National Council on Ethics in Human Research | Conseil national d'éthique en recherche chez l'humain

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Centre de toxicomanie et de santé mentale

CONFERENCE ON CONFLICTS OF INTEREST IN RESEARCH

SUMMARY OF PROCEEDINGS

Toronto, Ontario, Canada
February 22-23, 2007

Report prepared by:

Gordon DuVal, SJD

The Research Ethics *Project*

Principal Consultant

gordon@researchethicsproject.com
www.researchethicsproject.com

CONFERENCE ON CONFLICTS OF INTEREST IN RESEARCH

Toronto Marriott Bloor Yorkville Hotel
February 22-23, 2007

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This conference will offer simultaneous translation.

Des services d'interprétation simultanée seront offerts à cette conférence.

CONFERENCE ON CONFLICTS OF INTEREST IN RESEARCH

Toronto Marriott Bloor Yorkville Hotel
Room: Forest Hill Ballroom

Thursday, February 22, 2007

18:00 – 19:00	**Registration**
Session Chair: Dr. Padraig Darby, Centre for Addiction and Mental Health; President Elect, NCEHR	
19:00	**Opening Remarks** • Dr. Glenn Griener, President, National Council on Ethics in Human Research; University of Alberta • Dr. Geneviève Dubois-Flynn, Senior Ethics Policy Advisor, Canadian Institutes of Health Research • Dr. Catharine Whiteside, Dean, Faculty of Medicine, University of Toronto • Dr. Paul Garfinkel, President & CEO, Centre for Addiction and Mental Health • Dr. Melody Lin, Deputy Director, Office for Human Research Protections
19:30 – 21:00	**Up Stream and Down: Conflicts of Interest and Knowledge Production** Dr. Tim Caulfield, Health Law Institute, University of Alberta
21:00	**Adjournment**
21:00	**Reception -** *Buffet and cash bar will be offered.*

Friday, February 23, 2007

8:00 – 8:30	**Continental Breakfast and Registration**	
Session Chair: Dr. Peter N. Lewis, Vice Dean, Research and International Relations Professor of Biochemistry Faculty of Medicine, University of Toronto		
8:30 – 9:30	**How Should we Manage our Conflicts of Interest?** Dr. Martin McKneally, Joint Centre for Bioethics; University of Toronto	
9:30 – 9:45	**Discussion**	
9:45 – 10:15	**Refreshment Break**	
10:15 – 11:30	**Concurrent Breakout Sessions**	
Breakout #1 ***Forest Hill Ballroom*** 	*Clinical Trials* **Simultaneous translation provided.**	***Chair*** – Dr. Lorraine Ferris, University of Toronto ***Presenters*** – Dr. Jim Appleyard, World Medical Association and Dr. Lorraine Ferris, University of Toronto
Breakout #2 ***Hanlan Room***	*Genetics & Biotechnology*	***Chair*** – Dr. Padraig Darby, Centre for Addiction and Mental Health; President Elect, NCEHR ***Presenter*** – Dr. Aideen Moore, The Hospital for Sick Children
Breakout #3 ***McBride Room***	*Social Sciences & Humanities*	***Chair*** – Dr. Glenn Griener, President, NCEHR; University of Alberta ***Presenters*** - Prof. Marlene Brant Castellano; Tyendinaga Mohawk Territory
Session Chair: Dr. Michael Owen, Brock University; Member of NCEHR		
11:30 – 12:00	**Reporting Back to Plenary Session**	
12:00 – 13:00	**Lunch**	
Session Chair: Dr. Padraig Darby, Centre for Addiction and Mental Health; President Elect, NCEHR		
13:00 – 14:30	**Practical Challenges in Developing Conflict of Interest Policies For Research Institutions** • Dr. Michael Owen, Brock University; Member of NCEHR • Dr. Melody Lin, Deputy Director, Office for Human Research Protections	
14:30 – 15:00	**Refreshment Break**	
15:00 – 15:30	**Discussion**	
15:30 – 16:00	**Identification of "Take-Home" Messages** Dr. Glenn Griener, President, NCEHR; University of Alberta	
16:00	**Adjournment**	

Thursday, February 22nd, Evening Session

WELCOME AND OPENING COMMENTS

The following people offered words of welcome to conference participants:

Glenn Griener, PhD, President, NCEHR

Dr. Griener opened the conference by welcoming participants and providing a brief introduction. He pointed to the dangers of failing to appropriately manage conflicts of interest, including the potential to compromise the contributions of research participants and to yield unreliable scientific and biomedical results.

Geneviève Dubois-Flynn, PhD, Senior Ethics Officer, CIHR

Dr. Dubois-Flynn gave an overview of the federal funding agencies' Memorandum of Understanding (MOU) negotiated with funded institutions and discussed briefly the planned addition of a schedule imposing obligations relating to conflicts of interest. While the Schedule is not yet approved, it will include requirements relating both to individual and institutional conflicts of interest and will identify concrete strategies to assist institutions in managing conflicts. It is expected that institutions will be required to have a COI policy in place one year after the COI schedule is released to the institutions.

Katharine Whiteside, MD, PhD, FRCPC, Dean of Medicine, University of Toronto

Dr. Whiteside gave a brief description of steps taken within the U of T Medical Faculty, and among its affiliated teaching hospitals, to address conflicts of interest. She observed that a broad, cutting edge research agenda, with an emphasis on translational research and cooperation among institutions and clinical investigators, requires robust and effective conflict of interest policies and mechanisms.

Paul Garfinkel, MD, FRCPC, President and CEO, Centre for Addiction and Mental Health

Dr. Garfinkel urged the importance of respect for human dignity, which is particularly at risk among the population of those with psychiatric illness and addictions. The mandates of a teaching hospital include clinical care, teaching and research. Care must be client-centred and evidence-based. Research is how the evidence base is developed. Those we recruit into research should be treated with dignity and not merely as sources of data.

Melody Lin, PhD, Deputy Director, US Office of Human Research Protections (OHRP), DHHS

Dr. Lin sketched OHRP's role in developing approaches to conflicts of interest (COI) that focus on the three I's – Investigators, Institutional Review Boards and Institutions. She invited all to review the information about COI posted on the OHRP website.

"Up Stream and Down: Conflicts of Interest and Knowledge Production"
Prof. Tim Caulfield, Health Law Institute, University of Alberta

Professor Caulfield offered a comprehensive overview of some ways that the increasing commercialization of drug development and industry sponsorship of research threatens the integrity of research, the social presentation and translation of biomedical knowledge, and the protection of human participants. Backed by a canvas of the prevailing literature, Prof. Caulfield offered his observations on the following:

- The dollar value of private research is far greater than that of publicly funded research.

- The fact of such extensive industry involvement has an enormous impact on the evidence base guiding clinical and prescribing practices. For example:

  - Industry funded researchers are more likely to favour the use of the product being studied, and to employ a more positive tone in published reports.
  - Publication of industry funded studies, particularly those having unfavourable findings are more likely to be delayed or withheld altogether, and such studies are more likely to be discontinued early.
  - Ghost authorship, the practice of having a manuscript drafted by an industry employed or contracted individual, whose name does not appear as an author, is widespread and raises significant questions about the content and credibility of published reports.
  - Industry funded investigators are widely involved in the preparation of Clinical Practice Guidelines, that can be very influential among the broad community of clinicians.
  - Industry involvement impacts the quality of the educational experience of medical trainees.

- Industry has a profound effect on popular representations of scientific developments. The media is the primary source of such information for patients and clinicians and such reporting impacts their behaviour. In media reports:

  - Risks tend to be underreported.
  - Conflicts and funding sources are often ignored.
  - Methodological and other limits of studies are commonly downplayed.
  - Interviews with investigators may give a more enthusiastic impression than is warranted.
  - Neither the media source nor the investigator(s) being interviewed have an incentive to downplay the significance or implications of the scientific findings. Therefore, reports of new discoveries may tend to be unduly sensationalized.

- An erosion of public trust in the research enterprise has been identified. The public is increasingly suspicious of industry's role in drug development and knowledge production. Funding source is becoming a central test of credibility.

- At the same time, government encourages public/private collaborations with industry and other private sources both to make public research funds go farther and to spur economic growth.

Prof. Caulfield offered a number of policy responses to these problems:

- Encourage more independent (non-commercial) funding for research;
- Create more effective rules for publication, including comprehensive and easily accessed Clinical Trial Registries;
- Impose better controls over industry involvement in Clinical Practice Guideline development;
- Develop mechanisms to better balance and manage conflicts of interest.
- Encourage independent governance of research (for example, a broadly held and administered patent pool with authority over all intellectual property and the commercial elements of technology transfer initiatives).

A lively discussion followed, with discussants raising the following issues:

- What are the limits to the efficacy of disclosure of conflicts of interest? How ought journal readers, REB members and others deal with reported conflicts? How does disclosure enhance an evaluation of the worth of the study or its findings? Can reported conflicts be seen as evidence of the quality and reputation of the researcher and not as a reason for suspicion?

- To what extent should the drawbacks of industry involvement in research be balanced against the positive economic benefits that may result?

There was general agreement that:

- We ought to consider further the role and limits of disclosure of conflicts of interest in their various contexts.

- Clinical trial registries are slowly developing but may be of significant value in identifying existing studies and providing access to study findings, especially negative findings.

- For community researchers, not affiliated with an academic centre, licensing bodies should take a greater role in overseeing research, particularly that undertaken outside of the academic and publicly funded realms.

Friday, February 23rd, Morning Session

"How Should We Manage Our Conflicts of Interest?"
Dr. Martin McKneally, University of Toronto Joint Centre for Bioethics

Dr. McKneally proposed some practical approaches to managing conflicts of interest. By way of context, he pointed to the recently constructed MaRS facility in Toronto, the aim of which is to facilitate the commercialization of research innovation. Dr. McKneally cited the advantages of situating MaRS adjacent to a traditional teaching and research hospital, the Toronto General Hospital, and directly across the street from the University of Toronto Joint Centre for Bioethics. We have the opportunity to develop effective approaches to managing, rather than simply disclosing or prohibiting, individual and institutional conflicts.

He offered the example of Jesse Gelsinger, who died while taking part in a gene therapy trial at the University of Pennsylvania, under circumstances in which both the University and the primary investigator had significant financial interests. How can such tragedies be avoided? McKneally suggests that REBs are not realistically capable of monitoring and enforcing the appropriate management of conflicts of interest. They are overworked as it is and generally lack the expertise to identify and assess the practical effects of particular conflicts. He suggested then that a specialized CIRC – a Conflict of Interest Review Committee – could better provide oversight with respect to the commercial aspects of research. The CIRC would be an independent, or substantially independent, body with expertise in commercial aspects of technology transfer, for example patent and licensing processes, intellectual property rights, and the attending financial and equity issues. This approach is now widely practiced in the United States.

In summary, McKneally offered some lessons:

- Scientific and institutional obligations can be met by effectively managing conflicts of interest.
- Management requires transparency: disclosure is necessary but not sufficient.
- A CIRC requires expertise and the learning curve is steep.
- A CIRC can be efficient because of its narrow focus on relevant interests and obligations.
- Well-trained and focused staff is essential to the success of a CIRC.
- Community involvement is highly desirable.
- A CIRC can review a broad range of activities, from data management to research development and conduct, to institutional oversight.

Breakout Sessions:

COI in Clinical Trials – Jim Appleyard, World Medical Association and Lorraine Ferris, University of Toronto

Dr. Appleyard offered a variety of published characterizations of individual and institutional

conflict of interest pointing to the elusiveness of the concept and the diversity of contexts in which conflicts may arise.

He cited a recent study in support of the view that "[t]here is substantial variation among policies on conflict of interest at medical schools and other research institutions" and raising worries that COIs are not being adequately managed by existing policy mechanisms. Further, there is evidence that researchers commonly fail to comply with disclosure requirements and that research participants, and the public at large, are generally not aware of the extent of such financial conflicts.

The failure to adequately manage conflicts of interest has a number of harmful consequences:

- Findings reported in biomedical journals may be tainted. Author's conclusions about clinical trials have been found to be affected by competing financial interests. It appears for example that methodological and statistical rigour may be compromised by financial conflicts in ways that have not been found to be associated with competing academic or political interests.
- Ghost written manuscripts threaten the integrity of journal publications.
- The existence of inadequately managed conflicts threatens the trust relationships that are necessary elements of scientific partnerships.

Dr. Appleyard offered the following as general advice:

- Emphasize principles of protecting research from bias rather than paperwork processes.
- Develop processes collaboratively with researchers and administrators to promote broad understanding of the policies and the need for adherence.
- Use a three-fold approach to COI focusing on transparency, managing risk, and protecting the public interest.
- Control may be exercised on a number of levels – personal, professional, institutional and regulatory.
- Disclosure of interests should be comprehensively and widely made.
- Institutions can develop effective COI management processes including clear policies, peer review committees, education, monitoring and record-keeping.
- Monitoring of COI should focus on "critical control points:"
  - Research contracts
  - Grant applications
  - Relations with funding agencies
  - Publication
  - Technology transfer
- Researchers are accountable primarily to their patients and profession, but have responsibilities also to the wider public and to third party payers.

COI in Genetics & Biotechnology – Dr. Aideen Moore, Hospital for Sick Children and University of Toronto

Dr. Moore defined biotechnology as:

"Any technique that uses living organisms, or parts of such organisms, to make or modify products, to improve plants and animals, or to develop microorganisms for specific use."

The cost of biotechnological research and development rises sharply as it becomes more complex, and commercial biotechnology is potentially lucrative. So, conflict issues surrounding commercialization are acute. Four broad issues were identified:

- Consent:
  - The nature of the study should be described to potential participants.
  - Genetic counseling should be offered including warnings about effects on employment, insurability, etc.
  - Confidentiality should be appropriately protected and data safeguarded.
  - Choice of 'open' or 'closed' consent.
  - There should be disclosure of potential commercial uses

- Samples:
  - Ownership of samples and duration of storage should be considered and disclosed.
  - Results should be reported where feasible.
  - The treatment of participant's data upon withdrawal from study should be considered in advance and disclosed.
  - Consider and disclose the use of samples in future research and by other researchers.
  - Consider and disclose whether participants, families and groups should be contacted in future regarding ongoing developments.

- Interactions with industry require clear policies on:
  - Review of research contracts (by whom?)
  - Conflicts over patent rights, and licensing
  - Equity or other holding by researcher(s) or institution
  - Commercialization of samples
  - Also consider that the REB or its members may have a COI

- Involvement of Children:
  - Predictive testing in children is of concern– if no available treatment, testing should generally not be undertaken.
  - Consider in advance the role of parental decision-making.
  - Results generally should be made available to participants, including children, when maturity permits.

Dr. Moore summarized some 'take home points:'

- Research involving genetics and biotechnology is complex but increasing.
- Most COI issues are similar to those found in other types of research.
- Unique aspects include:

- The nature of informed consent
- Privacy and confidentiality of genetic samples
- Ownership of samples

COI in Social Sciences & Humanities – Prof. Glenn Griener, Chair, Prof. Marlene Brant Castellano, presenter.

Discussions of COI often miss the non-big money interests that nevertheless threaten the integrity of research and the safety and dignity of human subjects.

An important theme that arose from this session was the effect of power differential in the academic milieu, and the range of harms that may result.

- Misuse of students to further faculty or institutional research goals.
- Required participation of students in research for course credit.
- Other types of conflicts: a minister from a Theology faculty doing research within his own congregation; business students doing research with co-workers and even employees who report to the investigator.

Some responses:

- Use subject pools so that research participants for faculty studies are drawn from a broader base than the faculty member's course. There was some discussion whether such pools should be drawn exclusively from within departments, or should span departments?
- Require researcher to use non-conflicted research sample.
- Have someone else do the research involving a conflicted sample.

In the context of a Network of Centres of Excellence, one participant was concerned that particularly influential decision-makers may create conflicts resulting in skewed research priorities and an unfair distribution of research funding. The participant suggested that it can be awkward to question "old boys" clubs.

Reviewing proposed research protocols for conflict of interest problems is difficult. While REBs are overworked and often lack the expertise and resources to identify and manage COIs, review may be uncoordinated and less effective if compartmentalized.

Prof. Brant-Castellano observed that setting priorities is an everyday experience, requiring us to consider and balance competing demands. "Conflicts of interest" do not necessarily imply compromise of ethics. She drew two scenarios from her experience in the Aboriginal research context. The first highlighted potential tension between political leadership and research interests and the second the conflict between research interests and expectations of a collaborating group. Both of these cases inspired much discussion. In both cases the conflicting interests may be seen as legitimate in themselves, arguably with no natural ethical priority, requiring a balancing of valid interests.

There was consensus that those with conflicting interests should be approached respectfully and in an environment of trust, so that relationships are negotiated and balanced in good faith taking account of all legitimate interests. By identifying and honouring these key interests, research procedures can be negotiated cooperatively.

A significant example was that of the OCAP principles (ownership, control, access and possession) espoused in the context of Aboriginal and community research as a means to safeguard community interests in the ownership and control of data and publication rights. Issues discussed included the use of intermediaries for consent and combining community or collective consent with individual consent.

Friday, February 23rd, Afternoon Session

"Conflict of Interest Institutional Policy Development: Some Practical Challenges in Developing Conflict of Interest Policies for Research Institutions"
Dr. Michael Owen, Brock University

As the title suggests, Dr. Owen offered a detailed overview of the practical elements and challenges involved in the development and dissemination of COI policies in research institutions. The following potential elements may be useful in developing policy:

- Develop and maintain a written institutional policy on COI;
- Define clearly to whom the policy applies;
- Negotiate with affiliated Institutions whose funds are managed to ensure that there is consistency between the its COI policies and that these meet Tri-Council MOU proposal schedule, at a minimum;
- Ensure that all persons to whom a policy applies are appropriately informed of their individual obligations and responsibilities;
- Make every reasonable effort so that conflict of interest situations do not arise from any commitment or expenditure of research funds;
- Develop processes that provide for effective management of COI situations;
- Disclose to the Agencies any known conflict of interest that may affect a decision about a specific application or request for grants or awards;
- Ensure that appropriate and effective COI policies are in place to protect all research trainees.

An important theme was that policy is not made in a vacuum, that is, the process must take account of a number of contextual factors including:

- Institutional history and the prevailing institutional climate,
- The policies and temperament of primary funding bodies,
- The broader national policy environment.

Specific contextual factors may include:

- Existing policy;
- References in Collective Agreements to COI and research integrity;
- Earlier policy review processes;
- Drafts developed by HR and internal auditors or policy advisors.

Important issues relating to both individual and institutional COI were offered as essential policy elements. Institutional COI is concerned with the interests attending 1) holdings of an institution, and 2) holdings of an individual who makes institutional decisions affecting research or technology transfer. Examples of individual COI include financial conflicts, nepotism, interests in intellectual property, and the use of institutional facilities for private research.

Dr. Owen offered were a list of practical considerations in developing, drafting, and implementing such policies:

- An effective policy provides clear and consistent direction and encourages compliance.
- Long preambles lead to confusion and debate.
- Define the scope of the policy and terms being used.
- Indicate the goals sought to be attained by the policy. Why have this policy? What behaviours are to be encouraged or discouraged?
- Make policies positive rather than negative in tone.
- Avoid words that create ambiguity in interpretation.
- Use section headings and numbering.
- Reference the approval authority (ies).
- Identify the responsible individual(s)/office(s).
- Separate policy from procedures. Procedures may evolve more than policy.
- Consult, Consult, Consult.
- Where groups, associations or unions are involved, use normal consultative mechanisms to obtain advice and agreement.
- Cross reference to related policies.
- Create an implementation and communication plan – for example, prepare and distribute a memo explaining the reasons for the policy and describing its implications.
- Use appropriate approval processes: Senate, Board, etc.
- Create effective mechanism for disclosing potential COI and managing COI.

Lastly, some gaps were identified drawn from Dr. Owen's experience at Brock University, but which have broad resonance. These include the need for further work on institutional COI and better strategies for communicating policy to bolster institutional and individual buy-in and broaden understanding of the goals of policy development.

Dr. Owen also provided a list of best practice COI policies, from a variety of institutions that serves as a helpful reference. They are:

- Tri-Council MOU Consultation Document on Conflicts of Interest: http://www.nserc.gc.ca/institution/coi/toc_e.htm
- AAU Task Force on Accountability: http://www.aau.edu/research/conflict.cfm
- University of Alberta: https://www.conman.ualberta.ca/stellent/groups/public/@academic/documents/policy/pp_cmp_051034.hcsp
- Queen's University: http://www.queensu.ca/secretariat/senate/policies/conflict/index.html
- UBC: http://www.universitycounsel.ubc.ca/policies/policy97.pdf
- University of Kentucky: http://www.uky.edu/Regulations/AR/ar070.pdf
- Penn State: http://www.research.psu.edu/orp/ethics/instcoi/index.asp

"REB & COI Management for Human Subject Research"
Dr. Melody Lin, OHRP

Dr. Lin defined COI as "any situation or relationship that biases or has the potential to bias the conduct of REB review." She initially looked at potential risks to the integrity of REB review from both individual REB member and institutional conflicts of interest.

Individual conflicts:

- Member's ties to research, from financial ties to loyalty to involved colleagues
- Member's ties to the subject matter (familiar=too lenient; competitor=too strict)
- Decision that may affect member's own work situation
- Decision that may impact member's personal causes or agendas
- Conflict that may arise from member also having other institutional role such as legal counsel or member of contracts office.

Institutional conflicts:

- Conflict with institution's mission to protect, enhance or promote research
- Institutional fear of liability.
- Institutional or stakeholder values or political concerns may conflict with REB mission
- Pressure for speedy review.
- Institutional financial conflicts from its holdings of equity, patent rights, or technology licensing.
- Fees received from industry for REB review.

In order to help ensure that REB obligations are properly discharged, Dr. Lin made a number of suggestions:

- Remind REB members of conflict policies, ensure disclosure, exclusion, recusal and other policies at the outset of each REB meeting and document any actions taken relating to COI.
- Develop and deliver COI educational materials and initiatives for members.
- Have mechanisms in place to determine whether disclosure and other conflict management strategies are effective in protecting human subjects and research integrity.
- Place REB reporting as high as possible within the institution to negate influence.
- Appoint a diverse board, recruit non-affiliated members, and watch for conflict when selecting members from within the institution.

By way of conclusion, Dr. Lin reflected that conflicts are inevitable, but do not imply misconduct and are manageable. Education, guidance and awareness are essential.

Discussion Following Afternoon Presentations

One participant expressed concern about long-standing or "chronic" REB members, whose attitudes and practices may have become stale and who may no longer be making a meaningful contribution. In response, one panel member, while not disagreeing that there are such persons, pointed out that long service may also provide rich experience and continuity, so long as the member is prepared to continue to grow and learn as part of the board.

The importance of broad consultation in the policy-making process was emphasized by one participant. There was general agreement that it is important to seek buy-in from all affected constituencies to promote understanding of how proposed measures may reinforce and promote the mission and goals of the institution.

A lively discussion followed about the degree of flexibility, or "wiggle room" to include in the wording of policies. There was some difference of views on this point. One commenter felt that such wording allows the policy to be adapted more successfully to unfolding or unexpected developments. Another felt that "wiggle words" create unhelpful ambiguity and possibly deadlock. Flexibility may be introduced into the process through procedures but not in relatively short, clear policies.

The conference was reminded to consider what happens when COI policies are not followed, and the range of disciplinary responses that may be brought.

A question was raised about the conflicts arising from the ownership of different kinds of investments owned by an REB member when the company in question has a matter before the board. In general, it was felt that direct ownership of shares or other equity interests in the company (a pharmaceutical company, for example) was grounds for recusal. However, if a member owns a mutual fund that has an interest in the company among many others, such indirect ownership would likely not be cause for concern. This issue however does raise the question of whether the REB is best positioned to make such judgments that may require knowledge of complex financial relations and securities instruments.

Concern was raised about payment for REB members, whether internal or external. While no clear consensus emerged on this question, there was general agreement that REB service should be recognized in institutional and departmental decisions about promotion, tenure and the like.

One participant described a feeling among Aboriginal communities that there is an inherent conflict of interest in academic research as it is currently practiced. This is because the academic infrastructure in which research is undertaken benefits academics and university-affiliated researchers who are working within their own context using rules devised for their benefit. The resulting imbalance of power and resources renders research exploitive and impairs its integrity.

"COI Take Home Messages"
Dr. Glenn Griener, University of Alberta

Dr. Griener identified a number of "lessons learned" and sought to summarize areas of consensus reached during these proceedings.

1. The drive to commercialize research has generated new conflicts and a renewed interest in the management of conflicts. The research agenda, the completeness and integrity of reporting medical/scientific findings, and the development of Clinical Practice Guidelines are all affected.

2. Conflicts are not exclusively around money. Academic rewards, reputation and the pursuit of personal agendas and "pet theories" may also threaten scientific integrity and the protection of human subjects.

3. As Dr. McKneally pointed out, Banting was very resistant to patenting his discovery of insulin, thinking it would violate his Hippocratic obligations and compromise the free exchange and development of scientific knowledge. However, the principle underpinning the MaRS facility is that commercialization encourages innovation and permits technological discoveries to be brought to the public sooner. Whose principle is right? Did patenting allow insulin to become widely available to patients sooner? Does individual and institutional ownership of such intellectual property promote or stifle scientific advance? What other factors are relevant to consider?

4. With respect to these questions, there is little prospect of going back – there can be no elimination of financial and other conflicts, nor is it clear that we should wish to do so. We clearly do however need to develop effective means to manage unavoidable conflicts of interest.

5. We need to be very careful to achieve clarity when speaking of conflict of interest. Who is in conflict? Is it the researcher, institution, REB member, the REB itself, or someone else? What interests are in conflict? Depending on the answer to these questions, different policy responses and conflict management tools may be required. Federal funding agencies have policies that will continue to evolve.

6. The integrity of biomedical research has a 'normal flow' of development, review, conduct, analysis and reporting. An important challenge is to remove those barriers created by conflicts that may threaten the integrity of this process. For example, it is hoped that a workable clinical trials registration process can facilitate access to research data and thereby promote transparency.

7. Conflicts of interest are felt in many other realms including business, law, government, and in other academic fields. We can learn important lessons about the management of conflicts by looking to other organizational and institutional responses.

8. We need to carefully consider the most appropriate bodies to deal with different kinds of conflict of interest. The REB may not be the right body to deal with COI. They are generally overworked and under-resourced, and may lack the particular expertise and resources to do so effectively. In addition, many conflicts occur outside the context of research involving human participants. A Conflict of Interest Committee, or some other innovative body or mechanism, may be better able to play this role.

9. We need to consider carefully what new university policies may be required and recognise that many agencies already have COI policies of which we should be aware and could helpfully emulate. In doing so, we should be conscious of how a new policy should align with existing institutional structures, policies and agreements.

10. Do we need a better stocked tool box? Our approach should be multifaceted and include not only effective institutional policy, but also properly resourced bodies (REBs, CIRCs, funding, licensing and regulatory bodies, and journals) as well as appropriate policy practices (disclosure, prohibition, recusal, divestment, and discipline).

11. We are still struggling to understand the issues of COI in the social sciences and humanities. These issues include, among many others, the ways that conflicts can affect the research agenda and the relationship between social science research and policy deliberations.

APPENDIX 1

CONFERENCE ON
CONFLICTS OF INTEREST IN RESEARCH

CONFÉRENCE SUR LES
CONFLITS D'INTÉRÊTS DANS LA RECHERCHE

February 22-23, 2007 / Les 22-23 février 2007

Toronto Marriott Bloor Yorkville Hotel

Biographies

Jim Appleyard

Jim Appleyard is Past-President of the WMA with a special interest in Child Health. He is a convener of the Group that presented the Declaration of Ottawa on the right of a child to healthcare and human rights.

As Chair of the WMA Ethics Committee (1995-1999) Jim Appleyard oversaw the amendment to the WMA's Declaration of Helsinki in 1996 and has been active in the recent discussions about this very important Declaration that underpins clinical research internationally. He is convener of WMA Group on the ethical aspects of Health Databases, past member of BMA Ethics Committee (1992-2004) and current member of the east Kent Research Ethics Committee.

Jim Appleyard a déjà été président de l'Association médicale mondiale (AMM) et il s'intéresse tout particulièrement à la santé des enfants. Il est un des responsables du groupe qui a présenté la Déclaration d'Ottawa sur le droit d'un enfant aux soins de santé et à la protection des lois sur les droits de la personne.

À titre de président du Comité d'éthique de l'AMM (1995-1999), Jim Appleyard a supervisé la modification de la Déclaration de Helsinki de l'AMM en 1996 et il a participé activement aux discussions récentes sur cette très importante déclaration qui constitue le fondement de la recherche clinique internationale. Il est responsable du groupe de l'AMM concernant les aspects éthiques des bases de données sur la santé, il a déjà siégé au Comité d'éthique de la BMA (1992-2004) et il fait actuellement partie du Comité d'éthique pour la recherche de East Kent.

Marlene Brant Castellano

Marlene Brant Castellano is a Mohawk of the Bay of Quinte Band and Professor Emeritus of Trent University. She held a faculty appointment in Trent's Native Studies Department from 1973 to 1996, providing leadership in the development of the Department and in the emerging discipline of Native Studies. From 1992 to1996 she served as Co-Director of Research with the Royal Commission on Aboriginal Peoples (RCAP) with particular responsibility for drafting the integrated research plan, directing social-cultural, historical and community-based research, and editing and writing major portions of the final report under the direction of Commissioners. She facilitated the work of the Aboriginal subcommittee which drafted RCAP's Ethical Guidelines for Research now widely used as a reference for ethical research in Aboriginal contexts.

Professor Castellano's formal education is in social work (MSW 1959) and adult education (OISE/UofT 1980-81). Her teaching, research and publications are deliberately bicultural, promoting discourse between the worlds of Aboriginal knowledge and experience and the language and protocols of academics and policy makers. In recent years her writing has focussed on respectful treatment of Aboriginal knowledge in research. The inaugural issue of the Journal of Aboriginal Health published by the National Aboriginal Health Organization (NAHO) will include her paper on "Ethics of Aboriginal Research".

Professor Castellano serves on the Institute Advisory Board of the CIHR Institute of Aboriginal Peoples' Health and the College of Reviewers for Canada Research Chairs. She has been honoured with LLDs from Queen's University, St. Thomas University and Carleton University, induction into the Order of Ontario and a National Aboriginal Achievement Award. Most recently, Dr. Castellano has been named an Officer of the Order of Canada.

Marlene Brant Castellano *est originaire de la bande Mohawk de la baie de Quinte et professeure émérite à la Trent University. Elle a été affectée à un poste universitaire au Département des études autochtones de la Trent University de 1973 à 1996 où elle a fait preuve de leadership dans la mise sur pied du département et de la nouvelle discipline des études autochtones. Elle a été codirectrice de la recherche de 1993 à 1996 à la Commission royale sur les peuples autochtones (CRPA) et y était chargée en particulier de la rédaction du plan de recherche intégrée, de l'encadrement de la recherche socioculturelle, historique et communautaire, ainsi que de la révision et de la rédaction d'importances sections de la version définitive du rapport sous la direction des commissaires. Elle a facilité le travail du sous-comité sur les affaires autochtones qui a rédigé le Code d'éthique en matière de recherche de la CRPA largement utilisé maintenant comme référence pour la recherche éthique dans les contextes autochtones.*

La professeure Castellano est détentrice d'une maîtrise en travail social (1959) et est diplômée en éducation des adultes (OISE - Ontario Institute for Studies in Education - University of Toronto). Sa recherche, ses publications et son enseignement sont délibérément biculturels et soutiennent le dialogue entre le monde des connaissances et expériences autochtones et celui du discours et des protocoles des universitaires et décideurs. Ses écrits ciblent depuis quelques années le traitement respectueux des connaissances autochtones en recherche. L'Organisation nationale de la santé autochtone (ONSA) publiera son article sur l'Éthique de la recherche autochtone dans son premier numéro du Bulletin sur la santé autochtone.

La professeure Castellano siège au conseil consultatif de l'Institut de la santé des Autochtones des Instituts de recherche en santé du Canada (IRSC) et au Collège des examinateurs du Programme des chaires de recherche du Canada (CRC). Elle a obtenu un doctorat en droit à titre honorifique de la Queen's University, de la St. Thomas University et de la Carleton University. Elle a été honorée de l'Ordre de l'Ontario et elle a reçu le Prix national d'excellence aux autochtones. Plus récemment, elle a été nommée Officier de l'Ordre du Canada.

Tim Caulfield

Timothy Caulfield has been Research Director of the Health Law Institute at the University of Alberta, since 1993. In 2002 he received a Canada Research Chair in Health Law and Policy. He is also a Professor in the Faculty of Law and the Faculty of Medicine and Dentistry. His research has focussed on two general areas: biotechnology, ethics and the law; and the legal implications of health care reform in Canada. He has published well over 100 academic articles and book chapters and often writes for the popular press. He is the recipient of an Alberta Heritage Foundation for Medical Research Health Research Scholarship entitled "Regulating the 'Genetic Revolution;'" a Genome Canada project on the regulation of genomic technologies, is the theme leader for a recently awarded Stem Cell Network grant .(National Centres of Excellence) and is the Principal Investigator for a CIHR grant exploring the legal issues associated with the control of infectious disease. He has been a visiting scholar at the Hasting Center for Bioethics in New York, the University of Houston's Health Law and Policy Institute, and at Stanford University's Program in Genomics, Ethics and Society. In 2000, he was awarded the University of Alberta's Martha Cook Piper Research Prize, in 2002 received the Alumi Horizon Award and in 2004 received the University's Media Relations award. In 2006 he became a member of the Canadian Academy of Health Sciences. Professor Caulfield Chaired the Canadian Blood Services Ethics Committee; and is a Member of Genome Canada's Science Advisory Committee. He was on the Institute Advisory Board, Institute of Health Services and Policy Research, Canadian Institute of Health Research; was part of the Royal Society of Canada's Expert Panel on the Future of Food Biotechnology (2001) and was a member of the Canadian Biotechnology Advisory Committee (1998-2005). He Chairs and serves on numerous other research policy and ethics committees, is an editor of the Health Law Journal and the Health Law *Review*, teaches Law and Medicine in the Faculty of Law, and provides health law lectures for other faculties.

Timothy Caulfield *est directeur de la recherche au Health Law Institute de l'Université de l'Alberta depuis 1993. En 2002, il a mérité une chaire de recherche du Canada dans le domaine du droit et des politiques de la santé. Il est aussi professeur à la faculté de droit et à la faculté de médecine et de dentisterie. Ses recherches ont surtout porté sur deux grands domaines : la biotechnologie, l'éthique et le droit; les conséquences juridiques de la réforme des soins de santé au Canada. Il a publié plus de 100 articles savants et chapitres de livre et il écrit souvent pour la presse populaire. Il est titulaire d'une bourse de recherche en santé décernée par l'Alberta Heritage Foundation for Medical Research et intitulée « Regulating the 'Genetic Revolution' » –- il s'agit d'un projet de Génome Canada sur la réglementation des technologies de génomique. Il est aussi chef d'une équipe ayant récemment reçu une subvention du réseau de recherche sur les cellules souches (Stem Cell Network) – dans le cadre du Programme des centres nationaux d'excellence. Il est le chercheur principal dans le cadre d'un projet bénéficiant d'une subvention des IRSC et portant sur les aspects juridiques de la lutte contre les maladies infectieuses. Il a été chercheur invité au Hasting Center for Bioethics in New York, au Health Law and Policy Institute de l'Université de Houston et au Program in Genomics, Ethics and Society de l'Université Stanford. En 2000, il a mérité le Prix de recherche Martha Cook Piper décerné par l'Université de l'Alberta et, en 2002, il a reçu l'Alumni Horizon Award. En 2004, il a reçu le prix des relations avec les*

médias également décerné par l'Université. En 2006, il est devenu membre de l'Académie canadienne des sciences de la santé. Le professeur Caulfield a présidé le Comité d'éthique canadien de la Société canadienne du sang et il est membre du Comité consultatif des sciences de Génome Canada. Il a siégé au conseil consultatif de l'Institut des services et des politiques de la santé, dans les Instituts de recherche en santé du Canada; il a fait partie du Groupe d'experts de la Société royale du Canada sur l'avenir de la biotechnologie alimentaire (2001) et il a été membre du Comité consultatif canadien de la biotechnologie (1998-2005). Il préside divers autres comités d'éthique et des politiques sur la recherche ou il en fait partie, il est rédacteur en chef du Health Law Journal et du Health Law Review, il enseigne le droit et la médecine à la faculté de droit et il fait des exposés sur le droit de la santé dans d'autres facultés.

Padraig Darby

Padraig Darby is Deputy Clinical Director in the Law and Mental Health Program and Chair of the Research Ethics Board. He has chaired the REB in the Department of Psychiatry and at CAMH for 20 years and is the President-Elect of Council of the National Council on Ethics in Human Research, the body that provides guidance for researchers and ethicists on the ethical conduct of research in Canada.

***Padraig Darby** est directeur clinique adjoint au sein du Programme de la santé mentale et du droit et président du comité d'éthique de la recherche. Il a présidé le CER du Département de psychiatrie et celui du CTSM pendant 20 ans; il est président désigné du conseil du Conseil national d'éthique en recherche chez l'humain, organisme qui conseille les chercheurs et les spécialistes de l'éthique en ce qui concerne l'éthique de la recherche au Canada*.

Geneviève Dubois-Flynn

Geneviève Dubois-Flynn, Ph.D., has a background in international law and in philosophy. After teaching several courses at the University of Ottawa, including in bioethics, Geneviève joined the National Council on Ethics in Human Research in 2000. There, she was in charge of assisting research institutions improve their human research participants protection program. Since joining CIHR in 2002, Geneviève has been working in the areas of governance of ethics in research involving humans and conflicts of interest, and more recently, on ethical issues related to research involving Aboriginal Peoples, and in the area of global health. She is also committed to ethics education and to strengthening ties among organizations in the field of ethics. She has been a Research Ethics Board member for several years.

***Geneviève Dubois-Flynn, Ph. D.**, a étudié en droit international et en philosophie. Après avoir enseigné plusieurs cours à l'Université d'Ottawa, notamment en bioéthique, Geneviève s'est jointe au Conseil national d'éthique en recherche chez l'humain en 2000. Elle était alors responsable d'aider les établissements de recherche à améliorer leurs programmes de protection des participants à la recherche. Depuis son arrivée aux IRSC en 2002, Geneviève a travaillé dans les domaines de la gouvernance de l'éthique en recherche auprès des êtres humains et sur les conflits d'intérêt, et plus récemment sur les questions d'éthique relatives à la recherche en santé avec les personnes autochtones, et dans le domaine de la santé mondiale. Elle croit à l'importance de sensibiliser les gens à l'éthique et de solidifier les liens entre les différentes organisations oeuvrant dans le domaine de l'éthique. Elle est membre de comité d'éthique de la recherche depuis plusieurs années.*

Lorraine Ferris

Lorraine E. Ferris (PhD., C.Psych., LL.M., LL.M.) is a Professor of Public Health Sciences at U of Toronto and is a Senior Scientist, Clinical Epidemiology Unit, Sunnybrook Health Sciences Centre and in the Institute for Clinical Evaluative Sciences (ICES). Dr Ferris focuses on women's health, health services research, and medico-legal issues, especially issues concerning public protection, standards of care, confidentiality, regulation, and research environments. In 2001, she was appointed as the Judicial Affairs Advisor for the Faculty of Medicine and since 2005 has served as the Academic Advisor, Judicial Affairs and Policy to the Dean of Medicine/Vice Provost (Relations with Health Care Institutions). She has experience in such varied issues such as policy and governance issues, publication ethics, clinical trial agreements, as well as in complex relationships between universities, research institutes/hospitals and for-profit enterprises. Dr. Ferris is the Chair of the Ethics Committee, World Association of Medical Editors and serves on the Editorial Board for Medicine and Law and for Risk Management in Canadian Health Care.

***Lorraine E. Ferris** (PhD., C. Psych., LL.M., LL.M.) est professeur de sciences de la santé publique à l'Université de*

Toronto; elle est aussi scientifique principale à l'unité d'épidémiologie clinique du Sunnybrook Health Sciences Centre et à l'Institute for Clinical Evaluative Sciences (ICES). M^me^ Ferris s'intéresse particulièrement à la santé féminine, à la recherche sur les services de santé et aux questions médico-légales, notamment celles qui concernent la protection du public, les normes s'appliquant aux soins, la confidentialité, la réglementation et les milieux de recherche. En 2001, elle a été nommé conseillère en affaires judiciaires à la faculté de médecine et, depuis 2005, elle est conseillère universitaire – Affaires judiciaires et politique auprès du doyen de la faculté de médecine/vice-recteur (Relations avec les établissements de soins de santé). Elle possède une expérience dans divers domaines, dont les suivants : Politique et gouvernance; Éthique des publications; Accords sur les essais cliniques; Relations complexes entre les universités, les instituts/hôpitaux de recherche et les entreprises à but lucratif. M^me^ Ferris est présidente du Comité d'éthique de la World Association of Medical Editors et elle fait partie du conseil de rédaction des revues Medicine and Law et Risk Management in Canadian Health Care.

Paul Garfinkel

Dr. Paul Garfinkel is currently President and CEO of the Centre for Addiction and Mental Health and Professor, Department of Psychiatry, University of Toronto.
He obtained his medical degree from the University of Manitoba in 1969, and following an internship at the Toronto Western Hospital, did a psychiatric residency at the University of Toronto. He then studied in the Institute of Medical Science at the University of Toronto and later joined the staff of the Clarke Institute of Psychiatry. In 1982, he was appointed Psychiatrist-in-Chief of the Toronto General Hospital, and in 1989 of The Toronto Hospital. In 1990, he became Chair of Psychiatry at the University of Toronto and President and Psychiatrist-in-Chief of the Clarke Institute of Psychiatry. He was appointed President and Chief Executive Officer of the Centre of Addiction and Mental Health, an organization formed from the merger the Addiction Research Foundation, The Clarke Institute of Psychiatry, The Donwood Institute and The Queen St. Mental Health Centre, in 1997. In 1996, he was elected to Fellowship in the Royal Society of Canada. At various times, he has served as Visiting Professor in England, Ireland, Italy and the United States.

Dr. Garfinkel is a researcher, clinician and administrator. He has received grant support for investigations in a variety of fields, including affective disorders, schizophrenia and stress. He is particularly well respected, however, for his clinical and research expertise in the field of eating disorders. He established a comprehensive Eating Disorders Centre at Toronto General Hospital; this program received the Gold Award from the American Psychiatric Association in 1989. Dr. Garfinkel has received numerous research and clinical awards in support of his work in this field, including studies of the prevalence, determinants, diagnosis and outcome of anorexia nervosa and treatment of bulimia nervosa. He is the co-author of Anorexia Nervosa: A Multidimensional Perspective and has edited eight other books in the field, as well as contributing numerous articles to the professional literature (over 150 peer reviewed articles and 80 book chapters) and lecturing widely in his areas of expertise.

Dr. Garfinkel has served in a number of academic and administrative roles including member of the Boards of Trustees of The Clarke Institute, The Toronto Hospital and the Centre for Addiction and Mental Health. He was a member of the Board of Directors of the Canadian Psychiatric Research Foundation and chaired their Professional Advisory Committee. He has served on the Board of the Harvard Centre for Eating Disorders. He has been consultant to the National Institute of Mental Health, the McKnight Foundation, the Medical Research Council (Canada) and an examiner for the Royal College of Physicians and Surgeons of Canada.
Other contributions include a leading role in the advocacy of support for psychiatric science, professional education, public education, fighting the stigma to mental illness and addiction and mentorship of younger scientists in psychiatric research**.**

Dr. Garfinkel's work on eating disorders had been widely recognized to have made a significant contribution to helping people. He has previously been honoured with the ANAD Award (Anorexia Nervosa and Associated Disorders, Chicago), BASH Award (Bulimia Anorexia Self Help, St. Louis), the McNeil Award, the Ontario Mental Health Foundation John Dewan Award, the Canadian Psychiatric Association Award, and as a distinguished lecturer of the American Psychiatric Association. In May 2000, he received the Lifetime Achievement Award from the Academy of Eating Disorders. He received the Pacesetter Award from the Schizophrenia Society of Canada in 2004.

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*Le **D^r^ Paul Garfinkel** est actuellement président et chef de la direction du Centre de toxicomanie et de santé mentale et professeur au Département de psychiatrie de l'Université de Toronto.*

Il a obtenu son diplôme de médecine à l'Université du Manitoba en 1969 et il a fait un internat au Toronto Western Hospital; il a fait un stage en psychiatrie à l'Université de Toronto. Il a ensuite étudié à l'Institute of Medical Science de l'Université de Toronto, pour se joindre après coup au personnel du Clarke Institute of Psychiatry. En 1982, il a été nommé psychiatre en chef au Toronto General Hospital et, en 1989, à l'Hôpital de Toronto. En 1990, il est devenu recteur de la Chaire de psychiatrie à l'Université de Toronto et recteur et psychiatre en chef du Clarke Institute of Psychiatry. Il a été nommé président et chef de la direction du Centre de toxicomanie et de santé mentale, du Clarke Institute of Psychiatry, du Donwood Institute et du Queen St. Mental Health Centre en 1997. En 1996, il a été élu

membre de la Société royale du Canada. À divers moments, il a été professeur invité en Angleterre, en Irlande, en Italie et aux États-Unis.

Le D[r] Garfinkel est chercheur, clinicien et administrateur. Il a reçu des subventions pour mener des recherches dans divers domaines, y compris les troubles affectifs, la schizophrénie et le stress. Cependant, il est particulièrement respecté pour ses compétences de clinicien et de chercheur dans le domaine des troubles de l'alimentation. Il a mis sur pied un imposant Eating Disorders Centre à l'Hôpital général de Toronto; ce programme lui a valu la Médaille d'or de l'American Psychiatric Association en 1989. Le D[r] Garfinkel a mérité de nombreux prix en sa qualité de chercheur et de clinicien, pour son travail dans ce domaine; mentionnons les études sur la prévalence, les déterminants, le diagnostic et les résultats de l'anorexie mentale et sur le traitement de la boulimie. Il a co-rédigé l'ouvrage intitulé Anorexia Nervosa: A Multidimensional Perspective, et huit autres livres ont été publiés sous sa direction dans ce domaine; mentionnons aussi de nombreux articles parus dans la littérature professionnelle (plus de 150 articles évalués par des pairs et 80 chapitres de livre). Il a également fait de nombreux exposés dans ses domaines de compétence.

Le D[r] Garfinkel a rempli divers rôles dans les milieux universitaires et administratifs; il a notamment été membre du conseil d'administration du Clarke Institute, de l'Hôpital de Toronto et du Centre de toxicomanie et de santé mentale. Il a été membre du conseil d'administration de la Fondation canadienne de la recherche en psychiatrie et il a présidé le Comité consultatif professionnel. Il a siégé au conseil du Harvard Centre for Eating Disorders. Il a été expert-conseil auprès du National Institute of Mental Health, de la McKnight Foundation et du Conseil de recherches médicales du Canada et il a été examinateur pour le Collège royal des médecins et chirurgiens du Canada.

Parmi ses autres contributions, mentionnons le rôle de chef de file qu'il a rempli en militant pour la science psychiatrique, l'éducation professionnelle et l'éducation du public, en luttant contre les flétrissures laissées par la maladie mentale et l'assuétude, et en encadrant de jeunes scientifiques menant des recherches en psychiatrie.

Les travaux du D[r] Garfinkel sur les troubles de l'alimentation ont largement été reconnus comme ayant grandement aidé la population. Il a déjà mérité le prix ANAD (Anorexia Nervosa and Associated Disorders, Chicago), le prix BASH (Bulimia Anorexia Self Help, St. Louis), le prix McNeil, le prix John Dewan de la Fondation ontarienne de la santé mentale et le prix de l'Association des psychiatres du Canada. Il a aussi été chargé de cours émérite de l'American Psychiatric Association. En mai 2000, il a reçu de l'Academy of Eating Disorders le prix d'excellence pour l'ensemble de ses réalisations. En 2004, la Société canadienne de schizophrénie lui a décerné le prix Pacesetter.

Glenn Griener

Glenn G. Griener is an Associate Professor in the School of Public Health and the Department of Philosophy at the University of Alberta, and a member of the John Dossetor Health Ethics Centre. He is President of the National Council on Ethics in Human Research; he is chair of the Health Research Ethics Board: Behavioural and Social Research Panel (University of Alberta and Capital Health). ; and Associate Director of the university's Human Research Protections Office. He is NCEHR's representative to the Interagency Advisory Panel on Research Ethics's (PRE) Social Sciences & Humanities Research Ethics Special Working Committee.

Dr. Griener's undergraduate education was in physics (B.Sc., Loyola University, New Orleans). He studied philosophy at the University of Western Ontario (M.A. & Ph.D.) specializing in the philosophy of social science. His current research interests are the ethical aspects of health technology assessment, and the tension between protection of privacy and progress in research - especially the research potential of electronic health records.

***Glenn G. Griener** est professeur agrégé à l'École de santé publique et au Département de philosophie de l'Université de l'Alberta; il est aussi membre du John Dossetor Health Ethics Centre. Il est président du Conseil national d'éthique en recherche chez l'humain et du Comité d'éthique de la recherche en santé : Groupe d'experts sur la recherche comportementale et sociale (Université de l'Alberta et Capital Health). Il est aussi directeur associé du Human Research Protections Office de l'Université. Il représente le CNERH au sein du Comité de travail spécial sur l'éthique de la recherche en sciences humaines du Groupe consultatif interagences en éthique de la recherche.*

M. Griener a fait ses études de premier cycle en physique (B.Sc, Loyola University, Nouvelle-Orléans). Il a étudié la philosophie à la University of Western Ontario (Maîtrise et doctorat) et s'est spécialisé en socio-philosophie. Ses recherches actuelles portent sur les aspects éthiques de l'évaluation des technologies de la santé et sur la tension qui existe entre la protection de la vie privée et les progrès de la recherche – en particulier, le potentiel qu'offrent en matière de recherche les dossiers électroniques sur la santé.

Melody Lin

Melody Lin, as Deputy Director of the Office for Human Research Protections – OHRP (formerly the Office for Protection from Research Risks - OPRR), is responsible for the management of OHRP policy, personnel, and budgetary matters regarding biomedical and behavioural research at both the national and international levels. Dr. Lin also serves as the Director, Office of International Activities at OHRP.

Dr. Melody Lin, a native from Taiwan, received a B.S. degree in Pharmacy and is a Registered Pharmacist. She received her Ph.D. in Microbiology/Immunology in 1976 from the George Washington University Medical Centre and conducted research at the George Washington University Medical Center and the National Cancer Institute, National Institutes of Health (NIH). Dr. Lin is a Captain in the U.S. PHS Commissioned Corps. Previous OHRP/OPRR duties include serving as AIDS Coordinator, Chief of the Compliance Oversight Branch, and Director of Division of Human Subject Protections. Captain Lin is frequently invited to speak on research ethics in genetic testing and genomic medicine and the inclusion of women, minorities, and children in research; and on ethical issues involving international collaborative research. She frequently is invited, by various organizations, to discuss changing landscapes of human subject protection and compliance oversight in clinical trials and federal perspectives relating to IRB issues.

Captain Lin is a member of the Advisory Committee of the National Research Program in Genomic Medicine in Taiwan, is the U.S. liaison to the National Council on Ethics in Human Research in Canada and is a member of the Advisory Council in the European Forum on Good Clinical Practice. Notably, she has organized in excess of ninety conferences for OHRP/OPRR national workshops and scientific symposia. She has served on numerous special panels, task forces, and committees in the Public Health Service. Captain Lin also served as speaker and/or organizer for numerous national and international conferences.

En tant que directrice adjointe de l'Office for Human Research Protections OHRP (anciennement Office for Protection from Research Risks – OPRR), ***Melody Lin*** *est responsable de la gestion de la politique, du personnel et des questions budgétaires de l'OHRP concernant la recherche biomédicale et comportementale aux niveaux national et international. Mme Lin est également directrice du bureau des activités internationales de l'OHRP.*

Native de Taïwan, Mme Lin est titulaire d'un B.Sp. en pharmacie et est pharmacienne agréée. Le George Washington University Medical Centre lui a décerné un doctorat en microbiologie/immunologie en 1976. Elle y a par la suite poursuivi des recherches, de même qu'à l'Institut national pour le cancer aux Instituts nationaux pour la santé (NIH). Mme Lin est capitaine au sein du PHS Commissioned Corps des États-Unis. Parmi les fonctions antérieures qu'elle a occupées à l'OHRP/OPRR, mentionnons coordinatrice pour le SIDA, chef de la direction de la surveillance de la conformité et directrice de la division de la protection des sujets humains en recherche. La capitaine Lin est souvent invitée comme conférencière pour traiter de l'éthique en recherche pour le dépistage et la médecine génétique, des enjeux touchant l'inclusion des femmes, des minorités et des enfants dans la recherche, ainsi que des questions éthiques touchant la recherche internationale. Elle est souvent invitée par différents organismes à discuter de l'évolution de la protection des sujets humains et de la surveillance de la conformité dans les essais cliniques, ainsi que des perspectives fédérales concernant les questions touchant les comités d'éthique pour la recherche (IRB).

La capitaine Lin est membre du Comité aviseur du National Research Program in Genomic Medicine de Taiwan et sert de liaison pour son Bureau avec le Conseil national d'éthique en recherche chez l'humain au Canada. Elle est également membre du Conseil aviseur du European Forum on Good Clinical Practice. Elle a notamment organisé plus de 90 conférences, ateliers nationaux et symposiums scientifiques de l'OHRP/OPRR. Elle a été membre de nombreux panels d'experts, groupes de travail et comités au sein du Service de la santé publique américain. La capitaine Lin a également agi comme conférencière ou organisatrice de nombreuses conférences nationales et internationales.

Martin McNeally

Dr. McKneally is Professor Emeritus of Surgery at the University of Toronto, the Joint Centre for Bioethics, and Toronto General Hospital in the University Health Network. He completed general and cardiothoracic surgical training at the University of Minnesota in 1968. He served as Professor of Surgery and Chief of the Division of Cardiothoracic Surgery at the Albany Medical Center in Albany, New York until 1990. From 1990 to 1995, he served as Chairman of the Division of Thoracic Surgery at the University of Toronto. Since 1995 he has been a member of the University of Toronto Joint Centre for Bioethics, learning, teaching and conducting research on ethical issues in surgery, with a primary focus on informed decision making and innovative treatment.

He has served as Director of the American Board of Thoracic Surgery, Secretary of the American Association for Thoracic Surgery, President of the Thoracic Surgery Directors Association, and President of the Thoracic Surgery Foundation for Research and Education. He is a member of the Society of Thoracic Surgeons' Standards and Ethics Committee, and Ethics Editor of the Journal of Thoracic & Cardiovascular Surgery.

Aideen Moore

Dr. Aideen Moore has served as Chair of the Research Ethics Boards at the Hospital for Sick Children and the University of Toronto. She received her medical degree at the National University of Ireland, Dublin in 1976 and trained in Internal Medicine, Pediatrics and Neonatology before joining the paediatric staff at the Hospital for Sick Children. Dr Moore currently sits on the executive Committee for Human Subjects in Research at the University of Toronto and has a special interest in the ethics of genetic research in children.

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*Le **Dr Aideen Moore** a été présidente des comités d'éthique pour la recherche au Hospital for Sick Children et à l'Université de Toronto. Elle a obtenu son diplôme de médecine à l'Université nationale d'Irlande, à Dublin, en 1976, puis elle a reçu une formation en médecine interne, en pédiatrie et en néonatalogie, avant de se joindre à l'équipe de pédiatrie du Hospital for Sick Children. Le Dr Moore siège actuellement au comité exécutif pour les participants humains à la recherche, à l'Université de Toronto, et elle s'intéresse tout particulièrement à l'éthique de la recherche génétique chez les enfants.*

Michael Owen

Michael Owen, Ph.D. is Associate Vice-President, Research and International Development, Brock University. Dr. Owen has extensive experience in research management and administration and leadership in scholarly associations in Canada. He served as Vice-President Research Dissemination of the Canadian Federation of Humanities and Social Sciences, President of the Society of Research Administrators International (SRA International), and a member of the National Council on Ethics in Human Research.

He has published in the fields of research administration, technology transfer, educational history and Canadian church history. The focus of his current research is on the administration of research ethics and the administration of research in an international context.

His publications include:

Research Ethics and the Humanities and Social Sciences, in L. Chronister and E. Kulakowski, Research Administration and Management. Sudbury, Mass: Jones and Bartlett Publishers, 2006.

Conflict and Convergence: The Ethics Review of Action Research, The Journal of Research Administration, XXXV:II (November 2004), pp. 81-90.

Engaging the Humanities? Research Ethics in Canada, The Journal of Research Administration (2002) XXXIII:III pp. 5-12.

Ethics and Research, IN B. Singh Bolaria and Rosemary Bolaria (eds.) Racial Minorities, Medicine and Health (Halifax: Fernwood and University of Saskatchewan Social Research Unit, 1994), pp. 371-378.

***Michael Owen, Ph.D**., est vice-recteur chargé de la recherche et du développement international à l'Université Brock. Il possède une vaste expérience en gestion et en administration de la recherche et il a dirigé les associations de savants au Canada. Il a été vice-président chargé de la dissémination de la recherche à la Fédération canadienne des sciences humaines, président de la Society of Research Administrators International (SRA International) et membre du Conseil national d'éthique en recherche chez l'humain.*

Il a publié des ouvrages sur l'administration de la recherche, sur le transfert des technologies, sur l'histoire de l'éducation et sur l'histoire des églises canadiennes. Ses travaux actuels portent surtout sur l'éthique de l'administration de la recherche et sur l'administration de la recherche dans un contexte international.

Parmi ses publications figurent les suivantes :

Research Ethics and the Humanities and Social Sciences, dans L. Chronister et E. Kulakowski, Research Administration and Management, Sudbury (Mass.), Jones and Bartlett Publishers, 2006.

Conflict and Convergence: The Ethics Review of Action Research, The Journal of Research Administration, XXXV:II (Novembre 2004), p. 81-90.

Engaging the Humanities? Research Ethics in Canada, The Journal of Research Administration (2002) XXXIII:III, p. 5-12.

Ethics and Research, dans B. Singh Bolaria et Rosemary Bolaria (sous la dir. de), Racial Minorities, Medicine and Health (Halifax : Fernwood et University of Saskatchewan Social Research Unit, 1994), p. 371-378.

Catharine Whiteside

Dr. Whiteside is a medical school graduate of the University of Toronto in 1975. She completed Royal College of Canada postgraduate training in Internal Medicine and Nephrology. Following clinical training she obtained her PhD from the Institute of Medical Science, University of Toronto. Dr. Whiteside joined the Department of Medicine at the University of Toronto in 1985 as a Clinician-Scientist and has engaged in basic research in the field of cellular mechanisms of kidney disease with a particular interest in the study of diabetic nephropathy. In 1996, Dr. Whiteside became a full Professor of Medicine.

Throughout her career as a Nephrologist at the University Health Network and researcher, she has engaged in education at all levels in the Medical School. She is a 2-time winner of the W. T. Aikens Award for contributions to teaching in the undergraduate medical education curriculum. From 1993 to 1999, she was the Graduate Coordinator of the Institute of Medical Sciences, which is the largest graduate unit in the Faculty of Medicine serving the Clinical Departments. During this time, she organized the Certificate Program in Higher Education in the Institute of Medical Science for senior PhD students in health sciences. This program was designed to help doctoral students develop teaching skills in preparation for a future academic career. Dr. Whiteside has particular interest in promoting research training for MDs and directed the Clinician-Scientist training program in the Department of Medicine from 1997 to 2002.

In 2000, Dr. Whiteside assumed the position of Associate Dean Graduate and Inter-Faculty Affairs, Faculty of Medicine University of Toronto with oversight of all graduate and 2nd entry allied health academic programs, as well as the MD/PhD program. This decanal portfolio has enabled Dr. Whiteside to integrate her expertise in research and education. She has worked closely with The Michener Institute for Applied Health Sciences to establish a joint BSc/Diploma in Medical Radiation Sciences program with the Faculty of Medicine. On behalf of the Council of Health Science and Social Work Deans she has chaired the Inter-Professional Education Curriculum Planning Committee from 2001 to 2005.

From July to December 2005, Dr. Whiteside served as Interim Dean of the Faculty of Medicine and in January 2006, Dr. Whiteside became the Dean of Medicine and Vice-Provost, Relations with Health Care Institutions at the University of Toronto.

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*La **D^r^ Whiteside** est diplômée en médecine de l'Université de Toronto (1975). Elle a fait des études supérieures en médecine interne et en néphrologie au Royal College of Canada. Après avoir reçu une formation clinique, elle a obtenu son doctorat à l'Institut des sciences médicales, à l'Université de Toronto. La D^r^ Whiteside est arrivée au Département de médecine de l'Université de Toronto en 1985 à titre de scientifique clinicienne et elle s'est adonnée à la recherche fondamentale dans le domaine des mécanismes cellulaires de la maladie du rein, en s'intéressant particulièrement à l'étude de la néphropathie diabétique. En 1996, la D^r^ Whiteside est devenue professeur de médecine titulaire.*

Tout au long de sa carrière de néphrologue au sein du Réseau de la santé de l'Université et en sa qualité de chercheure, elle s'est intéressée à l'éducation à tous les niveaux de l'École de médecine. Elle a mérité deux fois le prix W. T. Aikens pour avoir contribué à l'enseignement en médecine au niveau du premier cycle universitaire. De 1993 à 1999, elle a été coordonnatrice des études supérieures à l'Institut des sciences médicales, là où se trouve la plus grande faculté d'études supérieures en médecine servant les départements cliniques. Pendant ce temps, elle a organisé le Programme de certificat en éducation supérieure à l'Institut des sciences médicales pour les étudiants en sciences de la santé au niveau du doctorat. Ce programme était conçu pour aider ces étudiants à acquérir des compétences en enseignement en prévision d'une carrière universitaire éventuelle. La D^r^ Whiteside s'intéresse particulièrement à la promotion de la formation des médecins en recherche et elle a ainsi dirigé le programme de formation des scientifiques cliniciens au Département de médecine, de 1997 à 2002.

En 2000, le D^r^ Whiteside a accepté le poste de doyenne associée – Affaires des étudiants diplômés et inter-facultés, à la faculté de médecine de l'Université de Toronto; elle a alors supervisé tous les programmes d'études supérieures et de réinscription pour les disciplines paramédicales ainsi que le programme MD/PhD. Ce mandat a permis à la D^r^ Whiteside d'intégrer ses compétences en recherche et en éducation. Elle a collaboré de près avec le Michener Institute for Applied Health Sciences afin de mettre sur pied un programme mixte de baccalauréat ès sciences et de diplôme en radiologie médicale avec la faculté de médecine. Au nom du Council of Health Science and Social Work Deans, elle a présidé l'Inter-Professional Education Curriculum Planning Committee de 2001 à 2005.

De juillet à décembre 2005, la D^r^ Whiteside a été doyenne intérimaire de la faculté de médecine et, en janvier 2006, elle est devenue doyenne de la faculté de médecine et vice-rectrice – Relations avec les établissements de soins de santé à l'Université de Toronto.

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LIST OF PARTICIPANTS / LISTE DES PARTICIPANTS

Dr. Jim Appleyard World Medical Association	Ms. Kimberly Banks Hart Heart & Stroke Foundation of Canada 1402-222 Queen Street Ottawa, ON K1P 5V9 Telephone / Téléphone : 613-569-4361 Fax / Télécopieur : 613-569-3278 E-mail / Courriel : khart@hsf.ca
Mr. Jason Bechtel University of Toronto Simcoe Hall, Rm. 133-5 27 King's College Circle Toronto, ON M3S 1A1 Telephone / Téléphone : 416-978-7040 Fax / Télécopieur : 416-978-5821 E-mail / Courriel : jason.bechtel@utoronto.ca	Mr. John D. Blackwell St. Francis Xavier University Research Grants Office P.O. Box 5000 Antigonish, NS B2G 1Y8 Telephone / Téléphone : 902-867-3773 Fax / Télécopieur : 902-867-3246 E-mail / Courriel :jblackwe@stfx.ca
Dr. Susan Blum University of Saskatchewan Rm. 304 Kirk Hall 117 Science Place Saskatoon, SK S7N 5C8 Telephone / Téléphone : 306-966-8585 Fax / Télécopieur : 306-966-2069 E-mail / Courriel : susan.blum@usask.ca	Ms. Andrea Budgell Social Sciences and Humanities Research Council 350 Albert Street P.O. Box 1610 Ottawa, ON K1P 6GA Telephone / Téléphone : 613-992-0562 E-mail / Courriel : abu@sshrc.ca
Mr. Jason Busby Health Canada 200 Eglantine Driveway, Tunney's Pasture Ottawa, ON K1A 0K9	Dr. Richard Carpentier National Council on Ethics in Human Research 240 Catherine Street, Suite 208 Ottawa, ON K2P 2G8 Telephone / Téléphone : 613-233-5445 Fax / Télécopieur : 613-233-0658 E-mail / Courriel : rcarpentier@ncehr-cnerh.org
Dr. Adriana Carvalhal Hamilton Health Sciences c/o REB Office 1057 Main St. W Hamilton, ON L8S 1B7 Telephone / Téléphone : 905-525-9140 E-mail / Courriel : carvalh@mcmaster.ca	Prof. Marlene Brant Castellano Trent University 174 Upper Slash Rd. P.O. Box 87 Tyendmaga Mohawk Territory, ON K0K 3A0 Telephone / Téléphone : 613-967-4697 E-mail / Courriel : castellano@kos.net

Prof. Tim Caulfield Health Law Institute, University of Alberta Law Centre, University of Alberta Edmonton, AB T6G 2HS Telephone / Téléphone : 780-492-8358 Fax / Télécopieur : 780-492-9575 E-mail / Courriel : tcaulfield@law.ualberta.ca	Ms. Felicetta Celenza National Council on Ethics in Human Research 240 Catherine Street, Suite 208 Ottawa, ON K2P 2G8 Telephone / Téléphone : 613-233-5445 Fax / Télécopieur : 613-233-0658 E-mail / Courriel : fcelenza@ncehr-cnerh.org
Ms. Alison Collins-Mrakas York University 4700 Keele St., 309 York Lanes Toronto, ON M3J 1P3 Telephone / Téléphone : 416-736-5914 Fax / Télécopieur : E-mail / Courriel : acollins@yorku.ca	Dr. Padraig Darby Centre for Addiction and Mental Health 1001 Queen St. West Toronto, ON M6J 1H4 Telephone / Téléphone : 416-979-6876 Fax / Télécopieur : 416-583-4327 E-mail / Courriel : padraig_darby@camh.net
Randee Melancon University of Saskatchewan 117 Science Place Saskatoon SK S7N 5C8 Telephone / Téléphone : (966-2084) E-mail / Courriel : randee.melancon@usask.ca	Dr. Geneviève Dubois-Flynn Canadian Institutes of Health Research (CIHR) 160 Elgin Street Ottawa, ON K1A 0W9 Telephone / Téléphone : 613-948-5851 Fax / Télécopieur : E-mail / Courriel : gdubois-flynn@cihr-irsc.gc.ca
Ms. Sonya Dudka Dalhousie University Office of Research Services Rm 320 Henry Hicks AA Bldg. Halifax, NS B3H 4H6 Telephone / Téléphone : 902-494-3866 Fax / Télécopieur : 902-494-1595 E-mail / Courriel : sonya.dudka@dal.ca	Jan Duff Carleton University 3100 Kerwin Ave Suite 2205 Mississauga, ON L5A 3S6
Dr. Gordon DuVal The Research Ethics Project 89 Walker Ave Toronto, ON M4V 1G3 Telephone / Téléphone : 416-922-9757 E-mail / Courriel : gordon@researchethicsproject.com	Mme Diane Fafard Conseil national de recherches Canada 1200 Chemin Montréal Édifice M-58 Ottawa, ON K1A 0R6 Telephone / Téléphone : 613-911-9920 Fax / Télécopieur : 613-991-0398 E-mail / Courriel : diane.fafard@nrc-cnrc.gc.ca
Prof. Lorraine Ferris University of Toronto Faculty of Medicine Health Sciences Building, 6th floor Toronto, ON M5T 3M7 Telephone / Téléphone : 416-978-7512 E-mail / Courriel : lorraine.ferris@utoronto.ca	Dr. Paul Garfinkel Centre for Addiction and Mental Health 1001 Queen St. West Toronto, ON M6J 1H4 Telephone / Téléphone : 416-595-6076 Fax / Télécopieur : 416-583-1288 E-mail / Courriel : paul_garfinkel@camh.net
Dr. Glenn Griener University of Alberta Human Research Protections Office 218 Campus Towers Edmonton, AB T6G 1K8 Telephone / Téléphone : 780-492-8208 Fax / Télécopieur : 780-492-9429 E-mail / Courriel : ggriener@ualberta.ca	Ms. Shawna Gutfreund Bloorview Kids Rehab 150 Kilgour Road Toronto, ON M4G 1R8 Telephone / Téléphone : 416-425-6220 x. 3507 Fax / Télécopieur : 416-425-1634 E-mail / Courriel : sgutfreund@bloorview.ca

Mr. Alexander Karabanow Ryerson University 350 Victoria Street Room EPH 415 Toronto, ON M5B 2K3 Telephone / Téléphone : 416-979-5000 x. 7112 Fax / Télécopieur : 416-979-5336 E-mail / Courriel : akaraban@ryerson.ca	Dr. Gerald Kidder University of Western Ontario 1151 Richmond Street, SLB 328 London, ON N0A 5B8 Telephone / Téléphone : 519-661-2031 Fax / Télécopieur : 519-661-3907 E-mail / Courriel : lclaro@uwo.ca
Mrs. Anne Klymenko Lakehead University Office of Research 955 Oliver Road Thunder Bay, ON P7B 5E1 Telephone / Téléphone : 807-343-8223 Fax / Télécopieur : 807-346-7749 E-mail / Courriel : anne.klymenko@lakeheadu.ca	Prof. Daniel Lagarec Université d'Ottawa Ottawa, ON K1N 6N5 Telephone / Téléphone : 613-562-5800x. 1060 Fax / Télécopieur : 613-562-5145 E-mail / Courriel : dlagarec@uottawa.ca
Dr. Glennis Lewis Health Canada - Research Ethics Board Secretariat 1600 Scott St. AL 3104 A, Suite 410 Ottawa, ON K1A 0K9 Telephone / Téléphone : 613-941-5249 Fax / Télécopieur : 613-948-6781 E-mail / Courriel : glennis_lewis@hc-sc.gc.ca	Peter Lewis Ph.D. University of Toronto 1 King's College Circle Faculty of Medicine, MSB Rm. 2331 Toronto, ON M5S 1A8 Telephone / Téléphone : 416-978-5150 Fax / Télécopieur : 416-978-5568 E-mail / Courriel : peter.lewis@utoronto.ca
Dr. Joel Lexchin York University / University Health Network 121 Walmer Rd. Toronto, ON M5R 2X8 Telephone / Téléphone : 416-736-2100 x. 22119 Fax / Télécopieur : 416-736-5227 E-mail / Courriel : jlexchin@yorku.ca	Dr. Melody Lin Office for Human Research Protections, DHHS 1101 Wootton Parkway, Suite 200 Rockville, MA Telephone / Téléphone : 240-453-8126 Fax / Télécopieur : 240-453-6909 E-mail / Courriel : mlin1@osophs.dhhs.gov
Michelle Lindsay York University 4700 Keele Street Room 214 York Lanes Toronto, ON M3J 1P3 Telephone / Téléphone : 416-736-2100 Fax / Télécopieur : 416-736-5512 E-mail / Courriel : mlindsay@yorku.ca	Mrs. Marie Lynch St. Joseph's Healthcare Hamilton 50 Charlton Avenue East Hamilton, ON L8N 4A6 Telephone / Téléphone : 905-522-1155 x. 3418 E-mail / Courriel : mlynch@stjosham.on.ca
Christine MacRae National Council on Ethics in Human Research 240 Catherine Street Suite 208 Ottawa, ON K2P 2G8 Telephone / Téléphone : 613-233-5445 Fax / Télécopieur : 613-233-0658 E-mail / Courriel : cmacrae@ncehr-cnerh.org	Ms. Susan Marlin Queen's University 78 Fifth Field Company Lane Fleming Hall, Jemmett Wing, Room 301 Kingston, ON K7L 3N6 Telephone / Téléphone : 613-533-6081 Fax / Télécopieur : 613-533-6806 E-mail / Courriel : marlins@post.queensu.ca
Dr. Brenda McDowell St. Michael's Hospital, 30 Bond Street Toronto, ON M5B 1W8 Telephone / Téléphone : 416-864-6060 Fax / Télécopieur : 416-864-6043 E-mail / Courriel : mcdowellb@smh.toronto.on.ca	Dr. Martin McKneally Joint Centre for Bioethics; University of Toronto 88 College St. Toronto, ON M5G 1L4

Ms. Romaine Miller The Royal Victoria Hospital 201 Georgian Drive Barrie, ON L4M 6M2 Telephone / Téléphone : 705-728-9090 x. 4376 Fax / Télécopieur : 705-728-9111 E-mail / Courriel : millerr@rvh.on.ca	Dr. Aideen Moore The Hospital for Sick Children E-mail / Courriel : aideen.moore@sickkids.ca
Dr. James Morrison IWK Health Centre 5850/5980 University Ave Halifax, NS B3K 6R8	Ms. Diann Nicholson IWK Health Centre 5850/5980 University Ave Halifax, ON B3K 6R8
Dr. Michael Owen Brock University 500 Glenridge Ave St. Catharines, ON L2S 3A1 Telephone / Téléphone : 905-688-5550 x. 3127 Fax / Télécopieur : 905-688-0748 E-mail / Courriel : mowen@brocku.ca	Anne Pastuszak Women's College Hospital 790 Bay Street, Rm. 749 Toronto, ON M5G 1N8 Telephone / Téléphone : 416-351-3732 x. 2206 Fax / Télécopieur : 416-351-3746 E-mail / Courriel : anne.pastuszak@wchospital.ca
Linda Piazza Heart & Stroke Foundation of Canada 1402-222 Queen Street Ottawa, ON K1P 5V9 Telephone / Téléphone : 613-569-4361 Fax / Télécopieur : 613-569-3278 E-mail / Courriel : lpiazza@hsf.ca	Ms. Susan Pilon Centre for Addiction and Mental Health 33 Russell St. Toronto, ON M5S 2S1 Telephone / Téléphone : 416-535-8501 Fax / Télécopieur : 416-260-4137 E-mail / Courriel : susan_pilon@camh.net
Ms. Rosalyn Reid York University 4700 Keele Street Toronto, ON M3J 1P4 Telephone / Téléphone : 416-736-2100 x. 33786 Fax / Télécopieur : 416-736-5512 E-mail / Courriel : rosalynr@yorku.ca	Ms. Celine Roehrig École de technologie supérieure 1100 Notre-Dame W. Montréal, QC H3C 1K3 Telephone / Téléphone : 514-396-8800 x. 7993 Fax / Télécopieur : 514-396-8525 E-mail / Courriel : celine.roehrig@etsmtl.ca
Mr. Jean Saint-Vil Networks of Centres of Excellence 350 Albert Street Ottawa, ON K1A 1H5 Telephone / Téléphone : 613-947-4538 Fax / Télécopieur : 613-992-7356 E-mail / Courriel : jcs@nce.gc.ca	Dr. Suzette Salama McMaster University c/o REB Office 1057 Main St. W Hamilton, ON L8S 1B7 Telephone / Téléphone : 905-521-2100 x. 42532 E-mail / Courriel : salamsuz@hhsc.ca
Ms. Jo Lynn Saunders University of Guelph, Office of VP (Research) 437 University Centre Guelph, ON N1G 2W1 Telephone / Téléphone : 519-824-4120 x. 54807 Fax / Télécopieur : 519-821-5236 E-mail / Courriel : josaunde@uoguelph.ca	Mrs. Gita Sobhi Hamilton Health Sciences 1200 Main St. W Hamilton, ON L8N 3Z5 Telephone / Téléphone : 905-521-2100 x. 73447 Fax / Télécopieur : E-mail / Courriel : sobhi@hhsc.ca
Ms. Rohini Soni Bloorview Kids Rehab 150 Kilgour Road Toronto, ON M4G 1R8 Telephone / Téléphone : 416-484-3861 Fax / Télécopieur : 416-425-1634 E-mail / Courriel : rsoni@bloorview.ca	Mr. George Taylor The Royal Victoria Hospital 201 Georgian Drive Barrie, ON L4M 6M2 Telephone / Téléphone : 705-728-9090 x. 705-728-9111 Fax / Télécopieur : E-mail / Courriel : millerr@rvh.on.ca

Nadia Taylor The Hospital for Sick Children 555 University Ave Room 5260 Elm Toronto, ON M5G 1X8	Prof. Valerie Thompson University of Saskatchewan 9 Campus Drive Saskatoon, SK S7N 5A5 Telephone / Téléphone : 306-966-6668 Fax / Télécopieur : 306-966-1959 E-mail / Courriel : valerie.thompson@usask.ca
Ms. Marleen Van Laethem St. Michael's Hospital 30 Bond Street Toronto, ON M5B 1W8 Telephone / Téléphone : 416-864-6060 x. 6308 Fax / Télécopieur : 416-864-6043 E-mail / Courriel : vanlaethemm@smh.toronto.on.ca	Mrs. Alison Van Nie McMaster University c/o REB Office 1057 Main St. W Hamilton, ON L8S 1B7 Telephone / Téléphone : 905-525-9140 x. 22057 Fax / Télécopieur : E-mail / Courriel : vanniea@mcmaster.ca
Dr. Nancy Walton Ryerson University 350 Victoria Street Toronto, ON M5B 2K3 Telephone / Téléphone : 416-979-5000 Fax / Télécopieur : 416-979-5332 E-mail / Courriel : nwalton@ryerson.ca	Dr. Catharine Whiteside University of Toronto Room 2109, Medical Sciences Building 1 King's College Circle Toronto, ON M5S 1A8 Telephone / Téléphone : 416-946-7810 Fax / Télécopieur : 416-978-1774 E-mail / Courriel : catharine.whiteside@utoronto.ca
Dr. Rachel Zand University of Toronto 27 King's College Circle #10A Toronto, ON M5S 1A1 Telephone / Téléphone : 416-946-3389 Fax / Télécopieur : 416-946-5763 E-mail / Courriel : rachel.zand@utoronto.ca	