# CANADIAN INSTITUTES OF HEALTH RESEARCH Workshop

**ETHICS POLICY ON CIHR PARTNERSHIPS WITH THE** 

For-Profit Private Sector March 19 & 20, 2007 Ottawa

**Final Report** 

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#### Introduction

The Director of Ethics for CIHR, Burleigh Trevor-Deutsch opened the workshop by stating that partnerships were central to CIHR's mandate. In the words of CIHR President, Alan Bernstein:

"Key to CIHR's success is an integrative vision that brings together all members of the health research enterprise, including those who fund research, those who carry it out, and those who use its results. Excellence, cooperation and <u>partnership</u> are the hallmarks that will characterize Canada's achievements in health research....Novel <u>partnerships</u> have been forged between CIHR and its partners and we are reaching out, as never before in Canada, to form international alliances."<sup>1</sup>

A key challenge for CIHR is how best to approach the ethical dimensions to partnerships with the for-profit private sector. This report captures the key ideas that emerged over the course of a  $1\frac{1}{2}$  day workshop on ethical issues with representatives from CIHR, industry, academia, non-governmental charities/foundations and federal departments, agencies and networks.

The objectives of the workshop were as follows:

- 1. Identify and foster discussion of the ethical issues associated with CIHR's partnerships with the for-profit private sector; and
- 2. Identify the elements that need to be covered in a CIHR Ethics Policy on partnerships with the for-profit private sector. This policy could be a stand-alone document or incorporated into a section of a broader CIHR policy.

Ethics is about values and principles. CIHR's partnerships to date have underscored the reality that there are significant differences in culture between CIHR and the for-profit private sector. In the context of this workshop on partnerships, discussions focused on values and principles that come into play when a funder like CIHR intersects with the for-profit private sector for mutual benefit. Each party may have different objectives and expected outcomes, and interests may coincide and diverge in different areas. The workshop was an opportunity for individuals to come together, share ideas and engage in constructive dialogue to produce an outcome that will benefit everyone.

In this report, attribution of views to individuals is restricted to those of the guest speakers as these views relate to their presentations and to their response to subsequent questions. Comments expressed in breakout groups, in questionnaires and in general discussion are reported here without attribution.

<sup>&</sup>lt;sup>1</sup> Excerpted from *Investing in Canada's Future: CIHR's Blueprint for Health Research and Innovation*, 2003/04-2007/08, Message from the President. http://www.cihr-irsc.gc.ca/e/20264.html.

# Ethical Considerations, Pitfalls and Opportunities of CIHR Partnerships with the Private Sector

#### **INTRODUCTION (BURLEIGH TREVOR-DEUTSCH, DIRECTOR, CIHR ETHICS OFFICE)**

Burleigh Trevor-Deutsch welcomed participants. In his remarks, he acknowledged that CIHR and its for-profit private sector partners function within different cultures and can bring differing objectives to the partnering relationship. Burleigh noted that both perspectives are valid in their own right but they don't necessarily coincide. These differences, and sometimes stereotypes, need to be identified and respected at all stages of partnership discussions in order to work in a collaborative manner.

#### PRESENTATIONS

Workshop discussions had the benefit of being informed by presentations given by a number of distinguished guests. What follows is a summary of some of the key ideas from these presentations, which provided an intellectual framework for the workshop discussions.

The following individuals performed the dual role of speaker and workshop participant. Complete copies of the presentations offered by each of these individuals can be downloaded from CIHR's website.

#### DOUG DAVIDGE, A/DIRECTOR, ADVERTISING COORDINATION & PARTNERSHIPS DIRECTORATE, PUBLIC WORKS GOVERNMENTS SERVICES CANADA

#### BEST PRACTICE MODEL AND TOOLS

- Doug Davidge began the morning by talking about the experiences that he has had at Public Works Government Services Canada (PWGSC) and as a member of PartnerNet, a community of practice within the federal Public Service. Doug Davidge spoke of the place of partnering in government activities and the importance of not taking ethics for granted, citing the Gomery Inquiry and the new *Federal Accountability Act* as having had a substantial impact on federal practices. In the current context, the public sector is being held to a higher ethical standard than the private sector. The partnering challenge for public servants centers on the ability to balance sound stewardship with innovation and to assess whether a partnering arrangement serves the best interests of the Government of Canada.
- Partnering activities are prevalent throughout the government of Canada. As a result, some departments and agencies have developed tools to better understand and manage the ethical risk environment associated with partnering. Doug Davidge told the participants that bringing to the table a <u>one-pager</u> setting out the government partner's ethics and values can guide the partnership from the start. The following tools were distributed by Doug Davidge and discussed during the workshop:

# • Statement of Partnering Values for Federal Public Servants

Identifies five values that are the core vision for ethical partnering to help guide public servants in their professional partnering activities.

#### • Ethical Partnering Checklist for Federal Public Servants

A checklist that helps to assess and manage the level of risk of a proposed partnering relationship for low or medium risk projects.

#### • High Stakes Partnering Assessment Tool

Helps to assess the ethical risks related both to individual behaviour as well as broader ethical risks associated with the Government of Canada's reputation and responsibilities in partnering activities. High stakes partnering is defined as an activity, event or project involving some or all of the following characteristics: high profile or high visibility impact, multiple partners and affiliates, significant financial investment, alliances with organizations who may be subject to litigation by the Government of Canada or have poor environmental practices and questionable reputations and affiliations.

• Doug also provided copies to the Ethics Office of another PWGSC document, *A Model for Successful Partnering Arrangements* (No. 2, February 2007, Best Practices in Government of Canada Partnering).

- A number of participants found Doug Davidge's best practice tools extremely useful and referred to them in discussions during the workshop.
- Doug was questioned about whether the Gomery Inquiry could rightly be framed as an ethics issue and argued that it went past ethics and was an outright fraud. In response, Doug pointed out that as a result of Gomery, senior managers have become risk averse and public servants have been required to take ethics courses, moving ethics discussions to the forefront of many issues.
- The question was raised as to whether there were some companies, for example tobacco companies or Merck Frosst after the withdrawal of Vioxx, that should not be partnered with, and whether the federal tools "had bite". Doug Davidge pointed out that there are legal restrictions on partnerships with tobacco companies.<sup>2</sup> In the discussion that followed, some participants suggested that these issues often are not "black and white"-

<sup>&</sup>lt;sup>2</sup> See Health Canada information on amendments to the *Tobacco Act* (http://www.hc-sc.gc.ca/hl-vs/tobac-tabac/fact-fait/fs-if/sponsor-commandite/index\_e.html). The Health Canada text states: "It should be noted that the Act will not prohibit tobacco companies from supporting cultural and sporting organizations and events. Rather, it is simply banning the promotion of such sponsorship."

- for example, with regard to Vioxx, many patients considered that drug beneficial and still want access to it; and, to make an analogy to the public sector, the fraudulent actions of a few federal employees shouldn't mean that partnerships with all federal departments are prohibited.

# DIANE FINEGOOD, SCIENTIFIC DIRECTOR, CIHR INSTITUTE OF NUTRITION, METABOLISM AND DIABETES, SIMON FRASER UNIVERSITY

#### CASE STUDY

- Diane Finegood provided a case study perspective and spoke about "Canada on the Move," CIHR's first partnership with the food industry. Canadians who used pedometers found in Kellogg's cereal boxes were encouraged to log on to the Canada on the Move website and record their steps in an effort to contribute to a national research project. The partnership created a unique link between the sales and marketing activities of Kellogg's, and benefits to the health of the Canadian public.
- Experience from the Kellogg's case study and other partnering activities have shown that a collegial approach to partnering is necessary, and trust is a key issue in a successful partnership. A partnership is based on creating or responding to an opportunity in which partners have complimentary expertise or resources that can be used to accomplish more together than either party could by themselves. Within this context, an effective partnering relationship will depend on continuous, honest and open communication; respect; clearly stated long term objectives/goals; and time to devote to the collaboration. Communication must be strong at the beginning and agreements must be confirmed continually at each step of the project. Difficulties can arise when communication is hindered by differences in assumptions and terminology, despite good intentions on all sides. There can be no hidden agendas and there must be transparency in the intentions of stakeholders. An 'us' versus 'them' mentality can be self-destructive.
- The following areas were identified by Diane Finegood as of particular importance to the ethics component of partnership relationships:
  - *Reputation*: Protecting respective brands is foremost for all parties.
  - *Culture*: Partners will speak different languages and will have different approaches to managing outcomes and communications.
  - *Governance and accountability systems*: Need to be established at the beginning and managed throughout the life of the partnership.
  - *Conflicting mandate, interests and priorities*: CIHR and for-profit private sector partners may have differing mandates that will need to be addressed.

- Following the presentation there was a short discussion of the issue of the poor quality of the Kellogg's pedometers and the impact they may have had on the research project. Diane Finegood described how this issue was addressed directly and openly in the research study.
- Participants were also interested in discussing the criteria used to assess partnerships. Diane Finegood mentioned reputation and reliability, but asserted she used no hard and fast rules.
- Diane Finegood also noted, in continuing the conversation from the earlier presentation, that "Canada on the Move" was brought to an end because her Institute could not seek additional sponsorship at the time due to the Gomery Inquiry.

# DAVID CASTLE, CANADA RESEARCH CHAIR IN SCIENCE AND SOCIETY; AND CIHR STANDING COMMITTEE ON ETHICS MEMBER

#### **DUALITIES OF INTEREST**

- David Castle began his presentation by walking participants through historical examples of partnership activities between for-profit industry and science that have led to significant discoveries, as well as the various perspectives that have been brought to bear on the issue of ethics over the years. He noted the mandate for partnerships that is established in CIHR's governing legislation (the CIHR Act).
- A key message from this presentation was that a more nuanced, ethical vocabulary is needed in the area of conflict of interest statements. Conflict of interest statements are important, but tend to be so broad that every party could be construed as being in a conflict of interest. Ethics should be about <u>real</u>, not perceived, harms; and conflict of interest statements should be restricted to <u>demonstrable</u> conflicts of interest. Standards regarding conflicts of interest can be codifiable at the level of policy, but not at the level of procedure. In the end, the issue is about creating the right kind of institutional culture, rather than a procedure-heavy policing environment.
- According to David Castle, *duality of interests* represents an associated concept that encourages disclosure, but also builds trust. It is a declared or undeclared ulterior motive not contrary to the interests of the partnering organizations. A duality of interest can include employment; membership on a board of directors or other fiduciary relationship; ownership of stock; receipt of honoraria or consulting fees; and receipt of financial support or grants for research.
- One of the key points for discussion was that the question about partnerships for CIHR is not *whether*, but *how*.

- Following David Castle's presentation, a discussion ensued as to the true value of partnerships with the for-profit private sector to CIHR. It was put forward that there is no evidence that such partnerships benefit the public at large or the Canadian economy. David Castle responded that there is a need to think through the underlying rationale for a partnership before engaging in one, and agreed that it can be very difficult to measure wealth creation as a result of these partnership activities.
- Participants were also very interested in better understanding the concept of a duality of interest. David Castle clarified that using a duality of interest statement doesn't force individuals or organizations to try to remove overlapping interest. Rather, it encourages the management of overlapping interests to an appropriate standard.
- The question was raised as to whether oversight over "dualities of interest" was needed. David Castle responded that self-policing can be effective, and CIHR is not faced with a string of partnership failures that need to be corrected. However, the formal language (of conflict of interest) needs to be improved, and there should be mechanisms for identifying problems and for mediation. The question remains as to whether a third party should set the standards.

#### JEAN MARION, DIRECTOR, SCIENTIFIC AFFAIRS, CANADA'S RESEARCH-BASED PHARMACEUTICAL COMPANIES (Rx&D); AND CIHR INSTITUTE OF CIRCULATORY AND RESPIRATORY HEALTH ADVISORY BOARD MEMBER

#### PRIVATE SECTOR REALITY: RX & D PERSPECTIVE

- Canada's Research-Based Pharmaceutical Companies (Rx&D) have a history of partnering with CIHR. Jean Marion outlined the areas of overlapping interest and public-private synergies between Rx & D member organizations and CIHR. He also summarized the ethical considerations and boundaries within which private sector organizations and researchers must operate and identified a variety of issues that are of continuing interest to pharmaceutical companies when considering a partnering relationship with CIHR.
- There is a significant overlap of interests between public and for-profit private sector institutions. Both parties want to enhance the capacity and the performance of health research in Canada by leveraging research investments, creating synergies between researchers in academe and industry, and developing highly qualified personnel. The translation of knowledge into medicinal therapies is also central, as is a contribution to disease management research.
- It is often said that public institutions are held to a higher standard due to their accountability for the management of public funds. However, Jean Marion noted that every stage of research conducted by the private sector is bound by an ethical framework, and there is an Rx & D Code of Conduct relevant to research ethics. Research ethics boards, international standards, Canadian Council on Animal Care reviews and the terms

and conditions within collaborative agreements for publication and disclosure, are all examples of the ethical checks and balances within the private sector research community.

- A myth associated with private sector funding opportunities is the existence of a 'magic pot of money.' According to Jean Marion, this can't be farther from the truth. Research funds in the private sector are generated through revenues and investments; and intellectual property, competitive advantage and knowledge management are essential for competing in science. Also, research and development efforts within Canadian businesses are generally part of global programs and are required to have internationally harmonized approaches.
- When considering collaboration with CIHR, Rx & D or member companies want to have the option of being involved early on in the process and have the opportunity to perform their own due diligence in order to assess the collaboration prospect against corporate strategic priorities and standards. Undertaking a relevancy review is also a key "go/no go" decision, which requires adequate information from all parties. Further involvement by industry within collaborative arrangements could include the option to suggest experts for peer-review committees; the opportunity to observe the value that peer-review adds; access to peer-review comments (with consent); and participation in the annual progress review of funded projects.
- Jean Marion expressed the view that health research can benefit from the intellectual capability of both public and private research communities with complementary expertise and research strategies. Reasonable safeguards are needed in order to manage potential conflicts between partners, but they can't be so strict as to deter interaction and the pursuit of good science for the benefit of society.

- Participants were interested in hearing further views on whether pharmaceutical companies use the concepts of "partnership" and "collaboration" interchangeably. Jean Marion explained that there are two broad ways for Rx & D member companies to interact with the public research sector: one is through a research contract that is managed within an academic milieu and is overseen by the sponsor; and the other is a research collaboration or agreement which may or may not involve intellectual property issues. For example, in the CIHR/Rx & D Collaborative Research Program, the Rx & D partners fulfill requirements for federal Scientific Research and Experimental Development (SR&ED) investment tax credits, support basic research, and have access only to the pre-print results of the research.
- Jean Marion was asked if there are relevant differences between the pharmaceutical sector and other for-profits, and he responded that a key difference between for-profits can be whether they have in-house capacity for research.

# DAVID BRENER, DIRECTOR, RESEARCH TRANSLATION UNIT, CIHR

#### **CIHR COMMERCIALIZATION STRATEGY**

- David Brener outlined the various collaborations in which CIHR engages with the private sector in operationalizing its commercialization strategy, through *research*, *talent*, *capital* and *networks/linkages*. Participants were informed of success stories from recent years and of the strengths and challenges associated with CIHR's current ethics infrastructure as it relates to partnership activities.
- The ethics policy framework for industry-partnered programs was outlined:
  - Any research carried out with funds from CIHR must respect all of CIHR's requirements for the ethical conduct of research as expressed in policy documents.
  - Primary responsibility for compliance is on the researchers and institutions in which the research is to be conducted are required to have in place ethics review committees.
  - CIHR reserves the right to deny or withdraw funding if the researcher or the institution does not comply with the required guidelines.
- Challenges associated with these industry-partnered programs include:
  - Eligibility requirements for private sector partners (e.g., is this a true partner or a "shell company'?);
  - Rules that encourage premature equity dilution by applicants (i.e., under CIHR guidelines, an individual is not eligible to apply for a research grant or award if he or she has financial interest holdings greater than 5% in the company proposed as the industry partner);
  - Project triaging (e.g., issues around the sharing of information for peer review);
  - Funding ratios (the ratio of CIHR to private sector contributions);
  - Peer review cycle for randomized controlled trials, which is too long for most external stakeholders; and
  - Institutional intellectual property (IP) policies and private sector objectives.

- Discussion following the presentation focused on the role of private funding and the process that is followed from a pharmaceutical perspective in reviewing an application.
- David Brener also noted that Canada has proven to be a leader in developing programs to work with the private sector, and other countries have now launched their own innovative programs that parallel the Canadian experience.

### JANET ATKINSON-GROSJEAN, SENIOR RESEARCH ASSOCIATE; LEADER, TRANSLATIONAL GENOMICS GE3LS PROJECT; THE W. MAURICE YOUNG CENTRE FOR APPLIED ETHICS, UNIVERSITY OF BRITISH COLUMBIA

# PUBLIC-PRIVATE PARTNERSHIPS AND HYBRID ORGANIZATIONS

- Janet Atkinson-Grosjean provided a comparison of the old and new orders of research. Unlike in the so-called "golden age" of research, the public/private divide is now open and permeable. The boundaries are messy and hybrid organizations have emerged that engage in <u>translational science</u> between academic institutions practicing pure basic science and commercial organizations practicing pure applied science.
- An "ethics gap" has opened that is unique to these hybrid organizations and other publicprivate partnerships (PPPs). Whereas public sector organizations are guided by public sector ethics and democratic values, and private sector organizations are guided by business ethics and commercial values, the question is where do hybrids fit.
- Janet Atkison-Grosjean described a research study she is engaged in which is investigating translational genomics (i.e., activities that tends to move genomics out of the laboratory, and into the market, the clinic, or society at large). The research team will be exploring the ethics gap in hybrid organizations engaged in this translational activity and the development of policy-relevant ethical guidelines.
- Question for further discussion included:
  - What is the problem that PPP's and other hybrid agencies were established to address?
  - In what ways do PPPs and other hybrid agencies add value to the research enterprise?
  - Are PPPs a novel and productive convergence of public and private interests? Or, are they an ideologically-driven policy reform? Are the two mutually exclusive?

### Discussion

• Janet was asked where CIHR should be placed on the paradigm between public, private and hybrid organizations. Janet acknowledged that research councils are unique bodies but suggested that they are faced with translational demands that are similar to those faced by hybrid organizations.

#### Workshop Discussions

#### DEVELOPING AN ETHICS POLICY ON PARTNERSHIPS WITH THE FOR-PROFIT PRIVATE SECTOR

Following the plenary presentations and discussions with speakers, participants were divided into four working groups and were asked to answer the following questions:

- What are the potential situations in which ethical issues arise for CIHR related to partnerships with the private sector?
- What might be some of the elements of an ethics policy (e.g. scope, principles, key content areas etc.)?
- Is it desirable and achievable to have a single policy on ethics for private sector partnerships (i.e. that applies to all Institutes and central CIHR; for commercialization and non commercialization partnerships)?
- How might a new ethics policy for partnerships with the private sector impact the way that CIHR currently approaches partnerships with the private sector? How can the policy serve to enhance partnership opportunities (i.e. ensure the right partnerships on the right terms)?
- What will make the policy meaningful and effective?

The working groups were organized into multisectoral groups with representatives from individuals internal to CIHR as well as external stakeholders. What follows is their collective response to the questions above.

# What are the potential situations in which ethical issues arise for CIHR related to partnerships with the private sector?

- Looking to commercialize research and working with the investment community (such as venture capitalists) to set and manage the conditions under which that can occur.
- When a relationship involves an 'active' partnership, in which case undue influence needs to be managed.
- When a pooled fund is being created or used versus funding for individual projects.
- When private money is required to move forward with a project.
- A change in government policy.
- A change in the partners involved in the project.
- When new knowledge raises new ethical issues.

#### What might be some of the elements of an ethics policy?

- Strategic objectives and mandate
- Start with large, broad issues and then adapt. Don't be restrictive and avoid overcompliance.
- Conflict of interest guidelines.
- High level set of principles for hybrid entities.
- Disclosure and due diligence requirements in order to assess risk.
- Alignment of values between and among partners.

- The need for clear, well articulated objectives.
- Clear definition of terms.
- Ability to tailor the policy/partnership tools to both large and small partners.
- Approaches to commercialization and intellectual property.
- Criteria for choosing appropriate partners.
- Recognition of the values systems of the partners and that organizational cultures may be different.
- It needs to be linked to international realities, not just the Canadian context.
- It should build on the strengths of each partner.

A recommendation was made to build on tools already developed by other organizations. PWGSC's High Stakes Partnering Assessment Tool was seen as particularly valuable and informed many of the discussions within the working groups.

#### Is it desirable and achievable to have a single policy on ethics for private sector partnerships?

- The use of a single policy is recommended, however, it will need to be designed to allow for consistency across strategic issues but with variability to allow for differences in partnering situations and potential changes in government policy and direction.
- An encompassing policy on partnerships, not just for ethics, would be beneficial.

# How might a new ethics policy for partnerships with the private sector impact the way that CIHR currently approaches partnerships with the private sector? How can the policy serve to enhance partnership opportunities?

- Potential to broaden and enhance CIHR's work and scope.
- New guidelines and policies will help to better balance risk and benefit.
- A wider range of opportunities will be opened to CIHR.

#### What will make the policy meaningful and effective?

- Enhanced capacity to take well informed risks.
- Create the capacity to respond to opportunities.
- Ensure buy-in from governing council and throughout various levels of stakeholders.
- Improved communication within CIHR and with stakeholders.
- Recognition and accommodation of diversity of institutes and partners.

# PARTICIPANT QUESTIONNAIRE: END OF DAY 1

After listening to presentations, dialoguing with speakers and engaging in small group discussions, participants ended the first day by filling out a short, one page survey. Participants were asked to respond to three open-ended questions: (1) identify the most important ethical issues associated with CIHR's partnerships with the for-profit private sector, (2) identify the elements that need to be covered in a CIHR ethics policy on partnerships with the for-profit private sector, and (3) other issues relevant to participants. The responses to the survey were presented to the group the next morning in order of frequency of mention.

#### MOST IMPORTANT ETHICAL ISSUES

• Clearly defined mission/objectives consistent with CIHR mandate

CIHR must be clear in its mission and objectives for partnerships at the institutional level. These elements will provide the framework within which partnerships can be created. Where the mission of CIHR and the partner are too diverse the partnership opportunity should be passed. If the high level missions are compatible, then an analysis of the mission and objectives at the project level is necessary to ensure compatibility on an ethical level.

In discussion it was suggested that a fundamental first step is for CIHR to perform a high level test to determine where the agency situates itself on a scale of organizational mandate between the poles of protecting the public's health at one end, and stimulating the economy at the other. The result of this determination will shape its partnership practices.

• *Management of risk and protection of CIHR reputation and independence* One of the most important components of a partnering relationship to all involved is the preservation of the institutional reputation. Balancing the opportunities that partnerships can bring with the need to manage risk will play an important role in the success of the relationship.

During the discussion, it was suggested that CIHR should also consider alternatives to a proposed partnership that involves risks.

- *Effective management of duality of conflict / conflict of interest* All partner relationships will involve conflict of interest and dualities of interest. Additional work is needed to define these two concepts and build a framework that is practical and realistic.
- *Due diligence and proper disclosure* Understanding the partner with which one is working and building transparency into the relationship at the early stages of development will be critical to the success of the partnership.

### • Determine/assess the value and benefits of the partnership

Each organization at the outset must have a clear understanding of the value and benefits that the partnership will offer. Partnerships allow for new opportunities but they are not necessarily the most appropriate tool in all circumstances. Partnerships should be used when suitable and when each partner has a clear understanding of its value and benefit.

# • Clarity on intellectual property issues

Managing the intellectual property involved in projects of a partnership nature can often be challenging and of utmost importance to the for-profit private sector partners. The relationship of CIHR to the commercial goals of the private sector partner needs to be clearly articulated and understood.

# ELEMENTS OF A POLICY ON THE ETHICS OF PARTNERSHIPS

Some participants at the workshop found it difficult to distinguish between the development of an ethical partnership policy and the development of a policy on the ethics of partnership. There was general agreement that this workshop should focus on an ethics policy as a component of a broader partnership policy. The long term goal of CIHR is to ensure that ethical principles are embedded in the partnership policy and in how individuals think and behave.

The following elements of an ethics policy were identified in participant questionnaires, and discussed in plenary.

### • Establish broad overarching principles

The partner relationship should be grounded in principles that all parties support and uphold. The public good, transparency, access to information, accountability and governance were recommended as a good starting point for the policy. In addition to establishing high level principles, it was recommended that the policy articulate the expected outcomes and consequences arising from valuable partnerships along with guidance on behaviour to ensure proper conduct at both an institutional *and* individual level.

### • Flexibility and balance

The importance of building an ethics policy that allows for flexibility and balance were articulated extensively over the course of the workshop. The issue of ethics requires reflection, wisdom and a balancing of demands that can rarely be characterized as black/white or yes/no. As a result, an ethics policy needs to encourage consistency but allow for flexibility to assess risk and respond to opportunities.

# • Language that encourages partnerships

An ethics policy needs to be written in a way that encourages partnerships and does not inhibit the ability of CIHR and for-profit private sector businesses to build relationships based on mutually beneficial goals. A conflict of interest statement needs to be practical. Support was also given for the development of a duality of interest statement that encourages disclosure, but also builds trust.

#### • Stewardship of resources

CIHR has been given the task of balancing sound stewardship (using resources wisely and acting in the public's best interest) with innovation (new and better ways to get greater value from the public dollar). At times these interests can be complementary, but more often than not, they are seen as competing. It can be difficult to balance the opportunities and challenges that are inherent in each. Ethics lies in the middle of this balancing act and an ethics policy specific to partnerships will need to help decision makers assess whether a partnering arrangement will serve CIHR's best interests.

### • Evaluation process

Ethics issues not only arise at the initiation of a relationship, but they can also surface at any time during the life of a partnership. An ethics policy should also provide guidance on how to manage challenges that emerge after a partnership relationship his been established and the project is in the middle of completion.

### • Best practices and tools

High level guidance on ethics is an important first step, but case studies, commentaries, criteria and tools would help to operationalize high level policies and provide guidance to practitioners. Ethical issues require reflection, balance and a certain amount of practice and wisdom. Building best practice tools in support of a high level ethics policy would make a valuable contribution to partnership activities at CIHR.

### • Minimal Bureaucracy

The need for a *practical* ethics policy was a consistent topic of discussion among participants. Along this vein, participants underscored the message that building a bureaucratic, top-heavy and complex process to review and 'approve' partnerships would be unhelpful.

# Where Do We Go From Here?

The Ethics Office within CIHR has taken the lead on building an ethics policy on partnerships with the for-profit private sector. The discussion and feedback provided through the workshop has provided a welcome starting point for this undertaking. In moving forward, the following steps were put forward for consideration by the Ethics Office in continuing the work of building the policy:

*Internal Discussions:* The topic of partnerships is one that involves many other individuals and groups within CIHR. The feedback from the workshop has provided a great deal of input which will be synthesized and shared with a recently established internal CIHR Partnerships Working Group, which has representatives from both the central level and the Institutes. The broader partnerships policy is currently under review and the Ethics Office will feed the intelligence gathered through this dialogue into the review process.

*External Consultations:* Additional input from the for-profit private sector is needed. The consultation process needs to ensure that the focus is not solely on the pharmaceutical industry.

Each industry within the private sector has its own experiences with partnerships. Feedback from a variety of perspectives should be sought to ensure the policy is comprehensive and unbiased toward a specific industry or type of company.

*Standing Committee on Ethics:* CIHR's Standing Committee on Ethics is mandated to provide high level advice on ethics and this body will be engaged to assist in the development of the Ethics Policy for partnerships with the for-profit private sector.

**Process – Timely and Ongoing:** It is recognized that the development of an ethics policy on partnerships will take time. CIHR was encouraged not to view the development of an ethics policy as the only goal or output, but to recognize that it should be part of a broader ethics process within which partners will function. Don't wait for a year or two to develop the perfect policy: be a learning organization. Partnerships have been occurring on an ad hoc basis for many years and experiential learning is going on right now. The earlier that CIHR can systematize these lessons and make them accessible to practitioners the better.

*Learn From Others:* Other federal departments/agencies and organizations external to the federal government have been working within a partnership model for many years. Effort should be taken to build on work already in practice, such as the *Best Practices in Government of Canada Partnering* document produced by PWGSC, the Industrial Research Assistance Program at the National Research Council, the Canada Foundation for Innovation, the Treasury Board Secretariat's public interest test (19 questions), Health Canada's risk management model and partnership policies within the private sector.

# Appendix A: Workshop Agenda

# **CIHR Workshop:** Ethics Policy on Partnerships with the for-profit Private Sector

#### Monday, March 19- Tuesday, March 20, 2007 Ontario Room, Lord Elgin Hotel 100 Elgin Street, Ottawa, ON K1P 5K8 Tel: (613) 235-3333 Toll Free: (800) 267-4298 Fax: (613) 235-3223 Web: http://www.lordelginhotel.ca

#### Workshop objectives:

- Identify and foster discussion of the ethical issues associated with CIHR's partnerships with the for-profit private sector.
- Identify the elements that need to be covered in a CIHR Ethics Policy on partnerships with the for-profit private sector. This policy could be a stand-alone document or incorporated into a section of a broader CIHR policy.

### Day One - Monday, March 19, 2007

- 9:00 9:15 Introduction Burleigh Trevor-Deutsch (CIHR Ethics Office)
- 9:15 9:25 **Workshop format & protocol** *Bob Plamondon (Workshop Facilitator)*
- 9:25 10:30 **Presentations & plenary discussion: Partnerships general principles** Speakers:
  - Doug Davidge, A/Director, Advertising Coordination & Partnerships Directorate, Public Works Governments Services Canada
  - Diane Finegood, Scientific Director, CIHR Institute of Nutrition, Metabolism and Diabetes, Simon Fraser University
- 10:30 10:45 **Break** (with refreshments)
- 10:45 12:00 **Presentations & plenary discussion**: **Ethical considerations, pitfalls and opportunities of CIHR partnerships with the Private Sector** *Speakers*:
  - David Castle, Canada Research Chair in Science and Society; and CIHR Standing Committee on Ethics member
  - Jean Marion, Director, Scientific Affairs, Canada's Research-based Pharmaceutical Companies (Rx&D); and CIHR Institute of Circulatory and Respiratory Health Advisory Board member

- 12:00 1:00 **Lunch** (*in plenary room*)
- 1:00 2:15 **Presentations & plenary discussion: More perspectives on ethical considerations, pitfalls and opportunities** *Speakers:* 
  - David Brener, Director, Research Translation Unit, CIHR
  - Janet Atkinson-Grosjean, Senior Research Associate; Leader, Translational Genomics GE3LS Project; The W. Maurice Young Centre for Applied Ethics, University of British Columbia
- 2:15-2:30 **Break** (*with refreshments*)
- 2:30 3:30 Break out groups
- 3:30 4:25 **Reports from break out groups & plenary discussion**
- 4:25 4:30 **Participant survey of viewpoints, issues**
- 4:30 Adjournment

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Day Two - Tuesday March 20, 2007

- 9:00 9:20 **Plenary report on participant survey** Bob Plamondon (Facilitator)
- 9:20 10:30 Break out groups: Policy development and next steps
- 10:30 10:45 Break (with refreshments)
- 10:45 11:45 Reports from break out groups & plenary discussion
- 11:45 11:55 Conclusion Burleigh Trevor-Deutsch (CIHR Ethics Office)
- 11:55 12:00 Workshop evaluation forms
- 12:00 1:00 **Networking lunch** (*in plenary room*)
- 1:00 **Adjournment** (CIHR leads are available until 2:00 p.m.)

#### March 19-20, 2007

# **Appendix B: List of Speakers and Participants**

#### **CIHR** Workshop, March 19-20, 2007, Ottawa Ethics Policy on Partnerships with the for-profit Private Sector

#### **Speakers and Participants**

Private sector: Industry

Jean Marion (speaker) Director Scientific Affairs Rx&D - Canada's Research Based Pharmaceutical Companies Kevin Fehr Director, Rx&D Alliances GlaxoSmithKline Inc.

#### Academia-Ethics/Law:

**David Castle** (speaker) CIHR Standing Committee on Ethics member, and Canada Research Chair in Science and Society, Department of Philosophy, University of Ottawa

James R. Brown Department of Philosophy University of Toronto Janet Atkinson-Grosjean (speaker) Senior Research Associate, The W. Maurice Young Centre for Applied Ethics, University of British Columbia

**Ron A. Bouchard** Doctoral of Juridical Science candidate Faculty of Law, University of Toronto

#### Federal Government/Agencies/Networks:

**Doug Davidge** (speaker)

A/Director Advertising Coordination & Partnerships Directorate, Consulting, Information & Shared Services Branch, Public Works and Government Services Canada

#### Mary Bush

Director General, Office of Nutrition Policy & Promotion, Health Canada Marie Émond Research Ethics Coordinator, Natural Sciences and Engineering Research Council of Canada

Jean E. Saint-Vil Senior Program Manager Networks of Centres of Excellence

**Robert Davidson** Director, Programs and Operations, Canada Foundation for Innovation

#### Provincial Funder:

#### Marielle Gascon-Barré

Vice Présidente et directrice scientifique Fonds de la recherche en santé du Québec

#### Non-Governmental Charities/Foundations

**Cathleen Morrison** Chief Executive Officer, Canadian Cystic Fibrosis Foundation

Josée Guimond, Director of Medical/Scientific and Community Programs Canadian Cystic Fibrosis Foundation

**Gavin Turley** National Executive Director, The Kidney Foundation of Canada Linda Piazza Director of Research, Heart and Stroke Foundation of Canada

**John E. Fleming** President and C.E.O. The Arthritis Society

**David Hawkins** Interim Vice President, Medical and Scientific Affairs The Arthritis Society

#### Universities: Research Offices

**Bill McBlain**, Senior Associate Vice-President (Research), University of Alberta

**Barbara Cox** Director, Office of Research, Memorial University

### Canadian Institutes of Health Research (CIHR)

CIHR Institutes:

**Diane Finegood** (speaker) Scientific Director, Institute of Nutrition, Metabolism and Diabetes (INMD)

#### **Louise Desjardins**

Assistant Scientific Director Institute of Musculoskeletal Health and Arthritis (IMHA) **Louise Poulin** 

Assistant Director, Partnerships and Int'l Relations, Institute of Human Development, Child and Youth Health (IHDCYH) **Richard Brière** Assistant Director Institute of Neurosciences, Mental Health and Addiction (INMHA) For the Institute of Population and Public Health (IPPH): **Dr. Roberta Ferrence** Executive Director, Ontario Tobacco Research Unit, Centre for Health Promotion, University of Toronto, and Senior Scientist, Centre for Addiction and Mental Health

#### Central Portfolios:

**David Brener** (speaker) Director, Research Translation, Research Portfolio

**Linda McKenzie** Deputy Director, Innovation Programs, Research Portfolio

**Rosa Venuta** Senior Policy Advisor, Partnerships Unit, Knowledge Translation

**Carmen Constantinescu** Evaluator, Evaluation and Analysis Unit

Kathryn Andrews-Clay

Director, Partnerships Unit, Knowledge Translation

Manon Lechasseur, Acting Senior Public Affairs Advisor-Issues Management, Marketing and Communications

**Sheila Chapman** Senior Ethics Policy Advisor, Ethics Office

**Genevieve Dubois-Flynn** Senior Ethics Policy Advisor, Ethics Office Nathalie Gendron

Deputy Director, Program Delivery-INMHA, INMD, ICRH, Knowledge Creation, Research Portfolio

#### Joanne Ledger

Associate, Team and Project Systems, Research Planning and Resourcing, Research Portfolio

**Burleigh Trevor-Deutsch** Director, Ethics Office

Jaime Flamenbaum

Senior Ethics Policy Advisor, Ethics Office