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 be 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

0052

Date: Tue, 14 Aug 2012 13:59:51 -0400
To: Bonnie Burstow <bonnie.burstow@utoronto.ca>
Cc: Z-SRCR <secretariat@rcr.ethics.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, concerninga 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." 0087

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

Kristin Taylor

From: Bruce Pollock
Sent: Tuesday, August 14, 2012 3:54 PM
To: Nyranne Martin
Subject: FW: Requesting you to intervene
Attachments: letter to Zimmerman.pdf; CAMH_Study_Consent[3].pd Study ad.pdf

Importance: High

From: Bonnie Burstow [mailto:bonnie.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 serio objection to the Secretariat. As you will see below, the Secretariat asked that the ob at the two institutions involved, University of Toronto, and CAMH, and more specific Paul Young, at Simcoe Hall and to the vice-president of research at CAMH—Dr. Bruce you. Attached please find 4 pieces of information, a) the initial letter to Dr. Susan Zi Secretariat's suggestion, I have not changed the letter to insert your name and institu and your institution be considered as the people to whom I am sending this objectio project; c) the brochure on the study; and d) one of the advertisements for the proje seriousness, I ask you to read my letter and the accompanying material and look into

I thank you.

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

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.

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

Toronto, Ontario M5S 1A8
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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.

Sunday, February 17, 2013 12:10:37 PM ET

Subject: RE: The ethics complaint
Date: Monday, August 20, 2012 3:56:06 PM ET
From: Judith Chadwick
To: Bonnie Burstow
CC: Catharine Whiteside, secretariat@rcr.ethics.gc.ca

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
Toronto, Ontario M5S 1A8
T: 416-978-5129
www.research.utoronto.ca

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.ethics.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

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

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

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

0107

Dr. Bonnie Burstow, Ph.D. Department of Leadership, Higher and Adult Education
August 24, 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 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 unethicality.

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

Sincerely,

Dr. Bonnie Burstow

Dr. Bonnie Burstow

CAMH
100 Stokes Street
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camh
Centre for Addiction and Mental Health
Centre de toxicomanie et de santé mentale

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,

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

0007

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

Dr. Bonnie Burstow

CAMH
100 Stokes Street
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camh
Centre for Addiction and Mental Health
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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,

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

0005

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camh
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Centre de toxicomanie et de santé mentale

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 Emisson Tomographty 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

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@rcr.ethics.gc.ca" <secretariat@rcr.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

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0124

[redacted]

From: Bonnie Burstow <bonnie.burstow@utoronto.ca>
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.

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