CAUT Independent Committee of Inquiry into the University of Ottawa, the Institute of Mental Health Research, and the Royal Ottawa Hospital

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Dr. James L. Turk, Executive Director
Canadian Association of University Teachers/ Association canadienne des professeures et professeurs
2705 promenade Queensview Drive
Ottawa, Ontario K2B 8K2

Oxford, March 28, 2013

Dear Dr. Turk,

Re: Inquiry Report

We hereby submit the report of the Independent Committee of Inquiry into the University of Ottawa, the Institute for Mental Health Research and the Royal Ottawa Hospital.

As you know, our Committee was charged to investigate the sequence of events leading to, and subsequent to, the seizure of research records from the offices of Dr. Anne Duffy at the Institute of Mental Health Research. We were also asked to investigate the institutional context in which this occurred, whether breaches of institutional and professional standards occurred, whether there was any impact on research subjects, and to make any appropriate recommendations based on our analysis.

These events took place in the spring of 2005. Our report has been delayed for various reasons. First because of various court proceedings that interfered with our inquiry and that seemed to widen its ambit. These procedures only ended in 2008. Second, because of work and health related issues that were beyond our control.

The Committee members strongly believe that it remains important for the wider academic community to render the report public because of the larger issues it raises. To prevent distraction from the core issues, the Committee avoided as much as possible naming people or assigning individual blame.

Institutional developments are reviewed in the report to show how the events unfolded as they did. It brought to attention the confusion about some key concepts related to informed consent, research ethics and professional integrity, as well as about the appropriate use of institutional tools to ensure compliance to research ethics standards. For a good understanding of our analysis and recommendations, it is necessary to read the full report.

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As you will see, the Committee members disagreed on some points raised in the report. But they agreed about the need to clarify the difference between informed consent in the context of research involving the collection of sensitive personal health information and informed consent in the context of research that exposes research subjects to risk of direct physical or psychological harm; the need to take this distinction into consideration when Research Ethics Boards investigate allegations of non-compliance; and the importance for institutions to respect the widely accepted concept of proportionate review when dealing with alleged violations of research ethics standards. The Report highlights the negative impact a drastic and disproportionate intervention such as seizure of research records can potentially have on research subjects and researchers.

We hope the Canadian Association of University Teachers and the larger Canadian academic community will be inspired by our Report to further explore and deliberate how such drastic events can be prevented in the future.

Please do not hesitate to contact us if we can be of any further assistance.

Yours sincerely,

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Final Report of the Independent Committee of Inquiry into the University of Ottawa, the Institute for Mental Health Research and the Royal Ottawa Hospital

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1. INTRODUCTION: INFORMED CONSENT

This document is the report of an Independent Committee of Inquiry set up by the Canadian Association of University Teachers, to investigate the seizure of the research records of a distinguished team of researchers at the Institute of Mental Health Research in Ottawa on the instruction of the President of the Institute. Since the seizure was triggered by allegedly missing consent forms, some issues related to the concept of informed consent are central to this report.

Informed consent was first stipulated as an ethical requirement for research involving human subjects at the international level in 1947 by the Nuremberg Military Tribunal, in what became known as the Nuremberg Code.[1] The key principles of the Nuremberg Code were incorporated into the 1964 Helsinki Declaration of the World Medical Association, which confirmed that researchers generally have to obtain informed consent from human research subjects prior to their enrollment in medical research.[2]

The requirement of informed consent became gradually entrenched in various professional ethical guidelines and in national regulations dealing with biomedical research. A key regulatory initiative was the 1966 Goddard amendment to the U.S. *Food, Drugs and Cosmetics Act*, which stipulated that whenever an investigational drug is used, investigators should obtain informed consent from each research subject included in the study.[3] In several countries, including Canada and the United States, courts also ruled that informed consent was a pre-condition for research involving human subjects.[4] In Canada, the requirement of informed consent in research became part of the common law.

The requirement of informed consent means that research subjects have to be informed of and understand the purpose of the research project and the procedures involved as well as the risks and potential benefits of participation; and explicitly agree to participate.

Over time, the informed consent process became formalized through the signing of an informed consent form.[5] It also became standard practice that researchers co-sign the informed consent form, expressing the idea that the researchers commit to respect ethical standards when conducting their research. The consent form thus came to reflect both an authorization given by the research subjects to involve them in the research procedures as stipulated in the protocol, as well as a commitment by the researchers to respect ethical standards.

During the 1970s and 1980s, the informed consent requirement was extended beyond those experiments with potential harm, to all medical research, even research in which research subjects provide only confidential information on their physical and mental state.[6] With this development, the informed consent form in medical research has become the formal document of agreement to be included in either an experiment in which one may be exposed to the risks of physical or psychological harm, or in a study in which one gives authorization to collect information about one's physical and mental state. In the first type of study, the emphasis is on ensuring that the research subjects agree to participate in research that exposes them to risks without being certain that the findings will yield benefits, and that the researcher will not prioritize the interests of the study over the physical and mental well-being of the research subjects. In the second type of study, the emphasis is on providing evidence that the research subjects allow researchers to collect and use personal health information and that the researchers will respect the confidentiality of the information and protect the privacy of research subjects. The signature of the researcher in second case is a formal symbol of his/her pledge that the information received from the research subject will be kept in confidence and will not be revealed without their permission, unless there is a pressing public interest for doing so.[7]

With the development of more specific regulatory and legal requirements in relation to research, institutions became bound to ascertain both the protection of research subjects from

exposure to potential harm without their prior knowledge, and the protection of the privacy and the confidentiality of the information received in the course of research by the investigators.[8] This has been accompanied by the creation of a research ethics governance structure in which Research Ethics Boards (REBs) were given the mandate to ensure that both researchers and institutions adhere to accepted research ethics standards.[9]

In many countries, health privacy statutes and privacy regulations further added legal rules about the protection of privacy and confidentiality of health information, including health information collected and used in the context of research.[10] In Ontario, this was done through the 2000 *Personal Health Information Protection Act* (*PHIPA*).[11]

Institutions have appointed Privacy Officers as contact persons, mandated to help institutions with ensuring that privacy law and regulations are respected within the institution.[12] At the same time, PHIPA, without regulating the operation of REBs in much detail, mandates REBs with the review of research protocols when researchers want to collect, use or disclose health information.[13]

In Ontario, it appears not entirely clear what the boundaries are of the REB's mandate or the mandate of Privacy Officers in institutions with respect to health research.[14] The confusion about the role of various officials and agencies and the absence of clarity about their roles in protecting privacy and confidentiality (see 2.3. and 2.4; and the discussion in 7.) has rendered the 'ethics' of informed consent vulnerable to misuse. The concern appears particularly significant in the context of research involving health information, where the informed consent process really focuses on issues of privacy and confidentiality.

The lack of distinction between informed consent for the protection of subjects of being exposed to potential harm without their prior knowledge and agreement, and informed consent for the protection of privacy and confidentiality has created confusion when institutions were

mandated to ensure that standards related to privacy and confidentiality are respected. (See 2.4). In the case that is the subject matter of this inquiry, this confusion led to the seizure of research records (see 2.7) by the Institute, for alleged procedural irregularities in obtaining informed consent in projects where the signing of the informed consent form by the researchers was a promise that they will protect the privacy of research subjects and the confidentiality of the information received from them (see 3.5).

2. OVERVIEW OF FACTUAL INFORMATION

2.1 THE SEIZURE

On March 22, 2005**,** some time after 2.30PM, five employees of the Institute of Mental Health Research (IMHR) and the Royal Ottawa Health Care Group (ROHCG) removed research records, clinical charts, personal files and computer discs from Dr. Anne Duffy's office and chart room at the IMHR.[15]

Neither Dr. Duffy nor any other member of her research team was present when this was done. Dr. Duffy, a researcher at the IMHR at the time, learned about the removal of these clinical charts and research records the next morning, from a note attached to the door of her office that read: "Please be advised that all clinical records and research records have been removed from this area."[16]

The note further indicated that the removal had been carried out by: 1. the ROH Administration; 2. the IMHR Administration; and 3. the Research Ethics Board.[17]

A memo by Sharyn Szick, Administrative Director of the IMHR, sent on the same day (March 23, 2005), independently acknowledged the inadvertent removal of some of Dr. Duffy's personal files.[18]

2.2 THE MATERIAL REMOVED

Dr. Duffy was a member of the "bipolar team" of the University of Ottawa's Department of Psychiatry that had once also included Drs. Grof and Alda. The research of the bipolar team was intimately linked to their clinical work. Thus, the material removed included the clinical charts of some patients Dr. Duffy was following clinically, in addition to their research records. As Dr. Duffy was, at that time, the last member of the bipolar team still affiliated with the Institute, the material removed from her office and chart room included research records from studies conducted by other members of the "bipolar team".[19] According to Drs. Duffy and Grof, the information in the records concerned more than 2,000 research subjects, including: current and former patients of the ROH and their family members; current and former patients of other hospitals in Ontario and Nova Scotia and their family members; and control subjects.[20]

In addition to the removal of clinical charts and research records[21] the electronic database of Dr. Duffy's research records was also altered to a "read only" status, and her computer files were moved to a different drive in the hospital network[22] that was inaccessible to her.[23]

2.3 WHO AUTHORIZED THE REMOVAL OF CLINICAL CHARTS AND WHY?

Dr. Duffy did not know the reason why her clinical charts and research records were removed until she received a letter from Dr. Paul Dagg, Director of Clinical Services, ROH, on March 23, 2005, the day after the removal. In his letter, Dr. Dagg informed her that it was he and Mr. Bruce Swan, CEO of the Royal Ottawa Health Care Group (ROHCG), who had authorized the removal of clinical charts, as an allegation had been brought to their attention that clinical charts had been scanned and downloaded to the hospital's network computer drives by someone from her office. As such activity was contrary to both the ROH's "Release of Information and Photocopying of Clinical Records Policy" and *PHIPA*, they had taken immediate action to

prevent further scanning and downloading of clinical charts to the hospital's network computer drives.[24]

In a follow-up letter the next day, Dr. Dagg informed Dr. Duffy that these allegations about scanning and downloading of clinical charts to the hospital's network computer drives were going to be investigated.[25]

The investigations took about three weeks. On April 13, 2005, Dr. Dagg informed Dr. Duffy in a letter of his conclusion that no serious breaches of privacy with the clinical charts had taken place. The only irregularity he noted was the sending of some confidential information, on one occasion, by e-mail. In the same letter, Dr. Dagg apologized for any inconvenience the removal of clinical charts might have caused.[26]

2.4. WHO AUTHORIZED THE TRANSFER OF RESEARCH RECORDS AND WHY?

It was from Dr. Dagg's first letter of March 23, 2005, related to the removal of their clinical charts that Drs. Duffy and Grof first learned that Dr. Merali's office had ordered the removal of their research records.[27] On the same day, in a memo from Ms. Szick about the accidental removal of her personal files, Dr. Duffy also learned that the IMHR had "secured" their research records for "audit purposes".[28]

The situation was further confounded on March 24, 2005, two days after the removal of the records, when Dr. Duffy received a letter from Dr. Alan B. Douglass, Chair of the Research Ethics Board (REB) of the ROHCG, in which he informed her that the ROHCG REB had not received any complaint about any of the projects Dr. Duffy was involved with, had not authorized the removal of her research records from her office, and had not even been informed in advance that any such removal would take place.[29]

The situation was clarified only on March 31, 2005, nine days after the seizure, when Dr. Duffy received a letter from Dr. Zul Merali, President and Chief Executive Officer of IMHR, from which she learned that their research records had been "transferred" from her office to the hospital for "checking", as some records allegedly lacked "informed consent" forms.[30]

2.5. The researchers' reaction

Concerned about their ability to continue their research[31] and the privacy of their research subjects,[32] Drs. Duffy and Grof retained legal counsel on March 23, the day after the seizure. Legal proceedings commenced before the Ontario Superior Court of Justice for immediate return of the research records.[33]

In the days following the seizure, Drs. Duffy and Grof also contacted the Information and Privacy Commission of Ontario (IPC) and filed a complaint regarding the seizure of the research records.[34]

Furthermore, Dr. Duffy wrote a letter on March 29, 2005, to Dr. Burleigh Trevor-Deutsch, who was at the time Associate Director of Ethical, Legal and Social Issues of the Canadian Institutes of Health Research (CIHR), to inform him of the seizure of the research records, many of which related to research funded through a CIHR grant on which she was the principal investigator.[35]

2.6. Privacy of research subjects

The first legal document raising concerns about the violation of privacy resulting from the removal of the research records was drafted by the lawyers of Dr. Duffy and Grof at WeirFoulds, two days after it happened. In their letter, dated March 24, 2005, they brought to the attention of the lawyers for the Institutes that some of the research subjects whose research

records had been removed, for example those from southern Ontario and Nova Scotia, had not provided consent for release of information to the ROH or IMHR. Therefore, they argued, the seizure and review of those files constituted a violation of the *PHIPA*.[36]

2.7. Privacy of research subjects vs ownership of records and adherence to research ethics standards

While the lawyers representing Drs. Duffy and Grof insisted that the removal of their research records violated the privacy of their research subjects and was unlawful,[37] some members of the Institutions argued that the research records were the property of the IMHR and it was the obligation of the Institute to have the research records in its possession, in order to ensure that research ethics standards were respected.[38]

The obligation to ensure that research ethics standards were respected, Dr. Merali pointed out, was based on the Memorandum of Understanding between the federal funding agencies and the University of Ottawa, which had delegated its authority regarding the assurance of research ethics standards to the IMHR.[39]

To support the claim that the research records were the property of the IMHR, Dr. Merali brought to attention also a policy of the University of Ottawa, which states:

> Unless a contractual obligation to a sponsor contains special provisions to the contrary, research documentation and material projects of all research carried out by members of the University of Ottawa are the property of the University (or a University of Ottawa affiliated institution or hospital research institute when the research is carried out on these premises).[40]

Dr. Duffy responded to this that this policy was only available on the University's website under a webpage for Graduate and Postdoctoral Studies entitled "Research and Thesis,"[41] and that it did not apply to clinical research conducted by faculty members. She also argued that this policy was not brought to her attention as part of her employment conditions when she came to

work at the IMHR, and that she was not aware of any other institution that claimed property interest in research records outside the context of research data containing patentable material or material of commercial interest.[42] In his letter in response to Dr. Duffy's argument, Dr. Merali provided her with the research policy of the Ottawa Hospital Research Institute, a research arm of the Ottawa Hospital which focuses on the development of new therapies,[43] and which explicitly grants ownership of research data to the institution.

While this interaction took place the immediate return of the research records was delayed and the parties started to negotiate, through their lawyers, how the researchers could obtain access to their research records in order to continue with their work.[44]

Following various court submissions and procedures, including the swearing of affidavits and cross-examinations of the people involved, the parties agreed to halt the proceedings. On April 15, 2005, Justice Manton endorsed an adjournment of the proceedings.[45]

2.8. A TEMPORARY AGREEMENT

Following this adjournment, an agreement was reached on April 18, 2005 between the two legal teams to suspend the proceedings under the following conditions:

i. the research records would be copied without delay and the originals returned to Drs. Duffy and Grof;

ii. the copies of the research records would be turned over to the REB without being reviewed;

iii. Dr. Zul Merali would outline, for the REB, IMHR's concerns about the "informed consents" in the research records;

iv. the REB would appoint an independent party to determine whether Dr. Merali's concerns warranted further investigation, and in the case they did, would request that the independent party conduct the investigation; and

v. Dr. Duffy would identify individuals who in her judgment were qualified to conduct the independent review.[46]

A couple of days later, the parties also agreed that the copying of the research records by IMHR's personnel would be completed in a week, with the original records being returned to Drs. Duffy and Grof by April 25, 2005.[47] Furthermore, the parties agreed on the identity of two possible independent reviewers.[48]

2.9. DISAGREEMENT ABOUT THE AGREEMENT

The agreement ran into an obstacle on April 22, 2002, four days after it was signed, when Dr. Duffy learned that after the removal of clinical charts, some of her research records were reviewed by Dr. Busby, the Scientific Coordinator of IMHR and Research Ethics Coordinator of the ROHCG REB**.** [49] In her view, this was contrary to Item 2 of the Agreement. It was also contrary to information she had received from Ms. M. Kate Stephenson, one of her lawyers who had allegedly received assurances from the legal team representing the Institutes that no person from the IMHR had reviewed the research records so far. Dr. Merali argued that this was not the case and that Dr. Duffy had only been assured that no one had reviewed her research records after they had been removed.[50]

On April 25, 2005, three days after this interaction Dr. Duffy informed her research subjects by e-mail that the IMHR had obtained access to personal information in their research records.[51] Upon receipt of this e-mail, some of her research subjects allegedly complained about this to the administration of the Institute and the ROHCG REB.[52]

2.10. The Information and Privacy Commissioner's Short-Lived Investigation

On May 13, 2005, about seven weeks after Dr. Grof filed the privacy complaint, IPC informed the lawyers of Drs. Duffy and Grof that it was moving ahead with an investigation of the alleged violation of the privacy of research subjects at the Institute resulting from the seizure of the research records.[53] The same day the IPC sent a letter to the ROHCG and the IMHR with a list of specific questions about the incident.[54] On May 17, officials of the IPC Office met with staff of the OHCG and the IMHR to discuss the specific questions that were raised in the IPC letter. Following the meeting, Carolyn Belzile and Sharyn Szick prepared a schedule for interviewing Dr. Duffy's research team to get information from them relevant to the questions raised by IPC. On May 20, Ms. Szick conducted a first interview with a member of Dr. Duffy's research staff, but as soon as Dr. Duffy learned that Ms. Szick had interviewed a member of her team and was planning to interview some other members, she went to see Ms. Szick and asked her to stop these interviews.[55]

The same day Dr. Duffy stopped Ms. Szick from continuing with the interviews, Mr. Robert B. Warren, one of Dr. Duffy's lawyers, wrote a letter to Information and Privacy Commissioner Ann Cavoukian to object that her office had reassured some of Dr. Duffy's research subjects that their confidentiality had been protected, as the seized research records were still in the possession of IMHR.[56] In addition, Mr. Warren also objected in his letter to Commissioner Cavoukian that the IPC had asked Ms. Szick to conduct interviews with Dr. Duffy's research team, as Ms. Szick had been involved with the seizure of the research records that was now being investigated for alleged violation of the privacy of research subjects. As the Institute was implicated in the alleged violation of the privacy of Drs. Duffy and Grof's patients, Mr. Warren argued, no institutional official should have been actively involved in conducting the

privacy investigation against the Institute. Mr. Warren instructed his clients not to participate in the privacy investigation as in his view the investigation could have a negative impact on their attempt to protect their research subjects' rights in the courts. To ensure that Mr. Warren's instructions were followed Dr. Duffy advised members of her research team not to participate in any further IPC investigation related to the seizure of research records.[57]

Shortly after Mr. Warren wrote to Commissioner Cavoukian, the IPC put its investigation on hold.[58]

2.11. THE CAUT BECOMES INVOLVED

By late May 2005, two months after the seizure, Drs. Duffy and Grof felt that there was no satisfactory resolution to their concerns about the events. So, on May 24, 2005, they contacted Dr. James Turk, the Executive Director of the Canadian Association of University Teachers (CAUT) and asked for CAUT's assistance. An Independent Committee of Inquiry, sponsored by CAUT, was set up to investigate the seizure of Drs. Duffy and Grof's research records and the circumstances in which it occurred. Dr. Thomas A. Ban, an Emeritus Professor of Psychiatry of Vanderbilt University, Dr. Louis C. Charland, at the time an Associate Professor of Philosophy in the Departments of Philosophy and Psychiatry and the School of Health Studies of the University of Western Ontario, and Dr. Trudo Lemmens, at the time an Associate Professor of Law and Bioethics at the Faculties of Law and Medicine of the University of Toronto, agreed to serve on the Committee. Professor Lemmens also accepted to Chair the Committee**.**

The mandate of the Committee was:

1. to investigate the sequence of events leading to, and subsequent to, the seizure of the research records;

2. to examine the institutional relationships between the University of Ottawa, the Institute of Mental Health Research, and the Royal Ottawa Hospital that might have had a bearing on the decision to seize the documents and on the institutions' response to the seizure;

3. to determine if there were breaches of institutional responsibility;

4. to determine the impact of the events on the academic integrity and academic freedom of those involved;

5. to determine whether research ethics standards had been breached;

6. to determine the impact of the seizure of research records on the researchers, the research subjects, the University of Ottawa, the Institute of Mental Health Research, the Royal Ottawa Hospital and on the organizations that funded the research; and

7. to make recommendations that might prevent the same or similar drastic measures being taken again.[59]

During the seven years of the Committee's operation, CAUT covered its expenses, which included costs of travel, photocopying of relevant material, and research and administrative assistance. The Committee members were not remunerated for their work. CAUT also provided the Committee with whatever information they gathered related to the seizure, including the transcripts of the legal proceedings, and forwarded the Committee's contact information to people who contacted CAUT about the Inquiry.

3. FINDINGS OF THE INDEPENDENT COMMITTEE OF INQUIRY

3.1. THE INQUIRY BEGINS

The Committee began to operate by the summer of 2005 by contacting many of those involved in the seizure by letter, fax, e-mail or phone. Many others learned of the inquiry from an announcement in the CAUT Bulletin,[60] from Ottawa newspapers, and by word of mouth.

By August 2005, the Committee started to receive phone calls, primarily from employees or former employees of the ROHCG, the University of Ottawa, and the IMHR, and also from members of the public who had some connection to the ROHCG or the IMHR.

From the outset, lawyers working for the University of Ottawa questioned the authority of the CAUT to set up an independent inquiry since the parties involved in the dispute were not members of a faculty association or union.[61] Lawyers for the ROHG simply suggested that there was no value in setting up an inquiry since the matters were being dealt with in court.[62] Dr. Turk responded by pointing out that the CAUT had a long history of setting up committees of inquiry to investigate allegations of violations of academic freedom and other faculty rights.[63]

3.2. THE INSTITUTIONS INVOLVED

The Committee identified three institutions that were involved directly or indirectly in the seizure and subsequent litigation:

1. The University of Ottawa via the Department of Psychiatry.
2. The Royal Ottawa Health Care Group (ROHCG) via the Royal Ottawa Hospital (ROH).
3. The Institute of Mental Health Research (IMHR), where the seizure of research records occurred.

The three institutions are in intricate relationships with each other. The ROH is one of the teaching hospitals of the University of Ottawa; the IMHR, located on the premises of ROH, is the research division of ROH, and the only mental health research facility of the University.[64]

Most of the players of the inquiry were at the time of the seizure affiliated with one or more of these institutions. Several had cross-appointments in all three.[65]

In addition to the three institutions, the ROH's Associates of Psychiatry, a group of practicing physicians at the ROH with an independent charter, was also indirectly involved in matters related to the seizure as all psychiatrists at the Institute, including Drs. Grof and Duffy were members of the group.[66]

3.3. Research Ethics Boards

Of the three institutions, only two – the University of Ottawa and the ROHCG – had REBs to evaluate research proposals and to ascertain that approved research is conducted with adherence to the applicable research ethics standards.

As the IMHR did not have its own Research Ethics Board, the ROHCG REB approved projects involving human subjects at the IMHR, including the projects at the centre of this inquiry. The ROHCG REB functioned as the REB for all research undertaken in the ROH, the IMHR or other ROHCG-affiliated institutions.[67]

The Chair of the ROHCG REB was Dr. Alan B. Douglass,[68] an Assistant Professor of Psychiatry at the time. The ROHCG REB had two paid employees but only one of them, Dr. Busby, the Research Ethics Coordinator,[69] played a role in matters related to this inquiry.[70]

3.4. THE PEOPLE INVOLVED IN THE DISPUTE AROUND THE REMOVAL OF THE RECORDS

The following is an alphabetical list of the people who were most directly involved in or affected by the dispute surrounding the removal of the records, with their affiliation(s) at the time of the seizure and, where relevant, their previous affiliations:

1. Dr. Martin Alda was an Associate Professor in the Department of Psychiatry, Dalhousissse University. After his departure from the Department of Psychiatry, University of Ottawa in the late 1990s, he was briefly affiliated with the Department of Psychiatry at McGill University.[71]

2. Ms. Caroline Belzile was the Administrative Director of Clinical Programs at the ROHCG.[72]

3. Dr. Jean-Claude Bisserbe was Clinical Director of IMHR's Mood Disorders Research Unit and Professor in the Department of Psychiatry at the University of Ottawa.[73]

4. Dr. Pierre Blier was Research Director of IMHR's Mood Disorders Research Unit and Professor in the Department of Psychiatry and Cellular and Molecular Medicine, University of Ottawa.[74]

5. Dr. Jacques Bradwejn was Chair of the Department of Psychiatry, University of Ottawa, and Psychiatrist-in-Chief at ROH.[75]

6. Dr. Keith Busby was IMHR's Scientific Review Coordinator and the Research Ethics Coordinator of the ROHCG REB.[76]

7. Ms. Suzan Crozier was Corporate Privacy Officer of ROHCG.[77]

8. Dr. Paul Dagg was Director of Clinical Services of ROH and Associate Professor and Vice-Chair of the Department of Psychiatry, University of Ottawa.[78]

9. Dr. Alan B. Douglass was the Chair of the ROHCG REB, psychiatrist at the ROH, and Assistant Professor in the Department of Psychiatry, University of Ottawa.[79]

10. Dr. Anne Duffy was researcher at the IMHR, psychiatrist at ROH and Associate Professor in the Department of Psychiatry, University of Ottawa.[80]

11. Dr. Paul Grof was Professor in the Department of Psychiatry, University of Ottawa, consultant psychiatrist at ROH, and psychiatrist at a private Mood Disorders Centre in Ottawa. A former Clinical Director of the ROH and Director of the Mood Disorders Research Unit of the IMHR, Dr. Grof left the IMHR at the end of 2004.[81]

12. Dr. Zul Merali was President and Chief Executive Officer of the IMHR and Professor of Psychology and Cellular and Molecular Medicine, University of Ottawa.[82]

13. Ms. Sharon Purvis was Director of Health Records at ROHCG.[83]

14. Mr. Bruce Swan was Chief Executive Officer of ROHCG.[84]

15. Ms. Sharyn Szick was Administrative Director, IMHR.[85]

16. Ms. Laurie Uildersma was a member of ROHCG's Clinical Records staff.[86]

3.5. THE SEIZED RESEARCH RECORDS: CURRENT STUDIES

A review of the seized research records revealed that only five of the six ongoing studies were relevant to the inquiry into the alleged procedural irregularity with respect to the handling of consent forms.[87] In each of these five studies, research subjects had provided only personal

and family health information, with or without biological samples to be used in genetic research.[88]

The one other ongoing study concerned quetiapine, an atypical neuroleptic developed by AstraZeneca, in the treatment of early onset bipolar disorder.[89] In this study, some experimental subjects were exposed to potential harm in a broad sense, inasmuch as they received quetiapine instead of medications otherwise indicated according to the current standard of care.[90] The question of irregularities with respect to informed consent in this study was not raised in the context of the dispute. The study was regularly monitored by a monitor working for the sponsor, AstraZeneca, and the clinical trials monitor did not report any irregularity in the records.[91]

3.6. THE SEIZED RESEARCH RECORDS: BEYOND CURRENT STUDIES

The material seized went beyond the studies of Dr. Duffy that were at the time being underway. It included research records of subjects in studies conducted under the leadership of Dr. Alda, who was investigating the neurobiological, psychosocial and genetic aspects of bipolar disorders;[92] and studies conducted by Dr. Grof, who started his research in patients with bipolar disorders in Canada in the late 1960s[93] at McMaster University. Dr. Grof's research team at the IMHR collaborated with laboratories and researchers in various Canadian institutions,[94] including McGill University in neurogenetics, Dalhousie University in genetic analyses, the University of Toronto in neurochemistry, and McMaster University in neuropsychology.[95] Dr. Grof was also participating in a large international research network involving seven centers in which patients receiving long-term care for bipolar disorders have been followed.[96] The research records of subjects included in all these studies were allegedly among those seized.

Issues related to informed consent in these studies are complex, as many of the studies build upon earlier studies of Dr. Grof involving family members of those who later participated

in research with Dr. Duffy.[97] For instance, Dr. Duffy's research on the risk of developing bipolar disorder of offspring of parents with bipolar disorders was built on Dr. Grof's studies of the clinical course and treatment of bipolar disorders. As many of the children Dr. Duffy studied were the offspring of subjects included in Dr. Grof's research, many of the research records seized in Dr. Duffy's study involved the same subjects as Dr. Grof's prior investigations.[98] At the time of the seizure, Dr. Duffy was involved in studying the risk of developing mood disorders in adolescents.[99] Her study was built on her prior research, in which she studied the incidence of bipolar disorder in offspring of parents with the disorder.[100] As Dr. Duffy's study included a control group of offspring of well parents from two local Ottawa schools,[101] the seized research records also included the records of control subjects.

4. THE CHAIN OF EVENTS

The events outlined in section 2 (Overview) of this Report were reconstructed by the Committee on the basis of transcripts of interviews, affidavits, memos, letters, etc., as follows:

4.1. PRIOR TO THE SEIZURE

Arond March 11, 2005, Sharyn Szick, the Administrative Director of IMHR, reported to Dr. Merali, the Institute's President and CEO, that Dr. Duffy's research coordinator at the time had informed her that a research assistant of Dr. Duffy's was scanning clinical charts and inserting printed copies into research records.[102] She also reported to Dr. Merali that the same research coordinator had told her that no informed consent forms were obtained from some research subjects in Dr. Duffy's research projects, and that in some other cases the informed consent forms were signed after the study was already initiated and were backdated in the records.[103]

After informing Dr. Merali of these allegations, Ms. Szick discussed the allegations at several meetings with Dr. Keith Busby, the Scientific Review Coordinator of the IMHR and Research Ethics Coordinator of the ROHCG REB, and Suzan Crozier, Corporate Privacy Officer of the ROHCG, and others.[104] Ms. Sharon Purvis, the Director of Health Records[105] at the ROHCG attended the meeting held on March 22, 2005; it was likely on that occasion that she heard for the first time about the alleged scanning of clinical charts by Dr. Duffy's assistant.[106]

As soon as she learned of the allegations, Ms. Purvis suggested that immediate action be taken to prevent the continued scanning of clinical health records, by removing the clinical charts from Dr. Duffy's office and 'chart room'.[107] Ms. Belzile, who was also present at the meeting, followed up on Ms. Purvis' suggestion by informing Dr. Paul Dagg, Director of Clinical Services at ROHCG, and Mr. Bruce Swan, CEO of ROHCG, about the allegations.[108] She also told Dr. Dagg that someone from the Hospital Information System had identified scanned clinical records on the general hospital network directory, and a partial listing of files by patient names.[109]

As soon as Dr. Dagg received this information from Ms. Belzile, he convened a small meeting with Ms. Belzile and Bruce Swan. At that meeting they agreed:[110]

1. to remove clinical charts from Dr. Duffy's office, on behalf of the hospital as owner and custodian of those records;
2. to secure the charts at a safe place;
3. to post a note to Dr. Duffy's door about the removal of the charts;
4. to advise Dr. Duffy in writing about the information they had received, that a research assistant on her team had been scanning clinical charts and placing copies into research records;
5. to inform Dr. Duffy about her ongoing access to the charts; and
6. to pursue an investigation, to find out what had actually happened.[111]

The first three steps (1–3) were carried out without delay;[112] the next two steps (4 & 5) were carried out the day after the removal of the charts, and step 6 took about three weeks to complete.[113]

4.2. THE SEIZURE

Once the clinical charts were relocated, Dr. Busby, who was a member of the team that relocated the clinical charts, carried out a "spot check," on Dr. Merali's request in approximately 20 research binders of Dr. Duffy's research subjects,[114] and in the course of this "spot check," he allegedly found that from five of the research binders he examined informed consent forms were missing.[115] As Dr. Merali knew from Ms. Szick about the allegation of missing consent forms from Dr. Duffy's research records, when he learned about Dr. Busby's findings immediately after the "spot check," he ordered the immediate transfer of the research records of the bipolar team to a "secure location" at the ROH in order to further investigate the allegations. He did this in his capacity as President and CEO of the Institute without consulting with the chair of the ROHCG REB, Dr. Douglass. In fact, as the Committee later found out in the course of the inquiry, prior to their removal, Dr. Douglass was at that point not aware of any allegation of irregularity with Dr. Duffy's research records.[116]

4.3. THE SEIZED MATERIAL

The material seized in Dr. Duffy's office consisted of paper and electronic research records, as well as material related to the electronic records.[117] As several of her ongoing research projects were connected to earlier studies of Drs. Grof and Alda, as noted before, the seized material included some of the same research subjects and families as the earlier studies.[118]

In 2004, Drs. Duffy and Grof had begun compiling research records from all the sites where their studies were conducted, and organizing the material into research binders for each individual subject involved in their various studies.[119] The seized material therefore also included these records for research subjects from other sites.[120] To keep track of their research activities, each binder contained a page inserted before the data sheets, which indicated the forms included in the binder and the information that was still missing.[121]

As Drs. Duffy and Grof were working, at the time, on a comprehensive database in ACCESS[122] for bipolar studies carried out by Dr. Grof and his associates over decades, the seizure included information on patients dating back many years.[123]

4.4. The chain of events after the seizure: The Interviews

The Independent Committee of Inquiry began its activities in the late summer of 2005, by interviewing people who might be able to provide information on the seizure and the sequence of events before and after its occurrence. By the end of 2005, several interviews had been conducted with Drs. Duffy and Grof, in Ottawa and Toronto, as well as with several other current and former employees and people affiliated with the IMHR and/or the ROHCG.

As interviewing progressed, the Committee learned that most of the people they spoke to, had little knowledge about the search and seizure. They brought up various issues that had been the subject of earlier reports of inquiries or investigations at the IMHR or the ROH. The interviews by the Committee provided an occasion to air various grievances. Although these grievances were not directly related to the seizure and violation of the privacy of research subjects, they shed light on the larger picture and the atmosphere in which those events took place.

Notably, with the exception of one person, none of those connected to the administrations of IMHR, ROHCG, or the University of Ottawa, agreed to participate when invited to do so by the Committee of Inquiry. One administrative official directly involved in the search and seizure, Dr. Dagg, agreed to be interviewed after he had left the ROHCG and moved to British Columbia. The Committee understood that those connected to the administration of the Institutions were advised by the lawyers of their respective institutions that, due to ongoing litigation, they were not to provide the Committee with any information related to the seizure.[124]

Although Dr. Merali declined the Committee's invitation to be interviewed, in a telephone conversation he told Professor Lemmens, the Chair of the Committee, that in his view the Committee was biased against his administration and in favor of Drs. Duffy and Grof.[125]

4.5. THE SETTLEMENT

On October 19, 2005, soon after the Committee began interviewing, a settlement was reached between the researchers and the institutions.[126]

With the settlement, the two parties agreed on:

1. the importance of obtaining written consent prior to conducting clinical research involving human subjects;
2. the right of the University of Ottawa IMHR to investigate allegations of missing consent;
3. the importance of bringing such issues to the attention of the REB;
4. referral of the allegations relating to research records, at the discretion of Dr. Alan B. Douglass, as Chair of the REB, to an independent research ethics board in the person of Dr. Darby of the Centre for Addiction and Mental Health for investigation;

> 5. acknowledgement by the parties that no further independent investigation would be required into the issues raised in the legal proceedings.[127]

As the settlement did not directly address the seizure of research records and what led to it, to be able to fulfill its mandate and give recommendations on the basis of findings that could prevent that such drastic event occurs again, the Committee decided to continue with the Inquiry, focusing on these issues.

4.6. SECOND INVITATION

Soon after the settlement was reached, the Committee again sent a letter, without success, to several members of the administration of the IMHR, the ROHCG, and the University, inviting them to provide the Committee with whatever information they had concerning the seizure and the events preceding and following it.[128] The reason for declining the invitation at this point in time was that the Settlement stipulated[129] that no further investigation was required.[130]

4.7. THE ROHCG REB AND THE SEIZURE

To pursue matters further, the Committee examined the role of the ROHCG REB and its Chair, Dr. Douglass, in the seizure and events before and after it took place. This investigation confirmed that the ROHCG REB was not involved in the seizure.[131] In the opinion of Dr. Douglass, the mandate of the REB was limited to: approving research proposals involving human subjects for study by reviewing their compliance with the Tri-Council Policy Statement (TCPS) before recruitment of research subjects begins[132]; ensuring that informed consent for participation has been freely obtained from all subjects involved in studies approved by the

Board; and ascertaining that all information related to informed consent has been properly documented.[133] In his response to Dr. Duffy, who inquired whether there were in fact guidelines for REB 'auditing', Dr. Douglass stated that, to his knowledge, no specific guidelines existed at the hospital and that the authority of the REB to conduct an audit would be based on the TCPS provisions related to 'continuing review', which may take the form of a periodic review by a third party of research documents or patients' charts, or by way of a random audit of informed consent forms.[134]

On April 21, 2005, i.e., about one month after the seizure, and three days after the Agreement was reached, the ROHCG REB met to discuss matters related to the seizure and "spot check."[135] After the meeting, Dr. Douglass expressed in a letter to Dr. Merali his regret about what had happened. The ROHCG REB felt that, if it had received itemized allegations, it could have performed its duties "with due process".[136]

With regard to the missing consent forms, the ROHCG REB requested clarification about the allegation, and with regard to the "spot check", it requested information on exactly what had been found.[137] In his letter to Dr. Merali, Dr. Douglass pointed out that ROHCG REB's Research Ethics Coordinator, had "no power to act on behalf of REB" and his actions "cannot be considered as an action of the REB".[138]

In order to carry out the agreement reached on April 18, 2005 between Drs. Duffy and Grof and the IMHR and the ROH, which required the submission of copies of the research records to a third party for review, the Chair of the ROHCG REB stipulated that the ROHCG Materials Management staff could copy the seized files only if appropriately supervised by the REB, and only if the REB could ensure that the confidentiality of research subjects' personal information was protected.[139] In the same letter, he also affirmed that Drs. Grof and Duffy should

continue their research and that patient care in the ongoing clinical studies should not be affected.[140]

4.8. THE THIRD PARTY REVIEW

On October 20, 2005,[141] one day after the settlement,[142] and about six months after the "Agreement", Dr. Douglass invited Dr. Padraig Darby to review the copies of research records, to verify whether all subjects in the studies of Drs. Duffy and Grof had been participating in ROHCG REB-approved research protocols, and whether a signed consent form had been obtained from each subject or his/her guardian prior to their involvement in any of the research projects.[143] Drs. Duffy and Grof pointed out that by asking him to examine whether all subjects were participating in an ROH REB-approved protocol, Dr. Darby was given a wider mandate than had been agreed upon in the settlement.[144] They also contacted Dr. Darby and met with him on January 25, 2006.[145] During this meeting, they asked Dr. Darby to let them know how he would obtain the requested information and allegedly Dr. Darby promised that he would do so.[146] As they did not hear from Dr. Darby for some time, Drs. Duffy and Grof followed up their request in a letter[147] and by sending Dr. Darby information on the events that led to his review.[148]

When the IMHR's legal counsel was informed[149] that Drs. Duffy and Grof had interacted with Dr. Darby, he sent a letter on February 2, 2006 to the legal counsel for Drs. Duffy and Grof, in which he suggested that any attempt by Drs. Duffy and Grof to stop the review by Dr. Darby would violate the settlement conditions.[150] Four days later, legal counsel for Drs. Duffy and Grof wrote a letter back to IMHR counsel stating explicitly that Drs. Duffy and Grof made no attempt to stop Dr. Darby's review. [151]

Dr. Darby had no further interaction with Drs. Duffy and Grof.[152] On November 10, 2006, he handed in his report to Dr. Douglass.[153]

4.9. THE "DARBY REPORT"

In reviewing the six ongoing studies of Drs. Duffy and Grof, Dr. Darby found that only one of them had REB approval. He also found that informed consent forms were missing from 77 (30.5%) of the 252 research records examined.[154]

On November 16, 2006, *i.e.* six days after the report was submitted to Dr. Douglass, Dr. Darby was informed that in fact for all of the studies he had reviewed, the ROHCG REB had signed approval forms on file.[155] His report on the missing consent forms was accepted by the ROHCG REB, with the understanding that he would provide further information on the identity of subjects whose signed consent forms were missing.[156]

4.10. DRS. DUFFY & GROF REACTION TO THE "DARBY REPORT"

Dr. Darby's findings, based on his review of copies of the original research records, did not correspond with the findings of Drs. Duffy and Grof,[157] based on their review of the original records returned to them after they were copied**.**[158] According to their count, signed informed consents were missing from only 11% of the records.[159] Regardless of these findings, Drs. Duffy and Grof maintained that they had always obtained written informed consent from all their research subjects.[160] They alleged that a former research assistant appeared to have failed to add consent forms to the research files[161] and also suggested that it was impossible to assess whether anything had been removed from the files after they had been moved out of Dr. Duffy's office.[162]

The Darby Report created further tension between the researchers and the institutions, as Dr. Duffy and Dr. Grof felt it was unfair to them and it would undermine their professional standing if published. This led to a new round of litigation, as they wanted to stop its publication.[163]

4.11. THE END OF ALL LITIGATION

In 2008, three years after the seizure, the second litigation was halted by Drs. Duffy and Grof, as the Canadian Medical Protective Association (CMPA), which was paying the legal costs of Drs. Duffy and Grof, was no longer willing to support further litigation. Drs. Duffy and Grof accepted to pay the legal costs of the other party in this litigation and the court further ordered that they were barred from starting further proceedings related to this dispute.[164] The litigation ended with the judge's suggestion that with this arrangement the dispute about the Darby Report should be closed.[165]

5. INTERIM STATEMENT OF THE INDEPENT COMMITTEE OF INQUIRY

5.1. THE STATEMENT

On January 18, 2010, almost two years after the end of litigation, the Committee, at the request of CAUT, submitted an interim statement on its findings that dealt exclusively with the allegedly missing informed consent forms, as this had been at the centre of the two legal inquiries.

The interim statement is based on checking informed consent forms in the five studies Dr. Darby reviewed` to find out whether the consent forms Dr. Darby found missing in the copied research records were also missing in the returned records; and on interviews with some patients whose informed consent forms were identified as missing in the Darby report.

The following excerpts reflect the conclusions of the interim statement:[166]

> The assessment in the Third Party Analysis [Darby Report] of the number and the identity of the missing informed consent forms in the copied research records does not correspond with the Committee's findings based on a review of the original research records in the possession of Dr. Duffy. The Committee found original consent forms

> in some research files that the Third Party Analysis identified as missing consent forms. In other research records, original consent forms were missing which were not identified as missing in the Third Party Analysis.
>
> The Committee also found that in all records where original consent forms were absent, new signed consent forms were present.
>
> All of the interviewed research subjects and parents of research subjects whose original consent forms were missing declared that they had always been fully aware of the fact that they or their children were participating in one or more research projects directed by Dr. Duffy.
>
> All the interviewed subjects had a very good understanding of the nature and the purpose of the research in which they were involved. They also expressed a strong confidence in the integrity of Dr. Duffy and in the importance of the research she conducted.

In essence, the Committee concluded that although it was no longer possible to determine with certainty whether any, and if so which, of the consent forms were missing from the research records of Drs. Duffy and Dr. Grof at a certain point in time in the past, new informed consent forms had been signed for those whose consent forms were reported as missing in the returned records. Most importantly, all research subjects of Dr. Duffy interviewed by the Committee's chair had been fully aware that they were participating in her research and had been participating willingly, even if several could not exactly remember if and when they had signed a consent form, due to the time that had passed. The Committee also pointed to the nature of the research projects involved, in particular their long-term nature, and the frequent interactions between Dr. Duffy and the research subjects.

5.2. COMMENTS ON THE INTERIM STATEMENT

The interim statement was sent by the Committee to Dr. James Turk, Executive Director of CAUT, Dr. Zul Merali, President and CEO of the IMHR, Mr. Bruce Swan, CEO of the ROHCG;

and Mr. Alan Rock, President of the University of Ottawa. There was no response from Mr. Swan. Mr. Rock acknowledged receipt, without further comment. Dr. Merali responded with a letter to Dr. Turk in which he suggested that the Committee had "an obvious misunderstanding of the issues involved".[167] He also made the point that "properly documented consent from research participants is an ethical issue of the utmost importance" that is "required by the IMHR's funding agencies and sponsors".[168] Dr. Merali objected to the Committee's reference to the missing consent forms as a procedural issue, and informed Dr. Turk that "further review by CAUT or any other party" of this incident "is of no benefit to the IMHR or to the researchers at this stage". In his opinion it was inappropriate for the Committee to contact Dr. Duffy's present or former research subjects. Furthermore, he made the point that "any inappropriate finding contained in the final report will be addressed with IMHR's legal counsel," and, that insofar as he was concerned "the matters have been resolved between the parties".[169]

6. PREPARATION OF THE FINAL REPORT

6.1. MISSING INFORMED CONSENT FORMS

Preparation of the final report was delayed because of the allegations concerning missing consent forms in some of the research records and the subsequent activities that culminated in the Darby report. All of which distracted attention from the seizure of the bipolar team's research records and thus it took some time for the Committee to get back on track.

Finally, with all the pieces in place, the Committee noted that from the very beginning the Institute did not follow the conventional process, as the allegation about missing consent forms in Dr. Dufy's records, made more than a week before the seizure, was not relayed to Dr. Douglass and the ROH REB. The Committee also noted that Dr. Duffy was not contacted at any

time before the seizure to make it possible for her to provide an explanation or to correct the situation if she had done anything wrong. It seemed to the Committee that the Institution prioritized the establishment of alleged wrongdoing of the researchers over the protection of the privacy of the research subjects, and did not properly consider whether these allegations justified a seizure.

6.2. SEARCH OPERATION VERSUS AUDIT

With the understanding that even if the allegations were correct, they alone could not justify the seizure of Drs. Dufy and Grof's research records, the Committee was looking for identifying other factors that might have played a role, given that such a drastic measure was taken. For this, it reviewed the transcripts and affidavits of the legal process and the transcripts of its own interviews, to reconstruct the background to the seizure and the role of officials in the different institutions involved in it directly or indirectly. In the course of this process, the Committee examined Dr. Jacques Bradwejn's possible involvement.

Dr. Bradwejn, as previously noted, was the Chair of the Department of Psychiatry at the University of Ottawa, and Psychiatrist-in-Chief at the ROH. He was also on the Board of Directors of the IMHR. The Committee found no evidence that he knew of the seizure in advance or that he was directly involved in any of the decisions related to the seizure. The Committee noted that in the course of the legal proceedings, when asked by the lawyers of Drs. Duffy and Grof whether he was aware of any precedents involving the seizure of research records, Dr. Bradwejn, in the opinion of the Committee, indirectly approved of the "spot check" by stating: "There have been ***audits*** of research records worldwide."[170]

In order to determine whether the "spot check," the findings of which triggered the seizure, would qualify as an "audit", the Committee consulted compliance and audit procedures adopted by various Canadian and American institutions.[171] Despite some variation between institutions that have such documented procedures, audits follow procedural conventions such as: written notice to the researcher that an audit will be conducted; the provision of a date for it in advance; the identification of the objectives; the scope of the audit; the identification of the administrative unit or person in charge of the audit; and so on.[172] Furthermore, an audit usually starts and ends with a meeting between the auditor and the investigator and is carried out with the involvement of the researchers, to allow for communication, discussion, and clarification of issues between the researchers and the auditors.[173]

Based on this information, the Committee concluded that the "spot check" could not be considered a proper "audit."

6.3. THE ALLEGATION REVISITED

After clarifying Dr. Bradwejn's position with respect to the events, the attention of the Committee turned to Ms. Szick, the Administrative Director of the Institute. It is she who was told by Dr. Duffy's research coordinator about missing consent forms from some of Dr. Duffy's research records, and who relayed the allegations about the missing consent forms to Dr. Merali.[174] Ms. Szick was also one of the five individuals involved with the removal of the clinical charts and research records from Dr. Duffy's office and chart room, as well as the person who relayed the information to Dr. Merali about the finding of missing consent forms from some of Dr. Duffy's research records in the "spot check."[175]

From Ms. Szick's deposition, the Committee learned that Dr. Merali knew of the allegations about missing consent forms in some of Dr. Duffy's research records about 11 days before the seizure. As Dr. Douglass was first told about missing consent forms in some of Dr. Duffy's research records after the seizure, the Committee concluded that Dr. Merali did not inform Dr. Douglass about the allegations of missing informed consent forms in Dr. Duffy's research records for at least 11 days.[176]

From Ms. Szick, the attention of the Committee moved to Dr. Duffy's research coordinator. It was her allegations about missing consent forms from some of Dr. Duffy's research records, and about the copying of clinical charts by her research assistant, that led to the chain of events that triggered the seizure of the bipolar tea's research records.[177] The Committee had no deposition available from this research coordinator, but from interviews, copies of correspondence, and affidavits, it learned that she had clashes with Dr. Duffy concerning reimbursements prior to making her allegations about Dr. Duffy to Ms. Szick. [178] The Committee also learned that she was transferred from working under the supervision of Drs. Duffy and Grof to working as an assistant to Ms. Sharyn Szick, [179] until her final departure from IMHR.

6.4. The environment at the Institute

In the course of interviews conducted in 2005, the Committee learned that at the end of 2004, several months before the seizure, a group of 'consumers' representing parents of interviewees, caregivers and doctors,[180] together with Drs. Duffy and Grof, presented to Richard Patten MPP a petition that called for an independent inquiry into the governance of the Institute.[181] The inquiry was conducted by Graham Scott QC and Lydia Wakulowsky in early 2005 and found "no evidence of bad faith" on the part of the Administration. It recommended

structural changes and better communication processes to deal with "strained relations" and "poor morale" at the Institute.[182]

This was the state of affairs at the IMHR at the time of the seizure. By the time of the seizure, two of the three members of the bipolar team, Drs. Alda and Grof, had left the IMHR and the third, Dr. Duffy, was known to be leaving.

6.5. Tension in the Department of Psychiatry

There was tension in the Department of Psychiatry between Dr. Bradwejn and some members of his faculty during his first term as Chair of the Department of Psychiatry at the University of Ottawa and Head of Psychiatry at the ROHCG**.**[183] Before his reappointment for a second term, an external review of his performance as head of the Department of Psychiatry was held.[184] The report of this review expressed concerns about several matters, but the reviewers found his shortcomings "remediable" and described him as a visionary and a community leader, and recommended his re-appointment for a second term.[185]

6.6. Consolidation of the IMHR

During his tenure, Dr. Bradwejn succeeded in 1999 in establishing the IMHR as a separate legal entity with its own Board of Directors, by incorporation. The Institute was founded in 1990 by his predecessor, Dr. Yvon Lapierre, under the auspices of the ROHCG, with strong links to the University of Ottawa via departments with activities related to mental health research.**[186]**

Since the time it was founded, the IMHR has been dependent on both parent organizations as a result of funding arrangements and cross-memberships in leadership positions. The ties

between the IMHR and the ROH have been even tighter than those with the University, as the IMHR research units had a parallel set up to the ROH's clinical programs, such as the Schizophrenia Program and the Mood Disorders Program. Furthermore, psychiatrists at the IMHR have been participating in the delivery of local mental health care by staffing the ROH's inpatient operations and outpatient clinics. As members of the ROH's Associates of Psychiatry they had been donating two per cent of their billings annually to the IMHR to assist the Institute in the administration of operating research grants.[187]

In 2002, Dr. Zul Merali, a Professor in the Departments of Cellular and Molecular Medicine and Psychology, was appointed as the first President and CEO of the incorporated IMHR.[188] By that time Dr. Bradwejn was a voting member of both the Board of Trustees of the ROHCG and the Board of Directors of IMHR.

At the time of Dr. Merali's appointment as President and CEO of the Institute in 1992, Dr. Grof was the Research Director of the Mood Disorders Research Unit at the Institute. Following Dr. Grof's appointment to this position in February 2001, Dr. Duffy decided to return to Ottawa to work in the Unit under the direction of Dr. Grof, her former mentor.[189]

6.7. LIQUIDATION OF THE BIPOLAR TEAM

Both Dr. Grof, who enjoyed international recognition for his contributions to the use of lithium in the treatment of bipolar disorders, and Dr. Duffy, who had an excellent research record, allege they were exposed to what they considered slanderous and discrediting comments at the IMHR. There was also a growing tension between the researchers and Drs. Bradweijn and Merali, which in the Committee's opinion might have been due to in part to their different visions of psychiatric research and of how to best develop the IMHR. The tension was probably

accentuated by the fact that Drs. Duffy and Grof were seeking external support for their cause, for example by calling for outside investigations.[190]

In the opinion of the Committee, the final chapter in the story began at the end of 2003, when Dr. Grof's directorship of the Mood Disorders Research Unit was terminated, the name of the Unit was changed to Bipolar Disorders Research Unit, and Dr. Grof's salary support for directing the Unit was transferred to Dr. Pierre Blier, an MD/PhD neuroscientist, who was to arrive at the Institute in 2004.[191]

These tensions were further aggravated by a proposed reorganization of the Institute in September 2004, in which the Bipolar Disorders Research Unit was given an apparent lower status as a Clinical Research Team. Dr. Duffy became Team Leader without remuneration,[192] under the research direction of Dr. Blier, and the clinical direction of Dr. Jean-Claude Bisserbe, a former Director of a clinical research unit at the Institut de Recherche Pierre Fabre, a French pharmaceutical company, and a former consulting psychiatrist at the University Hospital Fernand Widal in France.[193] In the new structural organization, Dr. Duffy would no longer report to Dr. Grof, who would become simply a "senior member" of her research team. In her letter of September 29 to Dr. Merali, Dr. Duffy argued that the reorganization changed the terms according to which she had accepted her position in the Mood Disorders Research Unit of the Institute.[194] She also expressed her concerns about being evaluated by Drs. Bisserbe and Blier, whose understanding of her work she questioned. She had had prior disagreements with both of them.[195]

The incident that led to the final break between Drs. Grof and Duffy and Drs. Merali and Bradwejn occurred in the Committee's opinion, in September 2004, at a meeting of the ROH Associates in Psychiatry. At this meeting, Dr. Grof allegedly asked the Associates to consider

stopping all contributions to IMHR's capital fund-raising campaign until allegations made by a former Administrative Director of the IMHR were investigated and cleared.[196]

Dr. Grof's advice to the Associates led to an exchange of letters between Drs. Merali and Grof via their legal representatives. In a letter dated September 28, 2004, Mr. James O'Grady, Dr. Merali's legal representative, demanded that Dr. Grof withdraw statements he had made at the meeting of the Associates and apologize for them.[197] In response, in a letter dated October 20, 2004, Mr. Robert H. Warren, Dr. Grof's legal representative, demanded that Dr. Merali not only retract the statements he had attributed to Dr. Grof in Mr. O'Grady's letter, but also inform all recipients of the letter of this retraction, since Dr. Grof did not make such statements.[198]

In late 2004, Dr. Grof resigned from his position at IMHR.[199] By the time of the seizure Dr. Duffy was in an advanced stage of negotiations to move from the University of Ottawa to McGill University.[200] But, to the Committee, it appears that the tension between the researchers and the administration remained intense even after the bipolar team had been dismantled and the researchers had departed or were at the point of leaving the institution. As late as July 2005, Dr. Bradwejn indicated that he would be contacting the Chair of the Department of Psychiatry of McGill University to know the exact start date of her new position there, while indicating that the University of Ottawa would continue to facilitate her move.[201] Early in August, Dr. Duffy's lawyer sent a letter to Dr. Bradweijn's lawyer, protesting the fact that while inquiring about Dr. Duffy's anticipated arrival time in her new position at McGill University, Dr. Bradweijn allegedly told administrators at her future university "his version of the events leading up to Dr. Duffy's departure."[202]

In the summer of 2005, the March 22, 2005 incident was reduced to allegations about irregularities in keeping informed consents by Dr. Duffy. Without this Committee pursuing its

inquiry, it would not have been known that the research records of Dr. Duffy and Grof had been seized for an alleged procedural irregularity related to informed consent, in studies where the informed consent was aimed at ensuring that researchers would protect the privacy and confidentiality of their research subjects.

Without rendering this report of the Committee accessible to the public it would also not be possible to share with the research community what the Committee concluded in this inquiry, which hopefully will diminish the likelihood that such an incident will occur again. The seizure of research records is a serious measure that can be justified in extreme circumstances only, where no other reasonable options are available. It is a measure that is difficult to justify, even in the context of medical experimentation that involves exposure of research subjects to the risk of physical or psychological harm.

What the Committee's inquiry brings to the fore is that when the informed consent is related to the protection of privacy of information and involves a pledge of confidentiality, as in the case of this inquiry, seizure of research records risks violating the essence for which the informed consent is obtained.

7. THE COMMITTEE'S DISCUSSION ABOUT THE TCPS AND THE SEIZURE

7.1 The Question of Minimal Risk

Dr. Merali justified the seizure on the basis of the Memorandum of Understanding between the IMHR and the federal funding agencies, which obliges the IMHR to ensure that the research ethics standards of the TCPS were respected. The Committee therefore also discussed whether the seizure could be seen as an acceptable action under the continuing review provisions of

TCPS1, the research ethics policy of the federal funding agency in force at the time of the seizure. According to article 1.11 of TCPS1, various continuing review procedures, including audits and review of consent forms, could be required for research that involves more than minimal risk.[203] At this point in the Committee's discussion, one of the three members of the Committee, Dr. Thomas Ban, an emeritus professor of psychiatry, intervened and argued that the continuing review provisions of the TCPS1 did not apply to the research projects that are the subject matter of this inquiry, as the TCPS1 provision of continuing review applies only to research that involves more than minimal risk. Professor Trudo Lemmens, a professor of law and bioethics, pointed out that according to current research ethics standards, research involving the collection and use of sensitive mental health information about families would generally be considered more than minimal risk, and that the TCPS1 did not clearly exclude this form of research from continuing review.[204] Accepting Professor Lemmens' authority in issues related to medical ethics, Dr. Ban pointed out that in this case the informed consent was not only trivialized by confounding the protection of patients from physical and psychological harm without their prior knowledge with protection of privacy and confidentiality of information they provide, but the term "risk" has also been confounded, as for the medical researcher who obtains the informed consent prior to including the subject in their research, the term implies physical and/or psychological harm, whereas for teachers of medical ethics and lawyers it also refers to potential breaches of privacy and confidentiality. Professor Lemmens suggested that the division between the opinion of lawyers and research ethics scholars and teachers on the one hand, and medical researchers on the other hand, was probably not so stark as suggested by Dr. Ban, and that many medical researchers, particularly many of those involved in research ethics scholarship or in REB review, would likely also argue that potential breaches of privacy and confidentiality are to be considered 'risk' factors.

7.2 THE DISCUSSION ABOUT THE "CONTINUING REVIEW" PROVISION.

Professor Lemmens, supported by Professor Charland, a professor of philosophy, felt that the TCPS1 provisions related to continuing review were ambiguous and could be too easily invoked to justify excessive actions. They therefore felt that the report should conclude with a statement that reads:

> The Committee believes that clearer guidance about continuing review, with clearly defined responsibilities and a more detailed explanation about how precisely review should take into consideration the nature of the research and be proportionate to the level and nature of the risks involved, would also have made it much less likely that the seizure would have been conducted. It could also have resulted in a faster resolution of the dispute once the seizure occurred.

Dr Ban objected to having such a statement conclude the report on a project in which continuing ethics review is not recommended in the TCPS and in which, in his opinion, the confounding of medical ethics with privacy legislation made it possible that the seizure occurred. Continuing ethics review entails checking whether the researchers obtained informed consent from their research subjects, by people other than the researchers, and in his view it would be illogical to recommend clearer guidance about continuing ethics review in projects such as those that form the subject matter of this inquiry (see 3.5 and 4.3), in which the essence of consent is that researchers will protect the privacy of their research subjects and keep the information received from them confidential. He also brought to the attention of Professors Lemmens and Charland that checking whether the informed consent procedure was adhered to in projects such as those that constitute the subject matter of this inquiry, is somewhat arbitrary as the projects of Drs. Duffy and Grof could not be carried out without the trust of research subjects in the researchers and without their willingness to provide them with the information that is relevant for their research. Professor Lemmens and Charland interpreted the TCPS provisions differently and noted that continuing review can, for example, include measures agreed upon by the researchers and carried out by them, which would in that case thus not involve any external person. They felt

that more detailed provisions on continuing review could have clarified that when there is no immediate risk of physical or psychological harm, and the research involves the collection and use of confidential health information by the research subjects' physician, continuing review involving third party access to confidential records is not appropriate.

Most importantly, the Committee as a whole agreed that the nature of risk in Drs. Duffy and Grof's research that is the subject of this inquiry, is clearly very different from the nature of the risk involved in research that may result in direct physical or psychological harm to research subjects. The term 'risk' in studies like those of Dr. Duffy and Grof, is associated with potential breaches of confidentiality and privacy. In the research that is the subject matter of this inquiry, informed consent was obtained for the protection of research subjects' privacy and confidentiality of information collected by researchers who in most cases had already access to much of the same information as the treating psychiatrists of the research subjects. The Committee agreed that seizing research files in response to allegations of missing consent forms, in the context of research where the informed consent focuses on the protection of the privacy and confidentiality of patient information and involves a pledge by the researcher to protect this information, appeared contrary to the concept of 'proportionate review', which is a general guiding principle in the TCPS.[205]

In the opinion of the Committee, continuing review or other measures cannot be considered "proportionate" if they create more risks to the confidentiality and privacy of research subjects than the alleged violations for which they are implemented. The Committee concluded that seizure of research records in general could not be justified on grounds of an institution's obligation to ensure adherence to TCPS1 provisions alone, whether or not the continuing review provisions applied.[206]

7.3 THE ROLE OF REBS UNDER THE CONTINUING REVIEW PROVISION OF TCPS

In their review of the continuing review provision of the TCPS1, the TCPS in force at the time of the seizure, the Committee noted that it did not explicitly indicate who had to decide on the implementation of the continuing review and how it should be conducted. It only suggested that the REB should normally not conduct continuing review itself, but it did not identify who should do so. Notwithstanding this ambiguity, which has been largely addressed in the 2012 version of the TCPS (TCPS2), the discussion of continuing review in the TCPS1 already reflected the idea that REBs were expected to take a leading role in all the decision making processes related to ensuring that research ethics standards are respected in the projects the REB reviewed.

From the available information (see 4.7 and endnote 180) the Committee learned that Dr. Douglass, the Chair of ROHCG REB was aware of the continuing review provisions of the TCP in force at the time of the seizure (see 4.7) and of the authority of the REB to review allegations about missing consent forms. Furthermore, from the available information the Committee also learned that Dr. Douglass felt that, if the ROHCG REB had received an itemized list of alleged procedural irregularities in obtaining informed consent in the projects of Drs. Duffy and Grof, prior to the seizure, it could have performed its duties "with due process".[207]

The Committee concluded that in the particular case that is the subject matter of this inquiry, in the opinion of the Committee, a disproportionate measure was taken without involvement of the ROHCG REB, for an alleged procedural irregularity in obtaining informed consent.[208]

8. THE MANDATE OF THE COMMITTEE: QUESTIONS AND ANSWERS

The mandate of the Committee was formulated by the CAUT in seven points.

8.1 THE SEQUENCE OF EVENTS LEADING TO, AND SUBSEQUENT TO, THE SEIZURE OF THE RESEARCH RECORDS.

The Committee tracked the sequence of events that led to the seizure of the research records of Drs. Alda, Duffy and Grof from November 2003, when Dr. Grof's appointment as Director of the Mood Disorders Research Unit was not renewed and the Unit was converted into a Bipolar Disorders Research Unit under the direction of Dr. Grof.[209]

The salient steps were as follows:

In 2004 the IMHR was reorganized and Drs. Bisserbe and Blier were appointed as Clinical and Research Directors, respectively, of the Mood Disorders Unit.[210] Through the reorganization of the Institute and the appointments of Drs. Bisserbe and Blier, the "Bipolar Disorder Research Unit" was converted into a Clinical Research Team, and became part of the Mood Disorders Unit, with Dr. Duffy as team leader reporting to Drs. Bisserbe and Blier.[211]

In September 2004, Dr. Grof advised the ROH Associates in Psychiatry not to contribute further to IMHR's capital fund-raising campaign until allegations against Dr. Merali had been cleared.[212] This was followed by an exchange of letters between Drs. Merali and Grof via their attorneys and by Dr. Grof's resignation from the Institute at the end of 2004, and his withdrawal from activities at the Royal Ottawa Health Care Group and the Department of Psychiatry.[213]

On March 11, 2005, Dr. Duffy's Research Coordinator, told Ms. Sharyn Szick, the IMHR's Administrative Director, about allegedly missing consent forms from some of Dr. Duffy's research records. She also told Ms. Szick that Dr. Duffy's research assistant was allegedly scanning and downloading information from clinical charts into research records.[214] Ms. Szick relayed the information about the allegations to Dr. Merali.

On March 22, 2005, Carolyn Belzile, the Administrative Director of Clinical Health Records of the ROHCG, learned from Ms. Szick about the alleged scanning and downloading of information from clinical charts to the hospital's computer drives, and relayed this information to Dr. Dagg, the Clinical Director of the ROH.[215] Dr. Dagg and Mr. Swan, the CEO of ROHCG, decided that all clinical charts should be transferred without delay from Dr. Duffy's office and chart room to the hospital until the allegations were investigated.[216] The transfer was carried out on the same day, some time after 2.30PM[217] After the transfer of clinical charts, Dr. Busby, on Dr. Merali's request[218], carried out a "spot check" of Dr. Duffy's research records and found that informed consent forms were missing from some of the research binders.[219] He informed Dr. Merali, via Ms. Szick, of the missing consent forms, and on Dr. Merali's instruction the research records from Dr. Duffy's office and chart room were transferred to a "safe place" at the ROH.[220]

On March 23, 2005, Dr. Duffy learned from Dr. Dagg that he and Mr. Swan had authorized the transfer of her clinical charts, because of allegations that her research assistant was scanning and downloading clinical charts into the hospital's computer drives.[221] The same day, she learned from Ms. Szick that her research records were transferred for 'audit' purposes.[222] It was also on that same day that Drs. Duffy and Grof retained legal counsel to get their research records returned and Dr. Grof filed a complaint with the Information Privacy Commission about the Institute's violation of the privacy of their research subjects by seizing their research records.

On March 24, 2005, the lawyers acting for Drs. Duffy and Grof brought to the attention of the IMHR, the ROH and the University that the seizure and review of these records was a violation of the Personal Health Information Protection Act as some of the research subjects whose research records had been seized had not provided consent for release of personal information to the ROH or the IMHR.[223]

On March 31, 2005, Dr. Duffy learned from Dr. Merali about the allegations of missing consent forms from some of her research records.[224]

On April 13, 2005, Dr. Duffy was informed by Dr. Dagg that the allegations concerning the scanning and downloading of clinical charts to the hospital's computer drives` were unfounded.[225]

On April 15, 2005, the parties agreed to halt the legal proceedings and the adjournment of legal proceedings was endorsed by Justice Manon.[226]

On April 18, 2005, an agreement was reached between the legal teams of the researchers and the Institutes. According to this agreement, the seized research records would be copied without being reviewed; the copies would be turned over to the ROHCG REB, and the originals returned to Dr. Duffy; Dr. Merali would outline concerns about informed consents in Dr. Duffy's research records; Dr. Duffy would identify individuals acceptable to her for carrying out an independent review of her research records; and the ROHCG REB would appoint an independent party to perform the review.[227]

On April 22, 2005, Dr. Duffy learned that a "spot check" was carried out in some of her research records after the removal of the clinical charts from her office and record room. On April 25, 2005, after she learned that Dr. Busby had carried out a "spot check," on her research records,[228] she informed her research subjects by e-mail that IMHR personnel had opened some of her research records that might have contained information on their health.[229]

On May 24, 2005, Drs. Duffy and Grof contacted Dr. James Turk of the Canadian Association of University Teachers, and CAUT set up an Independent Committee of Inquiry to investigate the seizure of the research records of Drs. Duffy, Grof and Alda, and the circumstances in which it occurred.

In the summer of 2005, Dr. Jacques Bradwejn allegedly informed McGill University of the March incident regarding missing consent forms in Dr. Duffy's research records.[230]

On October 19, 2005, a settlement was reached between Drs. Duffy and Grof and the Institutes (ROH, IMHR and the University of Ottawa). The settlement allowed Dr. Douglass to invite Dr. Padraig Darby, Chair of the Research Ethics Board of the Centre for Addiction and Mental Health in Toronto, to investigate whether Drs. Duffy and Grof had obtained informed consent from all subjects in their studies.[231]

On October 20, 2005, Dr. Douglass invited Dr. Padraig Darby to review copies of the research records in order to look into the question whether all subjects in the studies of Drs. Duffy and Grof were participating in ROHCG REB-approved research protocols, and whether a signed consent form had been obtained from each subject or his/her parent/guardian prior to their enrolment in any of her projects.[232]

On January 25, 2006, Drs. Grof and Duffy met Dr. Darby to discuss some of the issues related to the checking of their research records.[233]

On February 2, 2006, IMHR's legal counsel objected to the interaction between Drs. Duffy and Grof and Dr. Darby.[234]

On November 10, 2006, Dr. Darby submitted his report to Dr. Douglass.[235]

On November 16, 2006, Dr. Darby was informed that all the studies of Drs. Duffy and Grof had approval letters on file, and that his finding that only one of the six studies he reviewed had ROHCG REB approval resulted from the fact that the ROHCG REB had not provided him with all of the approval letters. Dr. Darby was asked to identify the subjects whose informed consent forms were missing from the research records.[236]

In late 2006, Drs. Duffy and Grof started a second round of litigation to block the release of Dr. Darby's report, as Dr. Darby's findings about missing consent forms did not correspond

with their own analysis of the original records that they had in their possession. They also objected to the procedure followed and the terms of the mandate given to Dr. Darby.[237] They felt the publication of the "Darby report" would tarnish their reputation.

In 2008, the second litigation was halted with the researchers agreeing to have the legal costs of the other party in this litigation paid on their behalf by the CPA.

On January 18, 2010, the Independent Committee of Inquiry submitted an Interim Statement that dealt with the issue related to allegedly missing informed consent forms from some of Dr. Duffy's research records as that issue was central to the two legal inquiries. Following interviews with some research subjects, the Committee concluded that those subjects who had been interviewed were fully informed that they were participating in research projects conducted by Dr. Duffy, even if some subjects could not remember with certainty whether and when they had signed a research consent form.

At the time of preparation of this report, in June 2012, Dr. Duffy is a Professor of Psychiatry at the University of Calgary, where she holds a Canada Research Chair; Dr. Grof is a Professor of Psychiatry at the University of Toronto and Director of a private psychiatric clinic in Ottawa,[238] dedicated to treatment and research in bipolar disorders ; Dr. Bradwejn is the Dean of the Faculty of Medicine at the University of Ottawa; and Dr. Merali is still in the same position as he was at the time of the Inquiry.

8.2 The effect of the institutional relationships between the University of Ottawa and the Institute of Mental Health Research and the Royal Ottawa Hospital on the decision to seize the documents and on the response of the institutions to the seizure.

The interconnections between University of Ottawa, the ROH and the IMHR are through the Department of Psychiatry of the University. Both the ROH, one of the teaching hospitals of the University, and the IMHR depend on the Department of Psychiatry for professional

personnel. Moreover, the IMHR is dependent on the ROH to pursue clinical research. Within this structure, the Chair of the Department of Psychiatry plays an important role in functionally connecting these Institutions.

Each successive Chair of the Department of Psychiatry represents a new stage in the development of the field, and it is the task of the Chair to facilitate the transition of clinical, educational and research activities in his/her department from one era to the next. Dr. Bradwejn, the sixth Chair of the Department, was moving his department into an age in which psychiatry would come to be seen by some as a part of the neurosciences. The incorporation of the IMHR and the recruitment of Dr. Merali, a neuroscientist, as its President and CEO were major steps in this direction.

The changes in the working arrangements of Drs. Duffy and Grof at the Institute led to increased tension and antagonism between the researchers and Drs. Bradwejn and Merali. In the seven months prior to the seizure, the bipolar team opposed the implementation of a proposed reorganization of the Institute, objected to the provision of unconditional financial support of the Institute by ROH's Associates of Psychiatry, and attempted to mobilize the community in support of their opposition.

In the Committee's opinion the state of affairs in the Department of Psychiatry and at the Institute may provide some insight into what led to the seizure of the research records of Dr. Duffy and her colleagues as well as the subsequent responses to the seizure by the Institutions.

8.3 Breaches of institutional responsibility.

An important aspect of this inquiry is that when the Institute, based on what it saw as its duty to ensure the respect of research ethics standards under the terms of the Memorandum of Understanding between the Institute and Federal Funding Agencies, seized the research records of the researchers, it breached, in the opinion of the Committee, its institutional responsibility in

ensuring the adherence to research ethics standards. The reason for this is that in the studies of the researchers the informed consent was not signed for the protection of patients from potential physical or psychological harm without their prior knowledge, but for the protection of their privacy and the confidentiality of the information they had given to the researchers. In the opinion of the Committee, under these circumstances, by supporting the seizure instead of ascertaining that the research records are returned to the researchers as soon as possible, the other institutional officials involved also breached their institutional responsibility.

Even if allegations about irregularities in obtaining informed consent by the researchers would have justified an audit of their research records, the Committee noted that the IMHR did not follow the conventional procedure in this case, in particular because the REB that approved the projects was not involved in the decision-making process.

As the seizure of the research records of the researchers in this case created concerns with respect to the respect of the privacy of research subjects and protection of the confidentiality of health information, the REB that approved this project, should, in the Committee's opinion, have requested the return of the seized research records without delay, as soon as it learned of the incident, based on the REB's authority to ensure adherence to research ethics standards.

The fact that the Institution and the University supported the litigation focused on allegedly missing consent forms instead of addressing the privacy and confidentiality concerns associated with the unwarranted seizure, constituted in the view of the Committee a breach of the institutions' responsibility of ascertaining that research ethics standards are respected.

Regardless of procedural irregularities on the side of the Institution that might have occurred because at the time the TCPS1 was not entirely clear about the task of the REB and of other institutional officials, the seizure of these research records for allegedly missing informed consent forms from some research records with the purpose of ascertaining adherence to research

ethics standards was, in the opinion of the Committee, a breach of institutional responsibility, as the informed consent in these studies was signed for the protection of patient's privacy and confidentiality of the information in the records. In this case, not interfering with the copying and reviewing of confidential information on patients and their families subsequent to the seizure was, in the opinion of the Committee, also a breach of institutional responsibility to ascertain adherence to research ethics standards.

8.4 THE IMPACT OF THE EVENTS ON THE ACADEMIC INTEGRITY AND ACADEMIC FREEDOM OF THOSE INVOLVED.

Reorganization of the Institute in the six months prior to the seizure had changed the working conditions under which Dr. Duffy's funding from the Canadian Institutes of Health Research and the National Alliance for Research on Schizophrenia and Depression had been approved. This, she felt, compromised her academic integrity as she was not able to conduct the research supported by different granting agencies under the conditions her funding was approved. [239] In the same context, after Dr. Grof resigned from the Institute, Dr. Duffy was no longer a member of a Mood Disorders Research Unit headed by Dr. Grof, one of the leading authorities in the area of research for which her support was awarded, but was now a member of a unit under the clinical direction of Dr. Bisserbe and the research direction of Dr. Blier, who had limited expertise in the area of Dr. Duffy's research interests.

The seizure and the events subsequent to it had a direct impact on Dr. Duffy's and Dr. Grof's professional integrity, as they were not able to protect the confidentiality of information they had received from the subjects enrolled in their research projects. Their inability to protect the confidentiality of information they had received from their research subjects resulted from Dr. Busby's "spot check", Dr. Darby's review, and the Committee's investigations. Although the Committee and Dr. Darby had the authorization of the relevant REBs to verify consent

procedures, and Dr. Busby was instructed to do the "spot check" by the Director of the Institute, nonetheless, in all three instances Drs. Duffy and Grof were not able ensure the confidentiality they had promised to their research subjects was maintained.

Rightly or wrongly, Dr. Duffy felt that the changes at the Institute had an impact on her "professional (academic) obligations," as allegedly internal support at the Institution became contingent upon demonstrations of collaborative behavior and harmonious relationships with the Research Unit Director(s), Clinical Director(s), the ROHCG, and the IMHR Governance and Staff. In her letter to Dr. Merali on September 29, 2004, she wrote that these requirements "represent an attempt to silence legitimate criticism and debate" and are inconsistent with one's "professional (academic) obligations."[240]

Finally, the seizure created a public impression of impropriety in the research conduct of Drs. Duffy and Grof and created a perception they were lacking in professional integrity.

8.5 Breaches of research ethics standards.

In the Committee's opinion, the seizure of research records, for an alleged irregularity in obtaining informed consents in studies where the informed consent was obtained for the protection of the privacy of the research subjects and confidentiality of sensitive information relevant to their mental illness and mental illness in their families, breached research ethics standards. It seems to the Committee, as previously noted, that in this case, priority was given to trying to establish the extent of the alleged transgressions of the researchers, instead of trying to correct, in collaboration with the researchers, an alleged procedural irregularity related to informed consent.

The alleged procedural wrong-doing of not having an informed consent form in each research record, while potentially a sign of a flaw in the informed consent process and in need of

correction, in the Committee's opinion, would not have justified the seizure of these records even if the informed consent would have been obtained for the protection from harm without prior knowledge. Even then, it would have been a disproportionate response and not in line with "proportionate approach to ethics assessment" that was emphasized even at that time by the TCPS1.

The Committee also noted that even if the seizure had been warranted, it was not carried out by a team designated or supervised by the REB of ROHCG, but by a team lacking legitimate representation of ROHCG's REB and therefore not in line with conventional procedure.

8.6 The impact of the seizure of research records on the researchers, the research subjects, the University of Ottawa, the Institute of Mental Health Research, the Royal Ottawa Hospital and on the organizations that funded the research.

The seizure itself caused only temporary difficulties for Drs. Duffy and Grof in getting access to their seized research records. The toll of the litigation that followed was greater, as it distracted Drs. Duffy and Grof from their research. The allegations of Dr. Duffy's research coordinator and Dr. Darby's report were damaging to Dr. Duffy's reputation.

The fact that the seizure was not carried out by the ROHCG REB, and the circumstances surrounding it, made it impossible to reliably investigate whether or not consent forms were missing from some of Dr. Duffy's research records at the time of the seizure. But even if the seizure had not taken place, the nature of the research of the bipolar team, with one project built on another and patients followed over long periods of time, would have made the checking of adherence to informed consent procedures difficult.

Regardless whether signed informed consent forms were missing or not from some of Dr. Duffy's research records, interviews with some of Dr. Duffy's research subjects revealed that, even if several subjects could not confirm with certainty that they had signed a consent form at a

certain point in the past, before providing Dr. Duffy information related to their illnesses and their families, all of them were aware that they were participating in her research projects and had significant trust in Dr. Duffy's integrity.

The seizure affected the research subjects involved. As many of the records that were seized and subsequently copied included not only information on subjects' bipolar illness, but also information about bipolar illness in their families, some research subjects became concerned that the researchers could no longer protect their information, and that information on their bipolar illness and on bipolar illness in their family members, had become available to individuals other than the researchers.

The incident has had no tangible impact on the three Institutes (the University of Ottawa, the IMHR and the ROH).

The Committee noted that in the first bout of court proceedings, the legal team of the institutes succeeded in putting the researchers, who were the plaintiffs in a defensive position. Subsequent procedures perpetuated the perception of possible wrongdoing by the researchers.

Inasmuch as Drs. Duffy and Grof managed to continue with their research, the organizations that funded their projects were not affected. The studies sponsored by AstraZeneca were actively monitored, and the research monitor working for the company confirmed in writing the presence of consent forms in the records of the ongoing study.[241]

The CIHR was not affected by the seizure. Dr. Duffy's letter to the CIHR Associate Director of Ethics, Law and Policy, in which she informed the agency of what happened, remained unanswered.

At the time of Dr. Duffy's move from the University of Ottawa to McGill, upon the request of Dr. Duffy, the Deputy Director of CIHR's Creation Programs Branch, Mary Ann Linseman, wrote a letter to Dr. Duffy on June 28, 2005, indicating that "it would be the expectation of the

CIHR that the research data" transfer with Dr. Duffy to McGill with her move "as is the normal procedure in such cases".[242] Although there was some initial opposition by the IMHR to the transfer of her research records and of the remaining funds from her grants, both were transferred to McGill.

8.7 Recommendations that could prevent this type of incident from happening again.

To prevent similar incidents, the Committee recommends that the question of ownership of research records and responsibilities related to research records be further clarified within the academic research community in Canada. Academic institutions should ensure that there is at all times a clear agreement on the ownership of and responsibilities related to research files with the understanding that research records are in principle the property of the researcher. There should be further reflection and deliberation to clarify what the exceptions to this principle should be.[243] Researchers should be able to move research files from one Institution to another when they are pursuing the same line of research and in particular when the research involves health information where there is an agreement of protecting the confidentiality between the research subject and the researcher.

The Committee further recommends that research institutes, hospitals, or academic units re-evaluate and clearly define the position of research teams which generate their own funding in support of their researchers and supporting staff, and renegotiate at regular intervals the administrative, educational, and clinical responsibilities of the researchers in such teams towards the institute, academic unit, or hospital. The relationship of the supporting staff of self-supporting research teams with the administrative personnel of the institute, academic unit, or hospital where they operate should also be clearly defined.

The Committee recommends to clearly identify for each research project in which informed consent is signed, whether the consent was obtained for the protection of research subjects from being exposed to potential harm without their prior knowledge, or for the protection of research subjects' privacy and the confidentiality of the information they provide to the researcher.

The Committee also recommends that the institutional responsibility for ensuring that researchers follow established research ethics standards be clarified in all institutions. There has to be a clear understanding that in accordance with the principles laid out in the TCPS2, the Research Ethics Boards that approved the study, and not other institutional officials, are primarily responsible for ascertaining and ensuring adherence to applicable research ethics standards.[244]

The Committee further recommends that the relationship between the Research Ethics Board and the administration of the Institute be clarified and that each institution in which research takes place establish clear rules for verifying adherence to research ethics standards, in accordance with the requirements of the TCPS2.[245] These policies have to indicate very clearly that seizure of research records can be mandated only by the Research Ethics Board itself, in line with the continuing review mandate now clearly identified as the mandate of the REB in the TCPS2. They have to indicate very clearly that seizure of research records is the last resort, where alleged breaches of research ethics expose research subjects to serious risk of imminent harm, and where seizure of records is necessary to prevent further harm. In the context of research involving the collection of health information, seizure of research records is *prima facie* violating the essence for which informed consent is obtained, i.e. the protection of the privacy and confidentiality of the health information contained in these records. Research of this nature,

in which the informed consent is aimed at the protection of privacy and confidentiality, should be treated differently from research in which the informed consent is aimed at the protection from physical or psychological harm**,** and the procedures to ensure that informed consent standards are respected in the context of such research should be clarified and be designed with proper attention to the privacy and confidentiality of the information contained in the files.

9. SUMMARY

On May 24, 2005, Dr. James Turk, Executive Director of the Canadian Association of University Teachers, set up an Independent Committee of Inquiry to investigate the seizure of the research records of Drs. Anne Duffy, Paul Grof and Martin Alda by the Institute of Mental Health Research, the Royal Ottawa Hospital and the University of Ottawa on March 22, 2005, and the circumstances in which it occurred. The mandate of the Committee included the provision of recommendations to prevent that such drastic measures be taken again.

The seizure of research records was the last episode of ongoing conflict between Drs. Grof and Duffy, researchers at the Institute of Mental Health Research, and Dr. Zul Merali, President and CEO of the Institute, and Dr. Jacques Bradwejn, Chair, Department of Psychiatry, University of Ottawa, and Psychiatrist in Chief, Royal Ottawa Hospital. At the time of the seizure, Dr. Grof, a Professor in the Department of Psychiatry, University of Ottawa, a former Clinical Director of the Royal Ottawa Hospital, and a former Director of the Mood Disorders Research Unit at the Institute, had already left the Institute, and had withdrawn from active involvement in the Department and the Hospital, and Dr. Duffy, an Associate Professor in the Department of Psychiatry, University of Ottawa, and a child psychiatrist on staff of the Royal Ottawa Hospital,

was already contemplating her departure from the Institute and the Hospital, and a move from the University of Ottawa to McGill University, because of the ongoing conflict.

The seizure was followed by two consecutive law suits initiated by Drs. Duffy and Grof, with the first ending with a settlement on October 19, 2005, and the second being halted in 2008.

The Committee encountered difficulties in accomplishing its task, as all those involved in the seizure representing the Institutions turned down invitations to provide information, on legal advice. It took the Committee seven years to establish that the seizure of the research records of Drs. Alda, Duffy and Grof for alleged irregularities in obtaining informed consent was in violation of research ethics standards, as the informed consent in these records was obtained for the protection of privacy of research subjects and protection of confidentiality of the information given by research subjects to the researchers.

The violation of research ethics standards by the Institutions began with the invasion of the privacy of Dr. Duffy's research subjects by a "spot check" of her research records. It was followed by two subsequent viewings of the files containing personal information on her research subjects in the course of two investigations: the first was carried out by Dr. Padraig Darby, Chair of the Research Ethics Board of the CAMH, at the request of Dr. Alan B. Douglass, Chair of the Research Ethics Board of the Royal Ottawa Health Care Group, to investigate allegations of missing consent forms in Dr. Duffy's copied research records; and the second was carried out by the Committee, with permission of the Chair of the Research Ethics Board of McGill University, in order to verify the results of Dr. Darby's inquiry.

By interviewing some of Dr. Duffy's research subjects, the Committee established that all those research subjects interviewed were aware that they had been participating in Dr. Duffy's research projects. The Committee also established that even if the alleged procedural wrongdoing had been substantiated, the seizure of research records would have been a violation

of research ethics standards as the informed consent in the studies of Drs. Duffy and Grof was obtained for the protection of patients' privacy and confidentiality of the information given to the researchers.

To prevent the re-occurrence of such an incident, the Committee recommends:

1. The issue of the ownership of research records should be clarified. The presumption should be that the researchers and not the Institution, own the research records.

2. The position of research teams that generate their own funding should be re-evaluated and clearly defined; and the administrative, educational, and clinical responsibilities of the researchers in such teams towards the institute, academic unit, or hospital have to be renegotiated regularly.

3. For each research project in which informed consent is signed, it should be clearly identified whether the consent was obtained for the protection of research subjects from being exposed to potential harm without their prior knowledge, or for the protection of research subjects' privacy and the confidentiality of the information they provide to the researcher.

4. The institutional responsibilities to ensure compliance to research ethics standards have to be clarified. The Research Ethics Board that approved the project and not other institutional officials has to ensure that researchers adhere to required procedures of research ethics, in line with the provisions of the TCPS2.

5. Institutional policies aimed at ensuring compliance to research ethics standards have to clearly state that seizure of research records can be mandated only as a last resort, where there is an immediate and serious threat to the wellbeing of research subjects. Institutional policies related to research ethics review have to

take into consideration the specific nature of research involving the use of health information, particularly where the privacy and confidentiality of health information is a core component of the informed consent process.

10. CONCLUSIONS

On the basis of interviews conducted, and affidavits, transcripts of cross-examinations, memos and other correspondence examined, the Committee concludes that the seizure of research records by the Institute of Mental Health Research and the Royal Ottawa Hospital, was in violation of research ethics standards.

The seizure of the research records and the conflict between Dr. Duffy and her former research coordinator at the time prevented the proper investigation of allegations made by this disgruntled research coordinator about missing consent forms in Dr. Duffy's research records. Based on the Committee's investigations and understanding of the nature of the research projects involved, and with due respect to Dr. Darby's findings, the Committee felt that it was very unlikely that research subjects were participating in any of Dr. Duffy's research without providing proper consent. More importantly, even if consent forms had been missing from the research files, this would have warranted only corrective action and not seizure of the bipolar team's research records. In the Committee's opinion, the seizure followed by an investigation of the research records, was not justified.

The Committee attributes the seizure of research records to the ongoing tensions between Drs. Duffy and Grof and Drs. Bradwejn and Merali (see 6.5 and 6.7). Without those tensions and without confounding the informed consent aimed at the protection of privacy and confidentiality with the informed consent aimed at obtaining consent for exposure to potential harm in research, mere allegations by an unhappy employee would probably not have led to the seizure of research

records of a distinguished team of researchers.

The Committee regrets that litigation and legal advice muting those representing the Institutes made it more difficult for the Committee to get to the root of the problem earlier.

ACKNOWLEDGMENTS

The Committee would like to express its gratitude to the people who agreed to be interviewed or who otherwise contributed to the inquiry, by providing information or by submitting written comments or documentation. Several people preferred to do so confidentially and we therefore do not want to name here any person in particular. The Committee would also like to thank various researchers who have contributed to the work of the Committee with summaries of documents, checking references, and conducting other background research; in particular Aman Dhillon, Tony Drake, Lori Luther and Sasha Kontic, all of whom contributed at one point to the work of the Committee. Finally, the Committee is grateful to the Canadian Association of University Teachers and particularly to all the people involved or affected by the events discussed in this inquiry for their patience.

ENDNOTES (*)

[1] "The voluntary consent of the human subject is absolutely essential." *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10*, vol 2, pp 181-182. Washington, DC: US Government Printing Office, 1949, accessed via the National Institute of Health Office of History, online at: http://history.nih.gov/research/downloads/nuremberg.pdf.

[2] World Medical Association Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects. Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964; amended by the 52nd WMA General Assembly, Edinburgh, Scotland, October 2000, available online at: http://www.who.int/bulletin/archives/79(4)373.pdf. The Declaration also introduced exceptions to this requirement of informed consent and indicated instances where research can be conducted without explicit informed consent.

[3] See James L. Goddard, "Consent for Use of Investigational New Drugs on Humans: Statement of Policy by the Food and Drug Administration" (1966) 6:6 *Journal of Clinical Pharmacology* 366.

[4] Key Canadian and US cases include *Halushka v. University of Saskatchewan et al.,* Sask CA 1965, 53 DLR (2d) 436; *Weiss v Solomon*, Que SC 1989, JQ no 312. *Burton v. Brooklyn Doctors Hospital*, NY App Div 1982, 452 N.Y.S. (2d) 875.

[5] This formal process has several functions. It helps ensure that all essential information is clearly stated in a document available to the research subject. The document provides evidence of the informed consent process. It is worth noting that the signing of the form itself is neither necessary nor sufficient to determine that informed consent has been respected. Although research ethics guidelines generally require the signing of an informed consent form, it is not an absolute requirement. Notwithstanding a signed consent form, a court can still conclude that no informed consent was obtained if it is clear, for example, that people did not understand what they were signing, or when a form was signed under coercion.

[6] The requirement for informed consent was later extended to apply to research in the social sciences in which participants would provide only their opinions on various issues.

[7] For a discussion of some of the public interest reasons in research, see Chapter 5, Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, December 2010 (hereafter TCPS2), available on line at: http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf.

[8] See for example TCPS2 at pp 8-11.

[9] The REB's role was originally limited to reviewing research protocols for their compliance with research ethics standards prior to the recruitment of human research subjects. Gradually, more emphasis was also placed on 'continuing research ethics review' of research projects by REBs, including verification of the consent procedures. The Term 'continuing ethics review' is used in the Canadian TCPS. See article 2.8 TPCS2, p. 21-22, and article 6.14 and discussion at p. 79-81. The term monitoring is also widely used in the literature.

[10] See for example s. 44(1) *Personal Health Information Protection Act* SO 2004, Chapter 3 Schedule A (*PHIPA*).

[11] S. 44(1) *PHIPA*. .

[12] These Privacy Officers perform the functions of the 'contact person' as described in s. 15 *PHIPA*, including facilitating compliance with the legislation, informing employees about their duties, responding to public inquiries and requests for access to or correction of personal records, and receiving complaints related to health information records.

[13] See for example *PHIPA* ss 36(1)(d) and 37(3). See also s 15 O Reg 329/4, last revised O Reg 331/11.

[14] The TCPS2 Article 6, Authority, Mandate and Accountability, contains a discussion of how REBs ought to operate. But there are some areas where the role of REBs is not so clear, for example with respect to "continuing research ethics review". The Committee is, however, not in agreement about how relevant these provisions are, as discussed in section 7 of the report. Review of the informed consent procedures in research is not elaborated upon in PHIPA, but documents from the Privacy Commissioner's office intended to clarify the implementation of

PHIPA indicate that privacy officers are in charge of solving privacy complaints and investigating these complaints, without excluding research activities and records from their mandate. See e.g. http://www.ipc.on.ca/english/access-to-information/for-the-public/default.aspx?print=1. Other earlier documents suggest that the institutions have to develop 'best practices' which should include the identification of a "person who will manage the breach [of privacy]" without specifying who that should be. But since the document specifically mentions the role of REBs with respect to approval of protocols, it leaves room for the interpretation that another institutional official is in charge of managing breaches of privacy. See Ontario Hospital Association, Ontario Hospital eHealth Council, Ontario Medical Association, Office of the Information and Privacy Commissioner/Ontario, *Hospital Privacy Toolkit: Guide to the Ontario Provincial Personal Health Information Protection Act* (September 2004) at 282. See also Lydia Wakulowsky, *Personal Health Information Protection Act: Implementing Best Privacy Practices (2nd ed.)* (Markham: LexisNexis, 2011) at pp. 115-137, discussing the implementation of 'best practices.'

[15] See CD.1.2K: Letter from Alan B. Douglass to Anne Duffy, Paul Grof and Martin Alda (March 24, 2005) at para 2: "I first learned that the removals had taken place when I was informed of the situation by members of the ROHCG administration at 17:00h Tuesday 22-Mar-2005."; CD.1.3: Affidavit of Paul Grof (April 11, 2005) at para 21: "Overnight on 22 March 2005, our research records and the clinical records of my former patients at the Hospital … as well as my personal records and the personal records of Dr. Duffy, we seized without notice or warning" and CD.1.2: Affidavit of Anne Duffy (April 2, 2005) at para 31; CD.1.5: Affidavit of Zul Merali at paras 22-28 and AD.2: Cross-Examination of Sharyn Szick (January 24, 2008) at paras 33-40 and 70-73. There was a meeting between at approximately 2:30pm on March 22, 2005 between Sharon Purvis, Keith Busby, Sue Crozier, Carolyn Belzile and Sharyn Szick where it was suggested that immediate action was necessary to secure the clinical health records. Immediately after the meeting, authorization was obtained to secure the clinical health records and then the meeting attendees proceeded with the seizure. Once the clinical records were relocated, the research records were also seized following a "spot audit" by Dr. Busby.

[16] CD.1.2D: Seizure Notice.

[17] CD.1.2D: Seizure Notice.

[18] CD.1.2G: Memorandum from Sharyn Szick to Anne Duffy (March 23, 2005*). *The memo is dated March 23, 2004 but this appears to be an error. This date of the Memorandum is likely to be March 23, 2005. See CD.1.3B: Letter from Paul Grof to Sharyn Szick (April 5, 2005) in which Dr. Grof states that he "recently" received the Memorandum regarding the removal of personal files from Dr. Duffy's office and chart room.

[19] CD.1.2: Affidavit of Anne Duffy (April 2, 2005) at para 4.

[20] CD.1.2: Affidavit of Anne Duffy (April 2, 2005) at para 11 and CD.1.3: Affidavit of Paul Grof (April 11, 2005) at para 5.

[21] CD.1.2D: Seizure Notice; CD.1.3: Affidavit of Paul Grof (April 11, 2005) at para 21; and CD.1.2G: Memorandum from Sharyn Szick to Dr. Anne Duffy (March 23, 2005*).

[22] CD.1.2: Affidavit of Anne Duffy (April 2, 2005) at para 32; CD.1.3: Affidavit of Paul Grof (April 11, 2005) at para 23; and CD.1.4I: Letter from Paul Grof and Anne Duffy to Burleigh Trevor-Deutsch and H. Alper (March 29, 2005) at para 1.

[23] See CD.1.2: Affidavit of Anne Duffy (April 2, 2005) at para 49 (d).

[24] CD.1.2F: Letter from Paul Dagg to Anne Duffy (March 23, 2005).

[25] CD.1.2H: Letter from Paul Dagg to Dr. A. Duffy (March 24, 2005).

[26] CD.1.4B: Letter from Paul Dagg to Duffy (April 13, 2005). "He and I agree that we do not find evidence that in fact this occurred, or that there was a breach of confidentiality with respect to the clinical record. […] We do of course take seriously the issue of security of patient files, given the confidential information contained therein, but I wish to apologize for the inconvenience this action caused you and thank you for your full co-operation in my investigation."

[27] AD.4: E-mail from Paul Dagg to Anne Duffy (March 23, 2005).

[28] CD.1.2G: Memorandum from Sharyn Szick to Anne Duffy (March 23, 2005*).

[29] CD.1.2K: Letter from Alan B. Douglass to Anne Duffy, Paul Grof and Martin Alda (March 24, 2005) at paras 2-4: "I first learned that the removals had taken place when I was informed of the situation by members of the ROHCG administration at 17:00h Tuesday 22-March-2005… No complaints about any of your projects were received by REB prior to this action taking place. The REB has not met to discuss this situation. As the Chair, I have taken no action regarding this matter."

[30] CD.1.2J: Letter from Zul Merali to Anne Duffy (March 31, 2005).

[31] CD.1.2E: Letter from Anne Duffy to Paul Dagg, Zul Merali and Alan B. Douglass (March 23, 2005) at para 3: "Our ability to complete our daily work and to apply for competitive grants is prevented and our productivity compromised in the current situation."

[32] CD.1.2: Affidavit of Anne Duffy (April 2, 2005) at para 21: "In obtaining [consent] we undertake to keep all of the information provided to us confidential…" and at para 49: "(a) I am now in breach of the undertakings which I have given to research subjects to maintain the confidentiality of the information they have provided me, and to disclose it only to members of the research team".

[33] CD.1: Amended Notice of Application (April 28, 2005).

[34] E-mail from Anne Duffy to Daielle Lithwick, Jane Hampson, Leah Crawford, Monique Cook, and Tammy Kraushaar (May 20, 2005).

[35] CD.1.4I: Letter from Paul Grof and Anne Duffy to Burleigh Trevor-Deutsch and H. Alper (March 29, 2005)

[36] CD.1.2O: Letter from Nicholas D.C. Holland to Zul Merali (IMHR), and Drs. Paul Dagg and J. Bradwejn, and B. Swan (ROH) (March 24, 2005).

[37] CD.1.2O: Letter from Nicholas D.C. Holland to Zul Merali (IMHR), Paul Dagg, Jacques Bradwejn and Bruce Swan (ROH) (March 24, 2005).

[38] See CD.1.11: Reply Affidavit of Zul Merali (October 3, 2005) at paras 8-15; CD.1.7: Affidavit of Howard Alper (June 30, 2005) at para 17: "[T]he research records are owned by the IMHR." and CD.1.3C: Memo from Sharyn Szick to Paul Grof dated April 8, 2005, "Please be mindful that research files, including research documentation and material products of all research, carried out by a member of a University of Ottawa affiliated hospital research institute, are the property of the institute." See also CD.1.11 at para. 17: "Furthermore, the IMHR is accountable to the research participants enrolling in studies conducted under its auspices. Confidential information, including genetic samples, is collected from these research participants and the IMHR is equally accountable to these individuals to ensure that research is conducted in accordance with applicable standards."

[39] See CD.1.11: Reply Affidavit of Zul Merali (October 3, 2005) at para. 5.

[40] See CD.1.5L: Graduate and Post-doctoral Studies – Research and Thesis (*Ethics Booklet*) at section 3.2 (print-out of 04-01-2005 of webpage: http://www.grad.uottawa.ca/regulations/thesis_research/ethical_booklet.htm, reproduced in Court Documents).

[41] Ibid. One IMHR employee used the 'property argument' without explicitly involving this policy. See CD.1.3C: Memo from Sharyn Szick to Paul Grof dated April 8, 2005, "Please be mindful that research files, including research documentation and material products of all research, carried out by a member of a University of Ottawa affiliated hospital research institute, are the property of the institute."

[42] CD.1.10: Reply Affidavit of Anne Duffy (September 14, 2005) at para 30-31. However, see CD.1.11

[43] Reply Affidavit of Zul Merali (October 3, 2005) at para 13-15. See CD.1.11A: Ottawa Health Research Institute, "Technology Transfer/Intellectual Property Policy" (June 28, 2001) at s.5.1.2 "Research Data: Unless a contractual obligation to a sponsor contains special provisions to the contrary, all Research Data produced during the conduct of research carried out by an Employee are the property of the Institute and/or hospital. All such research data shall remain with the Institute and/or hospital upon departure of the Employee from the Institute and/or hospital. The Institute and/or hospital may, at its discretion, allow research data to remain with an employee

who movies to another institution, and in the case of its scientific staff, such permission will not be withheld without valid reason." However, see CD.1.2: Affidavit of Anne Duffy (April 2, 2005) at para 15 where Dr. Duffy states "I am not an employee of the Royal Ottawa Hospital, the University of Ottawa or the IMHR. I am regarded as a self-employed individual." Since the OHRI policy refers to research conducted by employees, it is unclear whether the OHRI policy can be comparable to the current situation.

[44] CD.1.4C: Two Letters from Borden Ladner Gervais to WeirFoulds: Terms of Adjournment (April 13, 2005).

[45] CD.1.4D: Endorsement of the Settlement by Justice Manton (April 15, 2005). See also CD.1.4: Supplementary Affidavit of Anne Duffy (April 28 2005) at para 11.

[46] CD.1.4: Supplementary Affidavit of Anne Duffy (April 28 2005) at para 14; CD.1.5: Affidavit of Dr. Zul Merali (June 17, 2005) at para 44.

[47] See CD.1.4: Supplementary Affidavit of Anne Duffy (April 28, 2005) at paras 14 "i. that our research files will be copied immediately, and the originals returned to us" and para 20. See also CD.1.5: Affidavit of Dr. Zul Merali (June 17, 2005) at para 44, "(i) the IMHR would copy the research records…". However, the actual photocopying of the records was carried out by the ROHCG Materials Management staff and IMHR personnel. See CD.1.4F: Letter from Alan B. Douglass to Zul Merali (April 21, 2005) at Resolution 3 and see AD.2: Cross-Examination of Sharyn Szick (January 24, 2008) at paras 114-167.

[48] Prof. Timothy Caulfield and Dr. Padraig Darby were identified as possible reviewers. See CD.1.5: Affidavit of Zul Merali (June 17, 2005) at para 47.

[49] Dr. Duffy received on April 22, 2005 the letter from Dr. Douglass through which she learned that, "the Respondent IMHR had in fact reviewed the research files." See CD.1.4: Supplementary Affidavit of Anne Duffy (April 28, 2005) at para 22-24. However, the letter from Dr. Douglass itself does not directly state that Dr. Busby conducted the spot audits. Dr. Duffy received the letter from Dr. Merali on April 25, 2005 which does name Dr. Busby as the one who reviewed the research records. See CD.1.4 Supplementary Affidavit of Anne Duffy (April 28, 2005) at para 23.

[50] CD.1.4: Supplementary Affidavit of Anne Duffy (April 28, 2005) at paras 8-9 and 24, "…contrary to the assurances that I, and my solicitors, had been given earlier, the Respondent IMHR had in fact reviewed the research files." See however CD.1.5: Affidavit of Zul Merali (June 17, 2005) at para 43: "… since the relocation of the records, no one from IMHR had read, reviewed or copied the records… Dr. Busby, whom I assumed at the time had been acting in his capacity with the REB, had performed the spot audit of consent documentation prior to the relocation" [*emphasis in original*].

[51] See CD.1.4H: Sample Letter from Anne Duffy to research subjects (April 25, 2005) explaining breach of confidentiality.

[52] C.23: Letter Robert B. Warren (counsel for Dr. Duffy and Dr. Grof) to Bryan A. Carroll and Gregory P. Kelly (Counsels for the Institutions) (May 5, 2005): "… I would have thought that the expressions of outraged anger from research subjects, directed to your clients, and to the REB, would have persuaded someone to take the appropriate actions." In one of the interviews conducted by the Chair of the Committee with research subjects, one research subject declared he/she complained to the Institutions but did not receive any response.

[53] C.24: Letter from Robert B. Warren to Anne Cavoukian (May 20, 2005).

[54] CD: 1.5S: Email from Sharyn Szick to Susan Crozier (May 20, 2005)

[55] *Ibid.* Allegedly "very aggressively", which was denied by Dr. Duffy. See on this also CD.1.5U: Letter from Pierre Blier to Anne Duffy (June 10, 2005); and response by Dr. Duffy: CD.1.5T: Letter from Anne Duffy to Zul Merali (May 30, 2005)

[56] C.24: Letter from Robert B. Warren to Anne Cavoukian (May 20, 2005).

[57] AD.6: E-mail to Bipolar Research Team from Dr. Duffy (May 20, 2005).

[58] The Committee noted the procedure followed by the IPC, which upon receiving a complaint about a violation of privacy through institutional action invited the institutional players involved in the alleged violation to lead the investigation. It is worth noting that PHIPA had entered into force only briefly prior to the events which are the subject of this Inquiry.

[59] AD.7: CAUT Letter Regarding Committee Formation and Mandate (May 24, 2005).

[60] AD.8: Ottawa U Faces Inquiry Over Research Seizure, CAUT Bulletin, Vol 52, No 6, June 2005.

[61] AD.9: Letter from Debbie Orth to James L. Turk (May 19, 2005).

[62] AD.10: Letter from Gregory P. Kelly to James L. Turk (May 26, 2005).

[63] AD.11: Letter from James L. Turk to Debbie Orth (June 3, 2005).

[64] See AD.12: ROHCG and IMHR webpages Supporting Documents, Call for an Independent Inquiry into the Governance of the IMHR, "As a specialty teaching hospital affiliated with the University of Ottawa... In partnership with… the [IMHR], University of Ottawa… planning and funding agencies, and recognize UOIMHR as the entity responsible for the coordination of ROHCG's research conducted on the premises of ROHCG."

[65] See, for example, CD.1.5C: Letter from Jacques Bradwejn to Anne Duffy (May 28, 2001): Dr. Duffy held positions in the Department of Psychiatry of the University of Ottawa, and in the IMHR and the Mood Disorders Program and the Youth Program of ROH. See also CD.1.2F: Letter from Paul Dagg to A. Duffy (March 23, 2005): Dr. Dagg was the Director of Clinical

Services at the ROH, an Associate Professor of Psychiatry and the Vice-Chair of the Department of Psychiatry at the University of Ottawa during the time of the seizure.

[66] See C.38: Paul Grof, "Brief summary of background" (June 3, 2005) at p.4.

[67] See CD.1.2K: Letter from Alan B. Douglass to Anne Duffy, Paul Grof and Martin Alda (March 24, 2005) at paras 1 and 5. See also AD.5: Cross-Examination of Zul Merali (January 24, 2008) at paras 72-74.

[68] See CD.1.2K: Letter from Alan B. Douglass to Anne Duffy, Paul Grof and Martin Alda (March 24, 2005) at para 1.

[69] See CD.1.8: Affidavit of Keith Busby (June 17, 2005) at para 4.

[70] See CD.1.2K : Letter from Alan B. Douglass to Anne Duffy, Paul Grof and Martin Alda (March 24, 2005).

[71] CD.1.2: Affidavit of Anne Duffy (April 2, 2005) at para 4.

[72] See AD.2: Cross-Examination of Sharyn Szick (January 24, 2008) at para 354; and CD.1.9A: Response to the IPC (May 27, 2005), Question 15 at 'Page 17 of 27' para 2.

[73] See IMHR Researchers - Jean-Claude Pierre Léon Bisserbe. Available online: University of Ottawa Institute of Mental Health Research http://www.imhr.ca/research/researchers-jc-bisserbe-e.cfm .

[74] See IMHR Researchers - Pierre Blier. Available online: University of Ottawa Institute of Mental Health Research <http://www.imhr.ca/research/researchers-pierre-blier-e.cfm>.

[75] CD.2.14: Affidavit of Jacques Bradwejn (August 27, 2007) at para 2.

[76] CD.1.8: Affidavit of Keith Busby (June 17, 2005) at para 1.

[77] CD.1.8: Affidavit of Keith Busby (June 17, 2005) at para 8 and CD.1.5: Affidavit of Zul Merali (June 17, 2005) at para 21.

[78] See CD.1.2F: Letter from Paul Dagg to Anne Duffy (March 23, 2005).

[79] See: CD.2.11: Affidavit of Alan B. Douglass (March 9, 2007) at para 2; CD.1.2K: Letter from Alan B. Douglass to Anne Duffy, Paul Grof and Martin Alda (March 24, 2005) at para 1.; and see *IMHR Researchers* – Alan B. Douglass. Available online: University of Ottawa Institute for Mental Health Research <http://www.imhr.ca/research/researchers-alan-douglas-e.cfm>

[80] CD.1.2: Affidavit of Anne Duffy (April 2, 2005) at paras 2 & 17-19. See also CD.1.5C: Correspondence from Jacques Bradwejn to Anne Duffy (May 28, 2001).

[81] See: CD.1.3: Affidavit of Paul Grof (April 11, 2005) at paras 2-5 and AD.13: Cross-examination of Paul Grof on an Affidavit sworn September 13th, 2007 (December 19, 2007) at para 76.

[82] See: CD.1.5: Affidavit of Zul Merali (June 17, 2005) at para 1 http://www.imhr.ca/research/researchers-alan-douglas-e.cfm and *IMHR Researchers – Zul Merali*. Available online: University of Ottawa Institute for Mental Health Research <http://www.imhr.ca/research/researchers-zul-merali-e.cfm>

[83] CD.1.9: Affidavit of Sharon Purvis (June 16, 2005) at para 1.

[84] CD.1.5: Affidavit of Zul Merali (June 17, 2005) at para 23.

[85] CD.1.2G: Memorandum from Sharyn Szick to Anne Duffy (March 23, 2005).

[86] AD.2: Cross-Examination of Sharyn Szick (January 24, 2008) at paras 35-36.

[87] AD.14: Padraig L. Darby, *Report for Research Ethics Board Royal Ottawa Hospital (ROH-REB) on Complaint from Dr. Z. Merali Concerning Drs. A. Duffy and P. Grof* (not dated) [hereafter *The Darby Report*]. Study titles investigated by Dr. Darby: 1) A Study of Personality and Temperament in Youth at Genetic Risk for Bipolar Disorder: The Impact of Illness Onset and Clinical Course (REB 2003-15); 2) A Longitudinal Study of the Children of Bipolar Parents (REBL 2003-14); 3) The Genetics of Bipolar Disorder 1 (No REB #); 4) Cortisol Dysregulation as a Potential Risk Factor in Offspring of Bipolar Parents (REB 2002-27) 5) Quetiapine Maintenance Treatment in Early Onset Bipolar Spectrum Disorders: An open prospective longitudinal study of the effectiveness of quetiapine monotherapy in preventing relapse and minimizing neurocognitive dysfunction among adolescents manifesting bipolar spectrum disorders (REB 3003-1-38); 6) Longitudinal Prospective Study of Adolescent Offspring of Bipolar Parents (REB 1995-13)

[88] CD.1.2: Affidavit of Anne Duffy (April 2, 2005) at para 21. See also, CD.1.2A: The Nova Scotia Hospital Informed Consent Form (version: October 7, 2002).

[89] See CD.1.4O: Agreement between AstraZeneca and the IMHR (December 2, 2003) STUDY TITLE: *Quetiapine maintenance treatment in early onset bipolar spectrum disorders: An open prospective longitudinal study of the effectiveness of quetiapine monotherapy in preventing relapse and minimizing neurocognitive dysfunction among adolescents manifesting bipolar spectrum disorders*. See CD.1.5D: Various Funding Agreements signed by Drs. Duffy and/or Grof (various dates) at pp. 33 & 74.

[90] See C.15: Letter from Karen D. Clement, Coordinator, Protocol Review, Institutional Review Board Services, to Anne Duffy, August 5, 2005.

[91] C.16: Letter from Constanze Schweikert to Anne Duffy (June 11, 2007): "During these monitoring visits I explicitly documented the presence of these [informed consent] forms as a part of my routine review of the files."

[92] See. CD.1.2 Affidavit of Anne Duffy (April 2, 2005) at para 4-5. See also para 25 and 34. See also, CD.1.3: Affidavit of Paul Grof (April 11, 2005) at paras 5 and 15 and C.44 at p2.

[93] CD.1.3: Affidavit of Paul Grof (April 11, 2005) at para 5. See also CD.1.2: Affidavit of Anne Duffy (April 2, 2005) at para 11.

[94] CD.1.3: Affidavit of Paul Grof (April 11, 2005) at paras 5 & 15.

[95] C.44: Paul Grof, "A brief historical background of our initial studies" (September 1, 2007); CD.1.3: Affidavit of Paul Grof (April 11, 2005) at paras 5 & 15.

[96] C.44: A brief historical background of our initial studies (Paul Grof, September 1, 2007); CD.1.3: Affidavit of Paul Grof (April 11, 2005) at paras 5 & 14. See also CD.1.2: Affidavit of Anne Duffy (April 2, 2005) at paras 4-11.

[97] CD.1.2: Affidavit of Anne Duffy (April 2, 2005) at para 11: "Dr. Grof began conducting research on these issues in 1968 and we have compiled information from over 2,000 research subjects."

[98] See CD.1.5D: Various Funding Agreements signed by Drs. Duffy and/or Grof (various dates) at p 30. See also CD.1.2: Affidavit of Anne Duffy (April 2, 2005) at paras 23-25.

[99] CD.1.5D: Various Funding Agreements signed by Drs. Duffy and/or Grof at p. 100: *A Prospective Study of Neurocognitive Functioning among Adolescents at High Risk for Bipolar Disorder* and at p 102.

[100] CD.1.5D: Various Funding Agreements signed by Anne Duffy and/or Paul Grof at p 90: *A Longitudinal Study of the Children of Bipolar Parents* and at p 93.

[101] CD.1.5D: p 102. See also C.40.

[102] CD.1.5: Affidavit of Zul Merali (June 17, 2005) para 17-20.

[103] CD.1.5G: Summary of statement of former research coordinator, as summarized by Sharyn Szick (June 17, 2005). Note that this summary was written in the context of later court proceedings and contains other allegations about irregularities. The research coordinator conveyed the information to Ms. Szick in early March (see Affidavit Zul Merali at para 17), while the statement is dated June 17, 2005. See also CD.1.5: Affidavit of Zul Merali (June 17, 2005) at para 18 and AD.2: Cross-Examination of Sharyn Szick (January 24 ,2008) at paras 272-76.

[104] CD.1.5: Affidavit of Zul Merali (June 17, 2005) para 21.

[105] *Supra* note 86 – "CD.1.9: Affidavit of Sharon Purvis (June 16, 2005) at para 1."

[106] CD.1.5: Affidavit of Zul Merali (June 17, 2005) at para 22.

[107] CD.1.5: Affidavit of Zul Merali (June 17, 2005) at para 22.

[108] See CD.1.6: Affidavit Paul K.B. Dagg (June 17, 2005) at paras 1-2 and CD.1.5: Affidavit of Zul Merali (June 17. 2005) at para 23. Also AD.15: Trudo Lemmens telephone interview with Paul Dagg (March 7. 2008) at p 1.

[109] CD.1.6: Affidavit Paul K.B. Dagg (June 17, 2005) at para 2.

[110] CD.1.6: Affidavit Paul K.B. Dagg (June 17, 2005) at para 2.

[111] CD.1.6: Affidavit Paul K.B. Dagg (June 17, 2005) at para 3.

[112] CD.1.8: Affidavit of Keith Busby (June 17, 2005) at paras 9 and 12.

[113] See CD.1.2F: Letter from Paul Dagg to A. Duffy (March 23, 2005); CD.1.2H: Letter from Paul Dagg to Anne Duffy (March 24, 2005); CD.1.2I: E-mail from Paul Dagg to Anne Duffy (March 28, 2005); CD.1.4A: Letter from the Royal Ottawa Hospital to Anne Duffy and Paul Grof "dated April 19, 2005" (actual date: April 12, 2005); and CD.1.4B: Letter from the Royal Ottawa Hospital to Anne Duffy (April 13, 2005).

[114] CD.1.8: Affidavit of Keith Busby (June 17, 2005) at para 13. Note the conflicting information: See CD.1.4G: The letter by Zul Merali: "…I instructed the IMHR representatives, including Dr. Keith Busby who is a REB administrator, to perform a spot audit..." This information appears contradicted in the affidavits of Dr. Merali and Dr. Busby. See CD.1.5: Affidavit of Zul Merali (June 17 2005) at para 26, "Once the clinical records had been relocated, Dr. Busby performed a brief spot audit of approximately 20 research binders…At the time, I assumed that Dr. Busby was acting in his capacity with the REB." and CD.1.8: Affidavit of Keith Busby (June 17, 2005) at para 16: "I was not asked by Dr. Merali or Dr. Douglass to perform this spot audit."

[115] CD.1.8: Affidavit of Keith Busby (June 17, 2005) at para 15: "approximately 5 binders did not have the appropriate consent form located behind the Tab marked 'consent'".

[116] CD.1.2K: Letter from Alan B. Douglass to Anne Duffy, Paul Grof and Martin Alda (March, 24 2005).

[117] C.40: Anne Duffy, "Summary of the events of the seizure" (July 28, 2005) at pp 1 & 4-5. See also CD.1.2: Affidavit of Anne Duffy (April 2, 2005) at para 12.

[118] See CD.1.2: Affidavit of Anne Duffy (April 2, 2005) at paras 4-6, 9-11, 22-25, 31 & 47-48. See also C.40: Anne Duffy, "Summary of the events of the seizure" (July 28, 2005) at p 5.

[119] C.40: Anne Duffy, "Summary of the events of the seizure" (July 28, 2005). See also C.44: Anne Duffy, "A detailed historical background of the studies of offspring of bipolar parents" (September 14, 2007).

[120] C.44: Anne Duffy, "A detailed historical background of the studies of offspring of bipolar parents" (September 14, 2007).

[121] *Ibid*. See also C.40: Anne Duffy, "Summary of the events of the seizure" (July 28, 2005) at p 5 para 2: "We… recently completed an internal check that all documentation was in order and present including re-executing any missing contents not on file for whatever reason."

[122] C.44: Anne Duffy, "A detailed historical background of the studies of offspring of bipolar parents" (September 14, 2007).

[123] *Ibid*.

[124] See for example AD.16: Letter from Alan B. Douglass to Trudo Lemmens (July 25, 2005): "As you know, this matter is currently before the Courts. I therefore sought legal advice about your request from Mr. Greg Kelly, who is Counsel for the ROHCG. … His advice is that I should not appear before any parallel inquiry, but rather allow the matter to be resolved in Court."

[125] See *supra* note 58 ("Ottawa U Faces Inquiry Over Research Seizure, CAUT Bulletin, Vol 52 | No 6 | June, 2005)"

[126] CD.2.1: Minutes of Settlement (October 19, 2005).

[127] CD.2.1: Minutes of Settlement (October 19, 2005).

[128] See for example, AD.17: Letter from Trudo Lemmens to Bruce Swan (November 8, 2005). "I am following up on our invitation of July 6, 2005 to meet with the Committee of Inquiry … We have been informed that the parties involved have recently settled their dispute and are therefore confident that you will be able to meet with us. Indeed, there should no longer be a concern that our investigation overlaps or interferes with ongoing litigation."

[129] CD.2.1: Minutes of Settlement (October 19, 2005) at para 5.

[130] AD.18: Letter from Zul Merali to James L. Turk (May 17, 2011).

[131] CD.1.2K: Letter from Alan B. Douglass to Anne Duffy, Paul Grof and Martin Alda (March 24, 2005) and CD.2.11: Affidavit of Dr. Alan B. Douglass (March 9, 2007) at para 5.

[132] *Ibid.* at paras 8 and 13-15.

[133] *Ibid.*

[134] CD.1.2M: E-mail from Anne Duffy to Alan Douglass (March 31, 2005). See also the first Tri-Council Policy Statement, *Ethical Conduct for Research Involving Humans* (with up- dates of May 2002 and September 2002) (Ottawa: Tri-Council, 1998) (hereafter TCPS1) at Article 1.13. The text on continuing review of the TCPS1 at that time was: "Beyond scrutinizing reports,

the REB itself should not normally carry out the continuing ethics review, except in specific cases where the REB believes that it is best suited to intervene. For research posing significant risks, the REB should receive reports on the progress of the research project at intervals to be predetermined. These reports should include an assessment of how closely the researcher and the research team have complied with the ethical safeguards initially proposed. In accordance with the principle of proportionate review, research that exposes subjects to minimal risk or less requires only a minimal review process. The continuing review of research exceeding the threshold of minimal risk that is referred to in Article 1.13 (b), in addition to annual review (Article 1.13 (c)) might include:

- formal review of the free and informed consent process,
- establishment of a safety monitoring committee,
- periodic review by a third party of the documents generated by the study,
- review of reports of adverse events,
- review of patients' charts, or
- a random audit of the free and informed consent process.

Other models of a continuing ethics review may be designed by researchers and REBs to fit particular circumstances.

The process of a continuing ethics review should be understood as a collective responsibility, to be carried out with a common interest in maintaining the highest ethical and scientific standards. Research institutions should strive to educate researchers on the process of a continuing ethics review through workshops, seminars and other educational opportunities."

[135] CD.1.4F: Letter from Alan B. Douglass to Zul Merali (April 21, 2005).

[136] CD.1.4F: Letter from Alan B. Douglass to Zul Merali (April 21 2005) at Resolution 1.

[137] CD.1.4F: Letter from Alan B. Douglass to Zul Merali (April 21, 2005) at Resolution 4.

[138] CD.1.4F: Letter from Alan B. Douglass to Zul Merali (April 21, 2005) at Resolution 1.

[139] CD.1.4F: Letter from Alan B. Douglass to Zul Merali (April 21, 2005) at Resolutions 2 & 3. For the terms of the agreement surrounding photocopying, see CD.1.4: Supplementary Affidavit of Anne Duffy (April 28, 2005) at paras 14 "i. that our research files will be copied immediately, and the originals returned to us" and para 20. See also CD.1.5: Affidavit of Dr. Zul Merali (June 17, 2005) at para 44, "(i) the IMHR would copy the research records…" However, the actual photocopying of the records was carried out by the ROHCG Materials Management staff and IMHR personnel. See AD.2: Cross-Examination of Sharyn Szick (January 24, 2008) at paras 114-167. ROHCG Materials Management staff George Carvahlo photocopied at night. Heidi Vulin, ROHCG REB part-time clerical staff photocopied as well and checked that the copies corresponded to the originals. Sharyn Szick and her assistant Adele Mayhew were also involved in copying/checking for accuracy.

[140] CD.1.4 F: Letter from Alan B. Douglass to Zul Merali (April 21, 2005) at Resolution 5.

[141] See CD.2.7: Minutes of the special *in-camera* meeting of REB (November 21, 2006) to review the Darby Report; see also CD.2.9: Affidavit of Anne Duffy (December 7, 2006) at para 11.

[142] CD.2.1: Minutes of Settlement (October 19, 2005)

[143] CD.2.7: Minutes of the special *in-camera* meeting of REB (November 21, 2006) to review the Darby Report; see also CD.2.9: Affidavit of Anne Duffy (December 7, 2006) at para 11.

[144] CD.2.9: Affidavit of Anne Duffy (December 7, 2006) at para 13; CD.2.3: Preliminary Brief of Anne Duffy and Paul Grof to Patrick Darby (January 17, 2006); and CD.2.5: Letter from Robert B. Warren to Gregory P. Kelly (February 6, 2006).

[145] CD.2.6: Letter from Anne Duffy and Paul Grof to Padraig Darby (February 20, 2006). See also CD.2.3: Preliminary Brief of Drs. Anne Duffy and Paul Grof to Patrick Darby (January 17, 2006) at p 16.

[146] See CD.2.6: Letter from Anne Duffy and Paul Grof to Padraig Darby (February 20, 2006) at point 6.

[147] CD.2.6: Letter from Anne Duffy and Paul Grof to Padraig Darby (February 20, 2006).

[148] CD.2.3: Preliminary Brief of Anne Duffy and Paul Grof to Patrick Darby (January 17, 2006).

[149] CD.2.11: Affidavit of Alan B. Douglass (March 9, 2007) at para 24-25.

[150] CD.2.4: Letter to Robert B. Warren from Gregory P. Kelly (February 2, 2006).

[151] CD.2.5: Letter to Gregory P. Kelly from Robert B. Warren (February 6, 2006).

[152] CD.2.9: Affidavit of Anne Duffy (December 7, 2006) at para 17.

[153] See CD.2.7: Minutes of the special *in-camera* meeting of REB (November 21, 2006). (the *Darby Report*).

[154] AD.14: *The Darby Report* at p5.; CD.2.7: Minutes of the special *in-camera* meeting of REB (November 21, 2006) to review the Darby Report at resolution 2.

[155] CD.2.7: Minutes of the special *in-camera* meeting of REB (November 21, 2006) to review the *Darby Report* at resolution 1.

[156] CD.2.7: Minutes of the special *in-camera* meeting of REB (November 21, 2006) to review the *Darby Report* at resolution 2.

[157] CD.2.17: Further Reply Affidavit of Anne Duffy (December 7, 2007) at para 15. "Dr. Darby placed great weight on the sheer number of research files from which he claimed copies of

written evidence of consent were missing, and for which he assumed that Dr. Grof and I were responsible for obtaining written evidence of consent. In fact, the number of research files in that category is not the seventy-seven (77) which Dr. Darby claimed, but rather thirty (30)."

[158] CD.2.17: Further Reply Affidavit of Anne Duffy (December 7, 2007) at para 12.

[159] CD.2.17: Further Reply Affidavit of Anne Duffy (December 7, 2007) at para 3 and 15. Drs. Duffy and Grof state that only 30 of files for which they were responsible lacked documented consent out of the 252 files reviewed by Dr. Darby.

[160] CD.2.15: Affidavit of Anne Duffy (September 12, 2007) at para 54; and CD.2.17: Further Reply Affidavit of Anne Duffy (December 7, 2007) at para 14.

[161] CD.1.10: Reply Affidavit of Anne Duffy (September 14, 2005) at para 48

[162] CD.1.10: Reply Affidavit of Anne Duffy (September 14, 2005) at para 78.

[163] CD.2.9: Affidavit of Anne Duffy (December 7, 2006) at para 33.

[164] Order dated 4/12/2008 in *Anne Duffy and Paul Grof v. The Royal Ottawa Hospital, The University of Ottawa, the University of Ottawa Institute of Mental Health Research, Zul Merali, Jacques Bradweijn, and Alan Douglass*, Ontario Superior Court, Court File 06-CV-36883)

[165] *Ibid*., in particular comment in handwritten endorsement McNamara J.

[166] See AD.19: Letter from Trudo Lemmens to James Turk (January 27, 2011). AD.20: "Interim Statement CAUT Committee of Inquiry Regarding Allegations of Lack of Informed Consent in Research Conducted by Dr. Anne Duffy and Dr. Paul Grof" [January 19, 2010].

[167] AD.18: Letter from Zul Merali to James L. Turk (May 17, 2011) at para 2.

[168] AD.18: Letter from Zul Merali to James L. Turk (May 17, 2011) at para 3.

[169] AD.18: Letter from Zul Merali to James L. Turk (May 17, 2011) at para 3.

[170] AD.21: Cross-Examination of Jacques Bradwejn (February 4, 2008) at paras 171-72 and 173-74 (our emphasis).

[171] The policies, procedures, and documents the Committee consulted include Canadian policies such as: Sunnybrook Health Sciences Centre, "Internal Quality Assurance Audits" (2012) (available online at: http://sunnybrook.ca/uploads/121201_REB-SOP-IX-01-001.pdf); The Capital District Health Authority of Nova Scotia, *Audit Manual for Research Ethics Boards* (2011) (available online at www.cdha.nshealth.ca/system/files/sites/.../research-audit-manual.doc); The Ontario Cancer Research Ethics Board, "Quality Assurance Policy of the Standard Operating Policies and Procedures"; IWK Health Centre, "Research Ethics Auditing Committee Standard Operating Procedures" (2008), available online at

(http://www.iwk.nshealth.ca/index.cfm?objectid=0CF94578-D52C-A4DC-CF225EEA17CE0382); as well as some international policies, including: Johns Hopkins University, Faculty of Medicine, Office of Human Subjects Research--Institutional Review Boards, Compliance Monitoring Program (available online at http://www.hopkinsmedicine.org/institutional_review_board/about/compliance_monitoring/); Harvard Medical School, Harvard School of Dental Medicine, Committee on Human Studies, "Post-Study Approval Monitoring Program (P-StAMP)" (available online at: http://www.hms.harvard.edu/orsp/human/Documents-IRB/P-StAMP_Procedures_Manual_10-10-07.pdf); University of Virginia, Institutional Review Board for Health Sciences Research, "Post Approval Monitoring" (available online at: http://www.virginia.edu/vpr/irb/hsr/pam.html); Michigan State University, Human Research Protection Program, "MSU Human Research Protection Manual" (2009) (available online at: http://www.humanresearch.msu.edu/hrpmanual.html); Medical College of Wisconsin, Human Research Protection Program, "Quality Improvement Program" (available online at: http://www.mcw.edu/hrpp/QualityImprovementProgram.htm); University of Miami, "Audits" (available online at: http://uresearch.miami.edu/?p=172). It is worth noting that many Canadian institutions do not appear to have detailed audit or research ethics compliance procedures.

[172] See e.g. The Capital District Health Authority of Nova Scotia, *Audit Manual for Research Ethics Boards* (2011) (available online at www.cdha.nshealth.ca/system/files/sites/.../research-audit-manual.doc) at p. 4.

[173] See e.g. *ibid.*

[174] CD.1.5 Affidavit of Zul Merali (June 17, 2005) at paras 17-18.

[175] See: CD.1.5 Affidavit of Zul Merali (June 17, 2005) at paras 17, 20 and 26; AD.2: Cross-Examination of Sharyn Szick (January 24, 2008) at paras 33-34.

[176] CD.1.5 Affidavit of Zul Merali (June 17, 2005) at para 20; CD.1.8: Affidavit of Keith Busby (June 17, 2005) at para 7. CD.1.2K: Letter from Alan B. Douglass to Anne Duffy, Paul Grof and Martin Alda (March 24, 2005): "I first learned that the removals had taken place when I was informed of the situation by members of the ROHCG administration at 17:00h Tuesday 22-March-2005…"

[177] CD.1.4G: Letter from Zul Merali to Alan B. Douglass (April 6, 2005): "(i) In mid-March 2005, the IMHR receive concerns about proper process and documentation of informed patient consent for research participation… (iv) At the same time, and based on concerns raised (see (i) above), I instructed the IMHR representatives, including Dr. Keith Busby who is a REB administrator, to perform a spot audit on the research files to investigate the alleged informed consent concerns…In some files, the consent documentation appeared to be inconsistent with the steps actually being taken by the researchers. This prompted the decision to secure the research files for further review."

[178] AD.3: Conversation with Dr. Duffy (March 6, 2006) at pp 46-49. CD.1.10F: Email and Attachment from Patricia Clooney (March 23, 2005); and CD.1.15: Affidavit of Monique Cooke (September 12, 2005) at para 3.

[179] AD.5: Cross-Examination of Zul Merali (January 24, 2008) at para 122-123.

[180] C.54: Call for an Independent Inquiry into the Governance of IMHR Briefing Note at para 1.

[181] CD.1.5Y: Review of the Institute of Mental Health Research's Financial Management (Deloitte & Touche, May 12, 2005) at p 2 para 5. C.53: Call for an Independent Inquiry into the Governance of IMHR Backgrounder at p 2.

[182] CD.1.5Z: Review of the University of Ottawa Institute of Mental Health Research at p 3.

[183] This is confirmed in testimony and correspondence the Committee received, including from people not directly involved in the events.

[184] See AD.24: Review of the University of Ottawa, Department of Psychiatry (October 27-29, 2002).

[185] AD.24: Review of the University of Ottawa, Department of Psychiatry (October 27-29, 2002).

[186] *About the IMHR*. Available online: University of Ottawa Institute for Mental Health Research http://www.imhr.ca/about/index-e.cfm.

[187] AD.3: Conversation with Dr. Duffy (March 6, 2006) at p 18.

[188] C.38: Paul Grof, "Brief Summary of Background" (June 3, 2005).

[189] *Ibid.* See also AD.3: Conversation with Dr. Duffy (March 6, 2006) at p 19.

[190] See Affidavit of Dr. Zul Merali (June 17, 2005) at 68.

[191] See C.40: Anne Duffy, "Summary of the events of the seizure" at pp 7-8. See also IMHR Researchers - Pierre Blier. Available online: University of Ottawa Institute of Mental Health Research <http://www.imhr.ca/research/researchers-pierre-blier-e.cfm> See "Publications" for work regarding psychotropic drugs in animal models.

[192] See C.45.1: E-mail from Zul Merali to Anne Duffy and Paul Grof (September 23, 2004).

[193] See IMHR Researchers - Jean-Claude Pierre Léon Bisserbe. Available online: University of Ottawa Institute of Mental Health Research <http://www.imhr.ca/research/researchers-jc-bisserbe-e.cfm >

[194] See C.45.2: Letter from Anne Duffy to Zul Merali (September 29, 2004) and C.45: E-mail from Anne Duffy to Mr. George Langill (August 10, 2004): " I am concerned about 1. my ability to continue to work here under these unacceptable conditions (agreements broken, bullying, lack of due process)…"

[195] C.48: E-mail from Anne Duffy to Robert Warren (January 17, 2005).

[196] C.38: Paul Grof, "Brief Summary of Background" (June 3, 2005) at p 4.

[197] AD.25: Letter from James O'Grady to Paul Grof (September 28, 2004).

[198] Letter from Robert B. Warren to James O'Grady (October 20, 2004)

[199] See AD.13: Cross-examination of Paul Grof on an Affidavit sworn September 13th 2007 on December 19, 2007 at para 76.

[200] C.40: Anne Duffy, "Summary of the events of the seizure" (July 28, 2005) at p 2. It is worth noting also that the seizure of the research records, the subsequent discussions complicated Dr. Duffy's move to McGill. There was also tension surrounding the transfer of research funding obtained by Dr. Duffy as principal investigator from the University of Ottawa to McGill University.

[201] C.2: Letter from Jacques Bradwejn to Anne Duffy (July 22, 2005);

[202]C.5: Letter from Kate Stephenson (Counsel for Dr. Duffy) to Gregory P. Kelly (Counsel for Dr. Bradwejn) (August 2, 2005).

[203] Art. 1.11 TCPS1.

[204] See Article 1.13 TCPS1 and the discussion at p. 1.10-1.11.

[205] This principle of proportionate review was emphasized in the TCPS1, in force at the time, and is also a key principle of the TCPS2. See TCPS1 Article 1.6, and the discussion at p. 1.7-1.8 and p. 1.11 (continuing ethics review).

[206] See the detailed discussion of the disagreement on continuing review at 7.

[207] CD.1.4F: Letter from Alan B. Douglass to Zul Merali (April 21, 2005) at Resolution 1.

[208] The Committee notes that the revised TCPS [TCPS2] states much more clearly that "REBs make the final decision about the nature and frequency of continuing ethics review." It also emphasizes that institutions have to provide the necessary resources to fulfill their obligations with respect to continuing review, and emphasizes also that continuing review is a collective responsibility with a significant role for the researchers.

[209] C.40: Summary of the events of the seizure by Anne Duffy (July 28, 2005) at pp 7.

[210] *Ibid.* at p 9.

[211]See C.45.1: E-mail from Zul Merali to Anne Duffy and Paul Grof (September 23, 2004): "At that September 1st meeting, a firm and final offer was made with regards to the creation of a "Bipolar Clinical Research Team" within the Mood Disorders Research Unit."

[212] C.38: Paul Grof, "Brief Summary of Background" (June 3, 2005) at p 4.

[213] See: AD.25: Letter from James O'Grady to Paul Grof (September 28, 2004); AD.26: Letter from Robert R. Warren to James O'Grady (October 20 2004)**;** AD.13: Cross-examination of Paul Grof on an Affidavit sworn September 13th 2007 on December 19, 2007 at para 76.

[214] See CD.1.5: Affidavit of Zul Merali (June 17, 2005) at paras 17-20.

[215] See: CD.1.5: Affidavit of Zul Merali (June 17, 2005) at para 22-23 and CD.1.6: Affidavit Paul Dagg (June 17, 2005) at paras 1-2.

[216] CD.1.6: Affidavit Paul Dagg (June 17, 2005) at para 3.

[217] See note 15 supra. (See: CD.1.2K: Letter from Alan B. Douglass to Anne Duffy, Paul Grof and Martin Alda (March 24, 2005) at para 2: "I first learned that the removals had taken place when I was informed of the situation by members of the ROHCG administration at 17:00h Tuesday 22-Mar-2005."; CD.1.3: Affidavit of Paul Grof (April 11, 2005) at para 21: "Overnight on 22 March 2005, our research records and the clinical records of my former patients at the Hospital … as well as my personal records and the personal records of Dr. Duffy, we seized without notice or warning" and CD.1.2: Affidavit of Anne Duffy (April 2, 2005) at para 31; CD.1.5: Affidavit of Zul Merali at paras 22-28 and AD.2: Cross-Examination of Sharyn Szick (January 24, 2008) at paras 33-40 and 70-73; and CD.1.3: Affidavit of Paul Grof (April 11, 2005) at para 23.)

[218] See CD.1.4G: The letter by Zul Merali "…I instructed the IMHR representatives, including Dr. Keith Busby who is a REB administrator, to perform a spot audit..." However this information is contradicted in the affidavits of Dr. Merali and Dr. Busby. See CD.1.5: Affidavit of Zul Merali (June 17, 2005) at para 26, "Once the clinical records had been relocated, Dr. Busby performed a brief spot audit of approximately 20 research binders… At the time, I assumed that Dr. Busby was acting in his capacity with the REB." and CD.1.8: Affidavit of Keith Busby (June 17, 2005) at para 16, "I was not asked by Dr. Merali or Dr. Douglass to perform this spot audit."

[219] CD.1.8: Affidavit of Keith Busby (June 17, 2005) at para 15: "approximately 5 binders did not have the appropriate consent form located behind the Tab marked 'consent'".

[220] CD.1.5: Affidavit of Zul Merali (June 17, 2005) at para 26-27

[221] AD.4: E-mail from Paul Dagg to Anne Duffy (March 23, 2005).

[222] CD.1.2G: Memorandum from Sharyn Szick to Anne Duffy (March 23, 2005)

[223] CD.1.2O: Letter from Nicholas D.C. Holland to Zul Merali (IMHR), Paul Dagg, Jacques Bradwejn, and Bruce Swan (ROH) (March 24, 2005).

[224] CD.1.2J: Letter from Zul Merali to Anne Duffy (March 31, 2005).

[225] CD.1.4B: Letter from Royal Ottawa Hospital to Anne Duffy (April 13, 2005).

[226] CD.1.4D: Endorsement of Justice Manton (April 15, 2005).

[227] CD.1.4: Supplementary Affidavit of Anne Duffy (April 28, 2005) at para 14; CD.1.5: Affidavit of Zul Merali (June 17, 2005) at para 44.

[228] Dr. Duffy received the letter from Alan B. Douglass on April 22, 2005 through which she learned that, "the Respondent IMHR had in fact reviewed the research files." See CD.1.4: Supplementary Affidavit of Anne Duffy (April 28, 2005) at para 22-24. However, the letter by Dr. Douglass itself does not directly state that Dr. Busby conducted the spot audits. Dr. Duffy received the letter of Dr. Merali on April 25, 2005 which does name Dr. Busby as the one who reviewed the research records. See CD.1.4 Supplementary Affidavit of Anne Duffy (April 28, 2005) at para 23.

[229] See CD.1.4H: Sample Letter from Anne Duffy to research subjects (April 25, 2005) alleging breach of confidentiality.

[230] C.12: Letter from Jacques Bradwejn to Anne Duffy (July 22, 2005); C.17: Letter from M. Kate Stephenson (WeirFoulds) to Gregory P. Kelly (Counsel for Dr. Bradwejn) (August 2 2005). See also, C.17: Letter from M. Kate Stephenson (WeirFoulds) to Gregory P. Kelly (Counsel for Dr. Bradwejn) (August 2, 2005) at para 3: "We are disturbed to learn that Dr. Bradwejn has ignored Dr. Duffy's request and has been in direct contact with McGill University. He has not only inquired about Dr. Duffy's anticipated arrival at McGill (which is itself inappropriate), but he has discussed, in addition, his version of the events leading up to Dr. Duffy's departure from the ROH."

[231] CD.2.1: Minutes of Settlement (October 19, 2005).

[232] CD.2.7: Minutes of the special *in-camera* meeting of REB (November 21 2006) to review the *Darby Report*; see also CD.2.9: Affidavit of Anne Duffy (December 7, 2006) at para 11.

[233] CD.2.6: Letter from Anne Duffy and Paul Grof to Padraig Darby (February 20, 2006). See also CD.2.3: Preliminary Brief of Anne Duffy and Paul Grof to Patrick Darby (January 17, 2006) at p 16.

[234] CD.2.4: Letter from Gregory P. Kelly to Robert B. Warren (February 2, 2006).

[235] See CD.2.7: Minutes of the special *in-camera* meeting of REB (November 21, 2006).

[236] CD.2.7: Minutes of the special *in-camera* meeting of REB (November 21, 2006) to review the Darby Report at resolution 1: "Firstly, Dr. K. Busby clarified that all the research projects by Drs. Grof and Duffy mentioned in that report had received proper letters of approval from our REB, but these were not sent to Dr. Darby."

[237] CD.2.8: Notice of Application (December 2006).

[238] "The Mood Disorders Centre of Ottawa", see CD.2.6: Letter from Drs. Duffy and Grof to Dr. Darby (February 20, 2006).

[239] C.45.2: Letter from Anne Duffy to Zul Merali (September 29, 2004) especially at para 4.

[240] C.45.2: Letter from Anne Duffy to Zul Merali (September 29, 2004).

[241] C.16: Letter from Constanze Schweikert to Anne Duffy (June 11, 2007), "During these monitoring visits I explicitly documented the presence of these [informed consent] forms as a part of my routine review of the files."

[242] C.10: Letter from Mary Ann Linseman to Anne Duffy (June 28, 2005).

[243] The Committee is not in a position to make a comprehensive recommendation about the property interest in research records in all possible areas of research and in all possible situations. Whether researchers, institutions, or sponsors should have property interests in research records may depend on a variety of circumstances, such as: source of funding; nature of the research; nature of the research records; contributions by institutions to sample collections and infrastructure; position of the researcher; commercializable nature of the research; and intellectual property interests. Yet, the claim that the institution should own the research records certainly appears inappropriate in this type of research, which involved the long-term collection of data by clinician-researchers, involving multiple sources of funding, and based on a longstanding relation between clinical researchers and patients and their families, which reflected a significant trust by the research subjects in the clinician-researchers and in their ability to protect the confidentiality of the information. The property argument was in this dispute invoked after the seizure, to justify the intervention in the context of legal proceedings. Clarification of the issue of ownership could help avoid potential misuse of the concept.

[244] See the detailed discussion of the Governance of Research Ethics Review in TCPS2, Chapter 6. Introductory statement: "A key goal in establishing an appropriate governance structure for research ethics review is to ensure that REBs operate with a clear mandate, authority and accountability; and that roles and responsibilities are clearly defined. REBs need independence in their decision-making process to carry out their role effectively, and to properly apply the core principles of this Policy – Respect for Persons, Concern for Welfare and Justice – to their ethics review of research projects." See also at the discussion of art.6.2: "For the integrity of the research ethics review process, and to safeguard public trust in that process, institutions shall ensure that REBs are able to operate effectively and independently in their decision making."

[245] The Committee notes that the new TCPS2 emphasizes that it is the Research Ethics Board that determines the level of continuing review and that institutions have to enable the Research Ethics Boards to fulfill this task. See TCPS2 at p. 79-81. The Committee also notes that the

ROHCG Board of Trustees has approved on March 9, 2011 new Research Ethics Boards Terms of Reference which include a more detailed provision with respect to its continuing obligations. One of its core obligations is "5. Monitoring the ethical conduct of research at the ROHCG and its affiliates including, but not limited to: an annual review of approved research (or more frequently at the discretion of the REB), ongoing review of serious adverse events and reports from Data Safety Monitoring Boards (DSMBs), and review and approval of amendments/modifications to the research. Continuing review (protocol audits) will also take place within Quality Assurance for Research Excellence (QARE) program overseen by the REB." ROHCG Board of Trustees, ROHCG Committees Reporting to the Board of Trustees, Research Ethics Board Terms of Reference (Draft/Revised March 9, 2011) (copy on file with the Committee).

(*) Explanatory Note to the Endnotes:

In the endnotes, the codes CD, C and AD refer to the internal filing system of the Committee. These codes are left in the references to facilitate verification. The material on which the Committee bases its analysis consists primarily of affidavits, response affidavits, and evidence produced in the context of the two court proceedings described in this report, as well as interviews and correspondence with people involved in the events and other people who are or were at one point in time affiliated with the institutions involved. Documents in the endnotes with the code CD1 mostly come from the first court proceeding: *Anne Duffy and Paul Grof v. The Royal Ottawa Hospital, The University of Ottawa, the University of Ottawa Institute of Mental Health Research, Zul Merali, Jacques Bradweijn, and Paul K.B. Dagg*, Ontario Superior Court, Court File 05-CV-030735. Documents with the code CD2 mostly come from the second court proceeding: *Anne Duffy and Paul Grof v. The Royal Ottawa Hospital, The University of Ottawa, the University of Ottawa Institute of Mental Health Research, Zul Merali, Jacques Bradweijn, and Alan Douglass*, Ontario Superior Court, Court File 06-CV-36883. The code *C* refers to correspondence and documents the Committee received from various people outside these court proceedings. The code *A* stands for Additional Documents, which includes a variety of materials, including some letters and court documents the Committee has obtained and/or filed at a later stage of its inquiry. Some of the documentation may be confidential.