

Protecting People While Increasing Knowledge:

RECOMMENDATIONS

for a Province-wide Approach to Ethics Review of Knowledge-generating
Projects (Research, Program Evaluation, and Quality Improvement)
in Health Care

Alberta
Research
Ethics
Community
Consensus
Initiative

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List of Acronyms

AHFMR	Alberta Heritage Foundation for Medical Research
AHW	Alberta Health and Wellness
ARECCI	Alberta Research Ethics Community Consensus Initiative
CIHR	Canadian Institutes of Health Research
CPG	Clinical Practice Guidelines
HIA	Health Information Act
IRB	Institutional Review Board
NSERC	Natural Sciences and Engineering Research Council
PE	Program Evaluation
QA	Quality Assurance
QI	Quality Improvement
RCT	Randomized Control Trial
REB	Research Ethics Board
RHA	Regional Health Authority
SSHRC	Social Sciences and Humanities Research Council
TCPS	Tri-Council Policy Statement – Ethical Conduct for Research Involving Humans

Executive Summary

OVERVIEW AND STATEMENT OF PURPOSE

This report reflects work in progress. It follows the May 2004 initial version of *Draft Recommendations for Ethics Screening and Review of Research, Program Evaluation, and Quality Assurance or Quality Improvement* prepared by the Alberta Research Ethics Community Consensus Initiative (ARECCI) working group, now known as the ARECCI Phase I Working Group. The original document was modified following consultations that took place in the spring of 2004 and pilot projects undertaken in 2005 (Phase II).

...the goals and fundamental principles stated in the earliest phase of the Initiative have remained essentially unchanged.

The ARECCI initiative was undertaken to address ethics screening and review problems that were becoming evident in Alberta: it was sometimes unclear which projects needed review; the same project was sometimes treated differently by REBs in different jurisdictions; and there was an increasing sense that a wide range of projects would benefit from ethics review, but some of these were going to an REB unnecessarily.

This document incorporates lessons learned during the pilot projects that took place in 2005¹. Although changes have been made to certain aspects of the document, the goals and fundamental principles stated in the earliest phase of the Initiative have remained essentially unchanged.

GOALS

The key goals of the ARECCI initiative are:

- To develop a common understanding and broad consensus on issues of ethics review.
- To increase the clarity, consistency, transparency, and efficiency of ethics review processes in Alberta.

¹ A complete description of the pilot projects is available separately.

- To recommend an approach to answering the questions:
 - What kind of investigation or project is it?
 - What process of ethics review should be used for each kind of project?
 - What level of review is appropriate for a particular project: full or expedited?
- To develop guidelines and tools for Alberta's health researchers, managers, ethics boards and other stakeholders to implement the recommendations.
- To inform health authority, provincial and federal policy related to ethics review processes.

UNDERLYING PRINCIPLE

As work on the ARECCI recommendations evolved and consultations were held, an underlying principle emerged: all ethics screening and review processes across the province – whether for research or for quality and evaluation² – should occur in an efficient and timely manner that avoids duplication. This principle should lead to a general practice of ethics review in which multiple reviews are minimized or expedited, and in which reciprocal agreements amongst all bodies that do ethics reviews are the norm. A central point of the ARECCI recommendations is that not all projects requiring ethics review need to be reviewed by an REB.

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RECOMMENDATIONS

The ARECCI working group developed five key recommendations for ethics screening and review in Alberta. The first three are operational (i.e., they support specific decisions). Recommendations 4 and 5 are enabling (i.e., they support the implementation of the first three).

Operational recommendations

1. All projects that involve people or their health information would benefit from ethics screening to determine whether ethics review is needed, and if so, what kind and level of ethics review.
2. For the objective of ethics review, it is helpful to distinguish projects by primary purpose. If the purpose is to contribute to the growing body of knowledge regarding health and/or health systems that is generally accessible through standard search procedures of academic literature, then the investigation is best classified as research. If the purpose

² ARECCI uses the collective term 'quality and evaluation' to encompass knowledge generating projects understood to be something other than research such as quality assurance, quality improvement and program evaluation.

of the project is something other than this, then the project is best classified as quality/evaluation.

3. For each project determined by ethics screening to require review, the decision as to whether full or expedited ethics review is called for should be made on the basis of degree of risk to all those involved. Definition of risk includes, without limitation, risk to the privacy or to the physical, mental, psychological, emotional, or spiritual health of individuals or communities. Projects that involve more than minimal risk must undergo full review. In the absence of special circumstances, investigations that involve minimal risk should be vetted through an expedited review process.

Enabling recommendations

4. Capacities and resources for ethics screening and review of quality and evaluation projects should be developed throughout the province. Ethics screening and review processes should build on existing organizational structures for the design, implementation, and evaluation of these types of initiatives.
5. These Recommendations should be implemented in all organizations engaged in knowledge-generating projects involving people or their health information. Implementation should include evaluation and improvement initiatives at all levels of the health system.

TOOLS TO SUPPORT APPLICATION OF THE RECOMMENDATIONS

The ARECCI pilot projects have enabled the development of several tools to assist with the application of the recommendations. These tools include a checklist for classifying a project by its primary purpose (e.g., research or quality and evaluation), as well as several risk filters designed to determine a project's level of risk. We hope these tools will prove useful, at both REB and RHA levels, in sorting which projects need review through what kind of process. The intent is to provide a set of guidelines and tools to support consistent, high quality approaches to the ethics review of projects in various settings across the province.

Striking a Balance

WHAT IS THE PROBLEM?

It is widely accepted that people must be protected from the risks inherent in biomedical and other forms of health related research. It is also widely accepted that the pursuit of knowledge to improve health is an important societal commitment that can bring great benefit to individuals and communities. Over the past several decades, many jurisdictions have struck a balance between these two aspects of health research – protecting people while increasing knowledge – by adopting increasingly regulated approaches to the review of research for ethical acceptability.

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Convergence of research and management

More recently, the evolving need to strike an appropriate balance between protecting people and increasing knowledge has become more complex, as knowledge-generating activities in the health system have become widespread in a variety of forms to improve the planning and management of health services for public benefit. While not usually defined as research, quality assurance, quality improvement, program evaluation and administrative data analysis are seen as necessary activities for managing the health system.

At the same time, the distinction between such activities and research as it is traditionally understood has been challenged by the growth of research activities that occur within, and change, health services themselves. Such activities include health services research, collaborative projects involving both health services organizations and universities, and system-based policy research. Concurrently, there has been an increase in sophistication and prevalence of management strategies that draw on research methodologies.

While the relationships among all these knowledge-generating activities are not well defined, there is a sense that they exist along a continuum, and if ethical considerations apply at the research end of the continuum, they extend along the continuum to other forms of knowledge-generating

activity as well. The need for clarity regarding both the relationships and their ethical implications has become more urgent as legislation across Canada designed to protect personal health information has focused special attention on activities understood to be research. For certain projects, this creates a pressing question: are they research projects and, hence, subject to legislation, or are they quality and evaluation³ projects, hence not subject to legislation?

A related and equally pressing question is whether or not projects understood to be something other than research but that involve people or their health information should be ethically reviewed, and, if so, by whom. Questions about the appropriate role of Research Ethics Boards (IRBs in the US) have been raised, in particular, whether a Research Ethics Board (REB) is always the best mechanism for ethics review.

Need for consistency and clarity

In the context of Alberta REBs and Regional Health Authorities (RHAs), both of these questions are particularly pressing. It is increasingly unclear what projects need review or, if a project needs review, what level of review is appropriate. Different and mutually inconsistent decisions are made from one RHA or REB to another. A project labelled QI in one jurisdiction may be labelled research in another, where an REB may require changes before it can proceed. When a multi-site project is reviewed by different REBs, different levels of review may result, and different changes may be required before the project can proceed in one RHA or another.

ARECCI members believe that the most effective ethics review system will reflect the following characteristics:

- clarity
- transparency
- consistency
- timeliness
- non-duplication

It must be clear what needs review and why. Review processes must be transparent and consistent, whether undertaken by an REB or by another process or body. Reviews and projects should proceed in a timely fashion, and no project should face multiple review processes.

During the course of ARECCI work to date, it has become clear that in a majority of cases it is readily apparent whether a project should go to an REB or to another, non-REB process for review. ARECCI's work has played an important role in helping to clarify the middle ground, those "grey area" projects that are neither clearly research nor obviously quality and evaluation.

³ The term "quality and evaluation" is used to encompass health-related knowledge-generating projects understood to be something other than research. See definition on page 11.

Addressing the opportunity costs

The above values raise ethical concerns of their own. Quality and evaluation projects often promise more immediate benefits to patients or clients than research investigations do because they are typically designed to monitor and improve current health care delivery. Thus the people participating in these projects are often more closely related to the pool of expected beneficiaries than in a research investigation. Ethics review processes that impede or prevent the wide range of quality and evaluation projects that are currently being encouraged to improve health care across the province carry the potential for serious opportunity costs such as lost benefits to the very people who would participate in those projects.

Related opportunity costs may arise from the allocation of health care resources to ethics review within the RHAs. If time and money are devoted to ethics review, what other initiatives have to be forgone, at what cost, and to whom? How important is ethics review for the broad range of quality and evaluation projects, what benefits will it bring, how much harm will it avert, and how efficiently will ethics review processes function in an RHA context?

On the other hand, opportunity costs may arise from overburdening REBs with a wide array and high volume of projects that are not necessarily research. Such demand on REBs could lead to delays in obtaining ethics review of research projects as well as quality and evaluation projects, and efforts to respond to this demand could result in the inefficient use of REB resources.

ARECCI members believe that protecting people involved in quality and evaluation projects is in principle just as important as protecting people participating in research investigations. Moreover, protection is improved both in research and in quality and evaluation environments through explicit, consistent decision-making processes by those responsible for minimizing risks to people and their privacy. The general point of the document is that this protection can be provided in ways that minimize opportunity costs and are embedded in the organizations responsible for such projects. A closely related point is that only by establishing such alternative ethics review processes can REBs be used appropriately and efficiently to review projects that are better categorized as research.

...protection can be provided in ways that minimize opportunity costs and are embedded in the organizations responsible for such projects.

Processes currently exist in most organizations for determining if and under what conditions quality and evaluation projects should go forward. Historically, these processes have not explicitly included ethics considerations. By building ethics considerations explicitly into these processes, the recommendations in this document aim to strike an appropriate balance between the protection of human subjects and the advancement of knowledge while avoiding opportunity costs such as those described above.

THE ALBERTA CONTEXT

Research Ethics Boards in Alberta

Alberta's privacy legislation governing health research was passed in the form of the *Health Information Act* (HIA) in April 2001. The HIA specifies conditions under which health care custodians may disclose health information to researchers. It designates six provincial Research Ethics Boards (REBs) to review and approve or reject research proposals based on ethical standards and privacy safeguards. The designated committees and boards are:

- Alberta Cancer Board – Research Ethics Committee
- College of Physicians and Surgeons of Alberta – Research Ethics Review Committee
- Alberta Heritage Foundation for Medical Research – Community Research Ethics Board of Alberta
- University of Alberta – Health Research Ethics Boards
- University of Calgary – Conjoint Health Research Ethics Board
- University of Lethbridge -- Human Subject Research Committee

The University (Alberta and Calgary) REBs are administered by the universities but are conjoint boards with the local health authorities and have jurisdiction over both the university and the affiliated health region including all of its institutions. The University of Lethbridge REB has jurisdiction over its university researchers, and is not conjoint with the local RHA, Chinook Health Region. The Alberta Cancer Board REB covers all researchers and employees of the Cancer Board, which provides services province-wide. The College of Physicians and Surgeons of Alberta REB is administered by the College, the licensing body for Alberta physicians, and all physicians licensed in Alberta undertaking research are required to obtain ethics approval from this REB. The Community Research Ethics Board of Alberta, administered by the Alberta Heritage Foundation for Medical Research, serves community-based researchers across the province.

Regional Health Authorities in Alberta

There are currently nine RHAs in the province. Two are located in Alberta's major urban centers – Edmonton (Capital) and Calgary; the others are affiliated with a composite of many smaller communities with a diverse range of characteristics. In addition to the nine RHAs, there are two provincial health boards, Alberta Cancer Board and Alberta Mental Health Board. Together, the RHAs and the provincial boards are responsible for the delivery of services in hospitals, continuing care facilities, community health services, and public health programs.

ARECCI – AN ALBERTA RESPONSE

With the purpose of ensuring the best possible protection of people in Alberta within a world class knowledge-generating system that supports top quality health services to achieve the best health for Albertans, the Alberta Heritage Foundation for Medical Research (AHFMR) led the establishment of the Alberta Research Ethics Community Consensus Initiative (ARECCI). This initiative brings together research ethics boards, regional health authorities and research agencies (listed in Appendix 1) to address the question of how to determine the appropriate type, level and process for ethics review of all knowledge-generating activities in order to protect people while supporting worthwhile projects that benefit the community and society. Decision making that reflects this balance requires not only individuals with a common understanding of the issues and relevant considerations, but also system-wide organizational processes and structures that allow for the consistent implementation of such decision-making in universities, health care organizations, and other institutions in the health system.

ARECCI's goals are:

- To develop a common understanding and broad consensus on issues of ethics review.
- To increase the clarity, consistency, transparency and efficiency of ethics review processes in Alberta.
- To recommend an approach to answering the questions:
 - What kind of investigation or project is it?
 - What process of ethics review should be used for each kind of project?
 - What level of review is appropriate for a particular project: full or expedited?
- To develop guidelines and tools to support the implementation of the recommendations by Alberta's health researchers, managers, ethics boards and other stakeholders.
- To inform health authority, provincial and federal policy related to ethics review processes.

When the working group began discussions, it identified an important gap in ethics review processes. Many quality and evaluation projects have ethical implications, but ethics review processes and resources are limited and inconsistently applied in these areas. Investigations not deemed to be research but involving ethical issues appeared to be falling through the cracks or receiving review from REBs on an ad hoc basis and causing concerns about available resources for those committees. Questions arose as to whether such investigations should be reviewed by REBs or other bodies. If they should be reviewed through non REB processes, how should these processes be developed?

These questions led to the development of five recommendations...as long as they involve people or their health information.

These questions led to the development of five recommendations for providing ethics review for all investigations and projects across the province, however they are labelled, as long as they involve people or their health information. (These recommendations are listed in the Overview and Statement of Purpose section above and discussed in detail in ARECCI's Recommendations section below.)

The initial draft of these recommendations was discussed in two consultative workshops, one with external experts and one with regional stakeholders. Appendix 2 provides a list of participants in these two workshops. Numerous suggestions for improving the draft recommendations were made during both workshops and informed subsequent work.

In the workshop involving external experts, two important points became clear. First, many jurisdictions, nationally and internationally, are wrestling with the same issues and questions raised by the ARECCI process. Secondly, Alberta is well placed to develop a comprehensive response to these issues and responses. The province has a well developed set of REBs whose roles are in part enshrined in provincial legislation, and it has a set of health regions that are directly related to these REBs. AHFMR is well placed to facilitate a dialogue between these REBs and RHAs. Implementing these recommendations requires the close cooperation of all three groups.

ARECCI's recommendations are the result of intense and lengthy debate on many complex philosophical and practical issues. They are intended to provide a framework for decision-making at the individual and committee levels as well as for organizational development in all institutions in order to support consistent processes and decisions throughout the province.

These recommendations guided a set of pilot studies designed to take the issues raised in the initial document to their next level. While valuable insight was gained during the pilot projects, ARECCI recognizes that the current document remains somewhat open-ended: while important questions were answered during the pilot projects; new questions emerged.

LAYING THE GROUNDWORK

Assumptions

The following four assumptions underlie ARECCI's recommendations and its overall effort to strike the appropriate balance between protecting people and avoiding the possible opportunity costs that might arise in expanding the scope of ethics review processes across the province.

- While no single, internationally accepted definition exists to separate investigations or projects that are research from investigations or projects that are not research, it is nonetheless possible to pragmatically distinguish, for purposes of ethics review, between research and quality/evaluation.
- If an investigation or project is determined to require ethics review, it should be reviewed through its own particular process of ethics review by a body having appropriate jurisdiction and capacity, such as the following:
 - REB
 - RHA
 - Organizations within RHAs
- Although REBs currently provide the highest level of ethics review across the province, there is no reason in principle that a similarly high level of ethics review should not be developed and provided by other processes for investigations or projects that are deemed to be quality and evaluation. for purposes of ethics review.
- Each institution that is responsible for the protection of people and increasing knowledge will comply with legislation, regulations, and policy application to its function (e.g., TCPS, HIA, etc.)

Definitions

ARECCI's recommendations are directed to a variety of audiences, each with its own terminology. The terms defined below are meant to give researchers and REBs, as well as practice and management communities, a common language for talking about ethics review policies and practices in Alberta, regardless of whether such review relates to research or quality and evaluation. ARECCI asks that each group develop a more general terminology in accord with these definitions.

Under current terminology, only REBs do "ethics reviews", and typically the projects that receive review are research investigations. A main point of this document is that more projects need to be considered "investigations" requiring some form of "ethics review" than the current usage of these terms suggests.

ETHICS REVIEW: an institutionally defined, fully accountable process for determining, on the basis of methodological and ethical considerations, if and how a project may proceed.

Ethics review and approval may or may not involve an REB, depending on the nature of the project and whether other review processes are available. To be fully accountable in Alberta, an REB must be institutionally defined in accord with the TCPS and the HIA. Institutional definitions will need to be developed and communicated within RHAs to make their processes of ethics review transparent and consistent.

ETHICS SCREENING: an institutionally defined, fully accountable process to determine if a project needs ethics review and, if so, what kind of review.

EXPEDITED/DELEGATED ETHICS REVIEW: an institutionally defined process for determining if and how projects posing no more than minimal risk to those involved may proceed. For example, with REBs, projects posing no more than minimal risk are normally reviewed by a process that does not involve the entire REB.

FULL ETHICS REVIEW: an institutionally defined process for determining if and how projects posing more than minimal risk to those involved may proceed. For example, with REBs, projects posing more than minimal risk are normally reviewed by the entire REB.

INSTITUTION: any level of government, governmental agency, RHA, professional association, or health service delivery organization having an interest in, or role related to, screening, review, or approval of projects.

PROJECT: any inquiry, investigation, project, protocol, study or trial that is related to the health of individuals or communities, that involves people or their health information, and that takes place in a community, a health region, a service delivery organization, or an individual practice within the province. Projects defined in this way for the purpose of ethics review may be undertaken by principal investigators, project leaders, or by any other members of an RHA less formally acknowledged.

PROVINCE: the Province of Alberta.

RESEARCH PROJECTS: projects that for purposes of ethics review should go to an REB.

QUALITY AND EVALUATION PROJECTS: projects that for purposes of ethics review should go to a review process developed by the organization within which the project is occurring. These projects are understood to include quality assurance, quality improvement and program evaluation.

Pilot projects

In the first half of 2005, pilot projects were undertaken to assess the feasibility of the ARECCI recommendations and tools in practice. Pilot tests took place in seven regions and one pilot involved five REBs including one from Eastern Canada (see listing in Appendix 3). Main findings are summarized below.

USE OF THE TOOLS AND FEASIBILITY IN PRACTICE. The pilot projects revealed that there were differing interpretations of the tools in practice. Pilot site participants also recommended a number of improvements with respect to wording and clarity. Nonetheless, participants

reported that the tools had promise and were useful for generating discussion and creating awareness about important ethical issues. It was also noted that the time required to complete the tools was relatively quick (usually less than five minutes per tool), given an existing familiarity with the project.

FIT WITH CURRENT CONTEXT. Overall, the concept of having a tool to help classify projects as research or quality and evaluation was perceived as relevant within the existing provincial context, and the need for all research projects to undergo ethics review by a designated REB was confirmed. Similarly, the availability of a tool to help assign level of risk was also perceived as helpful to assess the risk of grey area projects and to assist with determining whether a project should be submitted for full or expedited review.

INFRASTRUCTURE AND SUPPORT. With respect to infrastructure and resources required to pilot test the ARECCI tools, the most commonly reported resource was time. This included time to use the screening instruments, time to review projects, time for pilot project administration, and time required for meetings and communication.

Relative to broader infrastructure needs to support an overall system of ethics review that incorporate quality and evaluation projects, participants were asked to comment on the suggestion for independent review and how this might be interpreted in practice.

Among REB participants, there was general agreement that independent review is important but that not everything needs review by an REB. Among RHA participants, there was agreement that the concept of independent review was an important question and for some participants was one of the key reasons for their involvement in the overall initiative. However, RHA participants further noted that not all projects need review by an REB and emphasized that support is needed to help make decisions regarding what should be submitted to REBs, particularly with respect to grey area projects. Participants felt that the ARECCI screening tools have promise to help meet that need. There was general agreement that ethical considerations should be integrated into all projects regardless of project classification. Participants cautioned that a structured or formal independent review of all quality and evaluation projects could serve as a disincentive to engaging in such projects. Instead, they advocated for flexible guidelines and tools to assist with ethics screening and appropriate review of quality and evaluation projects.

Perceived impact of the pilot projects. The process of participating in the ARECCI pilot project overall was perceived to have impacted participants, and sometimes their organizations, in a variety of ways. For example, participants reported that the pilots resulted in increased awareness of the need to consider ethical implications of all projects. Many also reported that the process of participating in the pilot projects had made the concept of “ethics” more concrete.

PARTICIPANT SUGGESTIONS REGARDING PROVINCE-WIDE IMPLEMENTATION AND NEXT STEPS. Participants provided a range of suggestions regarding province-wide implementation and next steps. Their recommendations were related to suggested modifications to the tools, broader dissemination and support needs, and broader system level awareness and education needs. One of the largest remaining gaps participants identified was the lack of direction regarding appropriate ethical review of quality and evaluation projects. Participants suggested this issue could be addressed independently of changes to the screening tools. They also affirmed that tools and structures to help integrate ethical considerations into program/project planning would be helpful.

On balance, pilot project participants urged ARECCI to sustain the collaborative momentum and to continue to modify tools, assist with capacity development for their implementation, and share information about helpful processes to support implementation.

ARECCI's Recommendations

INTRODUCTION

More than ethics

ARECCI's focus is ethics review. However, ethics review is tightly coupled with review of the methods used by a project to gather and interpret data (commonly called a "scientific review" in the research environment). As alternative ethics review processes are developed to provide ethical oversight of quality and evaluation projects, oversight of the methods used in these projects will inevitably be involved.

Knowledge gained through health-related research is highly valued in Canada. As well, there is an ethical imperative for health care providers to ensure the services they provide are efficient and effective. The purpose of ARECCI's recommendations is to ensure the protection of people in both research and quality and evaluation types of projects by determining appropriate ethics review processes while encouraging quality of services and improved outcomes of health care across the province.

Efficiency – an underlying principle

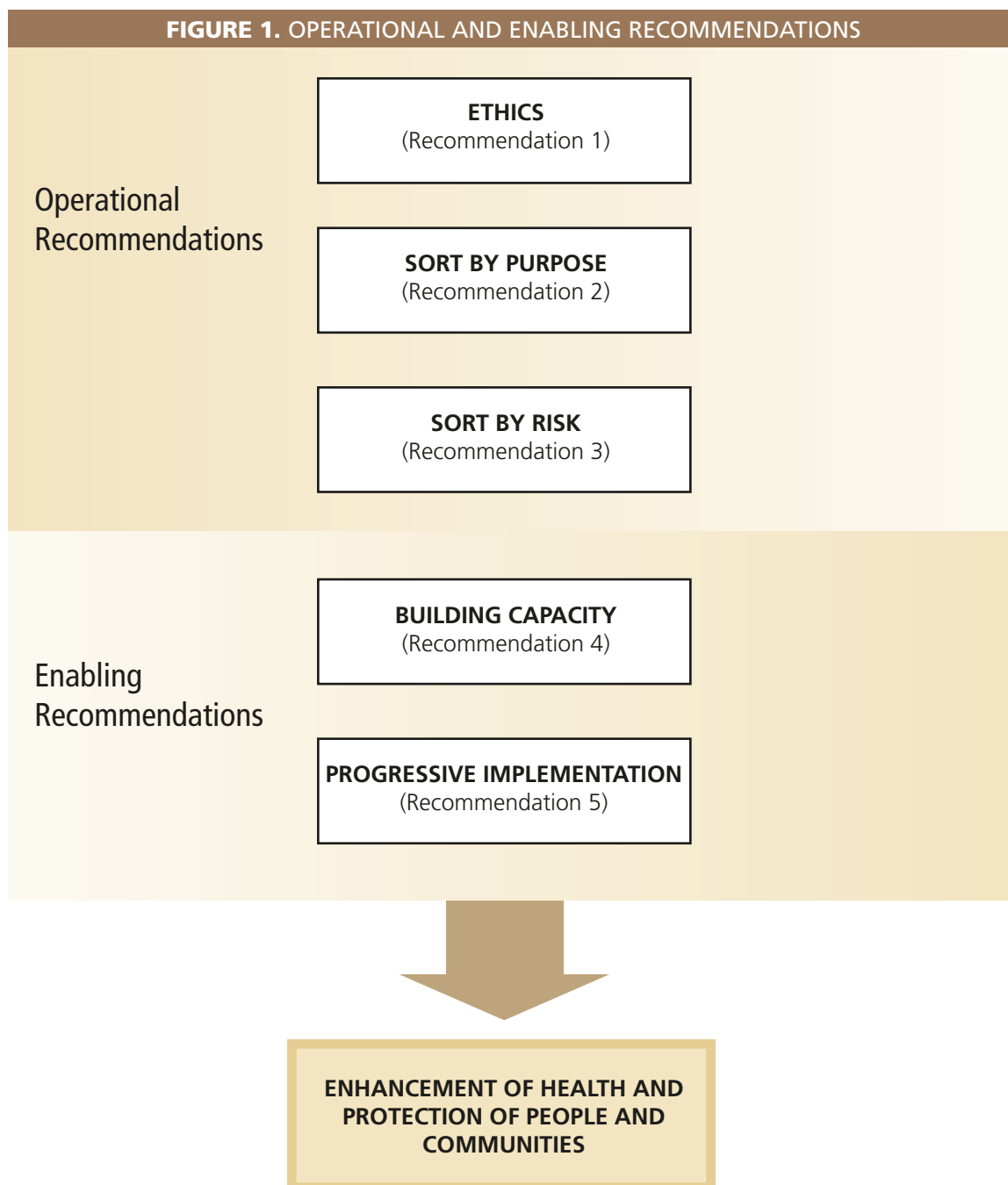
As work on ARECCI's recommendations evolved through consultations and pilot projects, one underlying principle came increasingly to the fore: All ethics screening and review processes across the province -- whether for research or quality and evaluation purposes -- should occur in an efficient and timely manner that avoids duplication.

This principle should apply whether projects are for research or quality and evaluation purposes. It should lead to a general practice of ethics review in which multiple reviews are minimized or expedited, and in which reciprocal agreements amongst all bodies that do ethics reviews are the norm.

Operational and enabling recommendations

ARECCI has presented five recommendations. The first three are operational in nature (i.e., they support specific decisions), while Recommendations 4 and 5 are enabling (i.e., they support the implementation of the first three).

Figure 1 depicts the recommendations graphically.



OPERATIONAL RECOMMENDATIONS 1, 2 AND 3

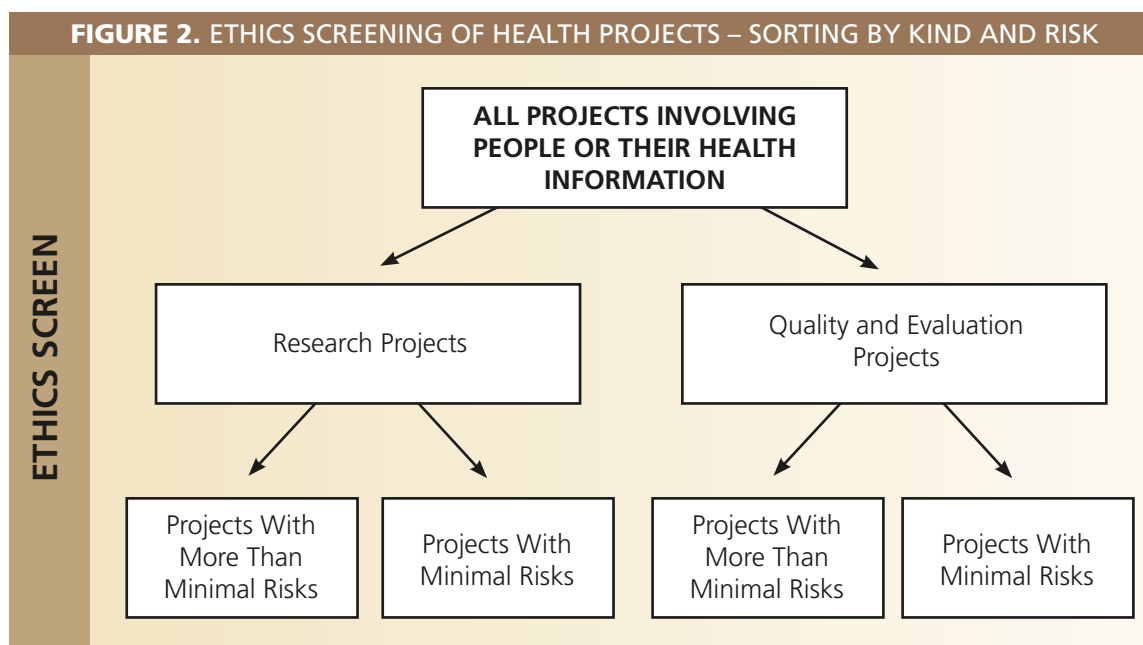
The appropriate ethics review process for a project that involves people or their health information is determined according to

1. The kind of project involved;
2. The degree of risk posed by the project to all those involved in it.

Projects are first sorted by kind and secondly by risk for three related reasons:

1. The factors that determine degree of risk differ depending on the kind of project -- i.e., on whether it is research or quality and evaluation.
2. *The Tri Council Policy Statement – Ethical Conduct for Research Involving Humans* (TCPS) (Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, 2003) implicitly sorts in this manner when it states that any investigation that is deemed to be research involving people, i.e., human subjects (sorting by kind) must be sent to an REB to determine whether it is minimal risk or more than minimal risk (sorting by risk).
3. In a parallel way, projects that are deemed for the purposes of ethics review to be something other than research (sorting by kind) should be reviewed within the organizations that have jurisdictional accountability for, and experience and expertise with, managing the risks that may be involved in such investigations (sorting by risk).

To ensure the protection of people and communities involved in or affected by health related research investigations and other types of projects, ARECCI builds on the sort by kind/sort by risk concept and makes the specific following operational recommendations:



RECOMMENDATION 1

Screen all projects to determine if ethics review is needed.

All projects that involve people or their health information would benefit from ethics screening to determine whether they need ethics review, and if so, what kind and level of ethics review.

An ethics screen is an institutionally defined process used to determine whether or not ethics review is required.

The term **ethics screen** refers to sorting projects first by kind (primary purpose) and secondly by risk and is depicted in Figure 2. At this stage in the process, ethics screening determines the appropriate type of review (if any) for health related projects involving people or their individually identifiable health information. It is important to note that an ethics screen is NOT a review. An ethics screen is an institutionally defined process used to determine whether or not ethics review is required.

Currently, the ethics screening processes for research, represented on the left hand side of Figure 2, are well established but not entirely consistent from REB to REB. Less is known about processes that exist for the types of projects represented on the right-hand side of Figure 2. Some degree of screening and decision making already takes place in some health regions, but such processes are more informal and differ greatly from one region to the next. ARECCI has helped to learn more about these processes and has contributed important lessons on how to make them more transparent, consistent, and explicitly accountable.

The questions of independent screening and review

There is general agreement that in the case of research projects, ethics screening and review by individuals with no involvement in the research or with the researchers is essential. There is less clarity with respect to screening and review processes for quality and evaluation projects. The concept of screening and review through a process that is independent from those responsible for the project is important for quality and evaluation projects. However, setting up independent processes may be complicated, particularly in smaller RHAs where the same individual or group of individuals may be responsible for designing, implementing, and evaluating all quality and evaluation projects. Issues surrounding independent screening and review emerged during the pilot projects. Limited time (human resources) was a key concern regarding the feasibility of fully independent screening and review. Suggested approaches tended to focus on ethics review versus ethics screening. Examples of what “independent review” might look like included: (a) internal review independent of program areas (e.g., independent research committee within a health region that operates independently of program delivery); (b) co-review across independent departments within the same organization; or (c) co-review across independent health regions. This last approach was piloted by three small health regions and was considered a potentially valuable way of working together in the future. This approach was not considered feasible in larger regions.

RECOMMENDATION 2	
Screen according to purpose.	For the purposes of ethics review, it is helpful to distinguish projects by primary purpose. If the purpose is to contribute to the growing body of knowledge regarding health and/or health systems that is generally accessible through standard search procedures of academic literature, then the investigation is best classified as Research. If the purpose of the project is something other than this, then the project is best classified as Quality and Evaluation.

Pragmatic distinctions

ARECCI recognizes that using definitions to classify projects as research or other is problematic: while many definitions of research and projects such as program evaluation, quality assurance and quality improvement exist, none are internationally accepted. For the purpose of ethics review, however, there needs to be a pragmatic way to distinguish between types of projects.

Primary purpose categorizes research in terms of the intended use of results. It is meant solely to be a pragmatic criterion for channelling investigations into appropriate processes of ethical review. Using primary purpose sorts projects by type, as depicted in Figure 2, and channels projects into the second-level screening process that sorts projects by risk.

Primary purpose is not meant to define the essential nature of an investigation. None of the existing definitions in the relevant literature are able to do this successfully.

Primary purpose is not meant to define the essential nature of an investigation.

The quality and evaluation category includes projects such as program evaluation, quality assurance, quality improvement and similar sorts of projects where the primary purpose is to assess or improve the quality of a treatment, service or program.

Determining primary purpose

Given a lack of internationally accepted definitions, ARECCI decided to develop tools to assist with classifying projects according to primary purpose and to assess the utility of the tools in practice. This approach was supported by external experts.

What if the purpose changes?

For purposes of ethical review, investigators must decide on the primary purpose of a project before it begins, and it is this decision that determines which process of ethics review is appropriate. However, the purpose of a project can change over time. For example, a project originally undertaken for the purpose of QI might produce an interesting result that would be worth sharing more widely. But risks to privacy, for example, may be amplified if project results are shared more widely than was

originally intended. Essentially the project's purpose has changed from the original intent and it may need to be reviewed again.

When a project's primary purpose changes and a new review is required, this second review may occur through the same review process the project originally went through. If, however, the primary purpose has changed significantly enough to move the project from quality and evaluation to research, the project must be sent to an REB for review. Even though the project received ethics review before it began, the REB may determine the review was not sufficient to allow it to proceed further as a research project. This question was not addressed in the pilot projects.

What if there is more than one purpose?

The criterion of primary purpose recognizes that projects may have more than one purpose. For example, a project that is primarily intended for quality assurance in a particular program or organization may be shared with other programs, organizations, or regions if the opportunity arises. If the project is being undertaken primarily for quality assurance, it is most appropriately reviewed by an RHA ethics review process, not by an REB.

If, on the other hand, a quality and evaluation project contains an element of research, or a research component, it must be sent to an REB for ethics review.

What if I might want to publish?

Intention to publish does not by itself determine the primary purpose of a project. It is important to note that all projects involving people or their health information will go through ethics screening and review. While not all such processes will directly involve an REB, non-REB processes will be institutionally defined and accountable. Depending on the publication, this may be sufficient for purposes of ethics review. Since many health organizations in the US, for example, have no equivalent of an REB, quality and evaluation projects occurring within the jurisdiction of such an organization will also have passed through some non-REB form of institutionally defined ethics review process.

Thus, intention to publish does not by itself determine the primary purpose of a project. If these Recommendations are followed, every project that needs ethics review should receive it. Alternative processes of ethics review, if they are well defined and fully accountable, should be able to approve projects and to say in writing that they have done so.

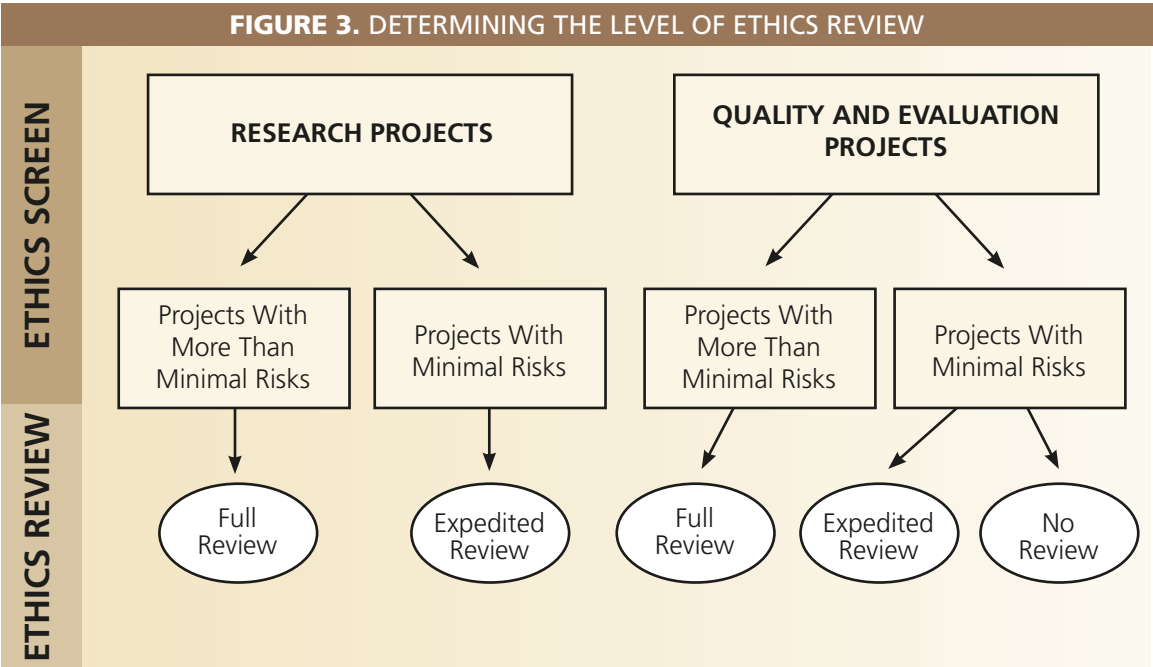
RECOMMENDATION 3	
Screen according to level of risk.	For each project (research or other) determined by ethics screening to require review, the decision as to whether full or expedited ethics review is called for should be made on the basis of degree of risk to all involved, including, without limitation, risk to the privacy or to the physical, mental, psychological, emotional, or spiritual health of individuals or communities.

- 3a) Projects that involve more than minimal risk must be vetted through a process of full review.
- 3b) In the absence of special circumstances, investigations that involve minimal risk should be vetted through a process of expedited review.

Determining the level of review required

After a project has been sorted by kind and its primary purpose (and therefore the appropriate organization and process for further screening and review) has been determined, it should undergo a second screen to determine the level of risk involved for the people participating as subjects. This second level screen determines whether the project should receive a full review, expedited review, or, in the case of some quality and evaluation projects involving people or their health information, no review.

Figure 3 builds on Figure 2 to illustrate how the ethics screening process channels projects into the most appropriate kind of ethics review based on level of risk.



...quality and evaluation projects are likely to present a different range of risks than research projects.

Tools were developed to help determine level of risk and are available separately. Although the question of risk is central to the review of any kind of project, two different sets of filters were developed, one for research projects and the other for quality and evaluation projects. This is because quality and evaluation projects are likely to present a different range of risks than research projects.

Differing processes in different contexts

While the processes in Figure 3 appear similar and parallel, in actual fact those developed and implemented for quality and evaluation projects are likely to be different from existing research ethics review processes. Variations will depend on many factors such as the size and type of organization in which the project is being conducted. In large organizations, different individuals or groups may be responsible for the design, implementation and evaluation of quality and evaluation projects such as PE, QA, or QI. This could result in a different review process for each of these types of projects. These different review processes could affect how the initial screening is done in these larger organizations, and could well be based on other administrative review and approval processes. In general, the pilot projects found that review processes dealing with QA or QI projects were more highly developed than those relating to PE.

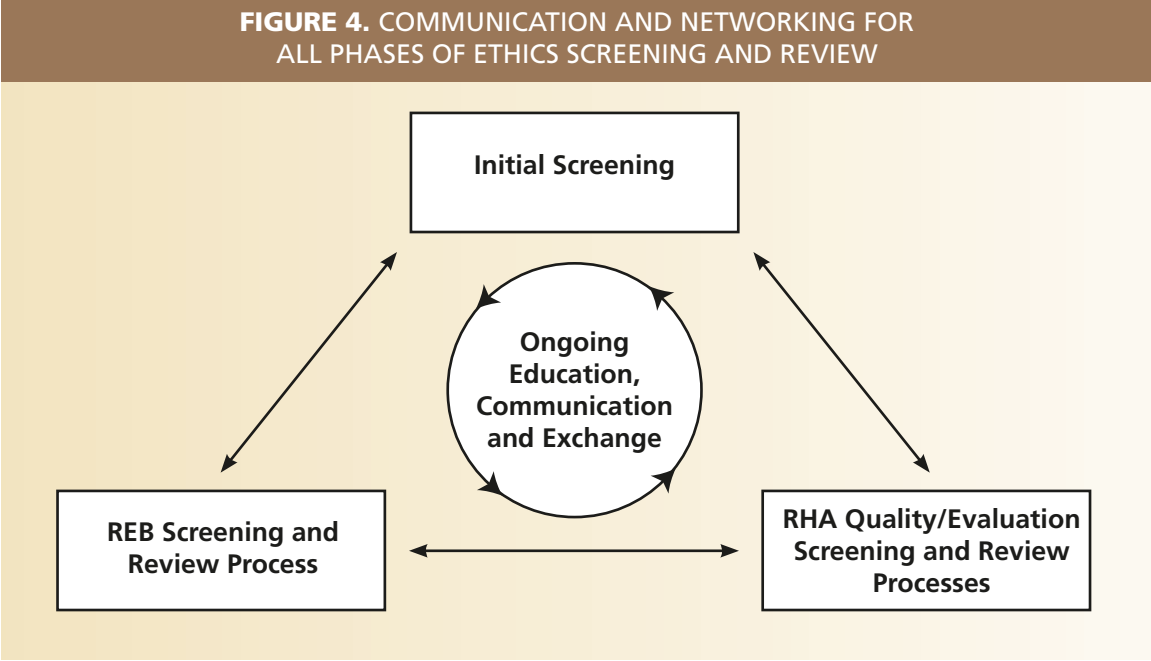
In smaller organizations, a single individual or group may be responsible for all quality and evaluation projects as well as for oversight of research policies. In such jurisdictions, there may be a single ethics review process for all quality and evaluation projects, and this single review process may also simplify the initial screening process.

Even in larger organizations, all quality and evaluation projects may be grouped together for the purposes of ethics review. **Health authorities must be allowed some flexibility in the implementation of these Recommendations so that systems and processes that work for each region can be developed and implemented.**

Working together

Communication and networking will be a vital part of the incremental adoption of ARECCI's recommendations. Within each RHA, there will need to be communication between the individuals or groups engaged in all components of the ethics screening and review process depicted in Figure 4 on the following page.

Communication and networking will be a vital part of the incremental adoption of ARECCI's recommendations.



While Figures 2 and 3 depict fairly linear and parallel ethics screening and review processes, Figure 4 illustrates the ongoing communication that must also exist to guide these processes. The two streams of screening and review should not proceed oblivious to each other. If the purpose of a project changes, ongoing communication will ensure that the project is channelled to the appropriate re-review body as necessary.

ENABLING RECOMMENDATIONS 4 AND 5

Recommendations 4 and 5 are more strategic in nature to enable the operational Recommendations 1 to 3. They provide overarching guidance on how to build sustainable ethics review processes across the province that help protect people and communities.

RECOMMENDATION 4

Build capacity and build on existing practices.

Capacities and resources for ethics screening and review of quality and evaluation projects should be developed throughout the province. Ethics screening and review processes should build on existing organizational structures for the design, implementation, and evaluation of these types of initiatives.

What does capacity building involve?

Institutional mechanisms for ethics screening and review of projects have not been clearly articulated in regulations, policy or practice across RHAs in Alberta. To provide appropriate mechanisms for ethics screening and review at regional or organizational levels, effective capacity building will be required. This is particularly the case for quality and evaluation types of projects where the infrastructure and resources available to support ethics screening and review are less developed and more scarce.

Capacity building needs to be considered at a system level regionally and provincially, and should be:

- Participatory and empowering with ownership at the level of application as a central element.
- Built on existing structures.
- Inclusive of initial and ongoing resources, processes, and networks to ensure sustainability.

There are three components of capacity:

1. Structural components

- Organizational support and motivation to address ethics screening and review.
- Policy or processes in place to meet the objectives described in the recommendations.
- Defined roles and responsibilities of departments/staff in relation to these policies and processes.
- Necessary technology/infrastructure to support processes.

2. Resource components

- Financial
- Human (staff and skill levels)
- Educational (for awareness and ongoing skill development)

3. Networking components

- Enabling environment to support development and sustainability of capacity.
- Formal and informal collaborations/linkages for ongoing learning and sharing.
- Formal and informal communication mechanisms.

RECOMMENDATION 5	
Progressive Implementation	These recommendations should be implemented in all organizations engaged in knowledge-generating projects involving people or their health information. Implementation includes evaluation and improvement initiatives at all levels of the health system.

The pilot projects have helped to solidify and reinforce the wisdom of the fundamental directions and principles proposed. The pilot projects reinforced the widespread relevance of the Recommendations to many organizations in the province, and participants strongly encouraged continued implementation and learning.

CONCLUDING COMMENTS

The basic principles and recommendations stated early in the ARECCI process have stood the test of time and trial. There is still significant energy (noticeably increased among health regions) to press ahead and improve the ethical review of knowledge-generating projects in the province.

The phrase “striking a balance” was used in the context of finding a balance between protection from risk and the pursuit of knowledge to improve health. This phrase re-emerged during the interpretation of findings from the pilot projects and served as a way of conceptualizing the balance that is necessary along a continuum of concepts related to ethics screening and review. Balance is needed to ensure ethical considerations are made for all projects within limited time and human resource constraints. Balance is also necessary between providing structure (to increase consistency) and flexibility (to accommodate regional and organizational uniqueness).

ARECCI recommends that “striking a balance” remain a key consideration in guiding its efforts as we move forward.

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Alberta Research Ethics Committee Consensus Initiative...continued

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APPENDIX 3

Phase II – Pilot Project Leaders

This appendix contains a list of pilot projects undertaken in Phase II and the project leaders.

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* Palliser Health Region was unable to participate as a pilot site but expressed interest in the initiative. A regional representative contributed during all Phase II workshops to add an informed perspective external to the pilot process.

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