Task Force on Ethics Reform at the Canadian Institutes of Health Research

Final Report

Prepared for Governing Council

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1. INTRODUCTION

a. Formation and mandate of the Task Force

CIHR's Governing Council formed the Task Force on Ethics Reform at CIHR in late November 2012. Its objective was to evaluate whether CIHR currently meets its ethics mandate and whether the current organizational structure is optimal to do so. More specifically, the Task Force is expected to review and make recommendations to CIHR's Governing Council on:

1. CIHR's performance in the area of ethics since its inception;
2. Innovative ways for CIHR to meet its ethics mandate;
3. Evolving needs in the ethics field and gaps that must be filled to address them in alignment with CIHR's Health Research Roadmap (2009-2014);
4. Current structures and their appropriateness to meet the CIHR ethics mandate in the future;
5. Role, accountability, and interrelationships of resulting entities should a new delivery structure be recommended.

The Task Force's members are Bartha Maria Knoppers (Chair), Timothy Caulfield, Jim Lavery, Michael McDonald, and Daryl Pullman. See Appendix A for short biographies.

Governing Council requested that the Task Force submit draft recommendations by mid-March 2013. A final report was submitted in May 2013, and a presentation was made to Governing Council summarizing the report in June 2013.

b. Process followed

The Task Force held a series of teleconferences (one in December, one in March) and communicated frequently by email to complete its work. CIHR provided funding for all Task Force members to attend a two-day, face-to-face meeting in Montreal where the general outline for this report was sketched out. In addition, some members attended a meeting of the Standing Committee on Ethics in November 2012. This report was developed after a thorough review of: 1) background materials on ethics at CIHR graciously prepared by the Ethics Office, 2) submissions received from the CIHR community (see next section), and 3) the Task Force's own internal discussions.

c. Who we heard from

The Task Force sought input from across the CIHR community, both those who work mainly in ethics and policy as well as those who conduct scientific research. To this end, both a targeted and an open call for submissions were issued. In particular, all of CIHR's Institutes were contacted. It was emphasized that the identity of respondents would be kept confidential. Letters were sent in early January 2013 to various individuals identified by the Task Force in virtue of their official capacity. An open call for submissions on the CIHR website and via its email newsletter was made in early January 2013.

Given our extremely tight timeline we are pleased with the number and quality of responses received. Of 57 targeted calls, we received 38 replies representing a 67% response rate. However, the actual response rate may be higher since some Institutes may have sent a joint response for both the Scientific Director and the Ethics Designate. In addition, we received 10 responses to our open call. The responses included submissions from many leaders in ethics, various ethics bodies/organizations/institutes both within CIHR and outside, the wider academic community, and international organizations. Telephone interviews were held where feasible.

All responses were reviewed in detail and main themes extracted. Many submissions were very extensive and well thought out, and they greatly helped in our deliberation process. We would thus like to sincerely thank everyone who took the time to submit their thoughts and recommendations to us.

d. Our timeframe

The Task Force was given a short timeframe to complete its work. It was formed in late November 2012 and draft recommendations were due in mid-March 2013. Thus, while we recognize that it would have been ideal to engage in more substantive consultations across the country (for example, by convening town hall meetings) neither the budget nor our tight timelines made this feasible. However, as noted, we took steps to elicit input from a range of communities.

2. CONTEXT OF ETHICS AT CIHR

A more detailed background to ethics at CIHR is contained in Appendix B.

a. A unique legislative mandate

CIHR has a unique legislative mandate in the area of ethics. While all public agencies have an implicit mandate to act ethically, CIHR is the only Canadian agency with an explicit health ethics mandate enshrined in legislation. The mandate is found in the legislation which established CIHR in 2000, the *Canadian Institutes of Health Research Act* (S.C. 2000, c. 6):

- promoting, assisting and undertaking health research that meets the highest standards of ethics [s. 4(e)];
- fostering the discussion of ethical issues and the application of ethical principles to foster health research [s. 4 (g)];
- and monitoring, analyzing and evaluating ethical issues pertaining to health or health research [s. 5(d)].

This legislative mandate was noted as one of CIHR's great strengths by both the 2006 International Review Panel and the 2009 internal audit on the "Management Control Framework for Research Ethics Activities."

The preamble to the *CIHR Act* states that CIHR was created to transform the way health research is conducted in Canada to improve the health of Canadians. That

improvement comes through innovation resulting from research. However, it was recognized early on when establishing CIHR that health innovation is often accompanied by challenging ethical issues and questions. Thus "an increased demand for research into ethics and the application of ethical principles to ensure that the new scientific innovations and discoveries that are transforming our lives are consistent with the values of Canadians" (The Final Report of the Interim Governing Council of the Canadian Institutes of Health Research, June 2000). Given that innovation and ethics should go hand in hand, and the role CIHR must play in ensuring the public trust, it was only logical – and more importantly, visionary – to include an explicit statutory ethics mandate in the *CIHR Act.*

Thus, the ethics function at CIHR is more than an ethical imperative or best practice in research. Instead, CIHR has a clear legal obligation to have a strong and substantive ethics programme as an essential part of its broader mandate to improve the health of all Canadians.

b. Nature of ethics at CIHR

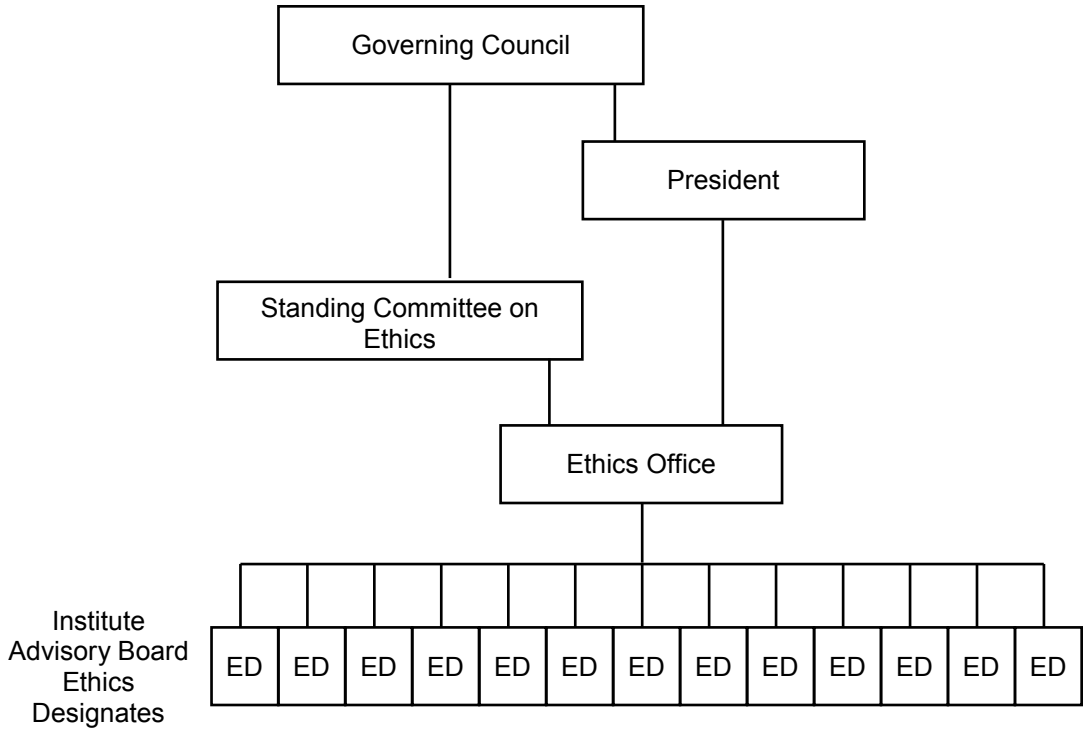
As noted above, ethics at CIHR does not have its own Institute. Instead, the initial structure was intended to provide both horizontal and vertical integration of ethics throughout the organization (see Diagram 1).

Ideally, the vertical function is accomplished by ensuring ethics representation at multiple levels throughout the governance structure, including the President, Governing Council (GC), and the Standing Committees. The horizontal function is achieved through the implementation of mechanisms to ensure communication and coordination of ethics activities (through the Ethics Office – the EO) across the Institutes (through the Institute Advisory Board Ethics Designates – IABEDs). A structure of shared responsibility across multiple actors was established to promote this. The overall goal is to promote a culture whereby ethics permeates decision-making throughout the organizations at all levels (e.g. Institutes, high-level administration, researchers). Ethics at CIHR is described by the EO as having three core functions:

1. Creating knowledge in health ethics and fostering its use (ethics *for* research and knowledge translation function);
2. Promoting scientific integrity and ethics among Canadian health researchers and institutions supported by CIHR (ethics *in* research function); and
3. Engaging in ethical reflection on the goals and social implications of health research (ethics *of* research function).

In fulfilling these functions, the EO adopted a model of collaborative endeavour and shared responsibility across the organization.

Diagram 1: Ethics at CIHR - A "Horizontal Institute" (2000-2010)



Each part in turn has its own specific mandate with regard to the ethics function. The Standing Committee on Ethics (SCE), one of six committees established by GC, was formed shortly after CIHR was incorporated with the mandate to identify for GC emerging ethical issues of strategic importance with respect to health and health research. The SCE Chair is drawn from the membership of GC.

Likewise, the EO was set up to operationalize ethics at CIHR in collaboration with the Institutes and other CIHR initiatives as well as with external bodies (e.g. Health Canada). Over the first decade of CIHR's existence the EO spearheaded a number of key initiatives including the *Privacy Best Practices* (2005), the *CIHR Guidelines for Research Involving Aboriginal Peoples* (2007), and the *Best Practices for Health Research on Children and Adolescents* (2012). CIHR has also taken a significant role at the Panel on Research Ethics and the Secretariat for the Responsible Conduct of Research, for example in the development and review of the 2nd edition of *Tri-Council Policy Statement for Ethical Research Involving Humans* (2010) and the *Tri-Agency Framework: the Responsible Conduct of Research* (2011). Such initiatives have been important not only to CIHR, but to the entire Canadian research community. Indeed, such CIHR initiatives have been recognized internationally.

Finally, the official mandate of the IABEDs is, in theory, fulfilled in applying an ethical framework to the Institutes' activities and research with the concomitant duties to advise, raise awareness, promote discussion, and liaise with other ethics bodies at

CIHR. However, there is great variation across the Institutes in the IABED's role and success in fulfilling their mandate.

The 2006 CIHR International Review Panel (IRP) described ethics as a "crucial component of CIHR's mandate" as evident in the important role ethics had in CIHR's governance. It recommended increasing emphasis on research in ethics and enhancing ethics governing responsibilities. The 2011 IRP was largely silent on ethics within CIHR and focused instead on the ethics issues raised by research generally.

Other initiatives, activities, and programmes in ethics since CIHR was founded include:

- Extensive collaborations with external bodies, such as the Panel on Research Ethics (PRE), the Secretariat on Responsible Conduct of Research (formerly, the Secretariat on Research Ethics), Health Canada, and the Canadian Council on Animal Care (CCAC);
- Development of a five-year strategic plan by the EO in 2009 along with logic models for the function of ethics at CIHR;
- A funding envelope of 2.3$ million in 2010-2011 with supported activities including: operating grants; priority announcements; fellowship and doctoral awards; catalyst grants; meetings, planning, and dissemination grants; workshop grants; and research network grants. (For more details, refer to Appendix B.)

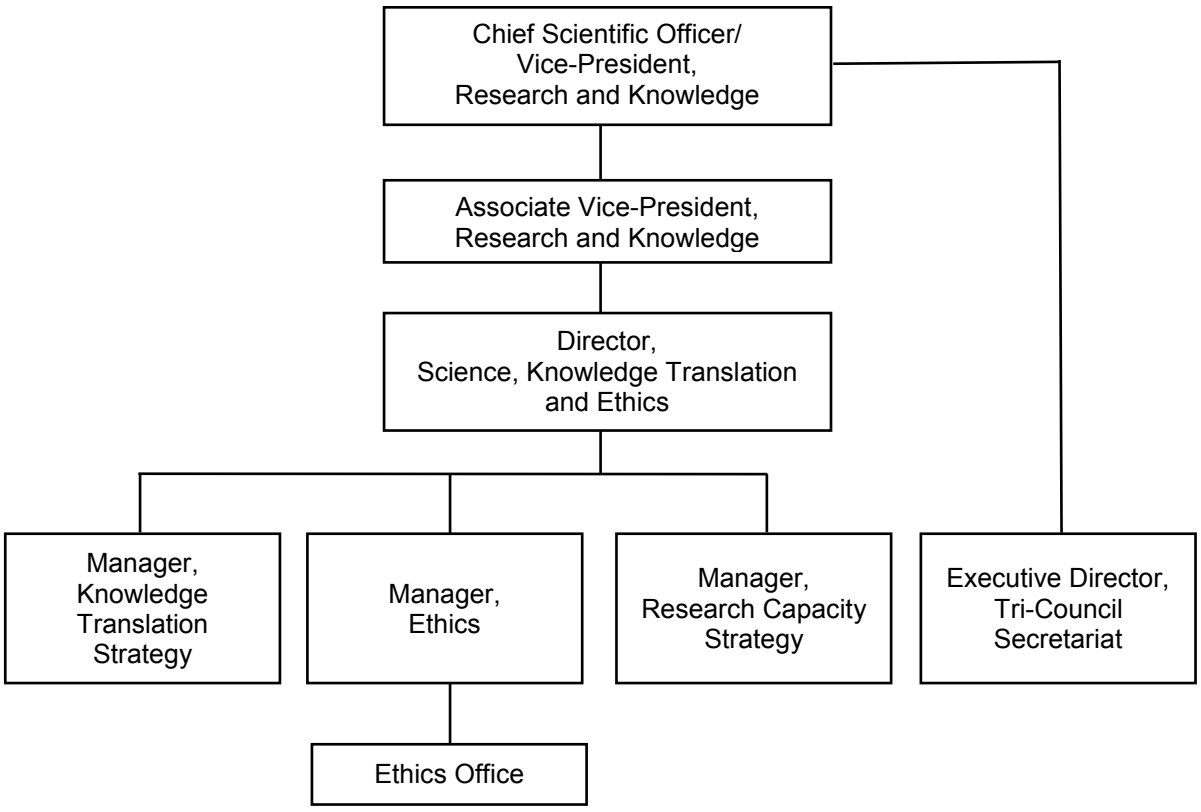
During CIHR's 2011-2012 re-organization, several changes were made to the reporting structures vis-à-vis ethics (see Diagram 2). Originally, the EO reported directly to the President of CIHR, and then to the Corporate VP. Now, the EO reports to the Director of Science, Knowledge Translation and Ethics – and is subsumed under the Research and Knowledge Translation portfolio. The EO also used to have its own dedicated Director; now the Director of Ethics is also the Director of Knowledge Translation and Research Capacity Development. Finally, IABEDs used to meet as a group annually, often in conjunction with the SCE, and for a period the IABED Chair was invited to all SCE meetings. This practice, while never formalized, was abandoned in 2011.

In addition, ethics at CIHR also involves other entities/programmes such as the Stem Cell Oversight Committee, the Strategy on Patient Oriented Research.

c. Summary

CIHR's mandate reflects a clear legislative commitment to treat ethics as an integral dimension of health research and not simply as an afterthought. Ethics is foundational to the formation, history, and function of CIHR. In fulfilling its mandate thus far, ethics has been organized through a distributed structure involving many different actors with overlapping roles and responsibilities as well as lines of accountability.

Diagram 2: Ethics Office after Re-structuring (2011-12)



3. WHAT WE HEARD FROM THE CIHR COMMUNITY

The following is a brief summation of the major themes that were conveyed to the Task Force. This is not a comprehensive or detailed reiteration of all the points raised in the submissions (for that, see Appendix C). Rather, these are the main issues that consistently emerged and which the Task Force relied upon for its deliberations and development of its recommendations.

a. Leadership

By far, the overwhelming majority of submissions identified a lack of leadership in the ethics programme at CIHR as the key issue in need of redress. While ethics leadership goes beyond any one person, the absence of a permanent EO Director was commonly cited as the prime example of this lack of leadership. Lack of leadership, we were told by many, has also contributed to the perception that ethics is drifting and has no secure place or visibility within CIHR.

Submissions identified the essential attributes the ethics leadership must have. It must have a vision for ethics at CIHR and have the power and credibility to be able to uncover and address broader ethical issues in research. The ethics leadership must be

vested with sufficient independence and decision-making authority to implement and give effect to CIHR's statutory mandate in ethics. It must be able to speak for ethics at the highest level of CIHR decision-making.

b. Integration

Many submissions highlighted the lack of integration of ethics across CIHR. Integration, in this sense, refers to the extent to which the ethical implications of the full scope of CIHR's mandate are represented and meaningfully incorporated into all policies, practices, programmes and activities of the organization. While attempts were made to foster integration through CIHR's organizational structure, in practice many felt that ethics has become increasingly fragmented thus contributing to the uncertainty surrounding who is supposed to do what.

Many examples were cited. For instance, submissions identified a lack of communication, connection and shared vision between CIHR senior management, the EO, SCE and Institutes. These problems were exacerbated when regular meetings of the IABEDs were discontinued in 2011. Up until that time, the IABED who served as chair of the IABED Committee as well as other IABEDs (on a rotational basis) had been attending the meetings of the SCE and, in recent years, an annual IABED-SCE joint session had been held. Moreover, there is a general sense of systemic lack of coordination for CIHR's activities in ethics as witness by the lack of integration of ethics activities within CIHR's Health Research Roadmap.

The result of this lack of integration has been that CIHR has been insufficiently pro-active in identifying and researching emerging issues in ethics, and in promoting a culture of ethics – in other words, CIHR was seen as not fulfilling its statutory mandate. It was stressed that any changes to the governing structure of ethics must be done with a view to: 1) enhancing how effectively CIHR is able to execute its mandate *across* all branches, programs and activities of CIHR, and 2) harnessing *capacity* (in the EO or otherwise) to meet its mandate. Indeed, this was one of the most consistent messages we heard.

c. Mandate

Submissions identified as a major problem a lack of clarity surrounding the mandates of the EO, SCE, and IABEDs. While each of these entities already has a written mandate, in practice there is much confusion and conflicting understandings surrounding the role of each entity and how they are supposed to work together in fulfilling CIHR's ethics mandate. Clear and strong directives from GC reflecting CIHR's statutory ethics mandate are required. Additionally, these directives must clarify linkages with external entities such as the Panel on Research Ethics. Finally, the criteria for persons serving the role of IABEDs should be specified (knowledge, interest and experience in ethics should be included), and the selection process for IABEDs must be clarified and transparent

d. Reporting structures

Many submissions pinpointed current reporting structures – especially after the 2011-2012 re-organization – as problematic for the place of ethics within CIHR. Previously, the EO reported directly to the President. Now, the EO reports to the Director of Science, Knowledge Translation and Ethics Branch and is housed under the umbrella of the Research and Knowledge Translation portfolio. This was seen, rightly or not, as diminishing the stature of ethics and limiting the ability to advance ethics within CIHR. Likewise, submissions indicated that for ethics to have influence at CIHR, it must have access to the highest levels of decision-making and be able to influence meaningful change at CIHR.

e. Functioning

There is a general sense that the ethics mandate has been, to some degree, minimised and lost its momentum. The SCE was recognized as a major source of expertise that could help to ensure that CIHR is a world leader in creating and disseminating research of the highest social and ethical value. At the same time the SCE was seen as an under-utilized resource with only marginal influence at CIHR, either at GC or at the Institutes. Many observed that the EO has had a dramatic reduction in staff, thus reinforcing the perception of the diminishing importance of ethics at CIHR. Although the EO was seen as having qualified personnel it lacks sufficient support to effectively coordinate ethics activities or engage with the Institutes. The recent practice (since 2009-2010) of appointing one EO liaison to each Institute was an attempt to reach out to the Scientific Directors, yet it has failed to greatly enhance Institute-EO collaborations beyond what was already existing. Before then, EO senior advisors collaborated with Institutes in a variety of ways and with some success depending on the Institute. Even before the establishment of liaisons, EO senior advisors were invited to Institute Advisory Board (IABs) meetings – some have ethics as a standing item on their IAB meeting agenda. Great uncertainty surrounds the role and responsibilities of IABEDs.

There is much variation in how individual Institutes approach ethics. Some take their ethics mandate very seriously and actively seek collaborations with the EO and other Institutes in ethics matters, while others appear less enthusiastic. Likewise, while some Institutes make great use of their IABED and have even set up an ethics subcommittee chaired by the IABED, others have failed to appoint IABEDs for some time.

f. Representation and culture of ethics

Submissions called for increased visibility and representation of ethics to promote a culture of ethics as a corporate value. Respondents observed that ethics is increasingly viewed as an afterthought within CIHR as evidenced by its continually diminishing status as the result of structural changes imposed by senior management and exacerbated by the absence of strong ethics leadership. For many respondents, this represents derogation from CIHR's founding ethics mandate and an under-

appreciation of the potential of CIHR's underlying capacity to promote ethics nationally and internationally. Respondents felt strongly that ethics should be built into every aspect of CIHR's work and the research it funds, rather than being an after-thought. There was a strong feeling that the potential and promise of ethics at CIHR is not being realized, and that renewed effort must be directed to developing and disseminating ethics knowledge as a substantive area of health research. The capacity of researchers to recognize and address ethical issues must be enhanced.

4. THE TASK FORCE'S OBSERVATIONS

The following observations are based upon the Task Force's review of the history and context of ethics at CIHR, the background documents, and the submissions received.

a. Different visions of ethics

The function of ethics is not always viewed in the same way. One perspective puts ethics in a service role that enables ethically-sound research through the preparation of material for ethics review or by acting as a quasi-regulatory oversight body. Ethics, under this approach, is driven in response to issues arising as research happens and is used as a way to address those issues through knowledge translation and application of various national and international guidelines. From this perspective, there is emphasis on the procedural, oversight, and process oriented aspects of ensuring that biomedical research is conducted in an ethical and legally-sound manner. This is how ethics is traditionally "seen to be done."

Another vision is that ethics is also an activity in knowledge generation and hence a specialized area of health research in itself alongside, but also informing, other areas of health research such as genetics, immunology, epidemiology, etc. On this account, ethics is an important area of health research to be promoted as a value and is not just an institutional or quasi-regulatory requirement. On this view, emphasis must be placed on pushing the field of ethics forward and developing the ethics knowledge base, including the relevant normative frameworks.

In reality, these seemingly contrasting visions are overlapping and complementary. This is already reflected in the three core functions of ethics at CIHR (also cited above):

1. Creating knowledge in health ethics and fostering its use (ethics for research and knowledge translation function);
2. Promoting scientific integrity and ethics among Canadian health researchers and institutions supported by CIHR (ethics in research function); and
3. Engaging in ethical reflection on the goals and social implications of health research (ethics of research function).

Ethics thus has a range of functions from ancillary/regulatory functions (such as corporate due diligence, public relations, and knowledge translation) to knowledge generation functions (strategic vision and planning, normative frameworks).

No one doubts that part of the role of ethics at CIHR is to help the research community by creating, interpreting, and applying ethical norms. This is a valuable contribution. But the tendency to think of ethics simply as a series of checklists must be resisted. While not always seen as such, ethics goes much further by creating infrastructure and knowledge to address the unique ethical issues that arise in the course of research, innovation, and translation – this is ethics research. Ethics research is more than research ethics; it creates new knowledge surrounding the ethics of new health care technologies, how innovation can take place in an ethical and sustainable manner, and how research can be ethically translated into improvements in health.

While we recognize that no one starkly subscribes to one vision over the other, we suggest that the confusion results from the absence of strong ethics leadership, which can articulate and operationalize the function and value of ethics at CIHR. The result is that views surrounding the role and value of ethics have become very diffuse, often collapsing into old and tired language that leaves people with the impression that ethics has little strategic value for the organization, aside from generating protective optics. CIHR thus needs a leader who can articulate and realize the full potential value of ethics, as reflected in the founding statutory mandate of CIHR.

b. Value

Despite CIHR's legislative mandate, to date ethics has not been emphasized as integral to the corporate vision. This is evidenced in the recent restructuring that saw the placement of ethics under a wider and ambiguous portfolio, and in the wide range of approaches the Institutes have taken to their individual ethics mandates and the roles of their IABEDs in particular. In many cases, ethics seems peripheral to CIHR and to Institute activities.

A refreshed vision for what ethics can do at and for CIHR is needed. Ethics can, inter alia, enhance research activities; help to ensure public trust in research outputs; situate health research in a wider global context and provide empirical data on the risks and benefits of particular forms of research and health innovations, thus informing policy and improving the health of societ;, and contribute creative solutions to ethical challenges that accompany new research opportunities. Such a vision can see CIHR as a national and international hub for facilitating innovation and informed dialogue around ethics in health research, thus further enhancing Canada's recognized role as a leader in the field.

We emphasize again that CIHR's ethics mandate is derived directly from the *CIHR Act*. As a result, CIHR is obligated legally to ensure that ethics has a central place within the organization. This is not optional; it is legally required. No one at CIHR has the authority to denigrate the value or place of ethics because the central place of ethics is proscribed by law. A refreshed vision for ethics must reclaim and re-establish the centrality of CIHR's ethics mandate by recommitting to its obligations outlined by statute through strong leadership.

c. Risks of inaction

There are several risks if CIHR fails to change the status quo or continues on its current path. These risks are against CIHR itself, with the potential for broader implications for its own stature as a pre-eminent health research body. CIHR must take steps to mitigate these risks, and ultimately the risk that it may be failing to meet its statutory obligations regarding ethics.

First, as mentioned, ethics has a distributed structure of shared responsibility between many CIHR entities. Current overlapping roles and responsibilities are confusing with the consequence that coordinated initiatives across CIHR are difficult. Such a structure also leads to fragmentation, which means that knowledge and experiences are not shared and emerging issues are not identified. The risk inherent in such a system is that ethics at CIHR never has a home or clear purpose, in other words it is "apparently everywhere, but really nowhere."

Second, by diminishing the status of ethics, CIHR will fall behind other major research organizations in the world (e.g. NIH, Wellcome Trust, Gates Foundation, etc.) that have demonstrated critical leadership in how ethics can contribute unique value to research. Canada has long been considered to "punch above its weight" in research ethics research. This status as an international leader is now in jeopardy if CIHR does not capitalize on the potential of CIHR's ethics mandate.

Third, left too long, CIHR may have difficulty recruiting top talent in ethics. This includes recruiting the key people who could work with CIHR management and the Institutes to enable the organization to fulfill its original statutory mandate. This would be a tragic outcome, since Canada probably has one of the highest concentrations of expertise in research ethics in the world.

Finally, there is a risk that public trust could be lost. The Canadian people who entrust Canadian researchers with public funds to conduct research for their benefit deserve assurances that this research is consistent with the highest ethical standards.

d. Ethics must be at the core of CIHR

To address these points, as well as the issues raised during the Task Force's consultations, ethics must be entrenched at the core of CIHR. Making ethics core at CIHR requires that ethics is understood as a source of knowledge, that it is valued at all levels of the organization as a forward-looking enterprise, and that clear mandates and lines of accountability are established. To begin, making ethics core means that everyone at CIHR from top to bottom must recognize that CIHR's ethics mandate is legislated. In other words, a strong ethics programme at CIHR is not optional; it is essential to the role CIHR plays in Canada's democratic society.

The Task Force draws upon CIHR's Health Research Roadmap, which has the following goal for ethics (part of its three-year implementation plan):

> Be nationally respected and internationally acknowledged for its role in the creation and continuous translation of health ethics knowledge to advance the highest standards of ethics and integrity in health research, policy and practice.

The following recommendations take this goal as their starting point, and are centred on how to make ethics core at CIHR.

Our recommendations are aimed at strengthening the existing ethics framework at CIHR. No one – either in our submissions received or the Task Force itself – suggests a radical departure from the current framework. In fact, everything we heard and reflected on suggests that had the original vision been fully implemented, adequately resourced, and carefully and consistently managed, it would be much closer to fulfilling its legislated mandate. Indeed, CIHR had a leadership role in ethics identified by the 2006 IRP; though by the 2011 IRB this leadership was largely absent. However, the underlying foundations and leadership potential for CIHR to once again be at the forefront of ethics internationally still remain strong. Thus, our recommendations have one goal in mind: restoring, strengthening, and refreshing the original vision for ethics at CIHR.

5. THE TASK FORCE'S RECOMMENDATIONS: MAKING ETHICS CORE AT CIHR

We have one key recommendation from which all others flow: provide ethics leadership to CIHR. Fulfilling its legislated mandate in ethics requires both a vision for ethics and responsible ethics leadership at every level of the CIHR corporate structure (including GC and the executive leadership) across all Institutes and programs. Leadership goes beyond any particular person and targets how the ethics mandate is implemented by all entities and even all persons at CIHR. Nonetheless, leadership also requires an individual who can lead and champion the effort.

A first (and this is only the first) step is to create a position of Vice President of Ethics (VP Ethics), or a position of equivalent stature, and then hiring a strong individual to fill that role. In order to properly reflect the prominence of ethics within the CIHR mandate, this person must have earned a standing within the research ethics community that is at least analogous to that of the Institutes' Scientific Directors. He or she must have the knowledge, skills and experience to elevate the status of ethics to a position within the organization that more fairly reflects the prominence of ethics in the CIHR mandate, and to develop and execute innovative, world-class programming in research ethics and related research policy. The person in this position should be recognized nationally and internationally as a leading scholar and researcher in ethics familiar with interdisciplinary approaches to research in and application of ethics. The establishment of such a position would require appropriate support and recognition with other entities within CIHR and outside.

It must be stressed again that the appointment of an outstanding individual as VP Ethics is only a starting point for ethics leadership. Additional steps, taken simultaneously to hiring a VP Ethics, are required. Effective ethics leadership at CIHR can only be achieved by ensuring *independence*, *integration*, and *interrelationships*.

While we call this person the VP Ethics, the crucial issue is the functionality of the leadership position and not the actual title of the position. We are concerned with leadership, reporting relations, and recourses. Whatever title is chosen, it should reflect

the importance of the position and carry with it the powers to implement the recommendations attached to the position outlined below.

See Diagram 3 (at the end of this section) for an organigram outlining the proposed new structures and linkages.

a. Independence

i. CIHR must recognize its statutory mandate in ethics and give a clear corporate commitment to the VP Ethics

The highest levels at CIHR – the President and Governing Council – must give their full support to the VP Ethics in fulfilling its ethics mandate. A resolution coming directly from GC to this effect is necessary.

ii. The VP Ethics must have a strong mandate based upon the CIHR Act

The Ethics VP's mandate must be taken directly from CIHR's founding statute. It should include specific reference to all sections of the *CIHR Act* addressing ethics and any antecedent powers necessary to fulfill that role.

iii. The VP Ethics' mandate should include knowledge generation and knowledge translation

As mentioned above, ethics is also an activity that generates new knowledge to inform heath research and is not just an institutional or quasi-regulatory requirement. The VP Ethics' mandate must thus include the development of new ethics knowledge to move the field forward as a substantive area of research.

iv. The VP Ethics must have decision-making autonomy within its mandate

The VP Ethics must be able to make decisions and effect change within the scope of the statutory ethics mandate without seeking approval from higher ups. This reflects the status of the VP Ethics as a member of senior management and the centrality of CIHR's ethics mandate.

v. The VP Ethics must report directly to Governing Council

In recognition of the importance of the ethics mandate, the VP Ethics must report to the highest level at CIHR.

vi. The VP Ethics must have a seat on Science Council and Governing Council

The VP Ethics must be on a level equivalent to the Scientific Directors. This recognizes both the importance of CIHR's ethics mandate and the calibre of the person

who should be selected to fill the role. Additionally, a seat on the Science Council ensures that the VP Ethics is plugged into the work of the Institutes and is able to hear concerns and emerging issues directly from the Scientific Directors.

The Chair of the SCE, who currently sits on Governing Council, would be replaced by the VP Ethics. This is because the SCE should become a new Ethics Advisory Board (see below) and hence would no longer be a standing committee of GC. However, to reflect the central role that ethics must play at CIHR, an ethics representative (i.e. the VP Ethics) must remain on GC.

vii. The office of the VP Ethics must have sufficient support and personnel to fulfill the VP's mandate

Again, reflecting the importance of the role, the VP Ethics must have support and personnel just as the Scientific Directors do in heading the Institutes. The support should be sufficient to enable the VP Ethics to tackle larger reforms, launch CIHR-wide initiatives, engage in research and policy development, and partner with agencies external to CIHR, in the same manner as the Scientific Directors.

b. Integration

i. The VP Ethics should be the head of the Ethics Office

It is only logical for the VP Ethics to head the EO. However, this implies that the EO must be taken out of the Research and Knowledge Translation Portfolio and placed directly under the VP Ethics. The VP Ethics can also provide the EO the stability and long-term management that has been lacking in recent years.

ii. The SCE should become a new Ethics Advisory Board (EAB) for the Ethics VP

The current SCE, while enormously respected, must evolve into the EAB and act in an advisory capacity to the VP Ethics (and IABEDs upon request). This will clarify the role of the SCE/EAB, ensure that it has an appropriate outlet for its high-level and forward-thinking advice, and avoid duplication of roles. Since the Ethics VP will be reporting directly to GC and acting as the "voice" of ethics within CIHR, it is unnecessary for the EAB to report to GC.

iii. The EO should have sufficient and trained personnel to support the VP Ethics, EAB, IABEDs, Institutes, and other ethics initiatives (e.g. SCOC, CCAC)

The EO already possesses tremendous talent and skill in its staff. However, recent cutbacks have meant that they no longer have sufficient resources to support ethics at CIHR. The EO must have enough human resources to take on the coordinating role of its mandate if CIHR is to fulfill its statutory mandate in ethics.

iv. The EO should have a dedicated financial envelope

Dedicated and stable funding is necessary for the EO to plan on a long-term basis. It is also required for the EO to take on its own initiatives under the auspices of the VP Ethics, be part of national and international partnerships, and enter into cost-sharing partnerships (for example, research funding opportunities with the Institutes).

v. The EO should be the point of contact for ethics at CIHR

The EO should be the point of first contact for any ethics-related initiatives or inquires across CIHR. This will ensure simplicity, help assure uniformity and avoid confusion as to who is the reference point for ethics at CIHR. It will further engrain the EO as the coordinating body for ethics at CIHR.

vi. The selection process for IABEDs should be clarified and made transparent

Currently, there is no formal process for selecting IABEDs. A formal recruitment process should be implemented in order to recruit IABEDs with the necessary background to fulfill the role. This should be done in conjunction with the Scientific Directors.

vii. The IABEDs should receive training in order to have the requisite skills to perform their function

There is great disparity in how IABEDs have been utilized at the Institutes. Much of this comes down to inadequate training in terms of what their role is and knowledge of the ethics programme at CIHR. A standardized training programme would improve this and ensure the Institutes utilize their IABED appropriately.

viii. The IABEDs must have a mechanism for regular meetings with the VP Ethics and EO

Lack of communication was commonly cited as a problem area. To ensure both input from the Institutes (via the IABEDs) into the EO and VP Ethics' activities and buy in, the IABEDs must meet regularly either in person or via teleconference. This would also provide opportunity to explore cooperation between the EO/VP Ethics and the Institutes, as well as between the Institutes.

ix. The Chair of the IABEDs should have a seat on the EAB as ex officio

This will ensure a sufficient link exists between the IABEDs and the EAB. The Chair can bring to the EAB concerns from other IABEDs and offer the Institutes' perspective.

x. *The* CIHR Ethics Strategic Plan 2009-2014 *and* Logic Model for the Function of the Ethics Portfolio *at CIHR should be updated, approved, and implemented*

Significant effort from the EO and other stakeholders went into developing these documents and to ensuring that they mesh with CIHR's overarching *Health Research Roadmap*. Despite this, they were never formally approved. The VP Ethics should immediately review these key documents and update them as necessary in conjunction with appropriate stakeholders. They should form the basis of the VP Ethics' agenda for the first few years. Governing Council and Science Council should then review them for approval.

c. Interrelationships

i. The Ethics VP and EO should partner with national and international groups on ethical issues of mutual concern

Most if not all of the ethical issues facing CIHR are also issues of national and international concern. Therefore, wherever appropriate, the VP Ethics and EO should enter into partnerships to address these issues on a national and global scale. CIHR can use Canada's prominence in research ethics to once again become a leader in the field.

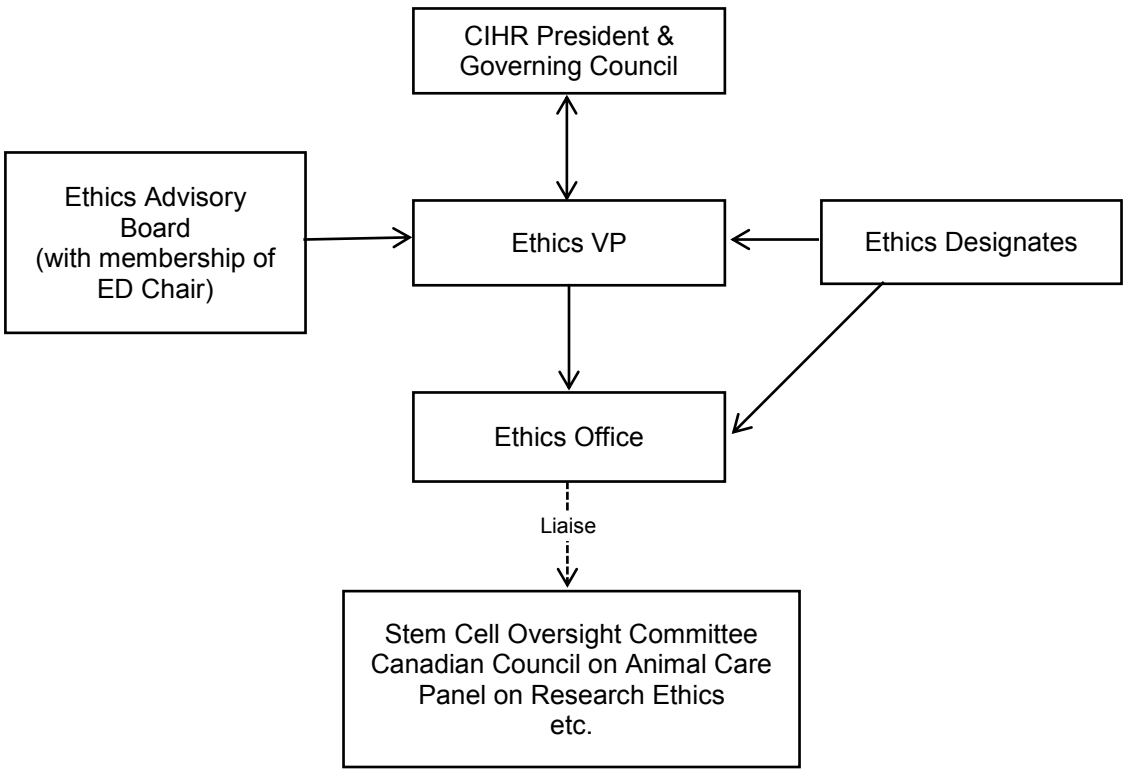
ii. CIHR should dedicate at least 3% of its research budget to research in ethics, distributed by the EO or the Institutes

A hard funding target in terms of percentage of overall budget is required to properly reflect the prominence of CIHR's ethics mandate. In this way, CIHR would be comparable to other health research funding bodies (for example, the National Institutes of Health) that have set a 3% target.

d. Substantive issues

While outside our mandate, submissions we received during consultations identified several substantive issues in ethics (see Appendix D).

Diagram 3: New structures and linkages



Appendix A

Short biographies of Task Force members

Bartha Maria Knoppers (Chair)

Bartha Maria Knoppers, PhD, is Director of the Centre of Genomics and Policy, Faculty of Medicine, Department of Human Genetics, McGill University, Canada Research Chair in Law and Medicine 2001- and the holder of Chaire d'excellence Pierre Fermat (France) (2006-2008), she was named Distinguished Visiting Scientist (Netherlands Genomics Initiative) (2009-2011). Formerly, Professor at the Faculté de droit, Université de Montréal (1985-2009) and Senior Researcher at the Centre de recherche en droit public (C.R.D.P.) (1996-2009). Graduate of McMaster University (B.A.), University of Alberta (M.A.), McGill University (LL.B., B.C.L.), Cambridge University, U.K., (D.L.S.), Sorbonne Paris I) (Phd.) she was admitted to the Bar of Québec in 1985. Professor Knoppers was the former Chair of the International Ethics Committee of the Human Genome Organization (HUGO), (1996-2004), and member of the International Bioethics Committee of the United Nations, Educational, Scientific and Cultural Organization (UNESCO) which drafted the Universal Declaration on the Human Genome and Human Rights (1993-1997). Co-Founder of the International Institute of Research in Ethics and Biomedicine (IIREB) (2000 – 2009), she founded the Population Project in Genomics (P3G) and CARTaGENE in 2003. From 2000-2006 she served on the Board of Genome Canada, became Chair of the Ethics Working Party of the International Stem Cell Forum, Co-Chair of the Sampling/ELSI Committee of the 1000 Genomes Project (2008-) and a member of the Scientific Steering Committee of the International Cancer Genome Consortium (ICGC) (2009-). She is an Officer of the Order of Canada and of Quebec.

Timothy Caulfield

Timothy Caulfield is a Canada Research Chair in Health Law and Policy and a Professor in the Faculty of Law and the School of Public Health at the University of Alberta. He was the Research Director of the Health Law Institute at the University of Alberta from 1993 to 2011 and is now leading the Faculty of Law's Health Law and Science Policy Group (HeaLS). Over the past several years he has been involved in a variety of interdisciplinary research endeavours that have allowed him to publish over 250 articles and book chapters.

He is a Health Senior Scholar with the Alberta Heritage Foundation for Medical Research and the Principal Investigator for a number of large interdisciplinary projects that explore the ethical, legal and health policy issues associated with a range of topics, including stem cell research, genetics, patient safety, the prevention of chronic disease, obesity policy, the commercialization of research, complementary and alternative medicine and access to health care.

Professor Caulfield is and has been involved with a number of national and international policy and research ethics committees, including Canadian Biotechnology Advisory Committee, Genome Canada's Science Advisory Committee, the Ethics and Public Policy Committee for the International Society for Stem Cell Research and the Federal Panel on Research Ethics. He teaches biotechnology in the Faculty of Law and is the editor for the Health Law Journal and Health Law Review. He also writes frequently for the popular press and is the author of The Cure for Everything: Untangling the Twisted Messages about Health, Fitness and Happiness (Penguin Canada, 2011).

Jim Lavery

Jim Lavery is a research scientist in the Centre for Research on Inner City Health and Centre for Global Health Research, St. Michael's Hospital, and an Assistant Professor in the Department of Public Health Sciences at the University of Toronto. Jim received M.Sc. and Ph.D. degrees at the Institute of Medical Science and Centre for Bioethics at the University of Toronto and subsequently received a post-doctoral fellowship in applied ethics and health policy from the Social Sciences and Humanities Research Council and Canadian Health Services Research Foundation, during which he studied priority-setting in home care in Canada at the Queen's University Health Policy Research Unit.

Most recently, Jim spent three years at the Fogarty International Center, and Warren G. Magnuson Clinical Center Department of Clinical Bioethics, both at the National Institutes of Health in Bethesda, Maryland. While at the NIH he worked on ethical and regulatory issues in international research and chaired a working group of the U.S. Department of Health and Human Services that issued a report on equivalent protections in international research. He is a member of the Advisory Board of the CIHR Institute of Infection and Immunity and a member of the Board of Directors of Public Responsibility in Medicine in Research.

Michael McDonald

Michael McDonald is Professor Emeritus of Applied at the University of British Columbia. He was founding Director of the W. Maurice Young Centre for Applied Ethics, which is now part of the Faculty of Medicine's School of Population and Public Health. He was also the first occupant of an endowed chair in ethics in Canada.

McDonald was part of the group that first defined the ethics function in CIHR and served as the first Co-Chair of the Standing Committee on Ethics. McDonald has received numerous research grants from CIHR, SSHRC and other agencies. He played a major role in the creation of the first Tri-Council Policy Statement on the Ethical Conduct of Research Involving Humans and has published extensively on issues in human research ethics and its governance. His current research focuses on human research protection that is evidence-based and participant-centred. The Canadian Bioethics Society awarded him its Lifetime Achievement Award in 2009.

Daryl Pullman

Daryl Pullman is Professor of Medical Ethics in the Faculty of Medicine at Memorial University where he holds cross appointments with the Department of Philosophy and the School of Nursing. He serves as well as a clinical ethics consultant for the Provincial Health Ethics Network for Newfoundland and Labrador. Daryl is a member of the Canadian Institutes of Health Research (CIHR) /Multiple Sclerosis (MS) Society Scientific Expert Working Group on Neurovascular issues and MS. He has served as co-Chair of the CIHR Ethics Advisory Committee for the Canadian Longitudinal Study on Aging, and has been a member of the CIHR Standing Committee on Ethics, as well as the advisory board for the CIHR Institute of Genetics. He was the GE3LS lead for the Atlantic Medical Genetics and Genomics Initiative (AMGGI), a large Genome Canada funded project in Atlantic Canada. His current research includes genetics and privacy, research governance, and the normative role for human dignity as it relates to public policy in bioethics. He has published widely on a variety of issues in research and clinical ethics.

Appendix B

Background Summary

1. INTRODUCTION

This document summarizes key events, structures, documents, and issues vis-à-vis ethics at the Canadian Institutes of Health Research (CIHR) since its inception in 2000. It is based upon the Briefing Book circulated to members of the Task Force prepared by the Ethics Office, and draws upon other publically-available materials from the CIHR website as needed. The intent of this summary is not to provide an in-depth or comprehensive review, but rather to provide an overview of the history of ethics at CIHR to date. It includes the following sections:

A. Introduction
B. CIHR's Ethics Mandate & Organization Structures
C. International Review Panel
D. 2008-2009 Audit
E. 2009 Health Research Roadmap
F. 2009 Draft Ethics Strategic Plan
G. Funding for Ethics Research

Key themes include the sharing of responsibility for CIHR's ethics mandate across many entities both within CIHR and external; recent changes to reporting and accountability structures as well as mandates; re-orienting of ethics at CIHR in key strategic directions; and development of a new structure proposed for CIHR's funding programmes.

2. CIHR'S ETHICS MANDATE & ORGANIZATIONAL STRUCTURES

The ethics mandate at CIHR derives from statute, the *Canadian Institutes of Health Research Act* (S.C. 2000, c. 6). The *Act* includes:

- promoting, assisting and undertaking health research that meets the highest standards of ethics [s. 4(e)];
- fostering the discussion of ethical issues and the application of ethical principles to foster health research [s. 4 (g)]; and
- monitoring, analyzing and evaluating ethical issues pertaining to health or health research [s. 5(d)].

In line with its mandate, CIHR organizes ethics into three core functions (taken from the 2010 *CIHR Draft Ethics Strategic Plan*):

1) creating knowledge in health ethics and fostering its use (ethics research and knowledge translation function);

2) Promoting scientific integrity and ethics among Canadian health researchers and institutions supported by CIHR (research ethics function); and
3) Engaging in ethical reflection on the goals and social implications of health research (ethics of research function).

One mechanism of the first function, ethics research and knowledge translation, is ethics granting programmes which are funded through open programs, targeted programs of the Institutes and Signature Initiatives, and funding opportunities launched by the Ethics Office. Second, the research ethics function targets the development and implementation of principle-based policies and guidelines to foster a culture of ethics that protects research participants and communities. Finally, third, the ethics of research function encourages ethical reflection on how the broader societal context impacts upon research choices.

CIHR fulfills its mandate and functions through a "collaborative" approach of "responsibility shared" with many internal stakeholders. These primarily include the tripartite structure established at CIHR's founding: 1) the Standing Committee on Ethics; 2) the Ethics Office (now part of the Science, Knowledge Translation, and Ethics Branch); 3) the thirteen Institutes and their Institute Advisory Board Ethics Designates – in addition to 4) other CIHR entities related to its ethics mandate.

a) Standing Committee on Ethics (SCE)

The SCE is one of six committees created by the Governing Council. Its mandate includes:

- identify current and emerging ethical issues of strategic relevance with respect to health and health research;
- provide high-level strategic advice on the ethical, legal and socio-cultural dimensions of CIHR's mandate, with regard to:
    - the exercise of ethics leadership
    - the development of ethically sound policies in health research
    - the development of the highest standards of ethics for CIHR and CIHR-funded research
    - the advancement of ethics research and training
    - the linking and bench marking of CIHR's ethics activities to community standards and other national and international organizations, standards and developments, to ensure that CIHR is at the forefront of excellence in these areas.

The SCE acts upon its own initiative or upon request by the President or Governing Council (2009 Internal Audit). It works with the Ethics Office to prioritize identified issues and propose appropriate action and in practice sets the Ethics Office's work agenda.

The SCE reports directly to, and is chaired by a member of, the Governing Council. The President is an ex-officio member. Members are appointed for 3 year terms, and may be appointed for a second term of 1-3 years.

Meeting minutes from 2009-2011 reveal that the SCE provided substantial input into the two drafts leading up to the 2nd edition of the *Tri-Council Policy Statement* (TCPS 2) as well as the *Tri-Agency Framework for Responsible Conduct of Research*. The SCE also provided additional input to policy and other documents developed by the EO (e.g. 2010 CIHR Ethics Strategic Plan) and into other ethics initiatives at CIHR (e.g. the President's request for the SCE to examine ethics review of multi-site research).

b) Ethics Office (EO)

The EO is charged with operationalizing ethics at CIHR. The EO's specific roles include:

- operationalizing strategic directions, activities, and projects identified and prioritized by the SCE and approved by Governing Council;
- supporting the SCE, including by identifying and monitoring emerging ethical issues;
- serving as an ethics hub for CIHR;
- serving as an information conduit for ethics-related research activities;
- collaborating with Institutes and partners with external stakeholders;
- support to Science Council and the Institutes in ethics-related matters; and
- collaboration with the Secretariat for the Responsible Conduct of Research.

The EO's annual reports reveal how some of these roles have been fulfilled. One major area of the EO's work is the development and implementation of ethical policies (e.g. *Best Practices for Health Research on Children and Adolescents* (2012), *Guidelines for Health Research Involving Aboriginal People* (2007), and *Privacy Best Practices* (2005). The EO provides funding support to ethics initiatives (through granting programmes or direct funding), sometimes in conjunction with the Institutes

The EO provides ethics expertise to several CIHR Committees (e.g. Science Council, Stem Cell Oversight Committee, ELSI Committee of the Canadian Longitudinal Study on Aging, Commercialization Advisory Committee [2002-2003]). It collaborates with other external stakeholders (e.g. Health Canada on standards of ethics review for clinical trials as well as the Secretariat on Responsible Conduct of Research regarding the evolution of the TCPS 2). It handles ethics education both within CIHR (e.g. brown bag lunches and discussion series) and external (e.g. commission research ethics training modules), and is involved in other joint educational initiatives with external groups (e.g. organizing annual workshops at the Canadian Society for International Health annual conferences or the Canadian Coalition for Health Research annual training events, chairing a Canadian Bioethics Society conference session with three successfully-funded CIHR researchers on lessons learnt from applying for.

The EO also provides operational support to various CIHR entities. It acts as secretariat to both the Stem Cell Oversight Committee and the Strategy on Patient

Oriented Research External Advisory Committee on streamlining ethics review for multicentre clinical studies. The EO also acts as a liaison between CIHR and the Canadian Council on Animal Care (in conjunction with the SPDA). Until 2011, the EO also provided further operational support to the Research Integrity Committee in investigating allegations of non-compliance with tri-council policies (this function has been transferred to the Secretariat for the Responsible Conduct of Research).

Each senior member of the EO is assigned to liaise with specific Institutes (called "Institute Liaisons") which includes, amongst others, informing and partnering on strategic funding opportunities, informing strategic planning, and collaborating on projects (e.g. an ethics casebook on population health research).

As of 2012, the EO is staffed by three senior ethics policy advisors (one of whom is the EO's Manager), one ethics policy advisor, and one administrative officer for the overall Science, Knowledge Translation and Ethics Branch.

A major re-organization of CIHR structures in 2011-2012 directly affected the EO's positioning within the corporation. The EO Director originally reported directly to the President, then to the Corporate Vice President. The EO, which was a standalone office, has been subsumed under the Research and Knowledge Translation Portfolio. The EO used to have its own Director, who was a member of Science Council. After the re-organization, that role was replaced by the newly-created Director of Science, Knowledge Translation and Ethics Branch (who has a voting seat on Science Council). This means that the director of ethics is also the director of knowledge translation and research capacity development. The EO now has a Manager who reports to this new Director.

c) Institute Advisory Board Ethics Designates (IABED)

The Scientific Director of each institute of CIHR is advised by an Institute Advisory Board (IAB). The terms of reference of the IABs includes the "application of an ethical framework to all Institute activities and research." Thus the Governing Council requires that at least one member – an Ethics Designate – of the IAB must have "particular knowledge and/or expertise in ethics either through education, training or broad pertinent experience." The broad role of the IABEDs is to "help the institutes promote a culture of ethics." The IABEDs' roles and responsibilities include (taken from the EO Internal Orientation Binder):

- serve in an ethics advisory capacity to their Institute with respect to the Institute's research mandate, strategic research programs and activities;
- raise awareness and promote discussion of ethical matters relevant to the Institute's mandate; and
- serve a communication function within their Institute, with the EO, and key stakeholders outside of the Institutes, regarding ethics.

In addition to ethics knowledge, the SCE suggested in 2010 that IABEDs also have (or show a willingness to develop) at least one of the following core competencies (taken from the EO Internal Orientation Binder):

- ability to foster discussions of ethical issues and the application of ethical principles to health research;
- ability to monitor, analyze and evaluate ethical issues relating to health research or health policy;
- ability to address ethical, legal and/or social issues (ELS) related to health, health research, and the delivery of health care;
- demonstrated leadership in the development of public policy from an ELS perspective; or
- demonstrated national and international leadership in mobilizing stakeholders to address important and complex ELS issues affecting fundamental human rights and global public interests.

As recently as 2011, IABEDs would be encouraged to participate in meetings (both teleconference and face-to-face) organized by the EO. In recent years, there was one joint face-to-face session with the SCE annually. In addition, one IABED would be designated as Chair of all IABEDs and join each SCE meeting. SCE members unanimously agreed that IABED meetings and Chair participation in its meetings should continue, however it appears that these practices were stopped in 2011-2012.

d) Other ethics entities

i. Stem Cell Oversight Committee (SCOC)

The SCOC was established in 2003 with the mandate to "provide review of human stem cell research funding applications submitted to CIHR and approved by CIHR's peer review committees" as well as "provide ongoing advice to CIHR's Governing Council about the ethical and scientific issues of human stem cell research." It reports directly to Governing Council.

ii. ELSI Advisory Committee of the Canadian Longitudinal Study on Aging (CLSA)

The CLSA ELSI Committee is mandated to provide independent advice on actions and best practices to address ethical, legal and social issues to the CLSA's Scientific Management Team. In addition, it is charged with contributing to the advancement of ELSI knowledge related to other CIHR-funded, population-based, longitudinal studies, databases, and biobanks. A member of the EO is an ex-officio member.

iii. Strategy on Patient-Oriented Research (SPOR) External Advisory Committee for the Streamlining of Health Research Ethics Review

This Committee has the mandate to assist the SPOR National Steering Committee with streamlining ethics review by examining the barriers to multi-centre review, providing recommendations to streamline and improve ethics review, and looking at ways to share information and enhance communication across REBs.

3. INTERNATIONAL REVIEW PANEL

CIHR is statutorily mandated to undergo an evaluation every five years by an International Review Panel (IRP). Two have been conducted, in 2006 and 2011. The first IRP highlighted ethics as a crucial component to CIHR's mandate and recommended that CIHR increase its emphasis on research ethics and governance responsibilities vis-à-vis ethics. It noted four key challenges for ethics at CIHR: leadership, focus, capacity, and the research ethics board system and governance.

The 2011 review had relatively little discussion of ethics. The SCE's Chair enquired about this, and was assured that this was because the IRP did not find any significant issues regarding ethics at CIHR. However, the internal assessments completed by each Institute for the IRP frequently mentioned ethics in terms of, amongst others, ethics research, need for capacity development, development of guidelines and best practices, and partnerships with the EO.

4. 2008-2009 AUDIT

In 2008-2009, an internal audit of the "Management Control Framework for Research Ethics Activities" was completed. The audit assessed the risk that the management control framework (including governance, planning and organization, management, and accountability reporting) does not support CIHR's ethics mandate. It found "moderate issues" in terms of control weaknesses, however concluded that "overall risk exposure is limited because either the likelihood or the impact of the risk is not high."

Specific strengths found in the audit (which must be interpreted in light of the 2009 organization structure) included the appointment of a full-time, executive level Director of the EO reporting directly to the CIHR President; provision of training and information by the EO to staff and other stakeholders; public nature of CIHR's ethics mandate through its policies; regular communication between the EO and its stakeholders; and monitoring by CIHR of the EO's activities.

Weaknesses identified by the audit as needing correction include the failure of the EO's formal mandate to include the "overall accountability, responsibility, and authority required for the effective coordination of research ethics activities across CIHR" and the lack of a mechanism for monitoring effectiveness of ethics activities across CIHR as a whole. The audit also recommended that the EO develop a strategic plan including measurable goals and objectives using a risk profile to identify strategic priorities and then prioritize issues for mitigating action.

Reforms were made pursuant to the audit. First, the EO's mandate was expanded to include overall accountability, responsibility and authority for ethics as suggested. Second, the EO developed a draft strategic plan (see relevant section below). Third, the EO must now submit an annual report to Governing Council, via the SCE, on the status of all ethics activities across CIHR. To facilitate this, an ethics template (based upon the Strategic Plan's four objectives) is now built into the annual operational planning cycle (planned activities) and annual report (completed activities) that each institute, strategic initiative and CIHR branch is required to complete.

5. 2009 HEALTH RESEARCH ROAD MAP

CIHR's Health Research Road Map (Road Map) or strategic plan for 2009-10 to 2013-14 endorsed the central role of ethics as part of international research excellence, stressing the need for CIHR to promote a "culture of ethics." The vision for ethics is acknowledged in its three-year implementation plan:

> Be nationally respected and internationally acknowledged for its role in the creation and continuous translation of health ethics knowledge to advance the highest standards of ethics and integrity in health research, policy and practice.

To meet this objective, the implementation plan of the Road Map proposed three actions:

1) develop and implement a health research ethics strategy;
2) enhance funding mechanisms to support the creation and foster the use of knowledge in health ethics;
3) develop and implement policies and guidelines to promote the ethical conduct of Canadian health researchers and institutions supported by CIHR.

Two indicators were selected to measure progress. First, the number of CIHR-funded research and trainees involved in ethics research. Data to date indicates an increased from 388 in 2009-10 to 486 in 2011-12. Second, CIHR expenditures in ethics research. This has remained relatively stable around $11.1-11.3 M for the past three years.

The Road Map also mentioned ethics in three distinct areas. First, the Road Map emphasized increasing training amongst the researcher community (especially new researchers) on ethical, legal, and social issues of research as part of overall capacity development to carry out world-class research. Second, the ethically sound application of new knowledge gained through research (knowledge translation) was stressed in the context of partnerships with industry for commercialization. Specifically, the Road Map mentioned the need for balanced ethics guidelines that will promote successful partnerships with industry. Third, the need for a less complicated research ethics review system was highlighted.

6. 2010 DRAFT ETHICS STRATEGIC PLAN

In 2009-2010, The EO developed a draft strategic plan for 2009-2014 to align its activities with CIHR's Road Map. It was based upon four strategic directions developed by the SCE with input from the IAEBDs and Scientific Council (through a survey of the ethical priorities of the Scientific Directors) based upon the 2006 IRP recommendations:

1) capacity building as a cross-cutting priority;
2) governance of health research;
3) development of ethics-based protection for health and health care research involving diverse communities and populations; and
4) the implications of globalization for Canadian health care research.

Each strategic direction listed several specific objectives. The draft strategic plan was never formally approved. However, the EO developed a draft implementation plan for it in 2011 to guide its activities over the next few years.

7. FUNDING FOR ETHICS RESEARCH

Funding for ethics at CIHR comes from two main sources. First, the EO has a funding envelope with which it can allocate grants and awards according to its own criteria. As of 2010-2011, this envelope was $2.3 M. Second, funding can come from the Institutes through the normal open or strategic granting competitions. Sometimes, the EO and Institutes partner in their funding efforts.

Proposals are reviewed by independent review committees (for example, the Humanities, Social Sciences, Law & Ethics in Health Peer Review Committee reviews operating grants and catalysts grants). Funded activities have included: operating grants; priority announcements; fellowship and doctoral awards; catalyst grants; meetings, planning, and dissemination grants; workshop grants; and research network grants.

Traditionally, funding for health ethics research was also available from the Social Sciences and Research Council of Canada. However, since 2009 all health-related funding (including ethics) from the tri-agencies must be funnelled through CIHR.

In 2011, the EO produced a detailed summary of the past and proposed future of funding for ethics research: *Towards a Funding Plan for Health Ethics Research and Capacity Building: A Primer*. The objective under this plan is to inform the development of "a sustainable funding structure that fosters the discussion of ethical issues and the application of ethical principles to health research."

In 2012, CIHR proposed major changes to the structure of its funding programmes and peer review system in response to the 2011 IRP report that criticized the complexity and onerousness of the current structures. Two new funding schemes are intended: 1) a foundation/programmatic research scheme used for longer-term support of people and teams; and 2) a shorter-term project scheme for supporting ideas and projects with a specific scope and defined timelines. Applications will be submitted for a multi-phased competition process designed to identify strong applications/weed out weak applications from the beginning, all of which is intended to reduce burdens on peer reviewers. Additionally a College of Reviewers will be established to ensure appropriate expertise is recruited to review applications. It is not known what impact these changes will have upon ethics research grants.

Appendix C

Themes Emerging from Submissions: What we Heard

1. *Need for strong leadership, a clear mandate/role, and place for ethics at CIHR*

An overwhelming number of submissions note the lack of leadership and pointed to a general sense that ethics is drifting at CIHR. It has been further weakened with recent structural changes at CIHR and the lack of a stable Director at the Ethics Office (EO).

a. *Leadership*: CIHR should take on a leadership role in ethics both within CIHR and nationally/internationally. Ethics must be a separate, strong, and independent branch/area of activity at CIHR. Part of this includes vesting the three ethics "prongs" (EO/SCE/IABED) with decision-making power to effect change. The face of ethics leadership at CIHR should be a strong EO Director.

b. *Clear mandate*: What ethics at CIHR does must be clear as well as the mandated the three main ethics "prongs". Suggestions include: proactive identification of emerging issues nationally and on a global scale, public advocacy, and promoting enlightened ethical practice. Ethics should not just be used to support decisions/actions already taken by CIHR leadership. Ethics needs a coherent governance structure or over-arching framework set by Governing Council.

c. *Place within organization*: Ethics must have a central place with access to the highest levels at CIHR. Previously the EO and its Director reported directly to the Director of CIHR and then to the Corporate VP. After 2011-2012, the EO now reports to the Director of the Science, Knowledge Translation, and Ethics Branch. Many suggest that the old reporting structures should be re-instated. Also more visibility is needed for the EO and its Director, as well as increased transparency in decision-making concerning ethics. Finally, a culture of ethics must be encouraged that goes beyond any one office or role within CIHR.

2. *Need for integration of ethics initiatives both within CIHR and outside*

Many commented that ethics, and the EO in particular, is not well integrated with the work of the Institutes or the PRE/SRCR. Any changes to governing structure must be done with the view to enhancing collaboration, communication, and interactive working arrangements. The structure of ethics should promote communication between both the higher levels and the working levels. There needs to be clear path for policy development within CIHR.

a. *Internal integration*: Greater integration is required with both the Institutes and with CIHR management. Better integration with management can be

accomplished by having the EO/SCE report to the highest level of decision-making at CIHR. At the Institutes, some thought that having a dedicated EO liaison was a good idea, but has the result in practice has been mixed. One radical suggestion (supported by the SCE) to better integrate ethics with the Institutes is that the IAEBDs should become the SCE members, who by default are plugged into the Institutes' work. Regular meetings and contact between the EO, SCE, and IAEBDs should be encouraged. Ethics activities must be integrated with CIHR's roadmap. Institutes could be also required to include an ethics component in their strategic planning. The Institutes' ethics representatives should have a seat during CIHR strategic planning (e.g. signature initiatives). Ethics in the Institutes should also be integrated with CIHR's knowledge translation activities.

b. *External integration*: Ethics at CIHR is not well integrated with other ethics bodies (e.g. the Panel on Research Ethics, Health Canada) resulting in duplication and a "silo" mentality. Proper communication mechanisms must be established. Suggestions include making partnerships with external bodies on initiatives of national concern (e.g. multi-centre review), operational norms, creating a "Health Portfolio Committee" charged with ensuring collaborations, more international outreach and visibility, and having the PRE set policy directions for the EO to work on.

3. Role of Institute Advisory Board Ethics Designates (IABEDs)

While their mandate on paper may be clear, many IAEBDs struggle with what they are supposed to do in practice. The practice of regular meetings of IAEBDs as well as having a representative at SCE meetings should be reinstated (it was abolished in 2011). At least one IABEDD, however, thought these meetings were a waste of time. Others wanted IABEDs to be more formalized within Institutes and have clear terms of reference. At least one Institute has an Ethics Subcommittee headed by their IABED.

The appointment process of IABEDs should be formalized and transparent. The qualifications required to be an IABED should be clear, and a strong background in ethics should be required. All IABEDs should undergo a tutorial meeting with the EO to clarify their roles/responsibilities and establish lines of communication. Suggested roles for IABEDs included:

- ensure integration of ethics into Institute activities;
- share success/opportunities/challenges to work in integrated manner;
- act as a resource person for ethics inquires, contact person to wider community, and key advisor of ethics-related matters;
- public outreach to the wider researcher community under the Institute.

4. Clarify proper role of Ethics Office

At present, there is confusion over the EO's role both within CIHR and towards external organizations. This inhibits the ability of the EO to take a leadership role for ethics at CIHR. Some argue that it should only implement decisions taken by GC or follow direction from the PRE, while others that it should be proactive and identify emerging issues. Other suggested roles include:

- support update of ethics knowledge or KT for ethical policies like the TCPS2, for example through developing supplementary guidelines and resources, training programmes (for researchers and research coordinators), and other means of dissemination;
- compile and disseminate past work;
- coordinate all ethics activities across CIHR;
- administer ethics granting programmes through its own budget, and the discretion to partner with other organizations in doing so;
- undertake scholarly work in ethics;
- be a vehicle for national collaboration across various agencies;
- consistently bring forward an ethics-lens to CIHR initiatives;
- promote a comprehensive substantive ethics agenda for researchers and policy makers across the country.

The EO should have the authority, capacity, and freedom to carry out its mandate. Its involvement with the Institutes and collaborations with external bodies should (like the SRCR) be enhanced. Some criticize the unclear division of labour between the EO and PRE/SRCR. In all cases, the EO must continue to have people with significant expertise in ethics who can integrate well with the health research community.

5. Director of the Ethics Office

The need for a stable and strong Director for the EO with proper qualifications was repeatedly mentioned. The role should not be purely managerial. The Director should have substantial freedom and autonomy to raise issues to highest level of CIHR executive, and be vested with sufficient decision-making authority to carry out their job effectively. He/she must be able to provide a vision for ethics, scholarly leadership, and promote ethics within CIHR and outside. Suggested qualifications include:

- in-depth understanding of ethics with national/international stature;
- strong scholarly record in research ethics; and
- strong administration skills.

CIHR must make a concerted effort to find suitable a suitable candidate by forming a search committee, similar to university recruitment.

6. Role of the Standing Committee on Ethics (SCE)

The SCE was universally recognized for the calibre of its members, however many felt that it has been underutilized and that its function is not clear. It must have

links both to Governing Council and Science Council. Suggested roles include:

- provide strategic guidance on CIHR strategies;
- coordinate CIHR's national and international ethics research agenda; and
- alternatively, be an advisory body to the ethics leadership at CIHR.

7. Sustainable and independent funding dedicated to grants for ethics research

Many called for dedicated funding for ethics research administered independently of the Institutes (e.g. through the EO or special programme). Ethics must be also be seen as an area of substantive health research creating an evidence base to guide ethics activities. There should be a mix of funding initiatives, both targeted and open calls as well as funding for networks/collaborations. The funding programmes should be sensitive to the needs of ethics researchers, many of whom do normative and not empirical work. Funding should also ensure that all disciplines related to ethics and health research are covered (e.g. humanities, social sciences, and human rights) – especially now that all health-related grants have been transferred from SSHRC. Funding must be provided for graduate students, fellowships, and research chairs. Some suggested that a fixed percentage of CIHR's or the Institutes' granting monies should always be dedicated to ethics. The EO could also provide in-kind support to ethics initiatives in partnerships with other entities and researchers. Peer review committees for ethics-related projects must have the proper expertise.

Appendix D

Substantive issues identified during consultations

The Task Force did not have the mandate to examine substantive issues in ethics facing CIHR or the wider research community. However, the submissions received during our consultations identified some key issues which are not addressed by CIHR. While outside our mandate, we believe they are important to bring to CIHR's attention:

1. Harmonization of ethics review for multi-site research
2. Data sharing
3. Commercialization
4. Peer review of ethics-related research projects