Canadian Institutes of Health Research | Instituts de recherche en santé du Canada

CIHR IRSC

Institutional Conflicts of Interest

CIHR Workshop held October 22-23, 2004, Château Cartier, Aylmer QC

Final Report of the Invitational Meeting

Prepared by CIHR Ethics Office
June 2005

Canada

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Acronyms

COI	Conflicts of interest
ICOI	Institutional Conflicts of Interest
REBs	Research Ethics Boards
MOU	Memorandum of Understanding
CIHR	Canadian Institutes of Health Research
SSHRC	Social Sciences and Humanities Research Council
NSERC	Natural Sciences and Engineering Research Council
SCE	Standing Committee on Ethics
DSMBs	Data and Safety Monitoring Boards
AAHRPP	Association for the Accreditation of Human Research Protection Programs
CMAJ	Canadian Medical Association Journal
PhRMA	Pharmaceutical Research and Manufacturers of America
Rx&D	Canada's Research-Based Pharmaceutical Companies

Abstract

This report summarizes the discussions that took place at the national invitational meeting on Institutional Conflicts of Interest (ICOI) hosted by the Canadian Institutes of Health Research (CIHR) on October 22 and 23, 2004 at the Château Cartier in Aylmer, Québec. The issue of institutional conflict of interest was identified as an emerging priority by CIHR's Standing Committee on Ethics (SCE). The SCE believes that CIHR has a role to play in promoting discussion in the health research community on how to manage ICOI, and through leading by example. The SCE suggested that CIHR invite representatives of the various interested parties to discuss these issues and identify solutions. Given the breadth of the issue of institutional conflict of interest, the planning committee chose to focus on two specific topics at this meeting: sponsorship of health research, and publication and dissemination of research findings.

Participants in the invitational meeting included public and private sponsors of research, researchers, research participants, research ethics board members, ethics and law experts, and journal editors.

The objectives of the meeting were to:

1. identify and clarify key ethical issues regarding potential conflicts of interest in the sponsorship of health research and the dissemination of research results including development, commercialization and publication;
2. identify concrete strategies, including immediate steps, for managing some types of institutional conflicts of interest; and,
3. identify areas in which more research is needed to fully understand and respond to the ethical complexities involved.

In addition, other desired outcomes of the invitational meeting included a suggested short-term action plan for CIHR and feed-back on the draft Tri-agency Memorandum of Understanding schedule on conflict of interest.

Introduction

I. Welcome and Opening Remarks

Christine Fitzgerald, Vice-President of Corporate Affairs, CIHR, welcomed participants to the workshop, and stressed the importance of the issue of conflict of interest (COI) for CIHR.

Susan Sherwin, Research Professor in philosophy at Dalhousie University and Chair of the Planning Committee, presented some of the reasons why the issue of conflict of interest is an important priority for CIHR. CIHR's mandate is to promote research, to ensure that research is ethical, and to facilitate commercialization. As a result, CIHR's position on conflict of interest needs to be clarified. A matter for concern involves potentially conflicting mandates of other institutions in the Canadian research scene, whether they are funding institutions or research institutions such as universities or hospitals. This situation arises from the current trend where government requires universities to more aggressively pursue research opportunities and private funding.

II. Overview of COI issues: Definition of Terms & Range of Issues

Gordon DuVal, Bio-ethicist, University of Toronto Joint Centre for Bioethics

G. DuVal opened his remarks with a quote from Dr. Jonathan Quick: "If clinical trials become a commercial venture in which self-interest overrules public interest and desire overrules science, then the social contract which allows research on human subjects in return for medical advances is broken." He stressed the importance of keeping in mind the social contract to which Dr. Quick is referring.

G. DuVal noted that the potential for financial and other conflicts of interest to influence decision-making by researchers is a familiar problem, and that conflict of interest policies have become increasingly prevalent, particularly among academic research centres and professional and regulatory groups. He also noted, however, that there is increasing recognition that institutions themselves may also be subject to financial and non-financial pressures that may distort responsible institutional decision-making.

G. DuVal described various secondary interests of an institution – or of its decision-makers – that may threaten the organization's ability to meet its primary obligations. He outlined several situations where appropriate decision-making is compromised in institutions, and suggested ways of dealing with them which included focusing on policies and procedures, disclosing ICOI, and developing oversight mechanisms.

G. DuVal's presentation elicited a number of questions and comments. COI committees were discussed as well as the role of Research Ethics Boards (REBs). Other observations included reference to the current situation in Canada in comparison with that existing in the U.S., which has more experience in using specific measures to deal with ICOI issues. Possible creative solutions suggested included the creation, in universities and academic centres, of separate research institutes that isolate commercially-supported research from other forms of research.

Presentation of Two Main Issues

I. Sponsorship of Health Research

Chair: Daryl Pullman, Associate Professor of Medical Ethics, Faculty of Medicine, University of Newfoundland

Position Statement
Michael McDonald, Bio-ethicist, Director of W. Maurice Young Centre for Applied Ethics, University of British Columbia

M. McDonald, SCE member and member of the Planning Committee, presented his views on institutional conflict of interest. He described a conflict of interest situation as one where there is good reason to believe that the independent judgment necessary to fulfill a fiduciary responsibility may be compromised. In such situations, the conflict should be avoided, declared or otherwise appropriately managed. M. McDonald also commented on the relationship between industry and universities and on the fundamental tensions inherent in the various roles that public institutions play. He also stressed the importance of determining who should bear the responsibility within an institution to deal with ICOI issues. He closed his presentation with a list of ten suggestions of practical solutions for addressing institutional conflicts of interest, and some thoughts on the implementation of the proposed measures. He recommended taking a concerted approach, and that there be as much transparency, public accountability and public participation in the process as possible. The list of recommendations discussed by the participants as a group is included in the "Focus on specific strategies section" of this report.

Response from the Perspective of a Research Institution
Bill McBlain, Senior Associate Vice-President (Research), University of Alberta

B. McBlain discussed institutional barriers that interfere with the ability of research institutions to address ICOI. He agreed with M. McDonald's suggestion that the onus in dealing with ICOI is on institutions, not on the public or the media. B. McBlain endorsed the idea of disclosure as a way to manage some institutional conflicts of interest, adding the importance of having consistency and country-wide ground rules for transparency for all universities in Canada. He added that some resistance can be expected where disclosure runs against the grain of university culture and notions of academic independence. He stressed the need for education to 1) recognize the complexity of the situation in universities; 2) acknowledge the importance of dealing with the perception of conflict of interest as much as its reality; and 3) move forward with practical solutions such as those suggested by M. McDonald.

Response from the Perspective of a Research Sponsor
Koenraad Blot, Director, Clinical Research Operations, Pfizer Canada Inc.

K. Blot discussed the importance of distinguishing between sponsors that are not necessarily responsible for the conduct of research and do not necessarily have an interest in the results of research, such as granting agencies, and those that, under the regulatory definition, bear some level of responsibility towards regulators and have a stake in the outcome of research. He agreed that all research sponsors have potential conflicts of interest and that the pharmaceutical industry has been developing and implementing stringent standards and operating procedures derived from the US, Canada and EU regulations. They emphasize the importance of training, as well as documenting, monitoring, validating, and auditing in regard to these COI issues. K. Blot also made a few remarks regarding the informed consent process, indicating that even though it is the most

critical juncture for patients involved in research, sponsors are usually not aware of how patient consent is obtained. He suggested that the consent process be administered by a neutral party.

Response from the Perspective of a Researcher
John Cairns, Project Leader, Clinical Research, Cross-Cutting Initiatives, CIHR

J. Cairns compared the significant progress made in Canada on individual COI with the much slower pace on ICOI. He strongly agreed that COI may threaten the institutional research agenda, trainees, human subjects and the integrity of the research itself, and affirmed that clear, transparent and well-communicated institutional policies are essential in dealing with these issues. Once such policies are developed, they must be closely enforced to ensure effectiveness. He suggested leveraging the successes achieved in the area of individual COI to deal with ICOI. J. Cairns expressed support for COI committees while highlighting potential issues in ensuring independence of their members. He also stressed the importance of a top-down approach to this issue and of ensuring that faculty members and university officers are educated about COI and ICOI policies. He emphasized that giving exclusive contract signing powers to designated university officers would reduce misunderstanding and mitigate liabilities. J. Cairns added that the issue of ICOI should also include a discussion about the CIHR commercialization agenda and the real potential conflicts that may arise.

Questions and Answers

Participants were invited to briefly discuss the presentations. While all agreed on the urgent need for coherent national standards, several questions were raised about how to ensure consistency of institutional policies across the country, who should be responsible for the monitoring and the enforcement role of such standards, how the independence of REBs or ICOI committees can be achieved, whether having regional committees could be a viable option in dealing with ICOI issues, whether a risk management approach to the management of ICOI would be possible, and what parameters should be used when partnering (e.g., is partnering with tobacco companies acceptable?). Comments were made on the danger of over-regulating which could create disincentives to do research, and on the importance of broadening the scope of such requirements to make sure that all health research is covered.

II. Publication and Dissemination of Research Findings

Chair: Susan Zimmerman, Associate, Borden Ladner Gervais

Position Statement
Timothy Caulfield, Research Director, Health Law Institute, University of Alberta

T. Caulfield addressed dissemination of research findings, taken in the broad sense to mean how results are transmitted to the public, and not just publications in peer-review journals. He first presented various sources of ICOI in dissemination of research, then discussed the various adverse impacts on the research environment and for the public perception of science.

On the topic of research and the economic agenda, T. Caulfield noted the increasing commercial ties of universities, and the legislated commercialization mandate of organizations like CIHR and Genome Canada. He used a concept called the “cycle of hype” to illustrate the tendency to publish overly positive messages regarding research and research results, and the increased risk of losing public trust.

T. Caulfield closed his presentation by proposing a number of recommendations to address issues of ICOI in the publication and dissemination of research findings. A list of the recommendations that were discussed by the participants as a group is included in the "Focus on specific strategies section" of this report.

Response from the perspective of a Research Institution
Sandra Crocker, Associate Vice-Principal (Research), Queen's University

Ms. Crocker discussed the difficulties of introducing changes to COI and ethics policies in the university environment, particularly when new policies show some departure from existing provisions of faculty collective agreements. She suggested that while COI may not be eliminated, the way we respond to COI (both individual and institutional) can be improved.

She indicated that it is not practical to compel REBs to review contracts for appropriate publication and confidentiality provisions as this would take them away from their principal mandate that involves the protection of human subjects. Rather, a mechanism should be in place to assure the REB that contracts are being reviewed with COI in mind. For instance, Ms. Crocker described the approach of Queen's University, which is to have a legal counsel assume responsibility for reviewing contracts, and report any issues or concerns to the ethics board. She also stressed the importance of making appropriate arrangements with companies in which universities hold equity, and spoke of the measures taken by Queen's University to address this issue.

Response from the perspective of a Research Sponsor
Marianne Vanderwel, Associate Director, Corporate Pharmaceutical Regulatory Monitoring, Pfizer Inc.

Mrs. Vanderwel introduced the Principles of Conduct of Clinical Trials and Communication of Clinical Trial Results that were issued by the US pharmaceutical industry trade association, PhRMA. These principles support the timely communication of meaningful study results of marketed products, regardless of outcome. Recent proposals regarding registration of clinical trials were discussed as well as the initial responses of PhRMA and various pharmaceutical companies indicating a commitment to better communicate the results of clinical studies of marketed drugs. She expressed a concern about the disclosure of results of early developmental trials with investigational products due to the need to protect intellectual property. Finally, she suggested alternative ways to improve public trust in the research process by establishing, for instance, a Canadian system of accreditation for human research protection programs.

Response from the perspective of a Researcher
Glenville Jones, Craine Professor, Head of Biochemistry & Professor of Medicine, Queen's University

G. Jones first remarked on the gap that usually exists in research institutions, between people knowledgeable in ethics and researchers. He commented that the lack of communication between them is an issue, and also that researchers in general do not give the issue of ICOI as much attention as they should.

G. Jones then described his involvement in the creation of a spin-off company, and shared some observations and lessons learned based on his experience. He identified instances in which publication is affected by commercialization, and where pressures not to publish come into play. He suggested the need to maintain a balance and a separation between spin-off activities and ongoing basic science research.

G. Jones recommended that CIHR and universities make greater efforts to understand the publication pressures put on researchers and that basic research contracts should be reviewed by REBs.

Response from the perspective of a Journal Editor
John Hoey, Editor in Chief, Canadian Medical Association Journal (CMAJ)

J. Hoey presented his perspective as an editor and as a member of the International Committee of Medical Journal Editors. He described the various levels of COI using a pyramid diagram, with financial COI at the top, as the small, visible portion that might damage public trust. At the level below are the personal, social and institutional biases from universities, sponsors, and disease-specific foundations, pushing for positive results. In the third band is some researchers' incompetence which often results in badly-conceived manuscripts, and the bottom tier is due to carelessness, or small errors that get picked up through the editing process. The last two tiers are seldom discussed and are the responsibility of universities.

J. Hoey also underlined the importance of the basic science funnel, which is heavily funded with venture capital funds. He expressed concern that increased targeting of research has a selection effect on basic science and might result in much larger numbers of "orphan diseases" that get ignored. This is because those who fund basic research will not be interested in pursuing certain types of research.

Table Discussions and Plenary Debrief

Following the panel discussion, Ms. Zimmerman facilitated an open discussion on the topic.
An animated debate took place about the registry of clinical trials. Some participants challenged the reluctance of industry representatives to publish trial results. The question of how much information should be included in the registry was also raised and a suggestion was made that patients should be advised before they participate when disclosure of research results will not take place. It was also suggested that the need for transparency be balanced with the business constraints of companies.

The question of public trust was discussed, as was the need to provide additional information to participants in clinical trials to ensure truly informed consent.

Focus on Specific Strategies

I. Recommendations

The recommendations M. McDonald and T. Caulfield developed in their respective position papers were discussed by the participants. The following recommendations received the general support of participants.

Sponsorship of Health Research

- Separate human subjects' research from investment management and technology licensing within research institutions;
- Explore the idea of implementing Institutional COI Committees;
- Provide adequate support for REBs to conduct monitoring of ongoing research (including the creation of DSMBs);
- Develop a standard Canada-wide contract governing university-industry relationships;
- Develop guidelines to help assess when a university-industry project is an academic activity, or when it is more commercial in nature;
- Establish an arm's length accreditation process for oversight of human subject research protection similar to the Association for the Accreditation of Human Research Protection Programs (AAHRPP) in the United States for the monitoring and enforcement of national standards on COI.

Publication and Dissemination of Research Findings

- Establish a Clinical Trial Registry;
- Develop national guidelines for acceptable dissemination/publication policies/contracts - with CIHR taking the lead in collaboration with other key players - and create a virtual network of interested institutions to develop best practices / guidelines / standards / models / templates as a baseline;
- In intellectual property rules, clarify what the concept of research exemption refers to for researchers and research institutions;
- Support open access publishing (i.e., making articles available to the general public free of charge, six months after publication);
- Support the creation of COI policies for publishers/editors/reviewers, etc.;
- Support continued research on the impact of ICOI on dissemination of research results;
- Support education of researchers and graduate students.

Additional recommendations were suggested by participants. They refer to measures that could be taken nationally:

- The development of national guidelines on ICOI: such standards could help guide procedures on ICOI and help unify REB functions. They could address issues such as appropriate disclosure for REB members and the selection of chairs.

- The entity developing such guidelines: an entity should take the leadership in establishing national standards on REB conduct and ICOI. CIHR could be a possible leader.
- The need for education: efforts should be made to enhance general understanding of what constitutes ICOIs. There is a need for the development of education material on ICOI for administrators, REB members, investigators, and patients who are potential research subjects. CIHR would be well positioned to help promote such education.

Suggestions for Research Topics. Participants offered many valuable suggestions concerning potential research questions related to ICOI. These questions have been clustered into the following general categories:

- ICOI: what are the financial or other incentives that create them within research institutions depending on the role of the individual? Which are inevitable? Which go against accepted practice?
- Research institutions: are they sufficiently aware of ICOI? How do they deal with them (a questionnaire or scenarios could be posed to those who develop COI policies)? Are there available resources to efficiently deal with them? How could resources be increased?
- Dealing with ICOIs: how should they be identified and managed? What are individual versus institutional responsibilities regarding situations of ICOIs? What would a risk management approach consist of? What is the current state of non-disclosure clauses? How can disciplinary measures or enforcement be dealt with? A survey of existing institutional policies, best practices and guidelines would be useful.
- Research participants: why do patients participate in clinical trials? What are possible implications for ICOIs? What should be disclosed in the consent process regarding potential ICOI situations? How would research participants respond to disclosure/non disclosure of potential COI during the consent process? What ICOIs may arise from competitive enrolment?
- Appropriate body to help manage ICOI: do REBs generally deal with ICOIs? If so, how do they deal with them and how efficient are they in dealing with them? If they deal with ICOIs, are they the appropriate bodies to do so? Which kinds of ICOIs are inherent within REBs (including REBs that receive a fee)? International comparative work on national or regional bodies that could be put in place would be useful.
- Private sponsorship: are there positive benefits for research institutions that receive funding from private sponsors? What are the negative impacts or threats that stem from such funding? What are the implications of public funding on dissemination of research results? What rights, if any, do private sponsors have concerning the termination of a study?

II. Feedback on the Schedule to the Tri-Council MOU

Participants were asked to provide feedback on the current draft schedule on COI developed by the three funding agencies (CIHR, NSERC, SSHRC) which is intended to form part of the Memorandum of Understanding regarding the roles and responsibilities of research institutions and funding agencies in the management of federal funds. The following feedback was provided by participants:

- There is a need to make reference to the development of quality assurance measures by research institutions to deal with ICOI issues in an effective manner.
- There is a need to include an explicit reference to ICOI in the schedule.
- The schedule should reflect the idea that the institution is responsible for developing mechanisms to identify and manage ICOI.

- The concept of reasonableness should be reflected in the draft schedule regarding what is expected from institutions in dealing with COI issues.
- There is a need to refer to the means whereby institutions and funding agencies would work together to investigate and monitor non-compliance regarding COI issues.
- With reference to paragraph 2.1.c (each institution agrees to ensure that all persons to whom a given policy applies are appropriately informed of their individual obligations and responsibilities under that policy), the statement is not strong enough regarding the responsibility of people concerned. Also, training should be provided and strongly encouraged.
- With reference to paragraph 2.1.e (each institution agrees to put in place a process that provides for effective management of COI situations): it is assumed that research institutions know what effective management of COI situations means, but in fact, guidance is needed.
- With reference to paragraph 2.1.f (each institution agrees to disclose to the Agencies any known COI that may affect decisions about specific applications or requests or grants or awards): this requirement needs to be more circumscribed because it could represent an enormous obligation on the part of institutions.

III. Action Plan for CIHR

Participants made recommendations to CIHR on an action plan in the coming year. The following suggestions were made:

- Publish the report of this invitational meeting, disseminate it and obtain feedback in order to move forward.
- Do an environmental scan on what the current situation is regarding ICOI issues (policies and best practices within research institutions, national and international guidelines).
- Develop an education strategy for researchers and institutions regarding ICOI issues.
- Launch an RFA to address priority ICOI issues in health research.
- Share information from this meeting with the President's Voluntary Sector Committee.
- Organize a stakeholders' conference to explore the idea of accreditation of Research Ethics Boards.

Conclusion

S. Susan Sherwin closed the meeting by thanking participants for their presence and engagement in the discussions. She indicated that the Planning Committee would be reporting back to the SCE on the results of the workshop.

Appendix A – Key ethical concerns and proposed concrete strategies

Groups were invited to discuss two case studies to identify key ethical concerns inherent in ICOI and propose concrete strategies to address them.

Case Study # 1

A brilliant young scientist working at a large hospital-based research centre has developed a molecule that holds promise as a revolutionary new treatment for Alzheimer's disease. However, bringing this potential drug even to the early clinical trial stage would be very expensive. So, the hospital negotiates with venture capital investors to provide the bulk of the funding required for drug development and the hospital would contribute its facilities and the scientific expertise and work to date of the inventor and his research team. A corporation is to be established that would own, develop and market the technology, and manage the research. Under the terms of the Agreement, the hospital would receive equity in the new company and would share evenly in the earnings derived from the technology, after the venture capital sums have been re-paid. The hospital is also entitled to appoint three persons to the new company's Board of Directors, and the plan is to appoint members of the hospital's Board of Trustees or senior management personnel. Corporate Board members would be paid a modest stipend but would receive also options to purchase shares that may become extremely valuable if the new drug is brought to market or licensed or sold to a large drug company. The hospital scientist would be appointed to a senior position in the new company and would be paid a salary and also be offered shares or options.

Key ethical concerns identified:

- There are risks to the protection of human subjects, especially where there is a lack of institutional guidance and leadership to address institutional conflict of interest;
- Pressure on clinicians in the hospital to use the product once it’s marketed;
- Possibility that intellectual freedom of the researcher is captured by financial interests because the Board makes the decisions.

Responsibilities of research institutions in dealing with ICOI issues:

- Develop policies and guidelines on COI on both individual COI and institutional COI;
- Conduct monitoring of ongoing research to ensure that the clinical research on a particular drug is not at the expense of pursuing other drugs.

Elements of an effective management of ICOI:

- Policies/guidelines on COI and ICOI should provide clear and consistent guidance to researchers and hospital representatives;
- Coordination of efforts should be made with broader, international bodies so that a single project carried out in many countries is handled in the same way;
- If the REB is internal, ensure independent reporting, include outside members on the REB, and implement ways to ensure transparency;
- Develop a robust consent form that would protect human subjects and withstand challenges.

Questions and Answers:

- **Who should appoint hospital members to the company?** The hospital could appoint a number of people to this spin-off, but they shouldn't be able to appoint themselves; the appointment function should not rest with the hospital board but with a technology transfer office.
- **What are the options for board members?** No institutional representatives should be on the corporate board of the new company or the University should not have a dominant presence on the Board or be in a position to unduly influence decisions; institutional representatives on the Board should not receive shares, but could be compensated for their role on the Board.
- **What kind of relationship should exist between the hospital board and the technology transfer office**? The technology transfer office should be independent of the hospital board; an arms' length office should be involved in the administration of equity stakes in companies so that it is not up to the board to decide when to sell an equity stake in this company; clear procedures should exist for when it is appropriate to sell; establish effective firewalls between the tech transfer offices and people who make decisions about how the resources of the hospital are invested.
- **What relationship should exist between the company and the research institution/researcher?** The company should be moved off-site, a non-profit company could be established where the venture capitalists get no or low profits; the hospital should not share in profits but profits could be given to a charitable organization; the researcher could be granted a leave of absence from the hospital to be associated with the new venture and his role as clinician should be clarified within the hospital.
- **What conditions should be attached to contract research agreements?** They should be reviewed by an offsite, independent REB or advisory committee; effective safeguards should be developed within the agreements themselves with a clause to allow a researcher to renegotiate certain aspects if he/she feels that the research is being pushed in an unforeseen direction; ensure ownership of the intellectual property is reflected in the researcher's employment contract.

Case Study # 2

Dr. Productive is the Chair of a large general hospital REB. She is also a senior researcher and is the Principal Investigator for a range of industry-funded clinical trials, primarily, but not exclusively, investigator-driven. She also has close ties to a number of pharmaceutical and biotechnology companies. She serves as a consultant and is a member of several speakers' bureaus for industry. Her studies are submitted for approval to her own hospital REB, but she takes no part in the voting with respect to her studies.

Key ethical concerns identified:

- The research institution should not have picked an REB chair with these many connections to the sponsored research;
- Ideally, the REB Chair would not be a researcher, and would not have research interests that would interfere with the proper working of the REB.
- Dr. Productive's presence during the deliberations and vote at REB meetings is an issue since she has an influence on discussions whether or not she votes;
- There is an ethical issue particularly if there is an expedited review process, and if the chair is responsible for expedited review. Solid staff support and presence of a co-chair could mitigate this issue;
- There might be an inherent COI if the chair has a role in developing policy or procedures;

- There is a problem posed by the relationship of the REB chair and other potential applicants coming to that REB for industry-related research in which the chair may have some involvements;
- It is not clear whether the money Dr. Productive receives benefits the hospital or not; the question of conflict of commitment (COC) needs to be addressed;
- The research institution is not able to identify how much money is coming in from any one sponsor under various guises.

Responsibilities of research institutions in dealing with ICOI issues:

- It should be the role of the institution to remind REBs of their fiduciary role to protect subjects of human experimentation in reviewing COI issues;
- Since institutions create situations of COI and COC for employees, they have the responsibility to manage these situations;
- The institution should pay special attention in choosing an REB chair and should be informed of his/her activities that could have an impact on his role as chair;
- REBs should not be asked to investigate COI situations as they have limited resources, officials designated by the institution should fulfill those functions and report to the REB any matter that appears to raise COI questions;
- Membership of the REB should be broadened keeping in mind the needed expertise to avoid it being weakened when a member self-excludes;
- The REB awareness and sensitivity to COI issues should be strengthened through education: training should be mandatory and documented;
- A central listing of all financial contributions of the institution should be maintained so the institution can keep track of how present a particular sponsorship organization is within their walls and be able to monitor possible COI situations.

Elements of an effective management of ICOI:

- REB members should declare any foreseeable potential COI they may have in reviewing research projects;
- The process for declaration of COI could include a more extensive annual process as well as provide an opportunity to declare a COI situation at the beginning of each meeting;
- Consider the question of the level at which the COI must be declared: for oneself only or also spouse's or family members'; specific questions should be asked such as "do you own any shares"; the form could also include a section where researchers could propose solutions to address potential conflicts of interest.

Questions and Answers:

- **What involvement could Dr. Productive have on the REB?** Dr. Productive should not be the chair, but she is valuable as a member of the committee. As a chair, it is not sufficient for her not to vote on her project, she should exclude herself from all of the deliberations. The institution administration should critically review the continued role of the chair.
- **Could Dr. Productive's projects be evaluated by the REB she sits on?** Dr. Productive's projects should go to a small subgroup of REB members in the same institution or to a different REB in another institution;

- **How could expedited review be carried out with Dr. Productive as the REB chair?** if expedited review is carried out by the chair, it should also be done by a small subgroup of REB members to minimize the risks;
- **Should size or ratio considerations be used when evaluating Dr. Productive's involvement in projects with industry?** It makes a big difference if a person is a major player in a small institution or one player among many others in a large institution. Size or ratio should be kept in mind.

Appendix B – List of Participants

Dr. Janet Atkinson-Grosjean
W. Maurice Young Centre for Applied Ethics
University of British Columbia

Mr. David Bell
Manager
Health Sciences Policy Division, PPPD/HPB
Health Canada

Dr. David Brener
Director, Research Translation Programs
Research Portfolio
Canadian Institutes of Health Research (CIHR)

Dr. Richard Carpentier
Executive Director
National Council on Ethics in Human Research (NCEHR)

Dr. An-Wen Chan
Research Advisor & Physician
University of Toronto

Dr. Denis Cournoyer
Associate Professor
Research Ethics Office
McGill University Health Centre

Ms. Barbara Cox
Director
Office of Research Administration
Memorial University of Newfoundland

Dr. Henry Dinsdale
Professor Emeritus
Queen's University

Prof. John B. Dossetor
Prof. Emeritus (Medicine/Bioethics)
University of Alberta

Ms. Martine Dupré
Corporate Secretary
Council Secretariat
Natural Sciences and Engineering Research Council of Canada

Dr. Diane T. Finegood
Scientific Director
CIHR Institute of Nutrition, Metabolism and Diabetes

Dr. Norman Frohlich
Professor
Dept of Business Administration,
I.H Asper School of Business
University of Manitoba

Dr. Brenda L. Gallie
Head, Cancer Informatics Division
University Health Network - Princess Margaret Hospital
Ontario Cancer Institute

Dr. Gordon R. Gray
Professor
Dept of Plant Sciences
University of Saskatchewan

Dr. Ronald Heslegrave
Chair, Research Ethics Board
University Health Network - Mount Sinai Hospital
Ontario Cancer Research Ethics Board

Mr. Derek J. Jones
Executive Director
Secretariat on Research Ethics
Interagency Advisory Panel on Research Ethics (PRE)

Dr. Lyne Létourneau
Professeure sous octroi
Centre de recherche en biologie de la reproduction
Département des sciences animales, Université Laval

Mr. Benoît Lussier
Assistant Director
CIHR Institute of Cancer Research

Dr. Jean Marion
Director, Scientific Affairs
Rx&D

Dr. Barbara McGillivray
President
National Council on Ethics in Human Research (NCEHR)

Mr. Gilles Morier
Director
Research Grants and Ethics
Ottawa University

Dr. Daryl Pullman
Associate Professor
Medical Ethics
Memorial University of Newfoundland

Ms. Stephanie Robertson
Assistant Director
CIHR Institute of Genetics

Dr. Francis Rolleston
Chair, NRC Ottawa REB

Dr. Noralou P. Roos
Professor
Community Health Sciences
University of Manitoba

Dr. Wayne S. Rosen
Clinical lecturer
Dept of Surgery
Office of Medical Bioethics, University of Calgary

Mr. Charles A. Shields, Jr.
Director, External Relations
Canadian Institutes of Health Research (CIHR)

Ms. Susan V. Zimmerman
Associate
Borden Ladner Gervais

CIHR ETHICS OFFICE STAFF

Ms. Patricia Kosseim
Acting Director, Ethics Office
Canadian Institutes of Health Research (CIHR)

Dr. Geneviève Dubois-Flynn
Senior Ethics Policy Officer, Ethics Office
Canadian Institutes of Health Research (CIHR)

FACILITATORS

Dr. Kathleen Oberle
Associate Professor
Faculty of Nursing
University of Calgary

Ms. Lise Hebabi
Groupe Intersol

SPEAKERS

Dr. Koenraad Blot
Director
Medical Operations
Pfizer Canada Inc.

Dr. John A. Cairns
Professor of Medicine
University of British Columbia, and
Project Lead on CIHR Clinical Research Initiative

Dr. Timothy Caulfield
Professor and Canada Research Chair in Health Law and Policy, Faculty of Law and Faculty of Medicine and Dentistry,
Research Director, Health Law Institute
University of Alberta

Ms. Sandra Crocker
Associate Vice-Principal (Research)
Queen's University

Dr. Gordon DuVal
Bioethicist
Joint Centre for Bioethics
University of Toronto

Dr. John Hoey
Editor-in-Chief
CMAJ

Dr. Glenville Jones
Craine Professor and Head, Department of Biochemistry
Professor, Dept of Medicine
Queen's University

Dr. William A. McBlain
Senior Associate Vice-President (Research)
Research Services Office
University of Alberta

Dr. Michael McDonald
Director
W. Maurice Young Centre for Applied Ethics
University of British Columbia

Dr. Susan Sherwin
Professor
Department of Philosophy
Dalhousie University

Ms. Marianne Vanderwel
Associate Director
Corporate Pharmaceutical Regulatory Monitoring
Pfizer Canada Inc.