



## *Ethics Live! @ CIHR*

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### Message from the Director

Dr. Burleigh Trevor-Deutsch

Director,  
Ethics Office,  
Canadian Institutes of Health  
Research



The Ethics Office has had a busy and exciting year. We played an important role in facilitating and supporting the development of the *CIHR Guidelines for Health Research Involving Aboriginal People*. The development of these Guidelines, which were launched in May 2007, is a crucial step forward in providing Aboriginal health researchers with a framework that is responsive and sensitive to the unique cultural and social circumstances of Aboriginal people in Canada. The Ethics Office will work with CIHR's Institute of Aboriginal Peoples' Health (CIHR-IAPH) to disseminate the Guidelines to the research community, research institutions and the Aboriginal community. The Guidelines are truly a groundbreaking development in indigenous health research that will serve as a prototype for other countries.

The Ethics Office also initiated a catalyst program this year as part of our strategic priority of building capacity in ethics. This important program engages young researchers who have been in the field of ethics for five years or fewer, as well as encouraging mid-career researchers from a variety of disciplines who are making the transition to the field of ethics. These mid-career researchers have a level of sophistication, life experience and stature within university settings that allow them to ramp up in the field quickly. This program is ideally suited for bioethics, a truly unique field that is still defining itself and that lends itself to people transitioning into it.

We are also extremely proud of two other initiatives we undertook this year, the Consensus Conference and the Global Health Initiative. The Consensus Conference is traditionally used to develop clinical practices and guidelines through consensus reached by a group of leading experts. This model has not, until now, been used in bioethics. The Ethics Office adapted this model, using it to develop a triage instrument that will help health-care workers determine which activities require REB (Research Ethics Board) review and which do not. The Global Health Initiative was a partnership with the World Bank's Global Distance Learning Network to deliver training to REB members in the Caribbean, under the auspices of the Caribbean Medical Research Council. This initiative was particularly innovative, as the training was delivered simultaneously from Ottawa to five Caribbean countries via video-conferencing.

Over the past few years, the Ethics Office has fulfilled its mandate as a stand-alone funding group. However, we believe strongly that ethics must cut across all CIHR activities. In the coming year, therefore, we will focus on building strategic alliances with CIHR's Institutes and increasing our cooperative research-funding initiatives. By building on our partnerships inside and outside CIHR, we will leverage our intellectual capital and help foster the ethical conduct of health research across Canada.

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## Aboriginal Ethics Policy



### A New Paradigm for Aboriginal Health Research

Aboriginal communities have had good reason to be wary of health research. For too many years, health researchers would parachute into communities, do their research, and leave, with no consultation and no sharing of results with the community.

Today, that is much more unlikely to happen, in part thanks to new guidelines for health research involving Aboriginal People, developed by CIHR and launched in May 2007. The *CIHR Guidelines for Health Research Involving Aboriginal People* were developed jointly by CIHR's Ethics Office and the CIHR Institute of Aboriginal Peoples Health (CIHR-IAPH). The development of the Guidelines is a significant policy breakthrough both for CIHR-IAPH and the Ethics Office. They will enable institutions and researchers to conduct ethically and culturally competent research that respects Aboriginal values, culture and traditions. The Guidelines will facilitate research and partnerships with Aboriginal communities in a cooperative fashion. They apply to all research where CIHR has made a financial contribution. The Guidelines are part of the Tri-agency process to update Section 6 of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)*.

"These Guidelines are important because they engage researchers in a dialogue about Aboriginal Health issues and set objectives for all of CIHR's institutes and the wider research community," says Dr. Jeff Reading, Scientific Director of CIHR-IAPH.

The development of the Guidelines was led by the Aboriginal Ethics Working Group (AEWG), which comprised a blend of Aboriginal health and policy researchers from universities and institutes across Canada. The actual drafting by the AEWG started in March 2004. Once the first draft was complete, widespread consultations were held with Aboriginal communities – consultation that did *not* happen when Section 6 of the TCPS was initially developed. Consultations with Aboriginal communities and other relevant stakeholders across Canada were subsequently a centrepiece of the development process, with the AEWG leading a two-year consultation, deliberation, education and outreach process. This consultation process was pivotal, according to Dr. Reading.

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*"We took the time to do it right. This involved a comprehensive review of published literature and extensive consultations. We had to be meticulous; the Guidelines would be a groundbreaking new standard for ethics involving health research and indigenous peoples."*

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The consultations would not have been at all as extensive without the involvement of the Aboriginal Capacity and Development Research Environments network (ACADRE, now known as the Network Environments for Aboriginal Health Research). These centres played a major role, providing a forum for engagement and consultation with Aboriginal health researchers and communities.

"The ACADRE's were exceptionally useful," says Professor Larry Chartrand, co-chair of the AEWG. "They were necessary contacts for getting input across Canada on the issues."

International guidance was sought from New Zealand, Australia and the United States, all of whom have

experience with indigenous health research codes. These codes provided valuable insight into areas such as specimen protection. Some of the concepts in the Guidelines were influenced by these codes and it is anticipated that these countries will, in return, draw from the Canadian Guidelines.

### **Reaching Out to and Beyond Aboriginal Communities**

For the Guidelines to be effective, research organizations, and in particular, research ethics boards (REBs) need to be engaged in and committed to their effective implementation. Before the Guidelines were launched, the AEWG conducted several workshops in conjunction with the National Council on Ethics in Human Research and the Canadian Society for International Health. These workshops enabled researchers and Aboriginal communities to learn about the objectives and potential impact of the Guidelines. CIHR's Ethics Office, in conjunction with the Network Environments for Aboriginal Health Research (NEAHRs), is planning several more workshops, for research ethics boards (REBs) and researchers over the next two years. The NEAHRs (nine in total throughout Canada) will play a vital role in outreach with the Aboriginal community, Aboriginal councils and community members.

### **Challenges to Overcome, Opportunities to Master**

The major challenge in developing the Guidelines was to ensure that the final document would be relevant and useful to researchers involved in Aboriginal health research. According to Dr. Francine Romero, co-chair of the AEWG, "We had to make sure something tangible came out of our efforts. We didn't want this to become an exercise where it got shelved somewhere and nothing became of it." But while aware of the complex process, the AEWG was also fully cognizant of the pressing need for these Guidelines. "The Guidelines were very much overdue, the Aboriginal community had expressed clearly the need for a set of guidelines to protect their interests," says Dr. Reading. Furthermore, he adds, the Guidelines are a logical extension of CIHR-IAPH's mandate and strategy, which includes ensuring adequate protections are in place prior to funding research.

The Guidelines comprise 15 articles (see below). Deciding on these 15 was an exercise in negotiation and compromise. According to Dr. Romero, "There was not a magic number of 15. We wanted to make it (the guidelines) precise, concise and easy to understand and ensure that the communities' conceptions and beliefs were being encapsulated in the final document. It was really a balancing act. In recognizing the need for brevity, we had to filter the document down to the major concepts."

### **Aboriginal Guidelines in Focus: The 15 Articles**

The CIHR Guidelines for Health Research Involving Aboriginal People has 15 distinct articles (articles 11 and 12 each have sub-articles) which cover a wide array of topics in Aboriginal Health Research:

Article 1: Sacred Space and Traditional Space

Article 2: Community Control and Approval Process

Article 3: Participatory Research

Article 4: Community and Individual Consent

Article 5: Confidentiality/Privacy

Articles 6 and 7: Inclusion and Protection of Cultural Knowledge in Research

Article 8: Intellectual Property Rights and Indigenous Knowledge

Article 9: Benefit Sharing

Article 10: Empowerment and Research Capacity Development

Article 11: Cultural Protocol, Language and Communication

Article 12: Initial and Secondary Use, Proprietary Interest, and Storage and Transfer of Data and Biological Samples

Article 13: Biological Samples on Loan

Article 14 and 15: Interpretation and Dissemination of Results

### **The Next Phase: Implementation and Evaluation**

Now that the Guidelines have been adopted by the Governing Council of CIHR, the most important challenge lies ahead: implementing them. The implementation process will include four major components: 1) Communication and dissemination; 2) Incorporation of the Guidelines into CIHR research applications, guides and processes; 3) Education and training of CIHR peer-reviewers, researchers and Aboriginal communities; and 4) Evaluation.

Given the extensive education, outreach and consultation that took place with researchers and the Aboriginal community, the implementation process is expected to run smoothly. According to Dr. Reading, however, there could be a period of adjustment for researchers who were not engaged in the development process of the Guidelines.

“It will also take some time to operationalize the Guidelines within REBs across Canada,” he says. Nonetheless, he believes the Guidelines will eventually be embraced by the research community. “Ultimately, the Aboriginal Guidelines will empower researchers and make their research better. The Guidelines can be viewed as a checklist that researchers can use to ensure that their work is respectful of Aboriginal culture, traditions and values.”

The *CIHR Guidelines for Health Research Involving Aboriginal People* is an evolving document and will be evaluated every four years, as required by CIHR’s Standing Committee on Ethics. The evaluation process will be consensus driven. The evaluation committee will include former members of the AEWG and staff from CIHR-IAPH, the Ethics Office, as well as from CIHR’s Research Portfolio and Evaluation and Analysis unit. The evaluation process will also include input from Aboriginal communities across Canada, facilitated through the NEAHRs.

### **A New Paradigm in Research**

The *CIHR Guidelines for Health Research Involving Aboriginal People* will have a significant impact on the way indigenous health research is conducted in Canada and potentially around the world. In addition to the benefits of ensuring that Aboriginal health research is culturally and ethically sound, the Guidelines could also have several spin-off effects, including: 1) discussion of access to information, publication and ownership of research results and discoveries; 2) the potential development of Aboriginal REBs; and 3) better understanding of the rights and responsibilities of researchers and participants. According to Dr. Reading, all of the stakeholders involved in the development of the Guidelines firmly believe in their potential.

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“The idea that individual protections can co-exist with collectivity-level protections where, for the first time, Aboriginal communities as a whole will have a say in the research ethics approval process is really groundbreaking,” he says.

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“This is really setting a new standard for ethics in Aboriginal health research.”

For more information on The *CIHR Guidelines for Health Research Involving Aboriginal People*, please visit: <http://www.cihr-irsc.gc.ca/e/29134.html>

Or for a pdf version:

[http://www.cihr-irsc.gc.ca/e/documents/ethics\\_aboriginal\\_guidelines\\_e.pdf](http://www.cihr-irsc.gc.ca/e/documents/ethics_aboriginal_guidelines_e.pdf) .

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## **Focus on Institutes: CIHR Institute of Infection and Immunity**

### **Placing Communities at the Core: Community-Based Research and the HIV/AIDS Research Initiative**

HIV and AIDS affect individuals from all backgrounds and walks of life and have unique scientific, political, cultural and socio-economic dimensions and impacts. As a result, community-based research (CBR), which engages community members in all stages of the research process while adhering to the methodological rigour and ethical standards of other research approaches, can help to prevent and manage HIV/AIDS.

CBR is an essential component of the Government of Canada’s Federal Initiative to Address HIV/AIDS in Canada (FI-HIV/AIDS), launched in January 2005. FI-HIV/AIDS doubles annual investments in the domestic HIV/AIDS strategy from \$42.4 million in 2003-04 to \$84.4 million by 2008-09. CIHR is one of four federal partners in the initiative, the other three being the Public Health Agency of Canada, Health Canada and the Correctional Service of Canada. CIHR, through its Institute of Infection and Immunity (CIHR-III), is responsible for setting research priorities and developing strategic research programs and partnerships in HIV/AIDS on behalf of the Federal Initiative. CIHR-III plans and coordinates the disbursement of funds across the four major areas: biomedical and clinical research, health services and population health research, CBR and the Canadian HIV Trials Network.

Ethics Live! @ CIHR spoke with Jennifer Gunning, Team Lead, HIV/AIDS Research Initiative (CIHR-III) about community-based research and its application to the HIV/AIDS Research Initiative.

1) What are the objectives of the HIV/AIDS Research Initiative?

*CIHR’s Institute of Infection and Immunity (CIHR-III) is in the process of developing the strategic plan and formal objectives for the Initiative, and this will take place over the next year. However, broadly speaking, the objectives are to advance HIV research, contribute to the Federal Initiative, build research capacity and partnerships and work collaboratively with our partners and stakeholders in order to devise a coordinated response to HIV and AIDS.*

2) Is CBR relevant for HIV and AIDS, is there an interrelationship?

*CBR is becoming a larger part of HIV research all the time. The reality is that HIV not only affects individuals but also communities. To truly understand the disease and effective responses, we need effective community engagement and community involvement in research. CBR has many strengths:*

*1) It can facilitate the research process by engaging communities as full partners in research rather than just as ‘subjects’. This can lead to a better understanding and appreciation for the research in the community and potentially higher participation rates;*

- 2) *It can help clarify the needs of communities and service providers who are responding to HIV and AIDS and ensures research can help improve programs and services;*
- 3) *It can facilitate the translation of knowledge into solutions and recommendations that are socially and culturally sensitive, which is particularly relevant for HIV research given the range of populations that are vulnerable to the epidemic, such as Aboriginals and men who have sex with men; and*
- 4) *It can help build capacity in community partners as well as with the research community through the sharing of knowledge and skill sets, something that CIHR-III is committed to doing.*

*The HIV/AIDS CBR Program is a central component of the HIV/AIDS Research Initiative. We will be evaluating the program over the next year to help us understand the needs of stakeholders so we can make improvements in available funding opportunities, policies and procedures.*

- 3) How does CBR ethics review differ from ethics review of institutional research?

*CBR ethics review often is carried out by institutional Research Ethics Boards (REBs) because there are simply not enough community-based REBs. The reality is, however, that institutional ethics review may not be appropriate for CBR. Institutional ethics review tends to focus on risks to individuals rather than communities, which is not the only important ethical lens through which community projects should be reviewed.*

*The HIV/AIDS Research Initiative recognizes that ethics review within the context of CBR requires further examination and solutions to the identified issues. The National Council on Ethics in Human Research is leading a project for the HIV/AIDS Research Initiative which will scan community-based REBs across Canada. The project will determine what the current capacity for review is, what they need to increase their capacity in and, through a face-to-face consultation, how the needs of the community-based research community can also be better met.*

- 4) Are there any special considerations that go into CBR involving people living with HIV?

*Confidentiality is an important issue in any type of research, and is particularly important in the CBR/HIV research context. There is a strong stigma and discrimination attached to HIV and AIDS, so protecting privacy is a special consideration in dealing with individuals and communities affected and at risk. Also, any CBR needs to have a strong education component which stresses prevention and access to services.*

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### Spotlight on Funded Researcher: Professor Elaine Gibson

Elaine Gibson

Associate Professor and  
Associate Director,  
Health Law Institute  
Faculty of Law  
Dalhousie University



#### Privacy vs. Confidentiality in Health Information

Elaine Gibson, LLB, LLM, is primarily interested in how health information is used within the context of

privacy laws. Professor Gibson is an Associate Professor and Associate Director of the Health Law Institute at the Faculty of Law of Dalhousie University in Halifax, Nova Scotia. She has received funding from the CIHR as both a co-investigator and primary investigator.

Ethics Live! @ CIHR spoke to Professor Gibson about her research interests and her most recent CIHR funded project, “Conceptual Paradigms: Responding to Privacy and Access Challenges in Health Research”.

1) How did you become interested in privacy and health information issues?

*My interests in privacy and health information commenced about six years ago. I started examining the use of health information for research purposes and its implications with regard to privacy legislation. This area of research intrigued me because of the complexity of provincial and federal privacy laws in Canada. I am really interested in what privacy laws in Canada ought to say, not necessarily what they currently say. This curiosity has led to my delving into a number of dimensions of health information and privacy, including studying the context in which consent should be required from various perspectives. My most recent CIHR project, “Conceptual Paradigms: Responding to Privacy and Access Challenges in Health Research”, which began in 2004, examines these different perspectives on consent.*

2) In your paper, “Conceptual Paradigms Responding to Privacy and Access Challenges in Health Research”, you posit that there is not a unified definition of privacy. Given this ambiguity, how can researchers both strive for excellence in research and scientific discovery and at the same time respect privacy rights?

*I have been referring to ‘privacy legislation’ in this discussion. However, this is a bit of a misnomer in that the laws tend not to focus on privacy but on access and confidentiality. What I mean is that when it comes to the use of health information for research purposes, the legislation tends to remove the need for consent and therefore individual choice – and therefore respect for the privacy interest. The fact that there is not a unified definition of privacy only adds to the confusion. Researchers and others alike need to examine these issues in greater depth to reach answers as to the appropriate circumstances for setting aside privacy interests in the conduct of research.*

3) Do you see your study as having implications for decision makers (such as those developing privacy legislation or policies)?

*I believe that the report is useful to decision makers because it will assist them in understanding their underlying assumptions about privacy. In my view, most decision makers assume that people fall into either the liberalism or communitarian models, as discussed in the report. Liberalism, with its focus on individual rights and non-interference in the private sphere, is the predominant model in a number of areas of Canadian law. In the communitarian model, individual control may, under certain circumstances, be treated as secondary to community interests and societal good. Although these are the predominant models for viewing privacy, I believe the report will help decision makers understand that there are several more perspectives that should be considered in planning. For example, the report also highlights Relational Theory, which asserts that people’s choices are impacted by their relationships and interdependencies with other people. Another perspective comes from the notion of Fiduciary Duty. This model recognizes that people engage in relationships with unequal bargaining power and unequal and incomplete sharing of information. Therefore, it is incumbent on the person in power to safeguard the interests of the less powerful, above and beyond their own interests.*

*Fundamentally, I believe this report will allow decision makers to gain a broader view of privacy rights, which will have implications for the policies and programs that they develop.*

4) Can privacy legislation and regulations in other countries (such as the U.S, UK and Australia, which were discussed in the report) be applied or adopted in Canada, given the “core values” of Canadians that you have identified in the report?

*Canadians’ core values tend to focus more on the common good and less on individual rights than Americans in particular. The U.K. and Australia are more similar to Canada in their orientation. The paths taken by other countries in terms of privacy and health information uses may be interesting to examine, but their potential application in the Canadian context must be approached hesitantly due to differences in political, social and economic orientation.*

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## **Hope for the Best, Prepare for the Worst: Ethics and the Pandemic Preparedness Strategic Research Initiative**

Pandemics can have devastating health, economic and social consequences. It’s been estimated that between 4.5 million and 10.6 million Canadians could be affected by a global influenza pandemic. This stark statistic underscores the need for Canada to be prepared in anticipation of this, or any one of the many other pandemics that may, one day, unleash on the human population.

Research is a critical element in our preparation. We need to understand as much as we can about these threats so that we can deal with them effectively. That is why the federal government has invested \$21.5 million over five years in the Pandemic Preparedness Strategic Research Initiative (PPSRI). This coordinated, focused research effort, which is led by CIHR’s Institute of Infection and Immunity (CIHR-III) and guided by a Task Group, is building Canada’s capacity to conduct pandemic influenza research.

National action has been spurred, in part, by avian influenza, which brought home the global nature of pandemics.

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**“The outbreak of avian influenza in Asia and its potential for becoming the next pandemic has galvanized the attention of the research community and the public as a whole,” says Carol Richardson, Manager, Programs and Evaluation, CIHR-III.**

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Ethical, legal and social elements underpin the scientific research into pandemic. For example, in a severe outbreak, there will be shortages of human and material resources, and health-care providers will be faced with the dilemma of assigning these resources equitably. And just what are the expectations, obligations and perceptions of health-care workers during a pandemic? There are legal and ethical dimensions that need to be explored.

“We normally expect health-care workers to put their patients’ interests first, but ultimately, health-care workers are people with families and lives of their own, so can we really expect them to do so during a pandemic?” notes Ms. Richardson. Equally challenging is the question of who should be treated when there is not enough treatment to go around.

Questions of ethics arise as much during as in planning for a pandemic. Rapid, targeted research during pandemic can help bring it to a hastier end, but this research often involves humans. Expeditious ethics

review of research protocols in these cases is critical. Consequently, more research is required into ways to improve the efficiency of ethics review. According to Ms. Richardson, a national ethics review process would go a long way to speeding up multi-centre trials, although establishing such a mechanism would prove challenging. “A centralized ethics review process would be helpful, since currently, redundant ethics reviews are conducted at each institution where the research will be carried out. However, a national ethics review mechanism is complicated because of overlapping responsibilities of federal, provincial and local institutions.”

More information on the PPSRI is available in the CIHR-III’s Report on the Pandemic Preparedness Strategic Research Initiative, available at <http://www.cihr-irsc.gc.ca/e/32573.html>.

### Spotlight on Funded Researcher: Dr. Chris MacDonald

Dr. Chris MacDonald

Associate Professor and  
Coordinator of Graduate  
Program  
Department of Philosophy  
Saint Mary’s University



#### Old Ethics, New Applications

Chris MacDonald, PhD, is interested in the ethical issues associated with the biotechnology and nanotechnology industries. An Associate Professor and Graduate Programme Coordinator in the Philosophy Department at Saint Mary’s University in Halifax, Nova Scotia, Dr. MacDonald has received a three-year CIHR Ethics Operating Grant in 2004 and a one-year CIHR grant to support his research. Dr. MacDonald has published widely in various ethics-oriented journals and was lead author for the Canadian Bioethics Society’s Draft Model Code of Ethics for Bioethics. Dr. MacDonald is a frequent speaker at international and national ethics conferences. He was the keynote speaker at the 18<sup>th</sup> annual Canadian Bioethics Society Conference on May 30<sup>th</sup>, 2007 in Toronto, Ontario. Ethics Live! @ CIHR interviewed Dr. MacDonald as part of its Spotlight on Funded Researchers.

1) Tell us about your research interests.

*My research is primarily about corporate ethics in the biotechnology industry. In practice, that means I’m interested in many of the research areas that other bioethicists are interested in, such as genetic testing and the pricing of pharmaceuticals. However, the focus of my research is specifically how corporate decision makers within the biotech industry ought to respond to such issues.*

*My research also has clear implications for decision making and ethics in the pharmaceutical industry and other industries too. Fundamentally, I am interested in the kinds of ethical challenges that managers in private enterprises face. Even in a publicly funded health-care system like Canada’s, industry plays a key role, so I think it’s really crucial to talk more about good corporate decision making.*

2) What are the interfaces between business ethics and bioethics – are there any?

*To a large extent they are separate disciplines with very little overlap. In fact, the researchers in business ethics and bioethics tend to be two totally separate groups. They go to different conferences and publish in different journals. Although there are a few prominent researchers who work in both areas, for the most part the disciplines are separate. However, both fields have their roots in philosophical ethics, so there is shared intellectual heritage, even though the two don't interact as much as they arguably should today.*

3) Private vs. public research: In your paper, “Higher Standards for Privately Funded Health Research”, you posit that privately funded research should be held to a higher standard than publicly funded research. Can you briefly discuss this position?

*The argument is basically that the source of funding matters. Privately funded research has been shown to be subject to a range of structural biases. This isn't necessarily anyone's fault, but it does suggest a need to hold privately funded research to higher standards, higher even than the very high standards to which research should generally be held. Take informed consent as an example. Consent is never perfect. It's always either more or less informed. It's always a matter of degree, and Research Ethics Boards (REBs) need to use judgment about whether a particular research protocol provides enough information to research subjects. I've argued that where research is privately funded, REBs should be even more cautious. They should insist that research subjects be given more information, to make sure they're able to make a truly informed decision to participate in research whose immediate goal is private profit, rather than the public good.*

4) This question pertains to your presentation at the Canadian Bioethics Society, “Real World Bioethics, Heroic Risks and the Risks of Heroism”. In your view are bioethicists trying to be heroes? Should they be?

*Well, a lot of the discussion of heroism in bioethics has been related to a handful of high-profile cases like the Nancy Olivieri case. But it actually relates to a much larger debate in the bioethics community about whether bioethics is or can ever be a profession or a quasi-profession instead of just another academic discipline. Specifically, should bioethics be thought of as being like professions such as medicine, law or engineering, where there are clear and enforceable codes of conduct? The challenge is that applying the same model to bioethicists is not currently possible, given that these other professions are licensed and bioethicists are not required to hold a license. There have been attempts to apply some of the ethical principles that govern other professions (such as those found in the Hippocratic Oath). For example, I was the lead author on a model code of ethics for the Canadian Bioethics Society ([www.bioethics.ca](http://www.bioethics.ca)). But there's still a very large debate to be had about what kind of endeavour bioethics is, and what kinds of behaviours on the part of bioethicists ought to be considered heroic, and what sorts of risk-taking simply go with the turf.*

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## **Public-Private Partnerships: Their Place in Health Research**

Public-private partnerships look familiar to many Canadians – it seems as if major infrastructure projects like convention centres, hospitals and libraries, are seldom even discussed without the ubiquitous “P3”, as they are known, being raised.

Such partnerships also take place in health research funding (though subject to less public attention). Now, funding agencies such as CIHR are beginning to examine their ethical implications. On May 14, 2007, CIHR hosted a workshop, *Ethics Policy on CIHR Partnerships and the For-Profit Sector*, to address this very issue.

The 1½-day workshop brought together representatives from industry, academia, federal government departments and agencies and non-governmental organizations to identify and foster discussion of the ethical issues associated with CIHR's partnerships with the for-profit sector and to identify the elements that need to be covered in a CIHR ethics policy on partnerships with this sector.

One of the main areas of discussion at the workshop was the potentially divergent interests, objectives and goals that for-profit and public sector partners bring to a partnership. Workshop participants had the opportunity to discuss the potential benefits and limitations of public-private partnerships and learn from presentations on current public-private partnerships. Ethics Live! @ CIHR spoke with Dr. David Castle, Canada Research Chair in Science and Society at the University of Ottawa, and CIHR Standing Committee on Ethics member, about his presentation entitled, "Dualities of Interest". Ethics Live! @ CIHR also spoke with Dr. Diane Finegood, Scientific Director, CIHR Institute of Nutrition, Metabolism and Diabetes, about her institute's partnership with Kellogg Canada entitled, "Canada on the Move".

### **Dr. David Castle:**

1) Can you please elaborate/expand on your discussion of the "Dualities of Interest"?

*The main point of my discussion was that 'conflict of interest' jargon is often not accurately used. More nuanced terminology like 'dualities of interest' recognizes that researchers often have multiple, but non-conflicting, interests. Researchers can work as consultants for government and the private sector while employed by a university without compromising their integrity or ability to be unbiased investigators. In fact, we expect researchers to have overlapping agendas that allow them to leverage new opportunities and find synergies that can benefit their research.*

2) In your view are public-private partnerships beneficial?

*First of all, it's important to recognize that public-private sector partnerships are not a new occurrence. If you look at past scientific research you'll often find some industry involvement. Perhaps these types of partnerships are more prevalent now, and we have become more conscious of the best and worst of these partnerships. The best cases show that private-public partnerships can be very beneficial for boosting innovation and economic growth.*

3) Are there circumstances where public-private partnerships are not appropriate or feasible?

*There are some cases where interests of public agencies such as CIHR would include making data publicly available and sharing research results through open source platforms. This might be at odds with private-sector partners who have commercialization interests or who seek to patent research discoveries. For example, a public-private partnership in pandemic research might not be appropriate since the public partner would most likely want to share the research results to create effective response mechanisms to pandemics. They would invariably not want to be tied up in patent or licensing negotiations.*

*I think the key criterion in determining if a private-public partnership is appropriate is to understand the expectations of each partner. Although private partners might have long-term objectives that include benefiting the public good, they will also have near-term commitments to maximize revenue, strategic position and return on investment. This can be at odds with the public-sector objectives, which tend to be focused on the public good, and transfer of knowledge to receptors, without always concentrating on the intermediate commercial step.*

**Dr. Diane Finegood:**

1) What was the impetus behind the CIHR Institute of Nutrition, Metabolism and Diabetes-Kellogg Canada “Canada on the Move” partnership?

*We became aware of Kellogg Canada’s plan to distribute more than a million pedometers in boxes of cereal. The Institute was interested in understanding the use of pedometers in health promotion programs, so we contacted Kellogg Canada about exploring a partnership. We wanted to develop a relationship that was mutually beneficial, that would enable us to jointly learn about the health impact of this program. We also wanted to learn if an approach such as this one, which is essentially both a natural experiment and sales-marketing exercise, can reveal useful health-related information.*

2) What were the “lessons learned” from this partnership?

*We learned that these relationships are not easy; there are challenges for both sides. For CIHR there was the risk of having our highly credible brand associated with a product that may not be considered healthy by all. For the private-sector partner there was the danger of being held to a higher standard than they are used to. For example, as a result of our partnership with Kellogg the low quality of the pedometers they placed in the boxes may have received more attention than they would have liked.*

*One of the benefits of this partnership was that we found new and more sustainable mechanisms for getting research done with natural experiments. As a result of our experience, we developed a new rapid turn-around request for applications (RFAs) that we launched in December 2006. We believe that we will be able to support new relationships between industry and the research community through this mechanism.*

*The partnership with Kellogg has also led us to further the dialogue on private-public sector partnerships. The first meeting was organized in collaboration with the Concerned Children’s Advertisers. We learned from this meeting and from the Kellogg partnership that building trust and managing expectations is crucial for a successful partnership. This is why the theme of our next workshop will focus on the links between ethical partnerships and trust and will be entitled, “Building Trust for Working Together with the Food Industry”. Dr. Castle is on the organizing committee for this workshop.*

3) In your view are public-private partnerships beneficial?

*I believe that public-private partnerships are essential in order to solve modern-day health problems such as the obesity crisis. We cannot demonize the food industry as we did with tobacco; rather we need to collaborate. Together we need to change the value proposition from quantity to quality.*

4) Are there any new CIHR Institute of Nutrition, Metabolism and Diabetes-industry partnerships on the horizon?

*Our partnership with Kellogg helped us increase our dialogue with other companies in the food industry. We are currently discussing partnerships to enhance research and knowledge translation with other companies in the agro-food industry.*

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## **Life-long Learning: The Canadian Longitudinal Study on Aging (CLSA)**

Aging occurs over time – ideally, a long time. Research on aging, it follows, should also take place over a long time. That’s the premise behind the Canadian Longitudinal Study on Aging (CLSA), an innovative initiative that will look at social, economic, environmental and behavioural influences on aging. Beginning in 2008, the CLSA will recruit 50,000 men and women aged 40 to 84, who will be followed for at least 20 years. This makes the CLSA one of the most comprehensive studies of its kind ever undertaken.

The CLSA, part of CIHR’s Canadian Lifelong Health Initiative (CLHI), will examine how we age by identifying potential risk factors and analyzing how they affect healthy aging. According to former CLSA Director Gary Catlin, “The impetus for the CLSA came from the CIHR’s Institute of Aging in 2001. It was recognized that both research questions and government policy issues could be addressed through a study focused on the impending demographic changes in Canada associated with an ageing population.”

Some of the challenges that have arisen with the CLSA include what kinds of information and samples to gather, follow-up with participants over the course of the study and informed consent.

It’s difficult to anticipate at the beginning what kinds of data are going to be important over the life of the study. New questions and new priorities will inevitably come up. For instance, environmental influences on aging are likely – but the kinds of samples that will be most useful in answering those questions isn’t really clear. The possibilities for information and sample gathering are almost limitless and choices will have to be made.

Following up with participants will not be easy either. People may move and be lost to the study because they cannot be traced. A certain proportion will decide not to continue their participation in the study. Others will die. The challenge to the researchers is to minimize attrition, to the degree possible.

Informed consent is another challenge. Of course, all participants sign consent forms before their enrolment. The form clearly indicates broad research areas that the data will and will not be used for. “Participants will have a clear idea of what the collected data will be used for,” says the former CLSA Director. “Furthermore, the partner organizations involved in the CLSA (including various CIHR Institutes, Health Canada, Statistics Canada and other governmental and non-governmental organizations) are committed to the principles of informed consent.”

However, one-time consent does not suffice for a 20-year project. Participants need to be given the opportunity to renew their consent at various intervals during the study. Also, any major changes in the use of the data have to be subject to fresh consent.

The CIHR Ethics Office is integrally involved in the CLSA consent process. The Office struck an ELSI (Ethical, Legal and Social Issues) Advisory Committee that was tasked with developing the Informed Consent package and identifying issues related to governance and public engagement. Chaired by Dr. Tim Caulfield of the University of Alberta, the ELSI Committee has developed a consent package designed to meet the needs of the CLSA and the thousands of people who will participate in the study.

The Principal Investigators of the CLSA are: Dr. Parminder Raina, McMaster University, [praina@mcmaster.ca](mailto:praina@mcmaster.ca), Dr. Susan Kirkland, Dalhousie University [susan.kirkland@dal.ca](mailto:susan.kirkland@dal.ca) and Dr. Christina Wolfson, McGill University [christina.wolfson@mcgill.ca](mailto:christina.wolfson@mcgill.ca). While the pilot phase of the study is now

underway, funding beyond this point has yet to be confirmed. However, the partner organizations of the CLSA are hopeful that this innovative and groundbreaking study will receive the funding required for its future success. For more information, please visit the CLSA website at [www.clsa-elcv.ca](http://www.clsa-elcv.ca), or contact the Principal Investigators at the email addresses above.

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## **Keeping Privacy Paramount: An Evaluation**

Canada is fortunate – because of our single-payer health-care system, we have access to large databases that can provide the foundation for extensive health research advances, advances that will do much to improve the health of Canadians. At the same time, however, the privacy of those contained in these and other databases used for health research purposes must be protected, because of both legislation and morality.

CIHR has been grappling with these two needs – to facilitate health research while protecting privacy – since 2002. The result has been *CIHR Best Practices for Protecting Privacy in Health Research* (PBP), which comprises 10 key elements (see text box below). The objectives of the PBP document are to provide guidance for the health research community on the use of personal information and to provide a privacy context for the interpretation of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS).

### **Privacy Best Practices: The 10 Elements in Summary Form**

Element 1: Determining the research objectives and justifying the data needed to fulfill these objectives

Element 2: Limiting the collection of personal data

Element 3: Determining whether consent from individuals is required

Element 4: Managing and documenting consent

Element 5: Informing prospective research participants about the research

Element 6: Recruiting prospective research participants

Element 7: Safeguarding personal data

Element 8: Controlling access and disclosure of personal data

Element 9: Setting reasonable limits on retention of personal data

Element 10: Ensuring accountability and transparency in the management of personal data

The PBP were evaluated between 2005 and 2007, to analyze the usefulness and impact of the document. The evaluators were users of the PBP document, primarily researchers and Research Ethics Board (REB) members. The evaluation was conducted using a variety of methods, including, telephone interviews, focus groups, face-to-face consultations, interviews and a web-based survey tool. The final report has found some broad lessons that emerged from the process ([Final Report](#)).

First, the evaluation has pointed to ways to integrate privacy protection into existing programs.

“The evaluation process has been instructive as it has provided insight on how to integrate the PBPs into existing educational programs that NCEHR and the Canadian Association of Research Ethics Boards (CAREB) has for researchers and REB members and administrators. This is important because we want the training sessions we provide to integrate privacy considerations,” according to Richard Carpentier, Executive Director of the National Council on Ethics in Human Research (NCEHR) and member of the PBP Initial Implementation Working Group (IIWG).

Second, the evaluation has highlighted ways in which the PBP document can be used in conjunction with the TCPS. “The PBP is not meant to be a normative document or a policy. Rather it’s an educational vehicle that can co-exist and help inform and implement the TCPS,” says Mr. Carpentier. Furthermore, according to Mr. Carpentier, the evaluation process confirmed the relevance of the PBP document for both institutions and the wider research community.

“From NCEHR’s perspective, the PBP document is a very welcome addition to the privacy-in-research dialogue. We can easily integrate it into some of our case studies, which we use to train researchers and REB members. The PBP document should be disseminated into the research community.”

The PBPs have their roots in a multi-stakeholder workshop held by CIHR in November 2002 on *Privacy in Health Research: Sharing Perspectives and Paving the Way Forward*. As a result of the workshop, the Privacy Advisory Committee (PAC) was established in 2003, with a mandate to advise CIHR on the development of PBPs for health research and strategies for consultation, communication and knowledge translation. PAC members included privacy commissioners, health researchers, research ethics board members, Aboriginal community members, policy makers and patients/consumer representatives. The PAC completed its work in December 2005 with the release of *CIHR Best Practices for Protecting Privacy in Health Research*.

The development of the PBPs and the subsequent evaluation process can be viewed as an important step in protecting the privacy of research participants. It also responds to needs of Canadians who are increasingly concerned about privacy issues.

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“Canadians are concerned about the potential invasion of their privacy. They are willing to let go of some of their privacy for the benefit of others, but there is a limit to this. There has to be safeguards put in place. It’s a difficult issue, but we hope that the PBP document will assist researchers in identifying privacy risks and help them to devise innovative ways to protect the privacy of research participants”, says Mr. Carpentier.

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For more information on the *CIHR Best Practices for Protecting Privacy in Health Research* please visit, [http://www.irsc.gc.ca/e/documents/et\\_pbp\\_nov05\\_sept2005\\_e.pdf](http://www.irsc.gc.ca/e/documents/et_pbp_nov05_sept2005_e.pdf) or <http://www.irsc.gc.ca/e/29072.html>

For additional information on the *Initial Implementation Working Group Final Report with Recommendations*, please visit [http://www.cihr-irsc.gc.ca/e/documents/iwgf\\_final\\_report\\_and\\_recommendations\\_2007\\_e.pdf](http://www.cihr-irsc.gc.ca/e/documents/iwgf_final_report_and_recommendations_2007_e.pdf) or <http://www.cihr-irsc.gc.ca/e/35348.html>.

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## ACFAS Conference: Ethics of Knowledge Translation in a Wider Arena

How do researchers balance the need for privacy of data and knowledge sharing? What are the ethical issues related to knowledge translation (KT)? Who has better ownership rights to research data? What are the roles of the researcher and the role of the sponsor in KT? Are these roles interrelated? And what happens when KT moves beyond its original meaning to encompass new audiences and new methods of dissemination?

As knowledge translation comes to the forefront, researchers are grappling with ethical questions such as these. Some of these discussions took place at the research conference held May 11, 2007 by the Association Francophone pour le savoir (ACFAS) at the Université de Trois Rivières. The conference, the first of its kind to be held in Canada, attracted academics from universities across Canada, representatives of research institutions and staff members from CIHR's Ethics Office.

Knowledge Translation (KT) is defined by CIHR as “the exchange, synthesis and ethically sound application of knowledge, within a complex system of interactions among researchers and users, to accelerate the capture of the benefits of research for Canadians through improved health, more effective services and products, and a strengthened health care system”. There were many definitions of KT referred to in discussions at the conference. It became clear, however, that the real challenge was not in defining KT, but in thinking about extending KT beyond traditional boundaries.

“Researchers have always shared their knowledge,” says Louise Rousseau, PhD, Scientific Director of ERAS (Équipe de Recherche Appliquée en Santé) for the Agence de la santé et des services sociaux de Montréal, who organized the ACFAS conference. “But they’ve mostly done so with peers through scientific publications where intellectual property and scientific integrity rules are quite clear.”

The ethical implications of KT between academic researchers and the wider community, however, are less well-defined. The ACFAS conference was an important first step in building consensus and starting the interdisciplinary dialogue on this important issue.

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## Upcoming Events

- February 15, 2008 (8:30-11:30), Ottawa – **PRE Conference: “Guidelines for Health Research Involving Aboriginal People: Getting to an Agreement – The Community Perspective”**  
**Website:** <http://www.ncehr-cnerh.org/english/events/2008%20Aboriginal%20Pre%20Conference%20English.php>
- February 15, 2008 (12:30-5:00), Ottawa – **2008 PRE Conference: “Towards a Second Edition of the TCPS”**, Sponsored by the Interagency Advisory Panel on Research Ethics (PRE)  
**Website:** [http://www.ncehr-cnerh.org/english/events/PRE\\_2008%20ENGLISH.php](http://www.ncehr-cnerh.org/english/events/PRE_2008%20ENGLISH.php)
- February 16-17, 2008, Ottawa – **2008 NCEHR National Conference: “Vulnerabilities: The Importance of Context in Ethical Research and Human Participation Protection”**  
**Website:** [http://www.ncehr-cnerh.org/english/events/national\\_2008%20ENGLISH.php](http://www.ncehr-cnerh.org/english/events/national_2008%20ENGLISH.php)
- May 4-6, 2008, Alberta – **ARECCI Inaugural National Conference: “Protecting People While Increasing Knowledge”**  
**Website:** <http://www.arecci.com/index.asp>
- May 8-10, 2008, Toronto – **CAREB Annual General Meeting**  
**Website:** <http://www.careb-accr.ca/?q=/node/8>
- May 29-30, Charlotte, NC – **2008 FOCUS Conference on Researchers and Ethical Review: Problems, Solutions, Moving Forward** (Conference offered only in English)  
**Website:** <http://www.ncehr-cnerh.org/english/events/2008%20FOCUS%20Conference.php>
- June 18, 2008, St. John’s, NL – **Pre-Conference to the annual CBS Conference 2008: “Development of Best Practices for Research Involving Children and Adolescents: Filling the Knowledge Gaps”**  
**Website:** <http://www.easternhealth.ca/cbsc2008/mainenglish.aspx>
- June 19-21, 2008, St. John’s, NL - **19<sup>th</sup> CBS Annual Conference 2008: “Family”**  
**Website:** <http://www.bioethics.ca/conference.html>

## Funding Opportunities

Researchers in ethics are eligible for grant support under a variety of CIHR funding programs:

- For a list of current **Ethics sponsored funding opportunities and Other funding opportunities of interest to the Ethics Research Community**, please visit CIHR's funding opportunities database at the following link: [www.cihr-irsc.gc.ca/e/780.html](http://www.cihr-irsc.gc.ca/e/780.html).

**We encourage you to apply.**

## Contact Us

The Ethics Office would like to thank Pradeep Chadrashekhkar and Heather Blumenthal for their contributions to the writing and editing of this newsletter. We hope you enjoyed it. If you have any story ideas for future issues or any feedback, we would be interested in hearing from you. Please send us your comments.

### **Ethics Office**

Canadian Institutes of Health Research (CIHR)

160 Elgin St., 9<sup>th</sup> floor

Ottawa, ON, Canada

K1A 0W9

Email: [ethics-ethique@cihr-irsc.gc.ca](mailto:ethics-ethique@cihr-irsc.gc.ca)

Web: [www.cihr-irsc.gc.ca/e/2891.html](http://www.cihr-irsc.gc.ca/e/2891.html)

