Ethics Office
Annual Update
Fall 2013

Ethics @ CIHR

Translating Ethics Knowledge for Impact

In this Update:

CIHR encourages interdisciplinary, innovative and integrative research on ethical issues pertaining to health, and also fosters the discussion of ethical issues to strengthen the culture of research ethics and integrity in Canada.

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Message from the Ethics Office

At the words "ethics" and "research", what may first come to mind is a research ethics board poring over submissions for ethics approval before eager researchers can receive their funds and their studies begin. Or perhaps you first think of a code of ethical conduct in research, such as the Research Integrity Policy contained in the Tri-Agency Framework for Responsible Conduct of Research.

In this Update 2013, however, we are focusing on **ethics researchers**: the cadre of those whose area of inquiry is health ethics or, for some, the intertwined ethical, legal and/or social issues (ELSI) in the health domain.

At the core of CIHR's legislated mandate is not only the *creation* of scientific knowledge, but also its *translation* into health-related benefits. What does "knowledge translation" mean for ethics research?

In *Harm, hype and evidence: ELSI research and policy guidance* (Genome Medicine, 2013 5:21), Timothy Caulfield and colleagues recount how the launch of the Human Genome Project in 1990 also launched, in parallel, an ELSI research program to examine the potentially profound social implications of discoveries in genomic science.

The Human Genome Project launched, in parallel, an ELSI research program to examine the potentially profound social implications of discoveries in genomic science

The outcomes, according to Caulfield et al, have been myriad: extensive public debate, policymaking, national legislation and international declarations. The authors argue for emulating this model more broadly, with "ELSI scholarship progressing in parallel with scientific and technical advances, not only for genomics but also other fields…"

We are pleased, therefore, to feature interviews with four CIHR-funded ethics researchers. All are generating new ethics knowledge and endeavoring to translate that knowledge into positive impacts on health and health research.

For more on Knowledge Translation at CIHR -- both "integrated" and "end-of-grant"-- see http://www.cihr-irsc.gc.ca/e/39033.html

2013 Douglas Kinsella Award for Research in Bioethics Recipient Marlee McGuire: On Expensive Orphan Drugs

Marlee McGuire, Doctoral Student, University of British Columbia. CIHR Frederick Banting and Charles Best Canada Graduate Scholar.

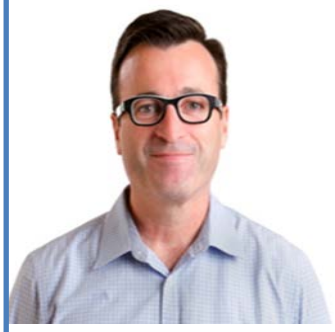
Spotlight Project: "Expensive Orphan Drugs and Translational Research in Rare Diseases" (2013-2016)

In your project on Expensive Orphan Drugs what is the ethics -- or ethical, legal and social (ELS) -- focus?

The ELS focus of my doctoral research is on the dynamics of research and development of orphan drugs for rare progressive-degenerative neonatal/childhood metabolic diseases. My research is ethnographic, which involves employing anthropological qualitative methodology and bioethical/ theoretical analysis to capture a) local and global policy frameworks and relationships, b) the moral landscape and cultural dimensions of orphan drug development and c) how patients and families are interacting with these

(continued on page 6)

Charles Weijer: On Cluster Randomized Trials



Charles Weijer, Western University.
Professor of Philosophy and Medicine, Canada Research Chair in Bioethics.

Spotlight Project: "International Dissemination of the Ottawa Statement on the Ethical Conduct and Ethics Review of Cluster Randomized Trials" (2012-2013). Dissemination Events Grant-Priority Announcement: Ethics

In your project on Cluster Randomized Trials, what is the ethics -- or ethical, legal and social (ELS) -- focus?

Our project is designed to promote the uptake of recent international ethics guidelines for cluster randomized trials—or "CRTs". The CRT is an important methodology in knowledge translation, health systems, and public health research.

In CRTs, social groups or "clusters" —rather than individuals—are randomized to different study arms. But CRTs pose ethical challenges due to unique features of their design. Who ought to be considered research participants in these complex studies? When interventions target entire clusters is individual consent required? Is the consent of a gatekeeper an acceptable substitute for individual consent?

Biostatistician Monica Taljaard, trialist Jeremy Grimshaw, and I led a CIHR-funded research project exploring these issues from 2007 to 2012. We documented practice in a number of empirical studies, and published a series of articles exploring ethical issues. All of this work fed into an international consensus process that resulted in the publication of the Ottawa Statement on the Ethical Design and Conduct of Cluster Randomized Trials, the first dedicated international ethical guidelines for CRTs.

What kind of impacts in the health arena do you see this project having—either directly or down the road? Who do you see as primary knowledge users?

The key question for us in our current project is: how do we get people to actually use the Ottawa Statement? Our primary knowledge users are researchers and research ethics boards. Until now they have had no ethical guidance for the design or review of CRTs. This has led to highly variable CRT practices, and delay and researcher frustration in ethics review. **The Ottawa Statement provides researchers and research ethics boards with much needed ethical guidance. We believe it will both promote ethical practices in CRTs and help streamline ethics review.** But no product in reality sells itself. We have used a number of strategies to promote uptake and use. We organized workshops at scientific and research ethics meetings, including the Society for Clinical Trials, Public Responsibility in Medicine and Research, and the Canadian Association of Research Ethics Boards. We published a brief user's guide for researchers and researcher ethics boards earlier this year in the British Medical Journal. We have also given presentations on the Ottawa Statement to government bodies, including CIHR's Standing Committee on Ethics and the U.S. Department of Health and Human Services Secretary's Advisory Council on Human Research Protections. Next steps include the development of country-specific users' guides for research ethics boards in Canada, the United States and the United Kingdom, and we are working with the Rotman Institute of Philosophy to develop creative and engaging online materials.

(continued on page 5)

Ethics Office Grant & Award Funding Recipients in 2012 - 2013: Congratulations!

The Ethics Office offers regular funding opportunities and funds applications relevant to ethics in other CIHR competitions. For all current CIHR competitions, go to: http://www.cihr-irsc.gc.ca/e/34178.html

Café Scientifiques
BAYLIS, Françoise; KRAHN, Timothy M; ORKIN, Aaron M; PEDERSON, Ann P; SHAW, Jacquelyn

Catalyst Grant: Ethics
MARCOUX, Isabelle; ORSINI, Michael; STRAEHLE, Christine; STRIKE, Carol; VAN MANEN, Michael

Dissemination Events-Priority Announcement: Ethics
AUSTIN, Wendy J; BLUM, Alan F; MACAULAY, Ann C; RAVITSKY, Vardit; RAYNAULT, Marie-France; REINER, Peter B; SAINT-ARNAUD, Jocelyne F; TALJAARD, Monica; VON KEYSERLINGK, Marina A

Doctoral Research Award: Douglas Kinsella Award for Bioethics
MCGUIRE, Marlene (Marlee)

Operating Grant- Priority Announcement: Ethics
BIRN, Anne-Emanuelle; DUMONT, Serge; GODARD, Beatrice

Planning Activities-Priority Announcement: Ethics
ASADA, Yukiko; BREHAUT, Jamie C; GIBSON, Jennifer; KNOPPERS, Bartha M; KOTALIK, Jaroslav; SNYDER, Jeremy C

Institute of Infection and Immunity- Program Grant: Transplantation Research
WEST, Lori J

Institute of Population and Public Health- Population Health Intervention Research
HOGG, Robert

Janice E. Graham: On Practices of Standardizing Health Technologies

Janice E. Graham, Dalhousie University.
Professor of Pediatrics, Faculty of Medicine. Scientific Director, Technoscience & Regulation Research Unit. Associate Director, Canadian Center for Vaccinology, Canada Research Chair in Bioethics (2002-2012).

Spotlight Project: "Articulating Standards: translating the practices of standardizing health technologies" (2011-2015). Operating Grant- Priority Announcement: Genetics-Ethics, Law and Society.

In your project on Practices of Standardizing Health Technologies, what is the ethics -- or ethical, legal and social (ELS) -- focus?

Better understanding the construction, development and consistent use of biomedical standards to regulate health risks is essential to the health and safety of people. **We began our project with the underlying premise that science is a cultural activity and that scientific data are valued, decided upon and put together in ways that are enabled or constrained by various incentives, persuasions, social relations and politics, and the technical instruments and skills of those making the observations.**

Our inter-disciplinary research team is investigating how diverse stakeholders build, negotiate and translate evidence towards the harmonization of standards through relational, material and discursive engagements. We are examining how knowledge is decided upon and 1) the development of human proteomics research standards for personalized medicines by the international Human Proteomics Organization (HUPO) and its Proteomics Standards Initiative (PSI); 2) the development of global vaccine safety standards and the capacity and capability for their uptake in developing countries; and 3) the negotiation of the Walpole Island First Nation, scientists and Shell Oil for biomedical standards that recognize environmental and health consequences of petrochemical pollutants.

Using qualitative ethnographic methods including interviews, observations and document analysis, this comparative study represents the continuum of standards development and stakeholder engagements from lab to industry to various publics: before a biotechnology reaches society-wide application and is integrated into public discourse (HUPO); during the implementation of global vaccine safety standards; and after technical standards of health risks have failed and been challenged in public discourses (Walpole Island).

What kind of impacts in the health arena do you see this project having—either directly or down the road? Who do you see as primary knowledge users?

We are examining knowledge being created, sometimes avoided, and translated between scientists, clinicians, industry, regulators and people living in diverse communities. We are collecting, analyzing and producing accounts of communication and mis-communication between stakeholders engaged in standard-making activities, which are purported to be innovative and contributing to better health. Our research findings are intended to identify strengths, challenges and flaws that occur in decision-making at various sites for the development of standards. Through a deep description of the contextual details involved in decision-making, that necessarily involve navigation through multi-sector interests and arrangements, we are mapping more effective democratic strategies to engage and translate between diverse stakeholders in future, and intend to produce a model of participation in biomedical standardization which will aid regulators, policy makers, researchers, practitioners and the end-user publics involved in assessing, implementing and benefiting from new, and truly innovative, standardized health technologies.

(continued on page 5)

Fall 2013 Ethics Funding Opportunities

Dissemination Events: Priority Announcement-Ethics: Application Deadline: October 15, 2013

Doctoral Research Award: Priority Announcement – Ethics:
Application deadline: October 1, 2013

Planning Grants: Priority Announcement-Ethics: Application Deadline: October 15, 2013

Chair: Applied Public Health:
Research Plan to include ethical considerations.
Letter of Intent deadline: October 30, 2013

Canadian Consortium on Neurodegeneration in Aging:
ELSI is a cross-cutting component. To signal interest in joining the research team, complete an online registration form by Dec. 2, 2013.

Open Competitions
Check CIHR's Research Funding Database for a complete list of current funding opportunities in open competitions: http://www.cihr-irsc.gc.ca/e/34178.html

Serge Dumont: on End-of-Life Deliberations

Serge Dumont, Université Laval,
Full professor, School of Social Work, Faculty of Social Sciences.

Spotlight Project: "End-of-Life Deliberations: Characterization of interprofessional clinical practices" (2013-2016). Operating Grant-Priority Announcement: Ethics.

In your project on End-of Life Deliberations what is the ethics -- or ethical, legal and social (ELS) -- focus?

Situations that demand ethical deliberation processes, which are usually a determinant for the patient's quality of life, are commonplace in palliative care settings. Indeed, healthcare professionals practicing in end-of-life care settings face numerous ethical challenges. Terminally ill patients and their families are the most immediately affected by these challenges, but the professionals who care for them are also impacted.

Challenges include disclosure of sensitive information, decisions regarding the choice or withdrawal of treatment, conflicting values, and various patient quality of life issues. The ethical dilemmas that often result entail decisions and professional conduct that cannot be regulated solely by the deontological norms, the legislation, or by the institutional norms and standards. In addition, two recent events in Canada are likely to significantly increase the frequency of such situations: the first one is the ruling by the Supreme Court of British Columbia declaring provisions of the Criminal Code prohibiting euthanasia and assisted suicide unconstitutional, and the second is the release of the findings of the Québec National Assembly Committee on Dying with Dignity, which will usher in legislative and regulatory changes surrounding the right to medically-assisted dying.

What kind of impacts in the health arena do you see this project having—either directly or down the road? Who do you see as primary knowledge users?

We expect that the knowledge generated by this study will shed light on interprofessional collaboration practices in regards to ethical deliberation throughout the healthcare network and provide insight into the factors that facilitate and hinder ethical deliberation in end-of-life care settings. professional training.

Moreover, this study coincides with the priority objective recently announced by the Réseau universitaire québécois en soins palliatifs to promote the teaching of interprofessional collaboration in palliative care among students in the applicable disciplines. Conducting the study in institutions involved in university training (internships and continuing education) as is planned, means that new knowledge can be put into practice quickly.

Looking into the future, do you have any thoughts on emerging areas where health ethics research could make an important contribution toward improvements in health?

We think that the primary value of this study remains its potential to alleviate the distress of dying patients and their loved ones, and also of health care professionals, which can arise from absent or suboptimal ethical deliberation when such deliberations are called for. It should be noted that **it is challenging for clinicians to evolve in a Canadian society that is in a process of rethinking its medico-legal norms and standards for euthanasia and assisted suicide**. This is creating a state of flux in the normative field in which palliative care workers operate that has compounded the complexity of ethical end-of-life decision-making processes.

Future workers in related disciplines need professional training in ethics and interprofessional collaboration so they can face current and future challenges. We are convinced that new knowledge generated by this study will contribute to their interprofessional collaboration and ethics education in university curriculums and continuing education through health and social services institutions./

Reforms of the Open Competition and Peer Review at CIHR

CIHR is working together with the research community to redesign the Open Suite of Programs and peer review process. For more information on the reforms, please see ***Designing for the Future, The New Open Suite of Programs and Peer Review Process*** at http://www.cihr-irsc.gc.ca/e/46099.html.

CIHR has developed **Questions and Answers** to further explain the new design. The upcoming pilots in Fall 2013 for the Fellowship competition and the Knowledge Synthesis Grant are also described. For details, see http://www.cihr-irsc.gc.ca/e/45284.html

Continued from Page 2- Charles Weijer: On Cluster Randomized Trials

Looking into the future, do you have any thoughts on emerging areas where health ethics research could make an important contribution toward improvements in health?

Our research group is interested in doing work on CRTs in other settings, including low and middle income countries. CRTs in international development may use economic interventions (such as access to small loans) to impact health outcomes, and the ethical issues raised by these studies have not been systematically explored. **More broadly, the experience of working with a research team comprised of philosophers, biostatisticians, and trialists has convinced me of the importance of collaborating with scientists.**

Collaboration in ethics research helps ensure that we ask the right questions and posit answers that are actually workable within the constraints of scientific practice./

Ethics Resources in Canada: On the WEB

(Selected)

Canadian Bioethics Society

- Bioethics in the News
- Canadian Bioethics Blog

Canadian Council on Animal Care

- Education and Training

Inter-Agency Advisory Panel on Research Ethics

- TCPS 2 Tutorial Course on Research Ethics (CORE)
- Upcoming Webinars

Novel Tech Ethics, Dalhousie University

- IMPACT ETHICS a forum for discussion

University of Toronto Joint Centre for Bioethics:

- Community Tools: Bioethics Seminar Series
- Public Health Ethics Portal
- Population and Public Health Ethics: Cases from Research, Policy, and Practice

Quebec Ministry of Health and Social Services

- Tutorial in Research Ethics

P3G - Public Population Project in Genomics and Society

- Biobanking Toolkit- see ELSI tools

Continued from Page 3- Janice E. Graham: On Practices in Standardizing Health Technologies

Looking into the future, do you have any thoughts on emerging areas where health ethics research could make an important contribution toward improvements in health?

There is a need for more publicly funded research for university researchers independent of corporate sponsorship. These research questions might be concerned, for instance, with the growing privatization and fracturing of our health, social and home care services and systems. We need research that addresses Canada's infant mortality rate, the second highest of all industrial countries, why children and adults go hungry and neglected, why vaccine research has moved from an investment in public health to sponsored clinical trials of expensive leaky vaccines with 49% efficacy, why too many people die from infectious diseases they catch in hospitals, why our schools and public health care decline with a proliferation of private schools and private health services, how petrochemical pollution of river and agricultural systems affects locals, why de-employed industrial workers are having coronaries in their forties and fifties while cheap, foreign-made products end up in dumps, and why our elders die alone and neglected while the term "innovative research" is reserved for developing commercial products for private gains.

We need more truly interdisciplinary transformative projects that challenge accepted dogma, that are led by social scientists as well as bench and clinical scientists./

Continued from Page 1- Marlee McGuire: On Expensive Orphan Drugs

multidimensional systems and how they feel about them. These treatments slow disease progression, but their high price points (between $100,000 and $850,000 per patient per year) raise several ethical dilemmas.

Orphan drugs are creating, mediating and transforming discussions of the ethics surrounding the accessibility of health care technology. They are also sparking clinical discussions of how best to measure and interpret therapeutic benefit on small patient populations with heterogeneous disease phenotypes and responses to treatment.

What kind of impacts in the health arena do you see this project having—either directly or down the road? Who do you see as primary knowledge users?

The impact that I envision for this project is that it will help determine frameworks for dealing with emergent genetic disease treatments and the interesting sets of problems that they pose. The translation of knowledge of rare genetic mutations into orphan drug commercial pathways involves institutional, academic, regulatory, political, and economic actors. A deep understanding of these complex networks of relationships is necessary to properly inform those with a stake in the future of orphan drug development and availability. These stakeholders are also the primary knowledge users of this research: policymakers, clinicians, patients/patient advocacy groups and provincial and federal regulators.

This research is timely, as the cost and sustainability of therapeutic development models is a key aspect of debates surrounding the viability of universal health care coverage in Canada and internationally. Knowledge of genetic variation and metabolic biomarkers are increasing, and so too is the pharmaceutical industry's focus on orphan drug pipelines. It is important that models of health resource allocation ethics develop alongside these cultural, scientific, and economic shifts.

Looking into the future, do you have any thoughts on emerging areas where health ethics research could make an important contribution toward improvements in health?

Health research ethics is in a unique position to combine ethical framework development with a deeper anthropological/sociological questioning of the world around us. For example, the dilemmas posed by orphan drugs are connected to several other important ethical/legal/social issues: models of governmental regulation, the ambiguous interface between the concerns of society and the concerns of industry, the ownership and profitability of scientific knowledge and how these types of problems add to the suffering and confusion often experienced by patients and families. Expanding our scope to include an understanding of the structural determinants of conflicts in care will increase our ability to contribute meaningfully to long-term systemic change./

Upcoming Ethics Events & Consultations in Canada

(Selected)

Reconnect 2013: Big Data – The Advance of Data-Driven Discovery, October 16-18, 2013, Ottawa, Ontario.

Till & McCulloch Meetings, October 22-25, 2013, Banff, Alberta. Stem cell research event.

Canadian Bioethics Society- First National Health Ethics Week, February 24-28, 2014.

Brain Science and Social Responsibility. Brain Matters Vancouver Conference, March 12-14, 2014. Vancouver, British Columbia. Hosted by the National Core for Neuroethics.

CAREB-ACCER 2014 National Conference, April 24 – 26, 2014 (with pre-conference workshops on April 23), Montréal, Québec.

25th Annual Canadian Bioethics Society Conference. Looking Back; Looking Forward. May 28-31, 2014. Vancouver, British Columbia.

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans- Revisions for Public Comment. Open until January 15, 2014.