochure you attached that the research involves two teams led by researchers from the University of Toronto. Typically, the contact person for such allegations is the Vice President of Research. The University of Toronto website shows the following contact information for the Vice President of Research:

Professor R. Paul Young, PhD, FRSC  
Vice President, Research  
The University of Toronto  
Simcoe Hall, Room 109  
27 King's College Circle  
Toronto, Ontario  
M5S 1A1  
vp.research@utoronto.ca

Phone: 416-978-4984  
Fax: 416-971-2647

The website for the Centre for Addiction and Mental Health shows the following contact information for its Vice President of Research:

Vice-President of Research: Dr. Bruce G. Pollock  
Research Services Office  
33 Russell St., T100  
Toronto, ON M5S 2S1

I hope this information is of assistance. If not, please do not hesitate to call me.

Sincerely,

Wendy Burgess

Policy Analyst | Analyste des politiques  
Secretariat on Responsible Conduct of Research  
Secrétariat sur la conduite responsable de la recherche  
Telephone | Téléphone : 613-996-4923  
350 Albert Street, Ottawa, ON K1A 1H5

From: Bonnie Burstow [mailto:bonnie.burstow@utoronto.ca]  
Sent: August 14, 2012 8:58 AM  
To: susan.zimmerman@rcr.ethics.gc; Z-SRCR; Zimmerman,Susan  
Subject: Requesting you to intervene  
Importance: High

I am a faculty member at University of Toronto who is deeply concerned about and am asking you to look into a research project called “Inflammation and Electroconvulsive Therapy”. Attached please find: a) my letter which outlines in detail the nature of the various ethical problems inherent in this project ("letter to Zimmerman"); and b) the letter of consent attached to the project; c) the brochure on the study; and d) one of the advertisements for the project. As this is matter of some urgency and seriousness, I ask you to read my letter and the accompanying material and look into this issue as soon as you possibly can.
I thank you.
From: Bonnie Burstow [mailto:bonnie.burstow@utoronto.ca]
Sent: August 14, 2012 8:58 AM
To: susan.zimmerman@rcr.ethics.gc; Z-SRCR; Zimmerman,Susan
Subject: Requesting you to intervene
Importance: High

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I thank you.

This email has been scanned by the CAMH Email Security System.

This email has been scanned by the CAMH Email Security System.

This email has been scanned by the CAMH Email Security System.
August 16, 2012.

Confidential

Professor Catherine Whiteside
Dean, Faculty of Medicine and
Vice-Provost, Relations with Healthcare Institutions
Medical Sciences Building, Room 2109
1 King’s College Circle
Toronto, Ontario M5S 1A8

Dear Dean Whiteside:

Re: Allegation of Research Misconduct 12-006: Meyer et al.

I am writing to inform you that concerns have been raised regarding a research study on inflammation and electroconvulsive therapy that appears to be conducted under the auspices of CAMH by individuals who also hold appointments at the University of Toronto. A copy of the correspondence received from the complainant is enclosed for your reference.

The concerns expressed by the complainant may fall within the scope of the University of Toronto Framework to Address Allegations of Research Misconduct (the “Framework”). It will be necessary to determine jurisdiction over this matter as between the University and the CAMH in accordance with the Framework’s addendum entitled Procedures for Determining Jurisdiction in Complaints Involving Certain Non-University Institutions.

The complainant has also corresponded with CAMH directly and has expressed concerns not only with the conduct of the study itself, but with the research ethics board that approved the protocol for the study. We understand that the protocol was not reviewed by a University research ethics board and presume that it was reviewed by the CAMH research ethics board. We suggest that the CAMH research ethics board should receive notice of this complaint as soon as possible.

The complainant has also notified the Secretariat on Responsible Conduct of Research. Our office has no information regarding the source of funding for the study. Should the study involve funding provided by the Tri-Agencies, further engagement with the Secretariat may be warranted.

.../2
Following the jurisdictional determination, the Framework identifies a two-stage process: an initial gathering and review of information at an inquiry stage and, if warranted, a subsequent investigation. The purpose of the inquiry is to gather and review factual information, to determine whether the threshold for proceeding further is met, and whether an investigation of the complaint is warranted. If the inquiry determines that an investigation is warranted, an investigation committee would be established to examine the allegations and to weigh the evidence to determine whether research misconduct has occurred.

Please do not hesitate to contact me if you have any questions regarding the application of the Framework or its addendum to this matter. We will look forward to receiving a report of the outcome and thank you for your assistance.

Yours sincerely,

\[Signature\]

Judith L. Chadwick  
Assistant Vice-President, Research Services and  
Interim Executive Director,  
Research Oversight & Compliance Office

Encls.
UNIVERSITY OF TORONTO
FRAMEWORK TO ADDRESS ALLEGATIONS OF RESEARCH MISCONDUCT

Revised Effective January 1, 2013

1.0 PREAMBLE

The University of Toronto's Policy on Ethical Conduct in Research states that the University “expects of its members (which include faculty, students and anyone holding a university post or any office that gives university status, such as that of a fellow or a research associate), the highest standards of ethical conduct in every aspect of research including applications, proposals, the research itself, reports and publication.”

These standards of ethical conduct are consistent with the requirements of granting agencies and others who sponsor research at the University.

A component of these standards is the need to have a process that addresses allegations of research misconduct. This Framework, which has been developed to comply with the requirements of the Tri-Agencies¹ (CIHR, NSERC or SSHRC) and other granting agencies, provides a common process for the entire University. Individual faculties and divisions may modify the examples of research misconduct in section 4.1 to fit their particular research circumstances and the norms of their disciplines. If other enhancement is viewed as necessary by a faculty or division, it must be discussed with and approved by the Vice-President Research and Innovation, to ensure compliance with the requirements of the Tri-Agencies.

Research activity at the University of Toronto depends upon freedom of inquiry, thought, expression and publication. The University also recognizes that as a community of scholars, we must be prepared to embrace novel ideas and methods.

Each member of the University has a responsibility to foster intellectual honesty and integrity and to be vigilant regarding the conduct of research and scholarship, whether his or her own or others. One feature of this Framework, therefore, is to communicate expectations, increase awareness of integrity issues and encourage scholars (be they faculty, staff or students) to assume personal responsibility for maintenance of the highest research standards.

The purposes of this Framework are to:

- Promote research integrity among scholars, in order to maintain and enhance the value of impartiality that universities offer society;
- Proscribe activities which breach generally acceptable standards of conduct in research;
- Ensure compliance with standards of granting agencies; and,
- Provide a process for dealing with allegations of research misconduct quickly and fairly.

¹ See section 3.2 of the Agreement on the Administration of Agency Grants and Awards by Research Institutions and the Tri-Agency Framework: Responsible Conduct of Research.
2.0 APPLICABILITY

This Framework applies to all persons who conduct research at, or under the auspices of, the University, including but not limited to all full-time and part-time faculty, librarians, staff (including research assistants and research associates), and students of the University (excluding undergraduate students doing research for credit, whose obligations are covered under the Code of Behaviour on Academic Matters), clinical faculty, visiting professors, adjunct professors, and post-doctoral fellows.

The Framework should be read in conjunction with existing University policies, including but not limited to the Code of Behaviour on Academic Matters, the Policy on Conflict of Interest - Academic Staff, the Policy on Conflict of Interest - Librarians, the Policy on Research Involving Human Subjects, the Policy on Ethical Conduct in Research, and any other applicable policy. Depending on the circumstances, aspects of research misconduct may be dealt with under such other policies in addition to or instead of this Framework. Each situation must be assessed based on its own particular facts to determine how to respond to an allegation.

3.0 GENERAL

Individuals are personally responsible for the intellectual and ethical quality of their work and must ensure that their research meets University standards and the standards of any entities sponsoring any component of the research. They must not commit Research Misconduct.

The University will respond to allegations of research misconduct in a timely, impartial, fair and transparent manner, maintaining appropriate confidentiality during the preliminary inquiry and investigation stages.

The procedures set out in this Framework should be interpreted in a way that allows for procedural fairness, objectivity and timely resolution/disposition.

4.0 DEFINITIONS

4.1 Research Misconduct

Research Misconduct is any research practice that deviates seriously from the commonly accepted ethics/integrity standards or practices of the relevant research community and includes but is not limited to intentional fabrication, falsification, and plagiarism as defined by the University’s Code of Behaviour on Academic Matters. However, in determining whether conduct deviates from relevant research community standards or practices, due regard is given for honest errors, honest differences in methodology, interpretation or judgement, or divergent paradigms in science; what is at issue are genuine breaches of the integrity of the research process.

Specifically, the following acts generally are considered instances of Research Misconduct, although Research Misconduct is not necessarily limited to these, and individual faculties may modify these examples to their own research circumstances and the norms applicable to their disciplines:

a) Fraud, including (but not limited to) fabrication of recording or reporting and other falsification of data, results, or source materials;
b) Committing plagiarism or any of the other offences as defined by the University's Code of Behaviour on Academic Matters in the context of research;

c) Failure to honour the confidentiality that the researcher agreed to maintain in exchange for receiving valuable information from a party internal or external to the Institution;

d) Financial misconduct, including (but not limited to) deliberate misuse of funds acquired for support of research; misuse of University resources, facilities and equipment; failure to identify correctly the source of research funds;

e) 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;

f) Material failure to comply with relevant laws or regulations, agreements or published policies of the University or sponsors that are applicable to the conduct and reporting of research;

g) Failure to comply with a direction of the University's Research Ethics Board upon which an approval to proceed with the research was granted or failing to notify the Research Ethics Board of significant protocol changes that may affect its prior decision to approve the research proceeding;

h) Failure to comply with a direction of the University Animal Care Committee or Biosafety Committee upon which an approval to proceed with the research was granted or failing to notify the committee of significant protocol changes that may affect its prior decision to approve the research proceedings;

i) Failure to provide relevant information or materials to the University's Research Ethics Board, Animal Care Committee or Biosafety Committee required by the institution or which the research or academic community considers to be materials relevant to decision-making;

j) Failure to reveal material conflicts of interest to the University, 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;

k) 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;

l) 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 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 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;

m) Wilfully misrepresenting and misinterpreting (for any reason) of findings resulting from conducting research activities;

n) Condoning or not reporting the performance by another University member of any of the acts noted above;

o) Encouraging or facilitating another researcher to carry out Research Misconduct (e.g. a supervisor telling his graduate student to falsify data) or otherwise creating an environment that promotes Research Misconduct by another;

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

4.2 **Administrator** – The person to whom a Complaint is assigned under section 7.1.

4.3 **Complaint** – An allegation of Research Misconduct that meets the formal requirements set out in section 5.2.

4.4 **Complainant(s)** – The person who provides a Complaint.

4.5 **Dean** – The person to whom the Vice-President refers a Complaint under section 5.5.

4.6 **Investigating Committee** – a committee appointed by a Dean to investigate a Complaint.

4.7 **Respondent(s)** – The person(s) against whom a Complaint has been made.

4.8 **Vice-President** – the Vice-President, Research and Innovation or the Vice-President and Provost, as set out in section 5.3.
5.0 SUBMISSION OF COMPLAINTS

5.1 Complainants

Any person, whether or not part of the University community, may make an allegation of Research Misconduct. Before doing so, complainants are encouraged to attempt, where appropriate, to seek an explanation from the subject individual to ensure that there was not a misunderstanding.

Anyone who alleges Research Misconduct is required to declare any conflicts of interest he or she may have and is expected to act in good faith.

5.2 Allegations

All allegations shall be made in writing and shall be signed, dated and identify the Complainant. They shall set out all relevant information and include supporting evidence, if available, and provide contact information for the Complainant. Allegations meeting this standard shall be treated as Complaints under this Framework.

Allegations of Research Misconduct made anonymously may be accepted only if accompanied by sufficient information to enable the assessment of the allegations and the credibility of the facts and evidence on which the Complaint is based without the need for further information from the source of the allegation. However, if the University decides to proceed with an anonymous allegation of Research Misconduct as a Complaint, the source of the allegation will not be entitled to participate in the procedures set out in the Framework or receive notice of the status of the Complaint or a report of the outcome of any inquiry or investigation conducted in respect of the Complaint.

5.3 Referral to the Vice-President

Complaints of Research Misconduct received by the University shall be forwarded promptly to the Office of the Vice-President, Research and Innovation. The Vice-President, Research and Innovation is normally sufficiently at arm’s length so as to be viewed as impartial and free of personal conflicts of interest and is therefore the central point of contact. If the Vice-President, Research and Innovation believes it would be inappropriate for the Vice-President, Research and Innovation to handle a particular Complaint for whatever reason, the Vice-President, Research and Innovation shall refer the Complaint to the Vice-President and Provost. The applicable Vice-President may delegate tasks required to respond to the Complaint. Reports of the status of the Complaint and its disposition shall be made to the Vice-President in writing, as particularized more fully below.

If multiple Complainants make essentially the same set of allegations, each Complainant shall submit a written signed statement. The primary spokesperson (if there is one) shall identify himself or herself as such and all other Complainants shall acknowledge this arrangement. If no primary spokesperson is declared or identified in subsequent communication, the allegations shall proceed with each Complainant treated separately, but the Vice-President in his or her sole discretion may designate a primary spokesperson and/or determine that the allegations be considered together such that there are not multiple processes in place to deal with the one Respondent.
5.4 Recurring Complaints

If a Complaint has already undergone an inquiry or an investigation and the matter has been closed, the Vice-President will not pursue the same allegation unless new and compelling information that could not reasonably have been available at the time of the original Complaint is brought forward. In cases of recurring Complaints based on the same allegations that are not made in good faith, the appropriate academic official may apply sanctions.

5.5 Referral by the Vice-President

Following receipt of a Complaint, the Vice-President will notify the Respondent that the Complaint has been made by providing a full copy of the Complaint as received by the Vice-President.

The Vice-President shall refer the Complaint to the Dean, who shall be the dean or principal of the academic division in which the Respondent holds his or her primary appointment unless:

a) the Respondent is acting in his or her capacity as a graduate student, in which case the Dean shall normally be the dean of the School of Graduate Students;

b) the Respondents hold primary appointments in different academic divisions, in which case the referral shall (subject to the preceding paragraph) be to the deans or principals of their respective academic divisions, who shall decide which of them shall serve as the Dean for purposes of the Complaint while keeping the other(s) informed of the status of the Complaint; or,

c) the Dean is the Complainant or the Respondent, in which case the referral shall be to the Vice-President and Provost, who may designate an appropriate person to undertake the tasks required of the Dean under this Framework.

5.6 Interim Measures

Pending the resolution of a Complaint, the Vice-President may, in his or her discretion:

a) take action to protect the administration of funds that support the research that is the subject of the Complaint, including without limitation, withhold funds, require authorization of expenditures by another University representative, or take such other measures deemed appropriate; or,

b) request the Dean to take appropriate action to obtain custody of and sequester such research or other records that may be necessary to process the Complaint.

6.0 GUIDING PRINCIPLES FOR PROCESSING OF COMPLAINTS

The processing of Complaints of Research Misconduct must be carried out carefully, thoroughly and as promptly as possible, to resolve all questions regarding the integrity of the research and those individuals that may be involved in an allegation.
The following general principles apply:

- The reputation of the University and its investigators and students, and their responsibility for the ethical conduct of research, require that any Research Misconduct that occurs be promptly detected and dealt with effectively;
- To this end, Complaints of Research Misconduct shall be taken seriously and vigorous leadership shall be exercised in their inquiry and resolution;
- All persons involved, those making allegations, those who are the subject of the allegations of misconduct, and those who assist in the inquiry, shall be treated with respect, fairness and with due sensitivity;
- All proceedings shall be conducted in a timely manner and shall be documented appropriately; and,
- The highest possible degree of confidentiality shall be maintained regarding all allegations, inquiries and investigations, subject to any disclosure that might be required by law or agreements with, or policies of, the University or sponsors of the research that is the subject of the Complaint.

7.0 PRELIMINARY INQUIRY

7.1 Introduction

Upon receipt of a Complaint from the Vice-President, the Dean shall appoint an Administrator to conduct a preliminary inquiry. The Administrator will have no actual, apparent, reasonably perceived or potential conflict of interest or bias and will normally be the Dean's vice-dean responsible for research (or equivalent) or another senior divisional officer appointed by the Dean.

The inquiry is a preliminary process where the Administrator gathers sufficient information to make threshold assessments and recommend whether the Complaint should proceed to an investigation.

The Administrator will not recommend that the Complaint proceed to an investigation if he or she determines any of the following:

a) The Complaint does not fall within the scope of the Framework;

b) The Framework does not apply to the Respondent as set out in section 2.0;

c) The Complaint involves allegations that, even if proven, would not constitute Research Misconduct;

d) The Complaint is clearly mistaken or unjustified, or frivolous, vexatious, or made in bad faith; or,

e) There is no reasonable prospect that a further investigation will enhance the integrity of the scientific process.

It is not the purpose of the preliminary inquiry to determine whether or not Research Misconduct has occurred. Instead, factual information is gathered and reviewed expeditiously by the
Administrator to assess whether the threshold for proceeding further is met, and whether an investigation of the Complaint is warranted.

The Administrator shall follow the procedures set out in this section 7.0 and shall be vigilant not to permit personal conflicts between colleagues to obscure the facts and divert attention from the substance of the allegation. The Administrator shall disclose any actual, apparent, perceived or potential conflicts of interest to the Dean. The Dean may decide, based on this disclosure, to appoint a designate.

The preliminary inquiry is to be conducted as a confidential process to avoid unwarranted publicity regarding allegations that have yet to be fully assessed. The Administrator shall take reasonable efforts to protect the privacy of the Complainant and the Respondent both of whom shall be advised of the need to maintain confidentiality. The preliminary inquiry also provides an opportunity to determine whether it is appropriate to offer the Complainant and the Respondent an alternative dispute resolution process.

7.2 Timelines

Normally, the following timelines will apply:

- The Vice-President will forward the Complaint to the Dean and to the Respondent within 7 working days of the Vice-President's receipt of the Complaint.
- The preliminary inquiry shall begin within 20 working days of the Dean's receipt of the Complaint from the Vice-President.
- Notice of the Administrator's recommendation shall be provided within 60 working days of the Vice-President's receipt of the Complaint.

There may be circumstances when it is not reasonably possible to comply with these timelines or where different timelines are required under agreements with, or policies of sponsors of the research that is the subject of the Complaint. Nevertheless, the Administrator shall work expeditiously in these exceptional cases and the Vice-President will be informed of any anticipated delay, including the reasons for the delay.

7.3 Process for Conducting the Preliminary Inquiry

a) The Administrator may request that supplementary information be provided in writing if the Complaint does not contain sufficient information or particulars to permit an assessment. Such supplementary information shall also be shared with the Respondent.

b) In conducting the preliminary inquiry, the Administrator may contact the Complainant and Respondent and consult confidentially within the University and externally if appropriate, to assist in the assessment of whether an investigation is warranted.

c) After consulting with the Dean and upon the consent of both the Complainant and the Respondent, the Administrator may conduct (either personally or through an appointed representative) non-binding, without prejudice, confidential mediation. If such mediation produces a resolution, the outcome shall be communicated to the Dean and the Vice-President.
d) After completing the preliminary inquiry, the Administrator shall make his or her recommendation in writing to the Dean, with copies to the Respondent and the Complainant and a copy to the Vice-President for information and for an assessment of whether reporting is required at this stage under section 8.3. The Administrator shall include a summary of the reasons for the recommendation and, if the Administrator recommends that an investigation be commenced or if the Respondent admitted committing Research Misconduct in the course of the preliminary inquiry, shall also include all material provided to the Administrator by the Complainant and the Respondent.

e) If the Administrator has reasonable grounds to believe that the Complainant did not act in good faith, the Administrator will write the Complainant and the Respondent to summarize these grounds and inform them that the matter is being referred to the Dean or other appropriate academic official to be assessed in accordance with the relevant policy. A copy of this letter shall be sent to the Vice-President for information.

### 8.0 INVESTIGATION

#### 8.1 Introduction

The investigation is a formal process to examine the Complaint and to weigh the evidence to determine whether or not Research Misconduct has occurred, and, if so, who the involved parties are. The Dean is responsible for arranging for the investigation of the Complaint.

#### 8.2 Timelines

Complaints vary greatly with their respect to urgency, seriousness and complexity. The Dean will exercise his or her discretion in determining the appropriate timelines for commencing, conducting and reporting on investigations, provided that where agreements with, or policies of, sponsors of the research that is the subject of the Complaint require reporting within prescribed timelines, all reasonable efforts will be made to meet those requirements.

Normally, the following timelines will apply:

- The Dean will appoint the Investigating Committee within 15 working days of receiving the Administrator's decision that an Investigation should be conducted.
- The Investigating Committee shall convene within 30 working days of its appointment or as soon thereafter as is reasonably possible.
- The investigation will ordinarily be completed within 60 working days of the first meeting of the Investigating Committee.
- The final report of the Investigating Committee shall be delivered within 30 working days after the completion of the investigation.

If these deadlines cannot reasonably be met, the Investigating Committee will submit a procedural report citing the reasons for the delay and progress to date to the Dean, with copies to the Complainant, Respondent and the Vice-President. The Dean or the Vice-President, at their discretion, may share this report with other appropriate individuals.
8.3 Reporting of the Commencement of the Investigation

The Dean shall inform the Vice-President that an investigation of a Complaint of Research Misconduct has been initiated.

With the concurrence of the Vice-President, others may be informed, if appropriate in the circumstances. Such others could include, for example, representatives of an affiliated institution, granting agency, or professional or regulatory body.

8.4 Investigating Committee

The Dean will appoint an Investigating Committee of two or more members to perform the investigation in accordance with these guidelines. The Investigating Committee shall appoint one of its members to act as a chairperson, for administrative purposes.

The members of the Investigating Committee will be senior members of the University or another academic institution. At least one member of the Investigation Committee shall be an external member who is not an employee, does not hold any academic appointment conferred by, and is not a student enrolled in an academic program of, the University. The members of the Investigating Committee will have no actual, apparent, reasonably perceived or potential conflict of interest or bias, and will jointly have appropriate scientific and administrative background to evaluate the Complaint and the response to it. If either the Complainant or Respondent alleges that a committee member is biased, and the Dean believes that actual, apparent, perceived or potential conflict of interest or bias has been clearly and reasonably demonstrated, the Dean shall alter the membership accordingly.

The Dean shall provide suitable administrative support to the Investigating Committee. The Dean may authorize the delegation of components of the investigation to an investigator who shall report to the Investigating Committee. The Investigating Committee may consult with others as necessary in order to make its assessment.

8.5 Instructions to the Investigating Committee

The Dean shall review with the chairperson of the Investigating Committee the following guidelines and procedures.

The chairperson of the Investigating Committee shall ensure that members of the Investigating Committee are informed of:

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

8.6 Authority and Responsibilities of the Investigating Committee

The Investigating Committee operates under the Dean and the chairperson of the Investigating Committee is responsible to the Dean.

The Investigating Committee shall conduct a thorough investigation of the Complaint. The Investigating Committee has the discretion to interview persons whose evidence could be helpful, to examine relevant documents and data records, and to consult with experts both within and outside the University, as appropriate.

If during the course of the investigation, the Respondent for any reason ceases to hold a position or appointment (e.g. faculty member, staff or student, post-doctoral fellow) at the University or leaves the jurisdiction, the Dean will decide in his or her own discretion whether the investigation will continue. If, where the investigation continues, the Respondent refuses to participate in the process after ceasing to hold a position or appointment at the University, the Investigating Committee shall use its best efforts to reach a conclusion and shall deliver its report with a statement as to the effect this lack of cooperation had on the Investigating Committee's review of the evidence.

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

The chairperson of the Investigating Committee has the authority to report uncooperative behaviour to the Dean.

The chairperson of the Investigating Committee shall notify the Dean of interim findings, if any, that he/she believes ought to be reported because of the University's obligations to students, staff and faculty members, obligations under agreements with, or policies of, sponsors of the research that is the subject of the Complaint, or where there are compelling issues of public safety, to the public. Any interim report shall be in writing and copied to all members of the Committee, to the Complainant and Respondent, and to the Vice-President. The report shall set out the findings, the reason for the interim report and a recommendation regarding appropriate administrative action.

8.7 Process for Investigating Complaints of Research Misconduct

a) The chairperson of the Investigating Committee shall send a letter to the Respondent and the Complainant advising them of the appointment of the Committee, outlining the process and highlighting their respective obligations.

b) In all cases the Investigating Committee must give the opportunity to the Complainant to provide any supplementary written materials in addition to the Complaint that the Complainant wishes to provide; all such materials shall be
provided to the Respondent who shall have the opportunity to comment, in writing, and provide any supplementary written response materials. The Respondent's written response, if any, shall be shared with the Complainant. The Committee is not to conduct a hearing and is only obliged to conduct a fair and objective investigation. It may in its discretion, request an interview with any or all of the Complainant, the Respondent, or other relevant people. Summaries of interviews (including the points or issues raised but not verbatim text) shall be prepared, provided to the interviewed party for comment or revision, and included as part of the investigation file.

c) If a Complainant decides not to participate further, the Investigating Committee may decide to proceed with the investigation in any event.

d) All involved parties who are associated with the University will be expected to cooperate with the investigation in a timely manner. This includes providing documentation and information and appearing before the Investigating Committee if requested.

e) The Investigating Committee will set a deadline by which all responses must be made and all evidence must be submitted. No response or evidence will be accepted after the deadline except in exceptional circumstances where no prejudice to the other party would result, and with the permission of the chairperson of the Investigating Committee.

f) The Investigating Committee will take reasonable steps to provide to the Respondent reasonable access to relevant documents in its possession so as to provide him/her with a fair opportunity to respond to relevant material. The Investigating Committee may provide access to particular documents to the Complainant in special cases where it is believed that a response from the Complainant is required to help in determining the facts of the case. The Respondent and if applicable, the Complainant, shall sign a confidentiality agreement before materials are provided.

g) To protect confidentiality, the chair of the Investigating Committee will assume the responsibility of restricting the dissemination of the information to only those who should receive it.

8.8 Decisions and Reports of the Investigating Committee

a) The Investigating Committee will prepare a written report that sets out its findings of fact and its decision as to whether or not there is Research Misconduct. The report may also state whether a serious scientific error has been made which does not constitute Research Misconduct.

The report will contain:

- The full Complaint;
- A list of Investigating Committee members and their credentials;
- A list of the people who contributed evidentiary material to the investigation or were interviewed as witnesses;
• A summary of relevant evidence;
• A determination of whether Research Misconduct occurred; and
• If Research Misconduct has occurred, an assessment of its extent and seriousness; and,
• Recommendations on any remedial action to be taken to correct the scientific or scholarly record in the matter in question and/or recommendations of changes to procedures or practices to avoid similar situations in the future, which may include, without limitation:
  • Withdrawing all pending relevant publications;
  • Notifying publications in which the involved research was reported;
  • Ensuring the unit(s) involved is informed of appropriate practices for promoting the proper conduct of research; and
  • Informing any sponsor of the research that is the subject of the Complaint of the results of the inquiry and of actions to be taken;

but shall not include recommendations with respect to disciplinary actions to be taken in respect of the Respondent under applicable University policies or procedures.

b) All members of the Investigating Committee shall sign a statement indicating that they agree to the release of the report based on majority rule. No minority reports shall be allowed.

c) The report will be delivered to the Complainant, the Respondent, the Dean and the Vice-President. If there is more than one Respondent or Complainant, reasonable efforts will be made to provide each only with the parts of the report that are pertinent to him or her.

d) The report of the Investigating Committee is final and not subject to revision. However, the Respondent and Complainant will have up to 15 working days to make submissions to the Dean regarding the findings, in advance of any administrative action recommended to be taken by the Dean.

e) After the Investigating Committee delivers its report, its chairperson shall notify all members of the Investigating Committee to return all documentation to the Dean. Copies of the decision, report and all relevant materials will be sent to the Vice-President for reporting and documentation purposes.

8.9 Report of the Dean

The Dean shall inform the Vice-President of the findings and conclusions of the investigation and the decision he/she has made about the appropriate administrative action.

If the Dean receives an interim report from the chairperson of the Investigating Committee, the Dean will determine, based on the nature of the case and in accordance with other relevant University policies, if restrictions of activity or suspension of the subject individual pending the results of the investigation are warranted. Moreover, the Dean shall determine, with the
The concurrence of the Vice-President, if a report of interim findings shall be disclosed to protect the public or to protect the best interests of students, staff and faculty. The Dean shall take into account the terms of agreements with, or policies of, the sponsor of the research that is the subject of the Complaint as well as relevant policies of the University.

9.0 ADMINISTRATIVE ACTION AND REPORTING REQUIREMENTS

9.1 Cases where no Research Misconduct has been found

When an investigation determines that no Research Misconduct occurred, the Dean shall ensure that a letter confirming the finding of no misconduct is sent to the Respondent, with a copy to the Complainant and, in the Dean’s discretion to other persons with knowledge of the Complaint. These persons may include co-authors, co-investigators, collaborators and others who may have notified of the Complaint.

In some circumstances, the investigation may disclose evidence of serious scientific error that requires further action, even when no Research Misconduct is found. The action may be, for example, a recommendation of retraction of published findings. In these cases, the Dean will consult with the chair of the Investigating Committee and the Respondent, and will consider the Respondent’s submissions, if any, and will decide what action, if any, to take.

No disciplinary measures shall be taken against the Complainant if the Complaint is found to have been made in good faith; moreover, efforts will be made to ensure that no retaliatory action is taken against the Complainant in such cases. The proceedings of the investigation will be held in confidence in accordance with this Framework. However, if the Complaint is found to have been made in bad faith, the Dean may apply or recommend the application of appropriate sanctions consistent with University policies. Similar appropriate sanctions may be taken against individuals who engage in acts of retaliation or intimidation against Complainants and/or Respondents who have been acting in good faith.

9.2 Cases where Research Misconduct has been found

The nature and severity of remedial and/or disciplinary action taken for Research Misconduct will be consistent with the established policy of the University and proportional to the misconduct.

When the Investigating Committee delivers a report which concludes that Research Misconduct has occurred, the Dean will consider what remedial and/or disciplinary action should be taken. Since there may be other procedural requirements under University policies before remedial and/or disciplinary action can be taken, the Dean will consult with the Vice-President and Provost before taking further action.

For Research Misconduct involving students or faculty members, remedial and/or disciplinary action may include the institution of disciplinary proceedings leading to sanctions up to and including suspension or termination under the Code of Behaviour on Academic Matters or the Policy and Procedures on Academic Appointments or other applicable University policies or agreements. For Research Misconduct involving a graduate student with respect to the student’s graduate studies, the responsibility for enforcing remedial and/or disciplinary action resides with the Dean of the School of Graduate Studies, and is determined in accordance with
the Code of Behaviour on Academic Matters or other applicable University policies or agreements.

If the Respondent is a student or faculty member and has admitted to committing Research Misconduct, the Dean may proceed to impose sanctions under the Code of Behaviour on Academic Matters.

As a general rule, the decision about remedial and/or disciplinary action will be rendered within not more than 15 working days from the date that the Dean receives any submissions from the Respondent concerning such proposed action. If there are no further procedural requirements under University policies or agreements, the Dean may impose sanctions which could include:

- Verbal warning;
- Special monitoring of future work;
- Verbal warning with a letter to be held temporarily on file in the appropriate office;
- Letter of reprimand to the individual’s permanent personnel file;
- Withdrawal of specific privileges;
- Removal of specific responsibilities;
- Suspension;
- Steps to terminate.

Any remedial and/or disciplinary action, including the foregoing and the steps that may be necessary to implement the foregoing, is subject to any applicable University policies and agreements, including, for example, the Policy and Procedures on Academic Appointments, and the Code of Behaviour on Academic Matters. Regard shall be had under such policies, subject to their terms, for findings made under this Framework.

9.3 Communication by Vice-President

The Vice-President at his or her discretion may communicate the outcome of the investigation, directly, or through senior University administration, to other parties within or external to the University, including but not limited to:

- Sponsors of the research that is the subject of the Complaint;
- Co-authors, co-investigators, collaborators;
- Editors of journals in which fraudulent research or erroneous findings were published;
- Professional licensing boards;
- Editors of journals or other publications, other institutions, sponsoring agencies and funding sources with which the individual has been affiliated in the past;
- Professional societies;
- Police services.
10.0 REVIEWS

Depending on the relationship between the University and the individual Respondent and depending on the nature of the disciplinary and/or remedial action, the Respondent may have rights of review, grievance or appeal under other applicable University policies such as the Code of Behaviour on Academic Matters, the Policy and Procedures on Academic Appointments, or may have a right to grieve the disciplinary and/or remedial action taken under a collective bargaining agreement.

Where any Respondent has no access to another process for a review of the decision with respect to remedy, that Respondent may seek a review of the appropriateness of the remedial action from the Vice-President, Research and Innovation. If the Vice-President, Research and Innovation believes it would be inappropriate for the Vice-President, Research and Innovation to undertake such a review for whatever reason, the matter shall be referred to the Vice-President and Provost. This review must be sought in writing within 5 working days of the issuance of the written notice of remedial action. The Dean will not institute irreversible remedial actions (such as public notifications) until 5 working days have elapsed from the issuance of a notice of decision and confirmation that the subject individual has received the notice. The decision of the applicable Vice-President shall be considered final and binding.

11.0 RECORD KEEPING

The report of the Investigating Committee will be maintained in a confidential and secure manner, with limited access, in the Office of the Vice-President, Research and Innovation.

The Office of the Vice-President, Research and Innovation may periodically prepare and publish summaries of decisions (with personal identifiers removed) for the purpose of educating University members on acceptable practices for scholarly integrity and research ethics.

12.0 PROMOTION OF RESEARCH INTEGRITY

To promote an understanding of research integrity issues, the University will use appropriate vehicles such as, but not limited to workshops, seminars, written materials and orientation for new employees.

Version 2: Effective for Complaints received after January 1, 2013
Replaces Version 1: November 27, 2006
August 16, 2012.

Confidential

Dr. Bonnie Burstow
Department of Leadership, Higher and Adult Education
Ontario Institute for Studies in Education
252 Bloor St. W.
Toronto, Ontario M5S 1V6

Dear Professor Burstow:

Re: Allegation of Research Misconduct 12-006: Meyer et al.

I am writing on behalf of the Vice-President, Research and Innovation to acknowledge receipt of your correspondence of August 14, 2012 and to advise you of the steps being taken with respect to the concerns raised therein.

Copies of the University of Toronto’s policies and procedures relating to ethical conduct in research are available on the University’s website at:

- Policy on Ethical Conduct in Research  
  http://www.governingcouncil.utoronto.ca/policies/ethicalr.htm
- Framework to Address Allegations of Research Misconduct (the “Framework”)  
- Addendum to the Framework: Procedures for Determining Jurisdiction in Complaints Involving Certain Non-University Institutions (the “Addendum”)  
  http://www.facmed.utoronto.ca/Assets/Facmed+Digital+Assets/research/res+misc-onduet+addendum.pdf

We understand that the individuals associated with the study in question hold primary appointments at a hospital affiliated with the University. Therefore, we have forwarded your correspondence to the Dean of the University’s Faculty of Medicine who, in her capacity as Vice-Provost, Relations with Healthcare Institutions, will determine which institution has appropriate jurisdiction over the matter in accordance with the Addendum.

.../2
Following the jurisdictional determination, the Framework identifies a two-stage process: an initial gathering and review of information at an inquiry stage and, if warranted, a subsequent investigation. The purpose of the inquiry is to gather and review factual information, to determine whether the threshold for proceeding further is met, and whether an investigation of the complaint is warranted. If the inquiry determines that an investigation is warranted, an investigation committee would be established to examine the allegations and to weigh the evidence to determine whether research misconduct has occurred.

The University views allegations of research misconduct seriously. Thank you for bringing this matter to our attention and please do not hesitate to contact me if you have any comments or questions.

Yours sincerely,

[Signature]

Judith L. Chadwick
Assistant Vice-President, Research Services and
Interim Executive Director,
Research Oversight & Compliance Office

cc: Dean C. Whiteside
   Ms. Wendy Burgess, Secretariat on Responsible Conduct of Research
August 17, 2012

Confidential

Dr. Catherine Zahn
President and C.E.O.
Centre for Addiction and Mental Health
901 King Street West, Suite 500
Toronto, Ontario M5V 3H5

Dear Dr. Zahn:

Re: Allegation of Research Misconduct 12-006: Meyer et al.

Please find enclosed correspondence received from the Office of the Vice-President, Research and Innovation regarding a research study on inflammation and electroconvulsive therapy. A number of concerns have been raised regarding patient safety and the general ethicality of the study. We understand that the complainant has also sent correspondence to Dr. Pollock directly.

The study appears to involve CAMH appointees who also hold University of Toronto appointments. Therefore, jurisdiction over the complaint must be determined in accordance to the addendum to the University’s Framework to Address Allegations of Research Misconduct (the “Framework”) entitled Procedures for Determining Jurisdiction in Complaints Involving Certain Non-University Institutions (the “Addendum”) and the complainant has been so advised. Copies of the Framework and the Addendum are available on the University’s website at:


A number of factors are considered in determining jurisdiction, including where the research is conducted, which institution administers the funding for the research and which institution’s research ethics board conducted the full review of the research. The Office of the Vice-President, Research and Innovation has advised that it has no record of...
the funding for this study and that the protocol was not reviewed by a University research ethics board.

Since concerns relating to the ethical review of the study and patient safety have been raised, I would ask you to notify the CAMH research ethics board of this matter expeditiously. The complainant has also corresponded with the Secretariat on Responsible Conduct of Research. Should it prove necessary or desirable to engage with the Secretariat further, an appropriate approach can be developed following the jurisdictional determination.

I look forward to discussing this matter with you at your earliest convenience. Thank you for your assistance.

Yours sincerely,

[Signature]

Catharine Whiteside

cc: Dr. Bruce Pollock, CAMH

Encls.
August 17, 2012

Confidential

Dr. Catherine Zahn
President and C.E.O.
Centre for Addiction and Mental Health
901 King Street West, Suite 500
Toronto, Ontario M5V 3H5

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- Framework:
- Addendum:
  http://www.facmed.utoronto.ca/Assets/Facmed+Digital+Assets/research/res+misconduct+addendum.pdf

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I look forward to discussing this matter with you at your earliest convenience. Thank you for your assistance.

Yours sincerely,

[Signature]

Catharine Whiteside

cc: Dr. Bruce Pollock, CAMH

Encls.
Research Misconduct Framework Addendum

Procedures for Determining Jurisdiction in Complaints Involving Certain Non-University Institutions

1.0 Preamble

In November 2006, the University of Toronto (the “University”) issued its Framework to Address Allegations of Research Misconduct (the “Framework”). The Framework is supplemental to the University Policy on Ethical Conduct in Research and prescribes detailed procedures for the handling of allegations of research misconduct. The Framework complies with the requirements of the Tri-Council Agencies (CIHR, NSERC, or SSHRC) and other granting agencies.

This Addendum provides a process for determining institutional jurisdiction over Complaints of research misconduct made against persons to whom the Framework applies who have appointments at, and/or conduct their research in, Affiliated Institutions.

2.0 Definitions

Unless otherwise defined in this section, capitalized terms have the meanings set out in the Framework.

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 Framework 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 this Addendum.

b) “Responsible Officer” means (I) for the University, 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.

c) “Status-Only Appointee” means a person who has a primary appointment at an Affiliated Institution (including those appointed under the Policy for Clinical Faculty) and excludes Teaching Staff, employees of the University and Students.

d) “Student” means a student enrolled in an academic program of the University.

e) “Teaching Staff” means employees of the University, University College, the constituent colleges and the arts and science faculties of the federated universities 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 and designated by it as an academic rank under the University of Toronto Act.
3.0 Applicability

This Addendum applies only to Complaints made against persons who conduct research under the auspices of either or both the University and an Affiliated Institution and who have an appointment at an Affiliated Institution and/or conduct their research at an Affiliated Institution.

The University and Affiliated Institutions agree to follow the procedures in this Addendum to determine jurisdiction and to determine if notice of the Complaint by one party to another is required hereunder. The University and Affiliated Institutions agree to comply with reasonable requests for information, documentation and attendance at meetings by the other.

Timeframes as provided by the Framework are not changed by this Addendum.

4.0 Receipt of Complaint

If the University receives a Complaint against a Status-Only Appointee or an employee of an Affiliated Institution or where the research that is the subject matter of the Complaint was conducted, in whole or in part, at the Affiliated Institution, the University shall notify the Affiliated Institution's Responsible Officer.

If an Affiliated Institution receives a Complaint against a member of the Teaching Staff, a Student or a University employee or where the research that is the subject matter of the Complaint was conducted, in whole or in part, at the University, the Affiliated Institution shall notify the University's Responsible Officer.

If either the University or the Affiliated Institution 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 Framework and this Addendum.

5.0 Determining Jurisdiction

a) For Complaints against Status-Only Appointees or employees of an Affiliated Institution, jurisdiction is presumed to be solely at the Affiliated Institution unless
the criteria below convince the Affiliated Institution’s Responsible Officer otherwise.

b) For Complaints against members of the Teaching Staff, Students or University employees, jurisdiction is presumed to be solely at the University unless the criteria below convince the University’s Responsible Officer otherwise.

c) For Complaints against an individual not listed in 5a) or 5b) above who is cross-appointed at both of the University and the Affiliated Institution, jurisdiction should not be presumed by either the University or the Affiliated Institution and must be determined as outlined below.

Jurisdiction will be determined by establishing which institution has the stronger connection to the Complaint. 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 and the Affiliated Institution should have joint jurisdiction.

Responsibilities 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 (e.g., who will act on their behalf to serve the role of Academic Administrator and who shall serve as Chair and members of any Investigation Committee that may be established) and any administrative action and reporting requirements shall be jointly determined by the Institutions. 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 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.

**Non-duplication and Sanctions**

Neither the University nor the Affiliated Institution will pursue the same or substantially similar allegation, 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 under this Addendum and will be subject to the jurisdictional determinations outlined herein.

Notwithstanding that the University or an Affiliated Institution did not participate in or have jurisdiction to conduct an inquiry or investigation in connection with a Complaint, nothing in the Framework or this Addendum prevents either the University or the Affiliated Institution from imposing the same or comparable sanctions in connection with the Complaint based on the conclusions reached in the inquiry or investigation.

<end of addendum>
UNIVERSITY OF TORONTO
FRAMEWORK TO ADDRESS ALLEGATIONS OF RESEARCH MISCONDUCT

1.0 PREAMBLE

The University of Toronto's Policy on Ethical Conduct in Research states that the University "expects of its members (which include faculty, students and anyone holding a university post or any office that gives university status, such as that of a fellow or a research associate), the highest standards of ethical conduct in every aspect of research including applications, proposals, the research itself, reports and publication."

These standards of ethical conduct are consistent with the requirements of granting agencies and others who sponsor research at the University.

A component of these standards is the need to have a process that addresses allegations of research misconduct. This Framework, which has been developed to comply with the requirements of the Tri-Council Agencies (CIHR, NSERC or SSHRC) and other granting agencies, provides a common process for the entire University. Individual faculties and divisions may modify the examples of research misconduct in section 4.1 to fit their particular research circumstances and the norms of their disciplines. If other enhancement is viewed as necessary by a faculty or division, it must be discussed with and approved by the Vice-President Research, to ensure ongoing compliance with the requirements of the Tri-Council Agencies.

Research activity at the University of Toronto depends upon freedom of inquiry, thought, expression and publication. The University also recognizes that as a community of scholars, we must be prepared to embrace novel ideas and methods.

Each member of the University has a responsibility to foster intellectual honesty and integrity and to be vigilant regarding the conduct of research and scholarship, whether his or her own or others. One feature of this Framework, therefore, is to communicate expectations, increase awareness of integrity issues and encourage scholars (be they faculty, staff or students) to assume personal responsibility for maintenance of the highest research standards.

The purposes of this Framework are to:

- Promote research integrity among scholars, in order to maintain and enhance the value of impartiality that universities offer society;
- Proscribe activities which breach generally acceptable standards of conduct in research;
- Ensure compliance with standards of granting agencies; and
- Provide a process for dealing with allegations of research misconduct quickly and fairly.

2.0 APPLICABILITY

This Framework applies to all full-time and part-time faculty, staff and students of the University (excluding undergraduate students doing research for credit, whose obligations are covered under the Code of Behaviour on Academic Matters) and any person (including but not limited to clinical faculty, visiting professors, adjunct professors and post-doctoral fellows) who conducts research at or under the auspices of the University.
The Framework should be read in conjunction with existing University policies, including but not limited to the Code of Behaviour on Academic Matters, the Policy on Conflict of Interest Academic Staff, the Policy on Research Involving Human Subjects, the Policy on Ethical Conduct In Research, and any other applicable policy. Depending on the circumstances, aspects of research misconduct may be dealt with under such other policies in addition to or instead of this Framework. Each situation must be assessed based on its own particular facts to determine how to respond to an allegation.

3.0 GENERAL

Individuals are personally responsible for the intellectual and ethical quality of their work and must ensure that their research meets University standards and the standards of any entities sponsoring any component of the research. They must not commit research misconduct.

The University will respond to allegations of research misconduct in a timely, impartial, fair and transparent manner, maintaining appropriate confidentiality during the inquiry and investigation stages.

4.0 DEFINITIONS

4.1 Research Misconduct

Research Misconduct is any research practice that deviates seriously from the commonly accepted ethics/integrity standards or practices of the relevant research community and includes but is not limited to intentional fabrication, falsification, and plagiarism as defined by the University’s Code of Behaviour on Academic Matters. However, in the latter respect, due latitude is given for honest errors, honest differences in methodology, interpretation or judgement, or divergent paradigms in science; what is at issue are genuine breaches of the integrity of the research process.

Specifically, the following acts generally are considered instances of Research Misconduct, although Research Misconduct is not necessarily limited to these, and individual faculties may modify these examples to their own research circumstances and the norms applicable to their disciplines:

a) Fabrication of recording or reporting and other falsification of data, results, or source materials. (fraud);

b) Committing plagiarism or any of the other offences as defined by the University's Code of Behaviour on Academic Matters in the context of research;

c) 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 the Institution;

d) 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 University resources, facilities and equipment; failure to identify correctly the source of research funds (financial misconduct);
e) 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;

f) Retaliation against a person who acted in good faith and reported or provided
information about alleged Research Misconduct;

g) Material failure to comply with relevant federal or provincial statues or regulations
applicable to the conduct and reporting of research;

h) Failure to comply with a direction of the institution's Research Ethics Board upon
which an approval to proceed with the research was granted or failing to notify
the Research Ethics Board of significant protocol changes that may affect its
prior decision to approve the research proceeding;

i) Failure to comply with a direction of the University Animal Care Committee or
Biosafety Committee upon which an approval to proceed with the research was
granted or failing to notify the committee of significant protocol changes that may
effect its prior decision to approve the research proceedings;

j) Failure to provide relevant materials to the institution's Research Ethics Board (or
to the University Animal Care Committee or Biosafety Committee) required by
the institution or which the research or academic community considers to be
materials relevant to decision-making;

k) Failure to reveal material conflicts of interest to the University, 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;

l) 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;

m) 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 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.

n) Wilfully misrepresenting and misinterpreting (for any reason) of findings resulting from conducting research activities;

o) Condoning or not reporting the performance by another University member of any of the acts noted above;

p) 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.

4.2 Academic Administrator – Either the Chair of the Department or the Dean or other appropriate person appointed by the Dean. Referred to herein as "Administrator".

4.3 Complaint – An allegation of Research Misconduct meeting the formal requirements set out in section 5.3.

4.4 Complainant(s) – The person who provides a written Complaint of Research Misconduct.

4.5 Dean – Dean of the respective faculty or his/her designate.

4.6 Investigating Committee – a committee appointed by a Dean for the purpose of investigating a particular allegation.

4.7 Principal Investigator – the person who has primary responsibility for a research project. In the case of a project that is not funded, this will normally be the initiator of the project. The Principal Investigator is usually the supervisor of the research team (which may include other researchers) and is usually a faculty member.

4.8 Respondent(s) – The person(s) against whom the allegations of Research Misconduct have been made.

4.9 Vice-President – the Vice-President, Research and Associate Provost or the Vice-President and Provost.

5.0 PROCEDURES

5.1 General

The following procedures should be interpreted in a way that allows for procedural fairness, objectivity, and timely resolution/disposition.
5.2 Complainants

Individuals, including those not part of the University community, may make allegations of Research Misconduct. Before doing so, complainants should attempt, if possible, to seek an explanation from the subject individual to ensure that there was not a misunderstanding.

If there are multiple complainants and if it can be reasonably assumed that there will be more than one complaint about the same situation, then complainants should make all attempts to identify a primary spokesperson from within the University community unless there are compelling reasons to do otherwise.

Anyone who alleges Research Misconduct is required to declare any conflicts of interest he or she may have and is expected to act in good faith.

5.3 Allegations

All allegations shall be made in writing, and shall be signed, dated and identify the Complainant. They shall set out all relevant information and include supporting evidence, if available. Allegations meeting this standard shall be treated as Complaints under this Framework.

If multiple Complainants make essentially the same set of allegations, each Complainant shall submit a written signed statement. The primary spokesperson (if there is one) shall identify himself or herself as such and all other Complainants shall acknowledge this arrangement. If no primary spokesperson is declared or identified in subsequent communication, the allegations shall proceed with each Complainant treated separately, but the Vice-President in his/her sole discretion may designate a primary spokesperson and/or determine that the allegations be considered together such that there are not multiple processes in place to deal with the one Respondent.

Complaints of Research Misconduct received by the University shall be forwarded promptly to the Office of the Vice-President, Research and Associate Provost. The Vice-President, Research and Associate Provost is normally sufficiently at arm's length so as to be viewed as impartial and free of personal conflicts of interest and is therefore the central point of contact. If the Vice-President, Research and Associate Provost feels it would be inappropriate to receive a particular allegation for whatever reason, he/she may refer the allegation to the Vice-President and Provost. The applicable Vice-President may delegate tasks required to respond to the Complaint. A report shall be made to the Vice-President in writing, indicating the outcome at the final stage of the process, as particularized more fully below.

5.4 Recurring Complaints

If a Complaint has already undergone an inquiry or an investigation and the matter has been closed, the Vice-President will not pursue the same allegation unless new and compelling information that could not reasonably have been available at the time of the original Complaint is brought forward. In cases of recurring Complaints based on the same allegations that are not made in good faith, the appropriate academic official may apply sanctions.
6.0 PROCESSING OF COMPLAINTS

6.1 General

The processing of Complaints of Research Misconduct must be carried out carefully, thoroughly and as promptly as possible, to resolve all questions regarding the integrity of the research and those individuals that may be involved in an allegation. The following general principles apply:

- The reputation of the University and its investigators and students, and their responsibility for the ethical conduct of research, require that any research misconduct that occurs be promptly detected and dealt with effectively.
- To this end, Complaints of Research Misconduct shall be taken seriously and vigorous leadership shall be exercised in their inquiry and resolution.
- All persons involved, those making allegations, those who are the subject of the allegations of misconduct, and those who assist in the inquiry, shall be treated with respect, fairness and with due sensitivity.
- All proceedings shall be conducted in a timely manner and shall be documented appropriately.
- The highest possible degree of confidentiality shall be maintained regarding all allegations, inquiries and investigations, subject to any disclosure that might be required by law.

7.0 INQUIRY

7.1 Introduction

All formal Complaints of Research Misconduct shall promptly be referred to the Vice-President who shall provide the Respondent with a copy in accordance with paragraph 7.3(c).

Upon receipt and review of a Complaint, the Vice-President will refer the allegation to the respective Dean who shall assign the Complaint to an appropriate Administrator to initiate an inquiry in accordance with section 7.3. For clarity, where the Complainant and Respondent are from different faculties, the Dean of the Respondent's Faculty will receive the referral. Where the Respondent is acting in his/her capacity as a member of a graduate department, the referral shall be the Dean of the School of Graduate Studies who shall inform the relevant Faculty Dean to ensure that the Faculty Dean is aware of the investigation.

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

- is the Complaint outside the jurisdiction of the Framework?
- is it clearly mistaken or unjustified?
- does it involve allegations that, even if proven, would not constitute Research Misconduct?
- is it frivolous, vexatious or in bad faith?
- and, if not any of the foregoing, is there a reasonable prospect that a further investigation will enhance the integrity of the scientific process?
The inquiry also provides an opportunity to determine whether it is appropriate to offer the Complainant and the Respondent an alternative dispute resolution process. It is not the purpose of the inquiry to determine whether or not Research Misconduct has occurred. Instead, factual information is gathered and expeditiously reviewed by the Administrator to determine whether the threshold for proceeding further is met, and whether an investigation of the Complaint is warranted.

The Administrator shall be vigilant not to permit personal conflicts between colleagues to obscure the facts and divert attention from the substance of the allegation. The Administrator shall disclose any actual, apparent, perceived or potential conflicts of interest to the Dean (or in the case of the Dean, to the Vice-President). The Dean (or Vice-President) may decide, based on this disclosure, to appoint a designate.

The inquiry is to be conducted as a confidential process to avoid unwarranted publicity regarding allegations that have yet to be fully assessed. The Administrator shall take reasonable efforts to protect the privacy of the Complainant and the Respondent both of whom shall be advised of the need to maintain confidentiality.

7.2 Timing

Ordinarily, inquiries shall begin within 20 working days of the Dean’s receipt of a Complaint from the office of the Vice-President and the report of the findings shall be delivered no more than 60 days from receipt by the Vice-President’s office. There may be circumstances when it is not reasonably possible to comply with these timelines. Nevertheless, the Administrator shall work expeditiously in these exceptional cases.

7.3 Process

a) After receiving the Complaint, the Administrator shall determine whether the Complaint concerns individuals who and matters that fall within the terms of applicability, as outlined in section 2.0. If it does not, the Administrator shall so advise the Complainant.

b) All Complaints that do not concern Chairs, Associate or Vice-Deans, or the Dean, and which involve individuals falling within this Framework shall be referred directly to the Chair (Dean for single-department faculties). Complaints about Chairs, Associate or Vice-Deans are referred directly to the Dean.

c) The Respondent should normally be provided with a copy of the Complaint within 7 working days of its receipt by the Vice-President.

d) If the Complaint involves graduate students and/or relate to graduate faculty members acting in that capacity, the Complaint shall be communicated by the Vice-President to the Dean of School of Graduate Studies (SGS).

e) Complainants will be sent a standard letter outlining the process and highlighting the Complainant’s obligations.

f) If the Complaint, as written, does not contain sufficient information or particulars to permit an assessment, the Administrator may request that supplementary
information be provided, in writing. Such supplementary information shall also be shared with the Respondent.

g) If the Complaint is not dismissed on jurisdictional grounds, or on other grounds listed as threshold issues in section 7.1, the Administrator will contact the Respondent for the purposes of discussing the Complaint.

h) In conducting the inquiry, the Administrator may consult confidentially within the University and externally if appropriate, to assist in the assessment of whether an investigation is warranted.

i) If the Administrator determines not to proceed with an investigation, then he/she shall provide written notice of his or her decision to the Complainant and the Respondent with a copy to the Vice-President for information. The Administrator’s notice shall include a brief written summary of the reasons for such a determination. This decision cannot be appealed.

j) The Administrator may, upon consent of both the Complainant and the Respondent, conduct (either personally or through an appointed representative) non-binding, without prejudice, confidential mediation. If such mediation produces a resolution, the outcome shall be communicated to the Vice-President.

k) Where the Administrator decides to recommend that a formal investigation be commenced, he/she shall provide written notice of his/her decision to the Respondent and the Complainant. The Administrator shall write a letter to the Dean outlining the general nature of the Complaint, and attaching all material submitted both by the Complainant and the Respondent. A copy of this letter and the accompanying material shall also be sent to the Vice-President for information and for an assessment of whether reporting is required at this stage under section 8.3.

l) If the Administrator has reasonable grounds to believe that the Complainant did not act in good faith, he/she will write the Complainant and the Respondent to summarize these grounds and inform them that the matter is being referred to the Dean or other appropriate academic official to be assessed in accordance with the relevant policy. A copy of this letter shall be sent to the Vice-President for information.

8.0 INVESTIGATION

8.1 General

The investigation is a formal process to examine the allegations and to weigh the evidence to determine whether or not Research Misconduct has occurred, and, if so, who the involved parties are. The Dean is responsible for arranging for the investigation of all allegations of Research Misconduct for those falling within the jurisdiction of these guidelines. The Dean may delegate any of his/her administrative responsibilities to an investigator. If the investigation concerns the Dean, the Vice-President or his/her designate shall be responsible for conducting the investigation.
8.2 Timelines

Complaints of Research Misconduct vary greatly with their respect to urgency, seriousness and complexity. The Dean will exercise his/her discretion in determining the appropriate timelines for commencing, conducting and reporting on investigations.

The following timelines will apply in the ordinary course, subject to the discretion of the Dean. The Dean will appoint the Investigation Committee within 15 working days of receiving the Administrator's decision that an Investigation should be conducted. The Committee shall convene within 30 working days of its appointment or as soon thereafter as is reasonably possible.

The investigation will ordinarily be completed within 60 working days of the first meeting of the Investigating Committee. The final report of the Investigating Committee shall be delivered within 30 working days after the completion of the investigation. If these deadlines cannot reasonably be met, the Committee will submit to the Dean a procedural report citing the reasons for the delay and progress to date. The report will be distributed to both Complainant and Respondent. The Dean, at his/her discretion, may share this report with other appropriate individuals.

8.3 Reporting of the Commencement of the Investigation

The Dean shall inform the Vice-President and the Dean of the School of Graduate Studies (if appropriate) that an investigation of a Complaint of Research Misconduct has been initiated.

With the concurrence of the Vice-President, others may be informed, if appropriate in the circumstances. Such others could include, for example, representatives of an affiliated institution, granting agency, or professional or regulatory body.

8.4 Investigating Committee

The Dean will appoint a committee of two or more members to perform the investigation in accordance with these guidelines. The Committee shall appoint one of its members to act as a Chair, for administrative purposes.

The members of the Investigating Committee will be senior members of the University or another academic institution. The members of the Investigating Committee will have no actual, apparent, reasonably perceived or potential conflict of interest or bias, and will jointly have appropriate scientific and administrative background to evaluate the Complaint and the response to it. If either the Complainant or Respondent alleges that a committee member is biased, and the Dean believes that actual, apparent, perceived or potential conflict of interest or bias has been clearly and reasonably demonstrated, the Dean shall alter the membership accordingly.

The Dean shall provide suitable administrative support to the Committee. The Dean may authorize the delegation of components of the investigation to an investigator who shall report to the Committee. The Committee may consult with others as necessary in order to make its assessment.
8.5 Instructions to the Investigating Committee

The Dean shall review with the Chair of the Committee the following guidelines and Investigating procedures.

The Chair shall ensure that members of the Committee are informed of:

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

8.6 Authority and Responsibilities of the Investigating Committee

The Investigating Committee operates under the Dean and the Chair of the Committee is responsible to the Dean.

The Investigating Committee shall conduct a thorough investigation of the Complaint. The Investigating Committee has the discretion to interview persons whose evidence could be helpful, to examine relevant documents and data records, and to consult with experts both within and outside the University, as appropriate.

If during the course of the investigation, the Respondent for any reason ceases to hold a position (e.g. faculty member, staff or student, post-doctoral fellow) at the University or leaves the jurisdiction, the Dean will decide in his/her own discretion whether or not the investigation will continue. If, where the investigation continues, the Respondent refuses to participate in the process after ceasing to hold their position at the University, the Investigating Committee shall use its best efforts to reach a conclusion and shall deliver its report with a statement as to the effect this lack of cooperation had on the Committee’s review of the evidence.

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

The Chair has the authority to report uncooperative behaviour to the Dean.

The Chair shall notify the Dean of interim findings, if any, that he/she believes ought to be reported because of the University’s obligations to students, staff and faculty members or, where there are compelling issues of public safety, to the public. Any interim report shall be in
writing and copied to all members of the Committee, to the Complainant and Respondent, and to the Vice-President. The report shall set out the findings, the reason for the interim report and a recommendation regarding appropriate administrative action.

8.7 Process for Investigating Complaints of Research Misconduct

a) The Chair shall send a letter to the Respondent and the Complainant advising them of the appointment of the Committee, outlining the process and highlighting their respective obligations.

b) In all cases the Committee must give the opportunity to the Complainant to provide any supplementary written materials in addition to the Complaint that the Complainant wishes to provide; all such materials shall be provided to the Respondent who shall have the opportunity to comment, in writing, and provide any supplementary written response materials. The Respondent's written response, if any, shall be shared with the Complainant. The Committee is not to conduct a hearing and is only obliged to conduct a fair and objective investigation. It may in its discretion, request an interview with any or all of the Complainant, the Respondent, or other relevant people. Summaries of interviews (including the points or issues raised but not verbatim text) shall be prepared, provided to the interviewed party for comment or revision, and included as part of the investigation file.

c) If a Complainant decides not to participate further, the Investigating Committee may decide to proceed with the investigation in any event.

d) All involved parties who are associated with the University will be expected to cooperate with the investigation in a timely manner. This includes providing documentation and information and appearing before the Investigating Committee if requested.

e) The Committee will set a deadline by which all responses must be made and all evidence must be submitted. No response or evidence will be accepted after the deadline except in exceptional circumstances where no prejudice to the other party would result, and with the permission of the Committee Chair.

f) The Investigating Committee will take reasonable steps to provide to the Respondent reasonable access to relevant documents in their possession so as to provide him/her with a fair opportunity to respond to relevant material. The Investigating Committee may provide access to particular documents to the Complainant in special cases where it is believes that a response from the Complainant is required to help in determining the facts of the case. The Respondent and if applicable, the Complainant, shall sign a confidentiality agreement before materials are provided.

g) To protect confidentiality, the Chair of the Investigating Committee will assume the responsibility of restricting the dissemination of the information to only those who should receive it.
8.8 Decisions and Reports of the Investigating Committee

a) The Committee will prepare a report that sets out its findings of fact and its decision as to whether or not there is Research Misconduct. The report may also state whether a serious scientific error has been made which does not constitute Research Misconduct.

The report will contain:

- The full Complaint;
- A list of Committee members and their credentials;
- A list of the people who contributed evidentiary material to the investigation or were interviewed as witnesses;
- A summary of relevant evidence;
- A determination of whether Research Misconduct occurred;
- If Research Misconduct has occurred, its extent and seriousness; and
- Recommendations on any remedial action to be taken in the matter in question and/or recommendations of changes to procedures or practices to avoid similar situations in the future.

Recommendations of the Investigating Committee may include, without limitation:

- Withdrawing all pending relevant publications;
- Notifying publications in which the involved research was reported;
- Ensuring the unit(s) involved is informed of appropriate practices for promoting the proper conduct of research;
- Recommending any actions to be taken; and
- Informing any outside funding sponsor(s) of the results of the inquiry and of actions to be taken;

b) All members of the Investigating Committee shall sign a statement indicating that they agree to the release of the report based on majority rule. No minority reports shall be allowed.

c) The report will be delivered to the Complainant, the Respondent, the Dean and the Vice-President. If there is more than one Respondent or Complainant, reasonable efforts will be made to provide each with parts of the report that are pertinent to him/her.

d) The report of the Committee is final and not subject to revision. However, the Respondent and Complainant will have not less than 5 working days to make submissions to the Dean regarding the findings, in advance of any administrative action recommended to be taken by the Dean.

e) After the Committee delivers its report, the Chair shall notify all members of the Investigating Committee to return all documentation to the Office of the Dean.
Copies of the decision, report and all relevant materials will be sent to the Vice-President for reporting and documentation purposes.

f) If the subject individual is funded directly or indirectly by one of the Tri-Council Agencies (CIHR, NSERC or SSHRC), a full copy of the report will be sent to the Agency within 30 days of its issuance, regardless of whether or not Research Misconduct is found to have occurred.

g) To protect agency funding, the Vice-President may authorize the withholding of research funds until the Complaint is resolved, if deemed necessary.

8.9 Report of the Dean

The Dean shall inform the Vice-President and the Dean of the School of Graduate Studies, if applicable, of the findings and conclusions of the investigation and the decision he/she has made about the appropriate administrative action.

If the Dean receives an interim report from the Chair of the Investigating Committee, the Dean will determine, based on the nature of the case and in accordance with other relevant University policies, if restrictions of activity or suspension of the subject individual pending the results of the investigation are warranted. Moreover, the Dean shall determine, with the concurrence of the Vice-President, if a report of interim findings shall be disclosed to protect the public or to protect the best interests of students, staff and faculty. The Dean shall take into account the guidelines or contract terms of the research sponsor as well as relevant policies of the University.

9.0 ADMINISTRATIVE ACTION AND REPORTING REQUIREMENTS

9.1 Cases where no Research Misconduct has been found

When an investigation determines that no Research Misconduct occurred, the Dean shall ensure that a letter confirming the finding of no misconduct is sent to the Respondent, with a copy to the Complainant and, in the Dean’s discretion to other persons with knowledge of the Complaint. These persons may include co-authors, co-investigators, collaborators and others who may have been notified by the Dean under the authority of section 8.3.

In some circumstances, the investigation may disclose evidence of serious scientific error that requires further action, even when no Research Misconduct is found. The action may be, for example, a recommendation of retraction of published findings. In these cases, the Dean will consult with the Chair of the Investigating Committee and the Respondent, and will consider the Respondent’s submissions, if any, and will decide what action, if any, to take.

No disciplinary measures shall be taken against the Complainant if the Complaint is found to have been made in good faith; moreover, efforts will be made to ensure that no retaliatory action is taken against the Complainant in such cases. The proceedings of the investigation will be held in the strictest confidence in accordance with this Framework. However, if the Complaint is found to have been made in bad faith, the Dean may apply or recommend the application of sanctions as set out in section 9.2. Similar appropriate sanctions as set out in section 9.2 may be taken against individuals who engage in acts of retaliation or intimidation against Complainants and/or Respondents who have been acting in good faith.
9.2 Cases where Research Misconduct has been found

The nature and severity of remedial action taken for research misconduct will be consistent with the established policy of the University and proportional to the misconduct.

When the Investigating Committee delivers a report which concludes that there is evidence of research misconduct, the Dean will consider what remedial action should be taken. Since there may be other procedural requirements under University policies before remedial action can be taken, the Dean will consult with the Vice President and Provost before taking further action.

For Research Misconduct involving students or faculty members, remedial action may include the institution of proceedings leading to sanctions up to and including suspension or termination under the Code of Behaviour on Academic Matters or the Policy and Procedures on Academic Appointments. For Research Misconduct involving a graduate student with respect to the student’s graduate studies, the responsibility for enforcing remedial action resides with the Dean of the School of Graduate Studies, and is determined in accordance with the Code of Behaviour on Academic Matters.

If the Respondent is a student or faculty member and has admitted to committing research misconduct, the Dean may proceed to impose sanctions under the Code of Behaviour on Academic Matters.

As a general rule, the decision about remedial action will be rendered within not more than 15 working days from the date that the Dean receives any submissions from the Respondent concerning penalty. If there are no further procedural requirements under University policies, the Dean may impose sanctions which could include:

- Verbal warning
- Special monitoring of future work
- Verbal warning with a letter to be held temporarily on file in the Department Head’s or Dean’s office
- Letter of reprimand to the individual’s permanent personnel file
- Withdrawal of specific privileges
- Removal of specific responsibilities
- Suspension
- Steps to terminate

Any remedial action, including the foregoing and the steps that may be necessary to implement the foregoing, is subject to any applicable policies, including, for example, the Policy and Procedures on Academic Appointments, and the Code of Behaviour on Academic Matters. Regard shall be had under such policies, subject to their terms, for findings made under this Framework.

The Vice-President at his/her discretion may communicate the outcome of the investigation, directly, or through senior University administration, to other parties within or external to the University, including but not limited to:
• Co-authors, co-investigators, collaborators
• Editors of journals in which fraudulent research or erroneous findings were published
• Professional licensing boards
• Editors of journals or other publications, other institutions, sponsoring agencies and funding sources with which the individual has been affiliated in the past
• Professional societies
• Police services.

10.0 REVIEWS

Depending on the relationship between the University and the individual Respondent and depending on the nature of the remedial action, the Respondent may have rights of review, grievance or appeal under other applicable University policies such as the Code of Behaviour on Academic Matters, the Policy and Procedures on Academic Appointments, or may have a right to grieve the remedial action taken under a collective bargaining agreement.

Where any Respondent has no access to another process for a review of the decision with respect to remedy, that Respondent may seek a review of the appropriateness of the remedial action from the Vice-President. This review must be sought in writing within 5 working days of the issuance of the written notice of remedial action. The Dean will not institute irreversible remedial actions (such as public notifications) until 5 working days have elapsed from the issuance of a notice of decision and confirmation that the subject individual has received the notice. The decision confirmed at the Vice-Presidential level shall be considered final and binding.

11.0 RECORD KEEPING

The report of the Investigating Committee will be maintained in a confidential and secure manner, with limited access, in the Office of the Vice-President, Research and Associate Provost.

The Office of the Vice-President, Research and Associate Provost will periodically prepare and publish summaries of decisions (with personal identifiers removed) for the purpose of educating University members on acceptable practices for scholarly integrity and research ethics.

12.0 PROMOTION OF RESEARCH INTEGRITY

To promote an understanding of research integrity issues, the University will use appropriate vehicles such as, but not limited to workshops, seminars, written materials and orientation for new employees.
FYI

From: Catharine Whiteside [mailto:Catharine.Whiteside@utoronto.ca]
Sent: Friday, August 17, 2012 12:27 PM
To: Catherine Zahn
Cc: Bruce Pollock; Meg Connell
Subject: URGENT - strictly confidential

Dear Catherine,

I have sent to your office by courier today the documents attached. I know you are traveling, but if we could speak by phone in the next few days once you have reviewed these documents, I would appreciate a discussion with you by phone to discuss and agree on the jurisdiction. Note that the Complainant, Professor Bonnie Burstow (OISE/UT) has copied her complaint to the Secretariat of the Tri-Agency Framework - Panel on Responsible Conduct of Research (Government of Canada). Since the allegation involves the CAMH REB, your direct involvement is both important and necessary.

The Office of Research at the University of Toronto assists me in following our Policy on Research Misconduct. I am guided by the Associate Vice Provost Policy and Strategy, Professor Lori Ferris who works directly with the Office of Research and Vice President Research, Paul Young. She will be keeping track of all of the steps required under the policy including the written documentation and correspondence.

Pleased to discuss these and other issues as they arise.

Regards,
Cathy

> Catharine Whiteside, MD PhD
> Dean of Medicine
> Vice Provost Relations with Health Care Institutions
> University of Toronto
> 1 King's College Circle, rm 2109
> Medical Sciences Bldg
> Toronto, ON, Canada, M5S 1A8
> Phone: 416-946-7810, Assistant - Amy Lee
> Fax: 416-978-1774
> email: catharine.whiteside@utoronto.ca
> >
> > This email may contain confidential and/or privileged information for the
> > sole use of the intended recipient. Any review or distribution by others is
> > strictly prohibited unless explicitly specified in the text above. If you
> > have received this email in error, please contact the sender and delete all
This email has been scanned by the CAMH Email Security System.
From: Bonnie Burstow [mailto:binnie.burstow@utoronto.ca]  
Sent: Monday, August 20, 2012 11:38 AM  
To: Bruce Pollock; Vice-President, Research (Professor R. Paul Young)  
Cc: Z-SRCR  
Subject: Re: Requesting you to intervene  

Thank you for the acknowledgment.

From: Bruce Pollock <Bruce.Pollock@camh.ca>  
Date: Mon, 20 Aug 2012 11:09:04 -0400  
To: Bonnie Burstow <bonnie.burstow@utoronto.ca>, "Vice-President, Research (Professor R. Paul Young)"  
<VP.Research@utoronto.ca>  
Cc: Z-SRCR <secretariat@rcr.ontology.gc.ca>  
Subject: RE: Requesting you to intervene  

Dear Professor Burstow, thank you for bringing your concerns regarding CAMH’s Clinical Research and REB to my attention. I have just returned from vacation this morning, but will discuss immediate next steps with the University as soon as possible. Sincerely, Bruce Pollock

From: Bonnie Burstow [mailto:binnie.burstow@utoronto.ca]  
Sent: Tuesday, August 14, 2012 2:56 PM  
To: Vice-President, Research (Professor R. Paul Young); Bruce Pollock  
Cc: Z-SRCR  
Subject: Re: Requesting you to intervene  
Importance: High  

I have a piece of research that I am asking be inquired into for I have extremely serious concerns with it. I sent a letter of objection to the Secretariat. As you will see below, the Secretariat asked that the objection be sent to the appropriate people at the two institutions involved, University of Toronto, and CAMH, and more specifically to the Vice President of Research, Dr. Paul Young, at Simcoe Hall and to the vice-president of research at CAMH—Dr. Bruce Pollock, hence my writing to you. Attached please find 4 pieces of information, a) the initial letter to Dr. Susan Zimmerman, at the secretariat. At the Secretariat’s suggestion, I have not changed the letter to insert your name and institution, but nonetheless now ask that you and your institution be considered as the people to whom I am sending this objection; b) the letter of consent attached to the project; c) the brochure on the study; and d) one of the advertisements for the project. As this is matter of some urgency and seriousness, I ask you to read my letter and the accompanying material and look into this issue as soon as you possibly can.

From: Z-SRCR <secretariat@rcr.ontology.gc.ca>  
Date: Tue, 14 Aug 2012 13:59:51 -0400  
To: Bonnie Burstow <bonnie.burstow@utoronto.ca>  
Cc: Z-SRCR <secretariat@rcr.ontology.gc.ca>  
Subject: FW: Requesting you to intervene  

Good afternoon Dr. Burstow,
This email is to follow up from our telephone conversation this morning.

Thank you for your email dated August 14, 2012 to the Secretariat on Responsible Conduct of Research, concerning a research project called "Inflammation and Electroconvulsive Therapy." The Secretariat on Responsible Conduct of Research is responsible for matters related to research misconduct on behalf of Canada’s research granting Agencies (the Natural Sciences and Engineering Research Council, the Canadian Institutes of Health Research and the Social Sciences and Humanities Council of Canada), under the terms of the new Tri-Agency Framework: Responsible Conduct of Research (http://www.rcr.ethics.gc.ca/eng/policy-politique/framework-cadre/).

Section 3.2 of the new Framework requires that all allegations be sent to the institution: “responsible allegations, or information related to responsible allegations, should be sent directly to the institution’s designated point of contact, in writing, with an exact copy sent to the [Secretariat]”. “Individuals are expected to report in good faith any information pertaining to possible breaches of Agency policies to the Institution where the researcher involved is currently employed, enrolled as a student or has a formal association.”

We would therefore ask that you send your allegation to the institution where the individuals who are the subject of your allegation are currently employed, with an exact copy to the Secretariat (I have copied the Secretariat email). Once received, the Secretariat will follow-up with the institution. It appears from the brochure you attached that the research involves two teams led by researchers from the University of Toronto. Typically, the contact person for such allegations is the Vice President of Research. The University of Toronto website shows the following contact information for the Vice President of Research:

Professor R. Paul Young, PhD, FRSC
Vice President, Research
The University of Toronto
Simcoe Hall, Room 109
27 King’s College Circle
Toronto, Ontario
M5S 1A1
vp.research@utoronto.ca

Phone: 416-978-4984
Fax: 416-971-2647

The website for the Centre for Addiction and Mental Health shows the following contact information for its Vice President of Research:

Vice-President of Research: Dr. Bruce G. Pollock
Research Services Office
33 Russell St., T100
Toronto, ON M5S 2S1

I hope this information is of assistance. If not, please do not hesitate to call me.

Sincerely,

Wendy Burgess

Policy Analyst | Analyste des politiques
Secretariat on Responsible Conduct of Research
From: Bonnie Burstow [mailto:bonnie.burstow@utoronto.ca]
Sent: August 14, 2012 8:58 AM
To: susan.zimmerman@rcr.ethics.gc; Z-SRCR; Zimmerman,Susan
Subject: Requesting you to intervene
Importance: High

I am a faculty member at University of Toronto who is deeply concerned about and am asking you to look into a research project called "Inflammation and Electroconvulsive Therapy". Attached please find: a) my letter which outlines in detail the nature of the various ethical problems inherent in this project ("letter to Zimmerman"); and b) the letter of consent attached to the project; c) the brochure on the study; and d) one of the advertisements for the project. As this is matter of some urgency and seriousness, I ask you to read my letter and the accompanying material and look into this issue as soon as you possibly can.

I thank you.
From: Bonnie Burstow  
Sent: Monday, August 20, 2012 3:41 PM  
To: Judith Chadwick; Catharine Whiteside; secretariat@rcr.ethics.gc.ca  
Subject: The ethics complaint

I am aware at this point, I need an answer to a question so that there is no misunderstanding. Judith Chadwick has addressed all email to me on this matter as "confidential", although no one else has. From this I understand that her emails are confidential. Is that correct or not correct? No one else has labeled any emails to me as confidential. I need to understand what is and what is not confidential here. I take it for example that my letter of April 14, which I addressed to the Secretariat and then sent to both U. of T. and CAMH is not considered confidential by anyone. Is that correct? Is anything that I write to you on this matter confidential? Please clarify.

I ask this because among other things the many very upset people that drew my attention to the Craigslist advertisement for this research have been asking for further information.

From: Judith Chadwick <j.chadwick@utoronto.ca>  
Date: Mon, 20 Aug 2012 11:21:26 -0400  
To: Bonnie Burstow <bonnie.burstow@utoronto.ca>  
Cc: Catharine Whiteside <Catharine.Whiteside@utoronto.ca>, "secretariat@rcr.ethics.gc.ca" <secretariat@rcr.ethics.gc.ca>  
Subject: RE: Confidential - Allegation of Research Misconduct

Dear Professor Burstow,

Thank you for your reply. We understand that your concerns regarding this research project relate to both its methodology and the circumstances under which it was, presumably, approved by a research ethics board. The Framework and its Addendum provide an appropriate procedure for addressing those concerns which has been agreed to by the University and its affiliated teaching hospitals. I understand that Dean Whiteside has contacted the President and CEO of CAMH directly regarding this matter and will be working expeditiously with her to determine next steps. Independently, CAMH administration can also assess whether matters of patient welfare warrant any immediate intervention on the hospital’s part. Our office will continue to monitor developments closely.

Thank you again for raising this issue.

Yours,
Judith

Judith L. Chadwick  
Assistant Vice-President, Research Services  
3rd Floor, McMurrich Building  
12 Queen's Park Crescent West  
University of Toronto  
Toronto, Ontario M5S 1A8  
T: 416-978-5129  
www.research.utoronto.ca
Cc: Catharine Whiteside; secretariat@rcr.ethics.gc.ca
Subject: Re: Confidential - Allegation of Research Misconduct

I am grateful for your response, and I thank you for clarifying the process. I have now had some time to look at the documents. I do have concerns with the process for I am claiming something that is both way less serious and way more serious than what is normally thought of as professional misconduct. As I stated in the letter, I am not claiming that the researchers broke with protocol (though they may indeed have done so and this would be legitimate to look into) or that they did not go through the normal channels, or even that they promulgated what they knew to be misrepresentation, though I am clear that misrepresentation has occurred. What I am claiming is that this duly authorized piece of research fails to meet many of the Tri-Council standards by which we judge whether or not research is ethical (e.g., such principles not only as accuracy but fundamental justice, good harm/benefits ratio, not providing inducement that might lead participants to agree to what they might not normally agree to). Much of this lay outside what is normally construed as "professional conduct" (hence my not framing it this way) but nonetheless is a reason why the research should be stopped—the ultimate purpose of this complaint. In this respect, I find the review board that authorized the study (if indeed they authorized what has transpired) as much at fault as the investigators themselves. The point is, much of what makes this research unethical may well not be covered by how this complaint is being theorized or framed. What I am alleging here is a type of incompetence with respect to deep ethical issues, not so much personal wrong-doing, which appears to be how this is being framed.

The issue of jurisdiction could also be a problem. I of course agree that you have to determine the appropriate jurisdiction. The standards that you using to make this determination, however, could easily end up with CAMH being that jurisdiction for among other things, that is where the research is lodged. Nonetheless, CAMH, I would argue, is in a conflict of interest here, given that:

- CAMH makes some of the same misrepresentations to people being treated with ECT.
- The Board who authorized the research (is the Ethical Review Board attached to CAMH
- The V.P of research at CAMH is on a research committee with the principle investigator of this piece of research.

As such, a conflict of interest appears to exist.

A further problem that I would like to identify at this time is that time is of the essence. The point is that if the research is not suspended pending an investigation, this could have a very negative effect on the lives of the already highly vulnerable participants in question, despite whether or not the allegation were eventually found to be with merit. This being the case, I am asking you to consider whether or not there is any way to put the research on hold, pending a decision about these allegations.

Again, I thank you.

Date: Thu, 16 Aug 2012 12:30:41 -0400
To: Bonnie Burstow <bonnie_burstow@utoronto.ca>
Cc: Catharine Whiteside <Catharine.Whiteside@utoronto.ca>, "secretariat@rcr.ethics.gc.ca"
<secretariat@rcr.ethics.gc.ca>
Subject: Confidential - Allegation of Research Misconduct

Dear Professor Burstow,

Thank you for your recent communication to the Vice-President, Research and Innovation. Please see the attached response.

Yours,
Judith

Judith L. Chadwick,
Assistant Vice-President, Research Services
3rd Floor, McMurrich Building
Hope that clarifies.
Yours,
Judith

Judith L. Chadwick
Assistant Vice-President, Research Services
3rd Floor, McMurrich Building
12 Queen's Park Crescent West
University of Toronto
Toronto, Ontario M5S 1A8
T: 416-978-3129
www.research.utoronto.ca

From: Bonnie Burstow
Sent: Monday, August 20, 2012 3:41 PM
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From: Judith Chadwick <j.chadwick@utoronto.ca>
Date: Mon, 20 Aug 2012 11:21:26 -0400
To: Bonnie Burstow <bonnie.burstow@utoronto.ca>
Cc: Catharine Whiteside <Catharine.Whiteside@utoronto.ca>, "secretariat@rcr.ethics.gc.ca"
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Thank you again for raising this issue.

Yours,
Judith

Judith L. Chadwick
Assistant Vice-President, Research Services
3rd Floor, McMurrich Building
12 Queen's Park Crescent West
From: Bonnie Burstow  
Sent: Thursday, August 16, 2012 5:26 PM  
To: Judith Chadwick  
Cc: Catharine Whiteside; secretariat@rcr.ethics.gc.ca  
Subject: Re: Confidential - Allegation of Research Misconduct

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- The V.P of research at CAMH is on a research committee with the principle investigator of this piece of research.

As such, a conflict of interest appears to exist.

A further problem that I would like to identify at this time is that time is of the essence. The point is that if the research is not suspended pending an investigation, this could have a very negative effect on the lives of the already highly vulnerable participants in question, despite whether or not the allegation were eventually found to be with merit. This being the case, I am asking you to consider whether or not there is any way to put the research on hold, pending a decision about these allegations.

Again, I thank you.

Date: Thu, 16 Aug 2012 12:30:41 -0400  
To: Bonnie Burstow <bonnie.burstow@utoronto.ca>  
Cc: Catharine Whiteside <Catharine.Whiteside@utoronto.ca>, "secretariat@rcr.ethics.gc.ca" <secretariat@rcr.ethics.gc.ca>  
Subject: Confidential - Allegation of Research Misconduct

Dear Professor Burstow,
Thank you for your recent communication to the Vice-President, Research and Innovation. Please see the attached response.

Yours,
Judith

Judith L. Chadwick
Assistant Vice-President, Research Services
3rd Floor, McMurrich Building
12 Queen's Park Crescent West
University of Toronto
Toronto, Ontario  M5S 1A8
T: 416-978-5129
www.research.utoronto.ca

This email has been scanned by the CAMH Email Security System.
Kristin Taylor

From: Anna Chow
Sent: Friday, August 24, 2012 2:50 PM
To: bonnie.burstow@utoronto.ca
Cc: judith.chadwick@utoronto.ca; Bruce Pollock; susan.zimmerman@pre.ethics.gc.ca
Subject: Letter from Dr. Catherine Zahn
Attachments: Bonnie Burstow 8-12.pdf

Dear Dr. Burstow:

Attached please find a letter from Dr. Zahn. The original will be mailed to you.

Thanks.
Anna

Anna Chow
Manager, Executive Office
Office of the President and CEO
Centre for Addiction and Mental Health
1001 Queen Street West
Bell Gateway Building, 100 Stokes Street, Room 6121 Toronto, Ontario M6J 1H4
Phone: 416-595-6076
Fax: 416-583-1288
Email: anna.chow@camh.ca
August 24, 2012

Dr. Bonnie Burstow
Department of Leadership, Higher, and Adult Education
Ontario Institute for Studies in Education
252 Bloor Street West
Toronto, Ontario
M5S 1V6

Dear Dr. Burstow:

I have received a copy of your letter dated August 14, 2012 directed to Dr. Susan Zimmerman of the Secretariat on Responsibility in Research at University of Toronto. I was made aware of your concerns by both Dr. Bruce Pollock, CAMH Vice-President, Research and Dean Catherine Whiteside, Dean of Medicine, University of Toronto. Given the seriousness of the allegations and the involvement of CAMH’s Research Ethics Board, I, as CAMH’s CEO, have assumed responsibility for reviewing and responding to your concerns.

CAMH is taking immediate steps to investigate the allegations stated in your letter of August 14, 2012. While the process is not yet formalized, I can advise that we intend to have a panel of external experts review the matters you raise and apprise me of its findings. We are moving forward expeditiously and will be in contact with you once the panel’s work is complete.

You have raised concerns about patient safety with respect to participants in CAMH’s research study - inflammation and electroconvulsive therapy. Patient safety is of utmost importance to me and I assure you that I will take the steps required to preserve patient safety.

I trust that you will allow our process reasonable time to properly review the matter such that we can respond to your concerns in a fulsome way.

Sincerely,

Catherine Zahn, MD, FRCP(C)
President and CEO

cc: Ms. Judith Chadwick, Assistant Vice-President, Research Services, University of Toronto
Dr. Bruce Pollock, Vice President, Research, CAMH
Dr. Susan Zimmerman, Executive Director, Secretariat on Responsible Conduct of Research
August 24, 2012

Dr. Bonnie Burstow
Department of Leadership, Higher, and Adult Education
Ontario Institute for Studies in Education
252 Bloor Street West
Toronto, Ontario
M5S 1V6

Dear Dr. Burstow:

I have received a copy of your letter dated August 14, 2012 directed to Dr. Susan Zimmerman of the Secretariat on Responsibility in Research at University of Toronto. I was made aware of your concerns by both Dr. Bruce Pollock, CAMH Vice-President, Research and Dean Catherine Whiteside, Dean of Medicine, University of Toronto. Given the seriousness of the allegations and the involvement of CAMH’s Research Ethics Board, I, as CAMH’s CEO, have assumed responsibility for reviewing and responding to your concerns.

CAMH is taking immediate steps to investigate the allegations stated in your letter of August 14, 2012. While the process is not yet formalized, I can advise that we intend to have a panel of external experts review the matters you raise and apprise me of its findings. We are moving forward expeditiously and will be in contact with you once the panel’s work is complete.

You have raised concerns about patient safety with respect to participants in CAMH’s research study - inflammation and electroconvulsive therapy. Patient safety is of utmost importance to me and I assure you that I will take the steps required to preserve patient safety.

I trust that you will allow our process reasonable time to properly review the matter such that we can respond to your concerns in a fulsome way.

Sincerely,

Catherine Zahn, MD, FRCP(C)
President and CEO

cc: Ms. Judith Chadwick, Assistant Vice-President, Research Services, University of Toronto
Dr. Bruce Pollock, Vice President, Research, CAMH
Dr. Susan Zimmerman, Executive Director, Secretariat on Responsibility in Research
FYI

From: Bonnie Burstow [mailto:bonnie.burstow@utoronto.ca]
Sent: Friday, August 24, 2012 05:52 PM
To: Anna Chow
Cc: Bruce Pollock; susan.zimmerman@pre.ethics.gc.ca <susan.zimmerman@pre.ethics.gc.ca>; Judith Chadwick <j.chadwick@utoronto.ca>; Z-SRCR <secretariat@srcr.ethics.gc.ca>
Subject: Response to letter from Dr. Catherine Zahn

Ms Chow: Could you please ensure that Dr. Zahn receives the attached email. Much thanks.

From: Anna Chow <Anna.Chow@camh.ca>
Date: Fri, 24 Aug 2012 14:50:27 -0400
To: Bonnie Burstow <bonnie.burstow@utoronto.ca>
Cc: "Judith.chadwick@utoronto.ca" <Judith.chadwick@utoronto.ca>, Bruce Pollock <Bruce.Pollock@camh.ca>, "susan.zimmerman@pre.ethics.gc.ca" <susan.zimmerman@pre.ethics.gc.ca>
Subject: Letter from Dr. Catherine Zahn

Dear Dr. Burstow:

Attached please find a letter from Dr. Zahn. The original will be mailed to you.

Thanks.

Anna

Anna Chow
Manager, Executive Office
Office of the President and CEO
Centre for Addiction and Mental Health
1001 Queen Street West
Bell Gateway Building, 100 Stokes Street, Room 6121 Toronto, Ontario M6J 1H4
Phone: 416-595-6076
Fax: 416-583-1288
Email: anna.chow@camh.ca
Dr. Bonnie Burstow, Ph.D. Department of Leadership, Higher and Adult Education
August 24, 2012.

UNIVERSITY OF TORONTO
OISE | ONTARIO INSTITUTE
FOR STUDIES IN EDUCATION

Dr. Catherine Zahn, President and CEO, Centre for Addiction and Mental Health

Dear Dr. Zahn:

This is to acknowledge and thank you for your letter of August 24, 2012, also to thank you for keeping me posted. I am glad that you are convening external experts, for indeed both externality and expertise is critical here. May I take this opportunity to suggest that a critical expertise in question is expertise on what constitutes ethical research, for in the absence of that, the process would be wanting.

I would also like to take this opportunity to bring up one additional point. Your letter ended with the statement, “I trust that you will allow our process reasonable time to properly respond to your concerns in a fulsome manner.” I understand your concern here. I most surely appreciate that an inquiry takes time, and I have no problem with that. What I would have a very large problem with, however, is something that I stated in most all of my correspondence and am restating now. There would be a problem, indeed, I am suggesting a compounding ethical omission were the research simply to proceed as scheduled in the interim. What adds to problem, the longer the investigation takes whether for good reason or otherwise, the more serious the omission becomes. And so once again, I am asking that the research be put on hold pending the investigation. The point is that if the research proceeds and the participants are subjected to ECT in the interim, little will have been gained by a finding of unethically.

I accordingly invite you to consider this part of my request quickly. And I thank you once again for your detailed response.

Sincerely,

[Signature]

Dr. Bonnie Burstow
Kristin Taylor

From: Catharine Whiteside <Catharine.Whiteside@utoronto.ca>
Sent: Friday, August 24, 2012 3:50 PM
To: Anna Chow
Cc: Lori Ferris; Professor R. Paul Young; Bruce Pollock; Kristin Taylor
Subject: Re: Letter from Dr. Catherine Zahn

Thanks very much Catherine. Lori will continue to assist in keeping track of the process on our behalf.
Regards,
Cathy

> Catharine Whiteside, MD PhD
> Dean of Medicine
> Vice Provost Relations with Health Care Institutions
> University of Toronto
> 1 King's College Circle, rm 2109
> Medical Sciences Bldg
> Toronto, ON, Canada, M5S 1A8
> Phone: 416-946-7810, Assistant - Amy Lee
> Fax: 416-978-1774
> email: catharine.whiteside@utoronto.ca
> This email may contain confidential and/or privileged information for the
> sole use of the intended recipient. Any review or distribution by others is
> strictly prohibited unless explicitly specified in the text above. If you
> have received this email in error, please contact the sender and delete all

From: Anna Chow <Anna.Chow@camh.ca>
To: Catharine Whiteside <Catharine.Whiteside@utoronto.ca>
Cc: Lori Ferris <Lorraine.Ferris@utoronto.ca>, "Professor R. Paul Young" <Paul.Young@utoronto.ca>, Bruce Pollock <Bruce.Pollock@camh.ca>, Kristin Taylor <Kristin.Taylor@camh.ca>
Subject: Letter from Dr. Catherine Zahn

Dear Dr. Whiteside:

Attached please find a letter from Dr. Zahn. The original will be mailed to you.

Thanks.
Anna

Anna Chow
Manager, Executive Office
Office of the President and CEO
Centre for Addiction and Mental Health
1001 Queen Street West
Bell Gateway Building, 100 Stokes Street, Room 6121 Toronto, Ontario M6J 1H4
Phone: 416-595-6076
Fax: 416-583-1288
Email: anna.chow@camh.ca
From: Bonnie Burstow [mailto:bonnie.burstow@utoronto.ca]
Sent: Thursday, August 30, 2012 1:28 PM
To: Anna Chow
Cc: Bruce Pollock; susan.zimmerman@pre.ethics.gc.ca; Judith Chadwick; Z-SRCR
Subject: Re: Response to letter from Dr. Catherine Zahn

Thanks very much, Anna. Could you see to it that the letter attached to this email is delivered to Dr. Zahn. Thank you again.

From: Anna Chow <Anna.Chow@camh.ca>
Date: Thu, 30 Aug 2012 12:25:26 -0400
To: Bonnie Burstow <bonnie.burstow@utoronto.ca>
Cc: Bruce Pollock <Bruce.Pollock@camh.ca>, "susan.zimmerman@pre.ethics.gc.ca"
<susan.zimmerman@pre.ethics.gc.ca>, Judith Chadwick <j.chadwick@utoronto.ca>, Z-SRCR
<secretariat@rcr.ethics.gc.ca>
Subject: RE: Response to letter from Dr. Catherine Zahn

Dear Dr. Burstow:

Attached please find a letter from Dr. Zahn. The original will be mailed to you.

Thanks.
Anna

Anna Chow
Manager, Executive Office
Office of the President and CEO
Centre for Addiction and Mental Health
1001 Queen Street West
Bell Gateway Building, 100 Stokes Street, Room 6121 Toronto, Ontario M6J 1H4
Phone: 416-595-6076
Fax: 416-583-1288
Email: anna.chow@camh.ca

From: Bonnie Burstow [mailto:bonnie.burstow@utoronto.ca]
Sent: Friday, August 24, 2012 5:52 PM
To: Anna Chow
Cc: Bruce Pollock; susan.zimmerman@pre.ethics.gc.ca; Judith Chadwick; Z-SRCR
Subject: Response to letter from Dr. Catherine Zahn
Importance: High
Ms Chow: Could you please ensure that Dr. Zahn receives the attached email. Much thanks.
August 30, 2012

Dr. R. Paul Young PhD, FRSC
Vice President, Research
The University of Toronto
Simcoe Hall, Room 109
27 King’s College Circle
Toronto, Ontario M5S 1A1

Dr. Catherine Zahn
President and CEO
Centre for Addiction and Mental Health
100 Stokes Street
Toronto, Ontario
M6J 1H4

RE: SRCR File # 902-2-2012-06

Dear Dr. Young and Dr. Zahn,

The Secretariat on Responsible Conduct of Research (the Secretariat) is responsible for matters related to allegations of breaches of Tri-Agency policies on behalf of Canada’s research granting Agencies (the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC) and the Social Sciences and Humanities Research Council of Canada (SSHRC)). On August 14, 2012, the Secretariat was copied on a letter addressed to your institution from Dr. Burstow of the University of Toronto. The letter expresses concerns about research involving electroconvulsive therapy (ECT) conducted at the Center for Addiction and Mental Health (CAMH) by Dr. Jeffrey Meyer and Dr. Z.J. Daskalakis, both of the University of Toronto. Dr. Burstow alleges that this research is not in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2).

Based on a letter from the University of Toronto to Dr. Burstow dated August 16, 2012, the Secretariat’s understanding is that the University of Toronto is determining which of the two institutions involved has jurisdiction over the matter. In accordance with the Tri-Agency Framework: Responsible Conduct of Research (the Framework), the Secretariat requests that the appropriate institution conduct an inquiry into the allegation. Should the inquiry determine that Agency funding was used directly or indirectly to support the research in question, the Framework requires the institution to
report its inquiry findings to the Secretariat by October 31, 2012. Should the inquiry conclude that an investigation is warranted, the institution will have an additional five months to conduct the investigation and report its findings to the Secretariat. If the research in question is not supported by Agency funds, the Secretariat requires notification in order to close its file. Please advise us as soon as possible which institution will be responsible for this matter.

Should you have any questions, please do not hesitate to contact me by phone at 613-947-7148 or by email at susan.zimmerman@rcr.ethics.gc.ca.

Sincerely,

Susan Zimmerman
Executive Director
Secretariat on Responsible Conduct of Research
August 30, 2012

Dr. Bonnie Burstow
Department of Leadership, Higher, and Adult Education
Ontario Institute for Studies in Education
252 Bloor Street West
Toronto, Ontario
M5S 1V6

Dear Dr. Burstow:

I am responding to your letter of August 24, 2012. No patients were recruited to this study. Enrollment through the allegedly inappropriate advertisement was stopped pending review.

Sincerely,

[Signature]

Catherine Zahn, MD, FRCP(C)
President and CEO

cc: Ms. Judith Chadwick, Assistant Vice-President, Research Services, University of Toronto
Dr. Bruce Pollock, Vice President, Research, CAMH
Dr. Susan Zimmerman, Executive Director, Secretariat on Responsible Conduct of Research
Dr. Bonnie Burstow, Ph.D. Department of Leadership, Higher and Adult Education  
August 30, 2012.

UNIVERSITY OF TORONTO  
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FOR STUDIES IN EDUCATION

Dr. Catherine Zahn, President and CEO, Centre for Addiction and Mental Health

Dear Dr. Zahn:

This is to acknowledge and thank you for your letter of August 30, 2012, in which you stated, "No patients were recruited for this study. Enrollment through the allegedly inappropriate advertisements were stopped pending review." Besides that I wanted to point out that these are prospective participants—not patients—I did want to clarify. The advertisement in question was not the only problem with this study, with my original letter of complaints specifying many more. This is only the way in which I and others in the community originally came to know of the study. This being the case, it becomes important for me to clarify: Are you stating that no one at all is being recruited for the study, or only that no one is being recruited via the particular route of that specific advertisement. If the former, of course, that is a good thing. If the latter, the problem still remains. Would you be good enough to clarify further?

Thank you once again for your efforts and your speedy attention to this matter.

Sincerely,

Dr. Bonnie Burstow
August 31, 2012

Dr. Bonnie Burstow
Department of Leadership, Higher, and Adult Education
Ontario Institute for Studies in Education
252 Bloor Street West
Toronto, Ontario
M5S 1V6

Dear Dr. Burstow:

No individuals are being recruited to undergo ECT. Patients who are undergoing ECT for clinically accepted indications will have the opportunity to contribute to our knowledge of its effects through PET imaging studies.

I acknowledge your opinions about ECT as a treatment and the spectrum of concerns that you have raised. Further action will be based on the results of our external review.

Sincerely,

[Signature]

Catherine Zahn, MD, FRCP(C)
President and CEO

cc: Ms. Judith Chadwick, Assistant Vice-President, Research Services, University of Toronto
Dr. Bruce Pollock, Vice President, Research, CAMH
Dr. Susan Zimmerman, Executive Director, Secretariat on Responsible Conduct of Research
January 28, 2013

Dr. Catharine Whiteside
Dean, Faculty of Medicine
Vice Provost, Relations with Health Care Institutions
University of Toronto
1 King’s College Circle, Room 2109
Toronto, Ontario M5S 1A8

Dear Dr. Whiteside:

I have received the report of the External Ad Hoc Panel convened to conduct an impartial review of the study protocol entitled "Does Electroconvulsive Therapy Cause Neuroinflammation? An [F]EPPA Positron Emission Tomography Study In Treatment Resistant Depression". The Panel was asked to:

1. review and comment on the management of ethical issues associated with the Study protocol; and
2. review the process of ethical review followed by the Research Ethics Board (REB) at CAMH.

The Panel was also instructed not to respond to concerns raised by Dr. Bonnie Burstow in her August 14, 2012 letter with respect to the clinical appropriateness of electroconvulsive therapy (ECT) or the investigators' compliance with the approved REB protocol. The former is a broad topic with a large body of evidence supporting the procedure in selected patients and the latter was addressed through an internal quality audit that showed compliance by the researchers. Upon review of the report, I can advise you that the Panel was able to keep to the parameters of the intended review and was able to conduct a thorough review resulting in a detailed, yet concise report.

The report will be shared with those who are directly impacted by its findings and recommendations. The Panel confirmed that this matter does not involve a breach of research integrity or research misconduct. Given your respective roles, this would be of most relevance to your organizations. The Study was carried out with full REB approval and the documents reviewed indicated consistent and responsible communication between the researchers and the REB during the process of review and approval.

The Panel’s recommendations focused on the need to ensure the rigor of CAMH REB processes. The panel did not find any lapses in REB processes that would have compromised the integrity of the study. In the context of this Study, specific feedback was received regarding the recruitment of subjects, informed consent documents, compensation for participants, management of potential conflict of interest and the scientific/scholarly review.

We are meeting with our REB and VP - Research to discuss the report and determine next steps. We will follow each of the Panel's recommendations including consideration of a wider review of CAMH's REB looking at best practice for the management of issues such as, but not exclusively, recruitment, conflict of interest and scientific review.

Thank you for your support and patience throughout this process. I am very pleased with the quality of the review and report. It will assist CAMH in ensuring that our research review policies and processes are reflective of excellent practice.

Sincerely,

Catherine Zahn, MD, FRCP(C)
President and CEO

cc: Dr. Lori Ferris, Associated Vice Provost, Health Sciences Policy and Strategy, University of Toronto
    Ms. Kristin Taylor, General Counsel, CAMH
January 31, 2013

Dr. Bonnie Burstow  
Department of Leadership, Higher, and Adult Education  
Ontario Institute for Studies in Education  
252 Bloor Street West  
Toronto, Ontario  
M5S 1V6

Dear Dr. Burstow:

I have received the report of the External Ad Hoc Panel convened to conduct an impartial review of the study protocol entitled “Does Electroconvulsive Therapy Cause Neuroinflammation? An [F]EPPA Positron Emission Tomography Study in Treatment Resistant Depression”. The Panel was asked to:

1. review and comment on the management of ethical issues associated with the Study protocol; and
2. review the process of ethical review followed by the Research Ethics Board (REB) at CAMH.

The Panel did not respond to the general concerns raised in your August 14, 2012 letter with respect to the clinical appropriateness of electroconvulsive therapy (ECT) or the investigators’ compliance with the approved REB protocol. The former is a broad topic with a large body of evidence supporting the procedure in selected patients and the latter was addressed through an internal quality audit that showed full compliance by the researchers.

The Panel confirmed that this matter does not involve a breach of research integrity or research misconduct. The Study was carried out with full REB approval and the documents reviewed indicated consistent and responsible communication between the researchers and the REB during the process of review and approval. However, the Panel’s recommendations focused on the need to ensure the rigor of CAMH REB processes. The panel did not find lapses in REB processes that would have compromised the integrity of the study. In the context of this Study, specific feedback was received regarding the recruitment of subjects, informed consent documents, compensation for participants, management of potential conflict of interest and the scientific/scholarly review. We will follow each of the Panel’s recommendations including a review of CAMH’s REB to ensure best practice for the management of issues such as recruitment, conflict of interest and scientific review.

Thank you again for raising this issue. It has provided us with the opportunity to review our practices and to improve. The report will assist CAMH in ensuring that our research review policies and processes reflect excellent practice.

The report is considered confidential. It will be shared with those who are responsible for implementing its findings and recommendations.

Sincerely,

Catherine Zahn, MD, FRCP(C)  
President and CEO  

cc: Ms. Judith Chadwick, Assistant Vice-President, Research Services, University of Toronto  
Dr. Susan Zimmerman, Executive Director, Secretariat on Responsible Conduct of Research  
Dr. Bruce Pollock, Vice President, Research, CAMH
Anna: Could you please convey this request for clarification to Dr. Zahn. I have emailed others on this for I need absolute clarification here.

A few points that I need clarification on. When I originally asked that the ethicality of this research be looked into, I raised the issue of "unethical research" not "research misconduct". However, Dr. Chadwick, you stated that the research misconduct framework would be used. As I understand it, it was then decided that CAMH had jurisdiction. I have two questions here, which I hope that Dr. Zahn and this group jointly can answer. I am in receipt of a letter of January 31, 2013 from Dr. Zahn, that states that the "External Ad Hoc Panel convened to conduct an impartial review of the study protocol entitled "Does Electroconvulsive Therapy Cause Neuroinflammation? An (F)EPPA Positron Emission Tomography Study in Treatment Resistant Depression." It then stated that the investigation has been completed, that there report is confidential, and there had been no ethical breach.

What is not crystal clear from the letter is: 1) Was this investigation conducted and framed under the "Research Misconduct" framework? If not, is the process under the framework still ongoing? If so, what stage is this process at?

To be clear, this is not a request that any investigation be so framed, for I have repeatedly stated that was not the nature of my complaint and I never intended anything to be done under that particular framework. This is merely a request for information.

---

From: Judith Chadwick <j.chadwick@utoronto.ca>
Date: Monday, August 20, 2012 2:56 PM
To: Bonnie Burstow <bonnie.burstow@utoronto.ca>
Cc: Catharine Whiteside <Catharine.Whiteside@utoronto.ca>, "secretariat@rrc.ethics.gc.ca" <secretariat@rrc.ethics.gc.ca>
Subject: RE: The ethics complaint

For my part, I marked my emails "confidential" as I consider allegations of research misconduct to be highly sensitive matters and, until the prescribed process has run its course, am inclined to contain the dissemination of information/correspondence to those with a specific role in the process. Others interested parties could be informed that the process has been initiated. I'm not sure what further information can realistically be provided until the process is complete.

Hope that clarifies.
Yours,
Judith

Judith L. Chadwick
Assistant Vice-President, Research Services
3rd Floor, McMurrich Building
12 Queen's Park Crescent West
University of Toronto
Anna: Could you please convey this request for clarification to Dr. Zahn. I have emailed others on this for I need absolute clarification here.

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To be clear, this is not a request that any investigation be so framed, for I have repeatedly stated that was not the nature of my complaint and I never intended anything to be done under that particular framework. This is merely a request for information.
Catherine Zahn

From: Catherine Zahn
Sent: Sunday, February 24, 2013 8:35 PM
To: bonnie.burstow@utoronto.ca
Cc: Catharine.whiteside@utoronto.ca; j.chadwick@utoronto.ca
Subject: The ethics complaint: Report of the External ad Hoc Panel, etc.

Importance: High

Dr. Burstow:

I can confirm that the review conducted by the Ad Hoc Panel was not framed as a "Research Misconduct" investigation. It was determined early on that there were no issues with respect to the actions of the researchers as they conducted the research in accordance with the REB-approved protocol. However, the Panel did confirm this initial determination in its report. As you know, in its review, the Panel focused on the management of ethical issues associated with the Study protocol and the process of ethical review followed by the CAMH REB.

Catherine Zahn

From: Bonnie Burstow
Sent: Thursday, February 21, 2013 1:08 PM
To: Anna Chow; Judith Chadwick; Catharine Whiteside; Bruce Pollock
Cc: secretariat@rcr.ethics.gc.ca; Reni Chang
Subject: Re: The ethics complaint: Report of the External ad Hoc Panel, etc.
Importance: High

Anna: Could you please convey this request for clarification to Dr. Zahn. I have emailed others on this for I need absolute clarification here.

A few points that I need clarification on. When I originally asked that the ethicality of this research be looked into, I raised the issue of "unethical research" not "research misconduct". However, Dr. Chadwick, you stated that the research misconduct framework would be used. As I understand it, it was then decided that CAMH had jurisdiction. I have two questions here, which I hope that Dr. Zahn and this group jointly can answer. I am in receipt of a letter of January 31, 2013 from Dr. Zahn, that states that the "External Ad Hoc Panel convened to conduct an impartial review of the study protocol entitled "Does Electroconvulsive Therapy Cause Neuroinflammation? An (F)EPPA Positron Emission Tomography Study in Treatment Resistant Depression." It then stated that the investigation has been completed, that there report is confidential, and there had been no ethical breach.

What is not crystal clear from the letter is: 1) Was this investigation conducted and framed under the "Research Misconduct" framework? If not, is the process under the framework still ongoing? If so, what stage is this process at?

To be clear, this is not a request that any investigation be so framed, for I have repeatedly stated that was not the nature of my complaint and I never intended anything to be done under that particular framework. This is merely a request for information.
Hi Sarah:

Here are the communiques.

Thanks,
Anna

Hi Anna

I am following up regarding the recent access request for access to all emails and correspondence to or from C. Zahn and the complainant (re: Craigslist and alleged recruitment of volunteers for ECT research). I believe that Kristin has spoken to you regarding the request. I will be back in the office tomorrow if you have any questions about the records requested and or the FIPPA process. I have all of Kristin’s records with respect to this issue, but the requester has specifically listed communications from C. Zahn related to this issue.

Thanks - Sarah

Sarah Funston-Mills, MLS, CIPP/C
Information and Privacy Analyst

Information Management Group (IMG)
Centre for Addiction and Mental Health
Bell Gateway Building, 100 Stokes Street
Toronto, Ontario  M6J 1H4
T: 416-535-8501 x 33809
F: 416-583-1299
E: sarah.funstonmills@camh.ca