DISCUSSION PAPER

A Strategy for Moving Forward Alberta's Health Research Ethics Boards

Final Report

March, 2010

Prepared by

The Council of Chairs of
The Health Research
Ethics Boards of Alberta

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1.0 Introduction

In July of 2009, the Council of Chairs of the Health Research Ethics Boards (REBs) of Alberta agreed to increase the "alignment" among the six health REBs in the province. They led this initiative based on their collective expertise and current roles across Alberta's health research ethics review processes. As a step in the alignment objective, the Chairs agreed to examine the potential for the use of a common electronic administrative support tool. The Chairs also agreed to the need to establish a strategic direction for health research ethics review in the province. Alberta Innovates – Health Solutions (funded by the Alberta Heritage Foundation for Medical Research Endowment Fund) was approached to provide secretariat services and to facilitate the project. The resulting work is reported in this document – a strategic plan for moving forward with alignment of health research ethics review in Alberta.

2.0 Alberta's Health Research Ethics Boards

The members of the Council of Chairs of the Health Research Ethics Boards (REBs) of Alberta are listed below together with key contributors during the planning process.

2.1 Council of Chairs

Kirk Barber (Chair of the Council of Chairs) - Chair, Research Ethics Committee
College of Physicians and Surgeons of Alberta (CPSA)

Scott North - Chair (until November 2009), Alberta Cancer Research Ethics Committee (ACREC), Alberta Health Services

Maeve O'Beirne - Chair, Community Research Ethics Board of Alberta (CREBA)
Alberta Innovates – Health Solutions

Shane Kimber - Chair, Panel A - Biomedical Research Ethics Board (HREB)
University of Alberta

Glenn Griener - Chair, Panel B - Health Research Ethics Board (HREB)
University of Alberta

Glenys Godlovitch - Chair, Conjoint Health Research Ethics Board (CHREB)
University of Calgary

2.2 Other Contributors during the Planning Process

Jacques Magnan, President & CEO, Alberta Innovates – Health Solutions

Bill McBlain, Acting Co-Lead, Senior VP, Research, Alberta Health Services

Bob Sheldon, Acting Co-Lead, Senior VP, Research, Alberta Health Services

Linda Barrett-Smith, Manager, Research Ethics Initiatives, Alberta Innovates – Health Solutions

Gabe Shelley, Consultant, SVS - Strategic Value Services Inc.

3.0 Executive Summary

The Chairs of Alberta's Health Research Ethics Boards (REBs) recognize that increased cooperation is desirable among the six boards. The Chairs undertook this planning effort to create a reasoned approach to change.

The overarching and defining principle that must be primary in any change is the independence of Alberta's health-related REBs to perform ethics reviews to ensure the protection of participants in health research.

Stakeholders interviewed for this work during the fall of 2009 stated that the outcome should be an Alberta ethics system for health research that offers the best approach possible to making Alberta an attractive jurisdiction for research investment. This could be characterized by:

- A system that is efficient (timely response to submissions) and applicant friendly
- With full reciprocity among the boards
- Where the independence of the boards is respected so that they can continue to protect the interests of the public while supporting health research.

Based on these inputs, the Chairs conclude that a process of ethics review must be developed with a robust view of the future that provides for rapid movement towards an integrated model for Alberta.

A spectrum of options was discussed from simply having common forms, through a common administrative platform, to full reciprocity across the institutions, to a dedicated REB dealing only with multi-centred applications, and finally, to having a single province-wide REB with local panels as required.

The last of these, the single province-wide REB, while conceptually pleasing, was seen to require major change over many years. A shorter–term view was developed with the following characteristics:

- A common consent form developed by the end of the first quarter of 2010, and a common application form by the end of the second quarter of 2010.

- Transition of all health REBs to a common administrative platform (for example, a version of the Click Commerce HERO product now implemented at the University of Alberta) by the end of calendar 2010.

- Mutual reciprocity and a process for dealing with multi-centred health research ethics review by the end of the second quarter of 2010.

- A new REB with the mandate of dealing with health information research applications; regulatory approval by the third quarter of 2010, with implementation in 2011.

During January – February 2010, this strategic plan was presented to stakeholders (including the sponsoring institutions of the health REBs). This, the final version, reflects key stakeholder concerns. This document is intended to communicate the intent of the Chairs to bring about change and to seek financial support for making it happen.

4.0 Environmental Scan in Alberta and Canada

4.1 Views Expressed by Stakeholders in Alberta

Key stakeholders of the Alberta health research ethics process were interviewed in the fall of 2009 during initial planning. The purpose was to gain an understanding of their perspectives with respect to the future of health research in Alberta and how research ethics would need to accommodate these changes. A full list of the people interviewed and the organizations they represent is provided in Appendix A.

There is general agreement that the outcome should be an Alberta ethics system that offers the best approach possible to making Alberta competitive. It might be best to summarize the views of the two Deputy Ministers (of Health & Wellness and Advanced Education & Technology) and then discuss how views of others agree or not with those.

The Deputy Ministers translated this competitive objective as:

- A system that is applicant friendly
- With full reciprocity among the boards
- Where the independence of the boards is respected so that they can continue to protect the interests of the public while supporting health research.

The Deputy Ministers feel strongly that change needs to happen quickly, and suggest that the Council of Chairs should design an implementation plan in which change is achieved in the space of months, not years. This will undoubtedly require high-level discussions and a willingness to move from current models.

They proposed that a "straw dog" be developed, and that the model of an integrated ethics review system then be discussed with other participants to identify where further issues might lie. These would include the University of Calgary (because that entity is assessing an approach for a cross-campus ethics review process), and perhaps the College of Physicians and Surgeons of Alberta.

They Deputy Ministers also proposed that a linkage be developed to the Council on Academic Medicine (CAM). Among its strategies is one to resolve the ethics review situation in Alberta. This is discussed later in this section.

The University of Alberta (U of A) is clearly on this agenda as well. Previous work has resulted in a reduction of the number of university-based REBs from 18 to 4. Key to making this change was:

- providing comparative data on the number of REBs at other universities in Canada (typically 3 or fewer)
- proposing a timely evaluation process (facilitated by the HERO system)
- including an efficient appeals process, and
- making investments in administrative support.

As well, under the previous health authority model, the U of A had reached an agreement with the Alberta Cancer Board (ACB) for reciprocity. This seems to have worked well, and provides evidence that reciprocity can be made to work. The intent is to broaden this agreement with the Alberta Health Services (AHS).

The situation is similar at the University of Calgary (U of C). Reciprocity had been negotiated with the ACB. U of C leaders are agreed that reciprocity is desirable, and, in fact, necessary, in the emerging world of research. Discussions have been ongoing between the Faculties of Medicine (& Dentistry at the U of A) for greater levels of collaboration. Ethics reciprocity would be an element of that. The U of C sees standardized processes as a key element in reaching reciprocity. A first step would be to implement mutually expedited reviews, while continuing discussions on a fully reciprocal process.

AHS is moving ahead with its research strategy. It contemplates a more focused research agenda, recognizing that this is a small province and we can be excellent in areas where we already have a competitive advantage. The best example of this is the fact that all 3.5 million Albertans are under one health care delivery entity and there is an opportunity to assemble research-relevant data. AHS representatives feel that with streamlined processes, Alberta can attract a higher level of research investment. Their greatest interest is in pillars 3 and 4 (health systems and services and population and public health) of the CIHR model, where they intend to be leaders. Campus Alberta is cited as a model for the

level of cooperation among stakeholders that is required to streamline processes across the province. This applies not only to research ethics review, but also to implementing common standards across the province, to removing legal obstacles and to creating a common framework for intellectual property. AHS is moving to reduce the number of business processes in all that it does.

Finally, there is anecdotal, and in some cases more direct, evidence that the ethics process as currently structured and operating is costing the province research investment. This takes two forms:

- Pharmaceutical firms located elsewhere have decided that Alberta is too complex a jurisdiction in which to do business and routinely "overfly" the province. This is likely a multi-faceted decision, resulting from a combination of factors, potentially including ethics review.

- The sometimes long turn-around times produce frustration on the part of researchers and donors; specific cases were cited in which donors have withdrawn, and researchers have abandoned applications because of months of delay, and requests for additional information that were seen to be onerous.

Finally, people interviewed see that any change will require a number of actions:

- Review of Tri-Council requirements to ensure that any new model meets these requirements as well as the realities of research in the 21st century, and the competitive nature of research investment. It appears that the TCPS draft 2nd edition provides for reciprocity and the possibility of new models of ethics review.

- Re-engineering the process of ethics review. Further investment in human resources alone is not seen to be the answer, although there is recognition that more administrative help is required to provide timely results. A new way must be found to do this work, effectively and efficiently. A common administrative platform (such as HERO) is a basis upon which new processes can be based.

- As a minimum, have mutually expedited ethics reviews, followed by reciprocity across the province; beyond that, some see the potential for more integration (one board for Alberta).

Driving Forces

There are two principal forces pushing for change in ethics review in Alberta:

1. Research Framework – AET has introduced (and the Legislature passed) legislation to create a research and innovation framework and supporting entities in Alberta. The intent is to focus research investment in the province. Quoting directly from AET's website,

> *Stakeholders collectively recognized that Alberta has a great opportunity to increase the effectiveness of its research and innovation system.*
>
> *The Alberta government is meeting the need for a more aligned system that would ensure the focused growth of Alberta's whole research and innovation system.*
>
> *This new framework will improve Alberta's research and innovation system by making it:*
>
> - *less complex*
> - *more focused on our strategic priorities*
> - *more consolidated*
> - *with less overlap and stronger links between the players.*

2. Alberta Health Services has been given the mandate to take a leadership position in clinically based research in the health system. Quoting from their ***Strategic Directions for Research*** chart:

   - ***Where We Are*** *– Most of the former health regions lacked a formal or tangible commitment to research, had fragmented research efforts, and were without a strategic research vision and purpose. While pockets of long-standing health research excellence exist in Alberta, the research culture is inconsistently fostered across the health system, resulting in lost opportunities to generate and/or use research findings to improve health services and health care delivery….*

- ***What We Are Trying to Achieve*** *– Transformation (centres of excellence with focused health research agendas that address key priorities to improve access, quality and sustainability for all Albertans); Application (a coordinated research program that increases clinical, translational, health services and public health research outputs applied provincially and globally to improve health service delivery and health outcomes; the program will attract and retain world-class clinician scientists in all health professionals); Infrastructure and Processes (a single provincial environment that facilitates and fosters health research).*

- ***We Will --*** *... Streamline and accelerate reviews of research protocols for ethical, scientific, privacy and resource impacts. Implement a single standardized risk assessment, and develop common legal processes and contractual templates….*

In addition, the Palmer/Tyrrell Report provides the following:

> *Dr. Bob Sheldon and Dr. Bill McBlain have attempted to identify key issues affecting the clinical trials and have identified five main issues for follow up:*
>
> *1 Ethics and science review*
>
> *2. Resource impact assessment*
>
> *3. Contract and legal services*
>
> *4. Indirect cost recovery and distribution*
>
> *5. Employment of research coordinators.*
>
> *The following is a summary of some of their comments.*
>
> *1. Ethics and Science Review*
>
> *Protection for the public is provided by a respected and reliable ethics and science review process for all clinical trials. The guiding principles of the ethical reviews are: respect for human dignity, respect for free and informed consent, respect for vulnerable persons, respect for privacy and confidentiality, respect for justice and inclusiveness, and minimizing harm and maximizing benefit (as required by the Tri-Council Policy Statement [TCPS]). The Research Ethics*

> *Boards (REBs) have massive tasks to review all of the research that is undertaken in their institutions; hence, repeated reviews of essentially the same protocol at multiple sites are inefficient. While individual REBs strive to provide excellent reviews, from a Provincial point of view, the review process may be seen as fragmented, redundant, and frequently slow. This frustrates investigators and sponsoring companies and undoubtedly affects our ability to attract our share of clinical trials to Alberta. The frequency of the REB meetings or the number of REBs may not be sufficient for the workload. A review and harmonization of ethics review processes within the Province will assist in the identification of opportunities where efficiencies can be gained (the use of an electronic database and on-line processes may be one component). Alberta is also participating in a national initiative to establish national standards for ethics review and needs to be well positioned for the implementation of new requirements.*
>
> *Recommendation 6: That AHS and its partners establish a working group to improve ethics reviews and contracting processes for clinical trials….*

As mentioned earlier, the recently formed Council on Academic Medicine (CAM) has research ethics review on its agenda. This committee consists of the Deputy Ministers of AHW and AET, as well as the CEO and other executives of AHS, the Provosts of the two large universities, the two Deans of Medicine, the CEO of AHFMR and the Registrar of CPSA. CAM has been working on a business plan for priority areas in academic medicine. One of the priority strategies is number 6 – Develop a Reciprocal Provincial Ethics Process. The intent is to streamline the ethics review process and thereby enhance the competitive position of this province in attracting research projects and funding. The members are agreed that they will work together to make this happen.

Conclusions on the Alberta Perspective

The Government of Alberta is moving ahead implementing the research and innovation framework, and creating new implementation entities, putting in place new governance boards, and hiring executives to manage the new processes. At the same time, AHS has created a strategic framework for its own involvement and leadership in elements of health research in this province.

These two leadership entities will drive much of the change agenda. The ethics review process is seen as a barrier rather than an enabler. Undoubtedly, there will be pressure to

streamline the overall process, and to make other changes, to make Alberta a more attractive jurisdiction for research investment.

4.2 Happenings Elsewhere

Similar work is occurring elsewhere in this country. A presentation on Canadian initiatives was made by Dr. Richard Neuman to the Council of Chairs in November, 2009, and a summary is provided here.

The Atlantic Provinces are working together to provide reciprocal review for multi-centred trials research across their jurisdictions. The goal is to adopt uniform application and consent forms, and to share educational resources, REB policies and procedures. The initiative suffers currently from a lack of efficient governance structure to control the overall processes.

Newfoundland has made progress with intra-provincial alignment. It has moved away from institutional review in favour of a Health Research Ethics Authority (HREA). The HREA is a not-for-profit corporation, at arm's length from government, university and regional health authority. It reports to an independent board of directors, who in turn report to the provincial Minister of Health and Community Services. The entire structure comprises the HREA, an Appeal Panel, a Monitoring entity and local Research Ethics Bodies.

The mandate of the HREA is to ensure high quality, uniform and timely ethics review, to govern ethics review of all human health research in Newfoundland and Labrador, and to provide education and public awareness of research ethics. The benefits of this structure are public accountability and transparency, reduced conflict of interest inherent in REB review processes, a centralized authority that provides efficient use of scarce resources, and a consistent review process for all high risk interventional studies.

The legislation to create the structure has been passed and is awaiting proclamation. Issues expected to be faced include no core funding (implementation was expected to be cost-neutral, but is unlikely to be so), no overall project manager to lead the work, and sponsor concerns about loss of autonomy.

Ontario has implemented the Ontario Cancer Research Ethics Board (OCREB), which is expected to provide high quality voluntary central REB review for multi-centre oncology trials. It has reduced workload across the province.

Saskatchewan is also working on REB alignment through the Saskatchewan Academic Health Science Network, comprising health regions and university management, REB chairs and administrators. They have issued a joint request for proposal for a web-based system, and have been working on this for about two years. Currently, their two behavioural REBS and three biomedical REBs are working on common consent and application forms.

And finally, British Columbia has initiated an Ethics Harmonization Project. Phase one involves a project to conduct an information sharing feasibility study, with the objective of creating a coordinated ethics system across the 23 BC institutions that conduct research and/or clinical trials that involve human subjects. The vision calls for reciprocity, a web-based coordinated system and a coordinated educational program to ensure researchers understand their obligations for ethics certification in compliance with Tri-Council, Provincial, Federal and international policies. Their goal is to implement a collaborative governance mechanism and thereby to collaborate on multi-site research projects, and to implement multi-site clinical trials with attendant societal and economic benefits.

In summary, interest in harmonization is widespread in Canada. Facilitation of clinical trial research and reducing workload are often cited as driving forces. The current process of review of most multi-centre research is recognized as problematic, involving redundant reviews and delays in research engagement. It is seen that increased harmonization should facilitate REB review and benefit the research community.

4.3 Summary

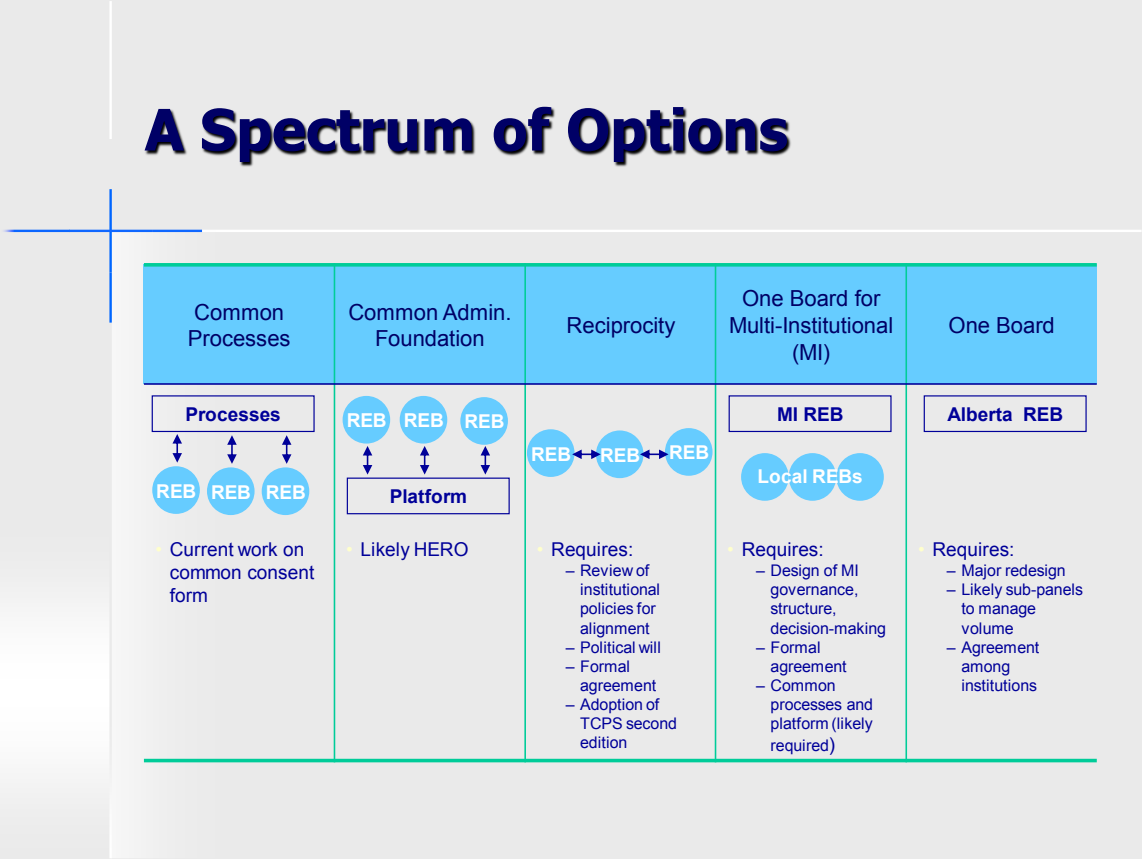
Based on these inputs, the Chairs conclude that a process of ethics review must be developed with a robust view of the future that provides for rapid movement towards an integrated model for Alberta.

5.0 Options Considered and Selected

5.1 Options Considered

Exhibit 5-1 shows a spectrum of options considered. From left to right, it displays movement towards ever more integrated models.

Exhibit 5-1:



Each is discussed in turn:

- Common processes – the Chairs could adopt common forms. They have been working on such, including a common consent form and a common application form. These would serve to simplify the process for researchers and pharmaceutical firms applying for approval in Alberta. Rather than dealing with a

variety of forms, they could learn one and thereby simplify the process overall. A common consent form is nearly agreed by the Chairs, and is expected to be in place in 2010.

- Common administrative platform – the business case for a common administrative platform (based on HERO), completed in September 2009, was an indication of the Chairs' interest in moving to such a common platform. The business case showed that there is a basis for this decision. Issues that must be dealt with include finding the initial and ongoing funding for the system, dealing with individual institutional perspectives on integration, and a number of operational differences between the REBs. The business case report found that these could all be addressed in short order.

- Reciprocity – the REBs could agree, together with their sponsoring entities, to recognize the decisions of other REBs. In other words, if a multi-centre trial were approved by one REB, it would be accepted by each of the other REBs. There are a variety of models that could be adopted here, ranging from expedited reviews to full reciprocity. As the reciprocity increases, the issues of implementation increase.

- Creating a single REB for multi-institutional research – a viable model would retain the current set of REBs, but superimpose one REB to deal with trials or other research that involves more than one institution. In this way, research sponsors and researchers would have to deal only with one REB. This would expedite the process, reduce the amount of re-work and create the view for sponsors that Alberta can deal effectively with multi-centred research.

- Create a single province-wide REB – the most radical solution calls for the elimination of all current REBs and the putting in place of a single province-wide REB. Local panels could be retained to deal with purely local research, but these panels would report to the provincial REB. This would allow for common policies, processes and systems.

The desired objectives for health research ethics review as stated in the previous chapter are:

- A single portal
- An integrated system
- With full reciprocity
- Timely and efficient results
- While retaining adherence to institutional policies

We show in Exhibit 5-2 a chart with the match of each option against these objectives.

Exhibit 5-2:

How the Options Line Up

Objectives	Common Processes	Common Admin. Platform	Reciprocity	One Board for Multi-Institutional (MI)	One Board
Single Portal	X	X	√	√	√
Integrated System	X	Somewhat	Somewhat	More	√
Full Reciprocity	X	Makes it easier	√	Assumed	√
Timely and Efficient	?	Helps	Helps	Helps	May reduce
Retain adherence to institutional policies	√	√	May jeopardize	For all but MI applications (assumes institutions are represented on MI board)	Unlikely

5.2 The Long-Term View

In reviewing this chart, the Chairs concluded that no option left of the central one would meet the objectives. Their discussion produced the conclusion that they should advance the case for one provincial board for all of Alberta in the longer term, with local panels, as required, reporting to it and handling local volumes. Feedback from three of Alberta's universities suggests that, while desirable, there is considerable complexity in achieving this final objective. Other stakeholders suggest that expeditious movement to the single REB is the desired future. (A full list of stakeholders consulted on the draft plan is provided in Appendix B.)

The Chairs recognize that moving to this model will require a significant change from today. In fact, each of the optional models shown in Exhibit 5-1 will need to be implemented as preconditions to making this rightmost model work. As a result, the Chairs selected an interim solution that is discussed in the next section.

5.3 The Shorter-Term View

Although conceptually pleasing, the long-term view may take years to implement. There are steps along the way that can produce necessary improvement over the current situation, and that can be implemented without undue difficulty. As a result, a shorter-term view was developed.

This view proposes that the fundamental problems extant are these:

- Difficulty dealing effectively and efficiently with multi-centred clinical trials and other health research that involves multiple jurisdictions within the province.

- The emergence of new types of applications having to do with use of health information. Increasingly, research at an epidemiological level is possible due to the greater technological capability and the amassing of huge data sets. But legislative privacy requirements make the use of these data sets complex. Established REBs typically do not have the high level expertise to deal completely with these applications. As more insight is possible through the creative use of these data sets, we expect that there will be more and greater complexity of such applications.

To deal with these issues, the REBs propose to:

- Employ a common consent form

- Operate under a common administrative platform (with a common application form)

- Establish mutual reciprocity across institutions (in which reciprocity is generally defined as: If one REB reviews an application, that review will satisfy other REBs)

- Put in place educational processes to ensure that all REB members have an understanding of the provincial processes, leading to coherence among the REBs in process and outcome.

- Dedicate an entity to the expertise required to deal effectively with health information applications (these are applications that fall within the legislative definition of health information, but exclude clinical trials).

All of the above can be dealt with in a minimal amount of time, with a relatively small amount of financial assistance. The Chairs have agreed as follows:

- To develop a common consent form by the end of the first quarter of 2010 to be finalized after consultation with key stakeholders, including members of the public, in the second quarter of 2010. The Chairs have been working on this topic, and conclusion can be drawn in this timeline.

- To begin transition to a common administrative platform and to have this completed for all health REBs by the end of calendar 2010. This will require agreement on a common application form by the end of the second quarter of 2010. A previous feasibility study on this matter found that some operational changes are required to meet the needs of the REBs, but the HERO system can accommodate most of these. The expectation is that the current U of C study across-campus will reach conclusion shortly and that, regardless of the route chosen, there will be a viable linkage between that campus and the other institutions in Alberta. There will be a one-time implementation cost of $650,000 to $1,100,000 if the transition is to a modified HERO product. This includes hardware, software and licensing costs, as well as training costs and expenses. There will also be an annual cost of maintaining the system, upgrading as required, and providing ongoing support. This has been estimated at $300,000 to $500,000 per year.

- To encourage their sponsoring institutions and organizations to develop mutual reciprocity for research ethics approval, and to have this done by the end of the second quarter of 2010. The Chairs wish to have their position represented in these discussions and will retain counsel to prepare a draft agreement for discussion with their sponsoring institutions. Legal counsel representing each of the sponsoring organizations will have to meet, discuss the objectives and obstacles, review the Tri-Council Policy Statement (copy of relevant section of version 2 of the TCPS document is provided in Appendix C) and institutional policy statements, and establish a reciprocity agreement.

- To work together to develop education that ensures REB members have an understanding of the provincial processes of all REBs, and that supports ongoing development of an aligned health research ethics process in Alberta.

- To develop a protocol for dealing with multi-centred health research by the end of the second quarter of 2010. In the first instance, this will require reciprocity (as above), and agreement that the review will be done wherever the principal investigator is located. A more robust model may be developed later if required, using a single point of entry "portal".

- To subscribe to the newly developed national standards for clinical trial research.

- To put in place a new REB with the mandate of dealing with health information applications. As the availability of administrative and other data increase, there will be more of these applications. These proposals raise issues of compliance with Health Information legislation, privacy, and IT security. All of these are specialized areas, requiring reviewers with a strong knowledge of the field and an ability to judge the risks attendant with the application. We conclude that an REB, with skilled people from the public, as well as academic institutions, current REBs, and from AHW and AHS, would provide the overview required. This recommendation would require regulatory change, which could be adopted by the end of the third quarter of 2010, with subsequent implementation of the REB in 2011.

Stakeholders largely support this set of actions. There is caution that access to ethics approval must be safeguarded for community physicians and other community-based health professionals who undertake research. There is also some caution expressed about accepting HERO as the administrative platform, with some suggesting that a

review of its attributes should be undertaken. There is also some question of the need for a separate REB dealing with health information. Finally, there is a question of whether there has been enough budget proposed for implementation.

These are all issues to be examined in the next stage of progress in this work.

6.0 Implementation Steps

The Chairs developed this view of the future and set of implementation strategies as a statement of their intent to meet the needs expressed by Alberta's leaders to operate in a more integrated way. We believe that the changes presented in the shorter-term view can be implemented in a straight-forward manner and timeline, and that they will produce a significantly higher degree of coordination throughout the province, and therefore position it as a competitive jurisdiction in the emerging health research world.

We see the next steps as follows:

- Seek financial support for implementation. The major costs are associated with a transition to a common administrative platform (e.g., a version of HERO) and the legal costs attendant with negotiating the reciprocal agreements. The one-time cost in total is unlikely to exceed $2 million.

- Appoint a project manager to flesh out the steps, to lead the effort overall and to ensure that financial and time commitments are met.

- Make the case to the Government of Alberta for a regulatory change that would allow for the creation of a specialized health information REB.

APPENDIX A

People Interviewed during Initial Planning

APPENDIX A

People Interviewed during Initial Planning

The stakeholders interviewed for this assignment in the fall of 2009 during the initial planning phase of this project are as follows, organized by entity represented:

- CPSA – Trevor Theman, Janet Wright
- AHW – Susan Williams (for Linda Miller)
- AET – Annette Trimbee, Ron Dyck, Grant McIntyre
- AHS – Barb Hambly, Chris Eagle
- U of A – Lorne Babiuk, George Pavlich, Lynn Penrod
- U of C – Alan Harrison, Tom Feasby, Charlene Anderson, Rob Hache
- ASRA – Marv Fritzler

Undoubtedly, others could provide views on the subject, and did indeed provide opinions in the earlier HERO work. These thoughts have been incorporated into this paper.

APPENDIX B

Stakeholders Consulted on the Draft for Discussion Plan (January – February 2010)

APPENDIX B

Stakeholders Consulted on the Draft for Discussion Plan (January – February 2010)

- AET – Annette Trimbee, Ron Dyck, Grant McIntyre
- AHW – Jay Ramotar, Susan Williams
- CPSA – Trevor Theman, Janet Wright, Jody Berube
- AHS – Stephen Duckett, David Megran, Alison Tonge (replaced Barb Hambly), Chris Eagle and representatives from the AHS Cancer Corridor: Cyril Kay / Carol Cass (ACRI), Scott North, Karen Mulder / Quincy Chu (interim co-chairs ACREC), Jocelyn Galye and Suzanne Marney
- U of A – Lorne Babiuk, George Pavlich, Wendy Rogers, Philip Baker, Susan Babcock, Charmaine Kabatoff, Judith Abbott, Kim Kordov and NACTRC – Richard Fedoruk
- U of C – Rose Goldstein, Alan Harrison, Gary Libben, Rob Hachè, Charlene Anderson, and Tom Feasby
- U of L – Dan Weeks/Lesley Brown, Martin Lalumière
- Athabasca University – Rory McGreal, Janice Green
- ARIA – Marvin Fritzler
- OIPC – Frank Work / LeRoy Brower
- Other Health Science Faculties/Departments –
    - Athabasca U: Donna Romyn (Health Disciplines);
    - U of A: Anita Molzhan (Nursing), Sylvie Stachenko, Cameron Wild, Duncan Saunders (School of Public Health), James Kehrer (Pharmacy), Martin Ferguson-Pell (Rehabilitation Medicine), Daniel Syrotuik / John Spence (Physical Education & Recreation);
    - U of C: Tom Noseworthy (Community Health Sciences), Dianne Tapp (Nursing), Gerald Zamponi (Physiology & Pharmacy), Anne Hughson (Community Rehabilitation & Disability Studies), Wayne Giles (Kinesiology); and
    - U of L: Christopher Osgood (Health Sciences), Lesley Brown (Kinesiology).

APPENDIX C

Alternative Models Allowed Under the 2nd Draft of the Tri-Council Policy Statement

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Alternative Models Allowed Under the 2nd Draft of the Tri-Council Policy Statement

Chapter 8

MULTI-JURISDICTIONAL RESEARCH

Modern research often involves collaborative partnerships among researchers from multiple institutions or countries. It may call upon the participation of a number of local populations and involve multiple research ethics boards (REBs).

Collaborative research may require institutions to adopt policies and procedures that permit arrangements for REB review off-site at other institutions. To be effective, these review arrangements should ensure that research involving humans is designed, reviewed and conducted in a way that is informed by the core principles of welfare, respect for autonomy and equal moral status for all humans. These core principles should be balanced with a proportionate approach to the research ethics review process for research being undertaken in Canada or abroad.

A. Review Mechanisms for Research Involving Multiple Institutions and Research Ethics Boards

This section primarily addresses research involving multiple sites and at least one institution that adheres to this Policy.

Institutions are accountable for research conducted under their auspices, irrespective of the location where it takes place. Prior ethics review of the proposed research at each collaborating institution affords the opportunity for local issues and values to be considered. However, multiple, independent reviews may lead to different decisions, which may delay or jeopardize the implementation of the research.

Research involving humans that may require the involvement of multiple REBs includes, but is not limited to, the following situations:

a. A research project conducted by a team of researchers affiliated with different institutions;

b. Several research projects independently conducted by researchers affiliated with different institutions, with data combined at some point to form one overall research project;

c. A research project conducted by a researcher affiliated with one institution, but that involves collecting data or recruiting research participants at different institutions;

d. A research project conducted by a researcher who has multiple institutional affiliations (e.g., two universities, a university and a college, or a university and a hospital);

e. A research project conducted by a researcher at one institution that requires the limited collaboration of individuals affiliated with different institutions or organizations (e.g., statisticians, lab or X-ray technicians, social workers, and school teachers); or

f. Researcher(s) working under the auspices of a Canadian research institution but conducting research in another province, territory or country.

Adoption of Alternative Review Models is an Institutional Responsibility

Article 8.1 An institution that has established a research ethics board (REB) may define specific review models for research involving multiple REBs or institutions, in accordance with this Policy.

Application In addition to the traditional review processes (see Point 1, below), the following models for multiple REBs or multi-institutional review are intended to provide flexibility and efficiency and avoid unnecessary duplication of review without compromising the protection of research participants. All other provisions of this Policy remain applicable.

1. Independent Review by Several Single REBs

The REBs involved at each participating institution conduct their independent research ethics review and provide their separate decisions, either concurrently or sequentially.

When several REBs consider the same proposal from their own institutional perspectives, they may reach different conclusions on one or more aspects of the proposed research. REBs may therefore wish to coordinate their review of projects requiring multiple REB involvement, and to communicate any concerns that they may have with other REBs reviewing the same project. When multiple REBs are involved, the REB of the principal investigator should define mechanisms to address inconsistencies or disagreements, defining criteria, roles and responsibilities.

Researchers should provide their REB with the name and contact information of the other REBs that will also review the project.

2. Research Ethics Review Delegated to a Specialized or Multi-institutional REB

Institutions allow research on specific content areas (e.g., clinical oncology research, research involving Aboriginal peoples) or research methods (e.g., qualitative research) to be reviewed by an external, specialized or multi-institutional REB, where such a body exists. In the agreements between the selected REB and the institutions submitting research for review, the specialized or multi-institutional REB must agree to adhere to this Policy. Specialized or multi-institutional REBs may be established regionally, provincially/territorially, or nationally, as necessary.

Another situation would include two or more institutions pooling their resources to create a single joint REB to whom the research ethics review is delegated. Such a delegation may be based on geographical proximity or other considerations such as capacity, volume of reviews, or shared expertise.

Some provinces have introduced legislation that designates one or more REBs for the review of certain types of research within the province. In addition to other provisions, provincial legislation may require adherence to this Policy.

Roles and responsibilities should be clearly defined in the agreement between institutions or in the legislation. The specialized or multi-institutional REB may act as the responsible REB, for any given review, if formally mandated as such by the institutions in question. Where relevant, agreements should specify how the specialized or multi-institutional REB will assure familiarity with particular populations that may be involved in the research. Central review by a specialized or multi-institutional REB need not be preceded or followed by local REB review.

3. Reciprocal REB Review

Multiple institutions may enter into agreements under which they will accept, with an agreed level of oversight, the ethics reviews of each other's REBs. This might involve specific agreements between institutions for sharing the workload of reviewing collaborative research.

Institutions may also decide that reciprocity agreements between institutions involved in such research are to be established for each research proposal on a case-by-case basis.

Whether the review is done by a single REB or reciprocal REB, researchers should ensure that the reviewing REB is provided with any relevant information about the local populations and circumstances that would ordinarily be available to the local REB and that may have a bearing on its review. Otherwise, local REBs might be called upon to provide such information, in addition to the information provided by the researchers.

Article 8.2 Every institution remains responsible for the ethical acceptability of research undertaken within its jurisdiction or under its auspices, regardless of the model adopted for multi-jurisdictional review of any given research project.

Application The selection, establishment and implementation of alternative models for REB review is a collective/collaborative responsibility within and between the participating institutions, their REBs, and the investigators whose research is reviewed. Regardless of the review model adopted for any given research purpose, the institution remains responsible for the ethics review and for decisions regarding research involving human participants that is carried out under its auspices or within its jurisdiction, irrespective of the location where the research is conducted. The ultimate responsibility for the REB reviews and decisions remains with the individual institutions.

Alternative procedures can range from multiple reviews of the same project to accepting the review of other REBs constituted in accordance with this Policy. An institution may authorize its REB to accept reviews of another institution's REB if both institutions have an official agreement that includes at least the following components:

- All institutions involved must agree to adhere to the requirements of this Policy, and the cross-institutional agreement must be formalized and documented;
- The decision to allow an REB to recognize decisions made by another institution's REB must be made at the highest institutional level, by the body that

originally defined the jurisdiction of the REB and its relationship to other relevant bodies or authorities (in accordance with Article 6.2 in Chapter 6 ["Governance of Research Ethics Review"]); and

- Approvals based on cross-institutional agreements should be brought to the attention of the full REB in each institution, in the same way as decisions made by delegated review.

Researchers should use the review models defined by their institution and facilitate coordination of ethics review when submitting their proposal to the REB. Whatever model is chosen, roles and responsibilities of all involved in the process should be defined and agreed to at the outset. Institutions might decide to adopt different models for the review of different research projects.