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The Raison d'Être of Mutual Recognition: An Analysis of the 2015 Reform to Research Ethics Review Policies, Processes and Problems in Québec

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Abstract

Ethics review is a pre-requisite to conducting research involving humans in Canada, and indeed in most international jurisdictions. The Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans (TCPS2) serves as the national policy framework for research ethics review in Canada, and outlines three potential oversight models: independent, delegated and reciprocal. While the independent model preserves institutional oversight of research, it contributes to a duplicative system that can unduly delay research and impose barriers to research collaboration. This analysis centres on a 2015 reform to the policy model of research ethics review for collaborative, multi-site studies in the province of Québec. Informal interviews with key informants supplemented a document analysis of provincial research ethics policies using the comparative framework proposed by Lavis and colleagues. Consolidating bureaucratic structures and preserving locally-relevant review studies that span multiple sites remain among the most pressing challenges to transitioning from an independent model, and could provide reference for other provinces that have, or are currently in the process of such a transition.

L'évaluation éthique est un passage obligé de toute recherche sur sujets humains au Canada, ainsi que dans la plupart des pays. L'énoncé de politique des trois conseils sur l'éthique de la recherche avec des êtres humains (EPTC2) joue le rôle de cadre national de réglementation de l'évaluation éthique de recherche au Canada, et identifie trois modes de régulations potentiels : indépendant, délégué, et réciproque. Alors que le modèle indépendant garantit la régulation de la recherche par l'institution, il contribue aussi à un système de duplication pouvant indûment retarder la recherche et pose des obstacles à la collaboration intercentrique. La présente analyse porte sur une réforme du modèle de politique d'évaluation éthique des études collaboratives multi-sites menée en 2015 au Québec. Des entretiens informels avec des informateurs clés ont complété une analyse de documents sur les politiques provinciales d'éthique de la recherche suivant le cadre comparatif proposé par Lavis et collègues. Créer des structures administratives consolidées tout en préservant des évaluations éthiques pertinentes au plan local pour des recherches multi-centriques reste le défi le plus pressant pour sortir du modèle indépendant, mais pourrait fournir un cadre de référence pour d'autres provinces ayant accompli ou entamé ce processus de transition.

Key Messages

- Despite significant growth in the number and types of scientific research collaboration across centres (and in some instances, across borders), the procedural inefficiencies of the independent model greatly challenge such collaboration. This is most notable in fields of research that require multi-site collaboration, thus underscoring a scientific rationale for reform from the researcher's perspective.
- A more streamlined ethics review approval policy and process was cited as a key strategy for enhancing Québec's research competitiveness by attracting top investigators to locate their research at Québec health institutions.
- That similar reforms are underway in otherwise different healthcare systems—including in other provinces across Canada, the United States and Australia—points to consensus on the value added of centralized ethics review for facilitating collaborative research, data sharing and innovation in health.

Messages-clé

- *En dépit de l'accroissement et de la diversification des collaborations de recherche multi-centrique (dans certains cas, internationales), le manque d'efficacité procédurale du modèle indépendant entrave sérieusement ce type de collaboration. Cela est particulièrement sensible en recherche multi-centrique, appelant une réforme justifiée sur le plan scientifique du point de vue du chercheur.*
- *Une politique et un processus d'évaluation éthique plus rationalisés ont été cités comme facteurs clés de l'amélioration de la compétitivité de la recherche québécoise, afin de convaincre les meilleurs chercheurs de mener leur recherche dans des institutions sanitaires du Québec.*
- *Le fait que des réformes similaires soient en cours dans des systèmes de santé par ailleurs très différents—entre autres des provinces canadiennes, les États-Unis et l'Australie—démontre un consensus sur la valeur ajoutée des évaluations éthiques centralisées dans la recherche collaborative, le partage de données et l'innovation en santé.*

1 BRIEF DESCRIPTION OF THE HEALTH POLICY REFORM

Ethics review is a prerequisite to the conduct of research involving humans in Canada, and indeed in most jurisdictions around the world (Council for International Organizations of Medical Sciences 2016). Like the provision of health services, health research in Canada falls under the jurisdictional purview of the provinces;[1] as a result, guidelines for ethics reviews of health research is determined by provincial legislations.

These provincial legislations must follow the national policy framework for research ethics in Canada, the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans (TCPS2) put forth by the three federal research funding agencies (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada and the Social Sciences and Humanities Research Council of Canada). Compliance with the TCPS2 is mandatory for "all research conducted under the auspices of any institution that is eligible to receive and administer research funds from any of the three federal Agencies" (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada and Social Sciences and Humanities Research Council of Canada 2014). The TCPS2 outlines three core ethical principles of research involving humans,[2] and also opens the possibility of different procedural models for conducting ethics review. Until recently, the independent model of ethics review (a separate ethics review required for each site at which the research would be conducted and/or where participants would be recruited), was the most widely adopted model in Canada. Several provincial reforms to ethics review of multi-site studies have since transitioned to alternative models outlined in the TCPS2. These include delegated (one external organization serves as the main reviewing body) and reciprocal review (agreement between centres in a project). Table 1 provides more details on each of these procedural models.

The TCPS2 is but one guiding framework upon which the provinces may rely for ethics review oversight. Indeed, the Civil Code of Québec (CCQ) and the Cadre de référence pour l'autorisation d'une recherche multicentrique (Ministère de la Santé et des Services Sociaux (MSSS)) both govern the organization, operation and funding of research ethics review (REB) at all health institutions in Québec. Both guidelines complement the philosophical foundations of research ethics in the TCPS2, yet differ with respect to several procedural items, such as the age of consent for research involving minimal risks (age 14 in Québec). Québec is also unique in that it maintains two parallel governance structures for research ethics review. Research ethics review conducted in academic institutions (e.g., universities and secondary schools) act in accordance to the TCPS2 guidelines and applicable provincial

[1] Newfoundland and Labrador is the only exception.

[2] The principled approach adopted in the TCPS2 names respect for persons, concern for welfare, and justice as the leading core principles guiding the ethical conduct of research involving humans (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada and Social Sciences and Humanities Research Council of Canada 2014, 6).

laws/regulations recognized by the Ministère de l'Éducation et de l'Enseignement supérieur, whereas the MSSS governs research conducted at all health institutions within its network (e.g., hospitals, community clinics and private practices). Investigators who conduct research at Québec universities, but recruit participants from Québec hospitals therefore require separate ethics approval from the hospital (governed by the MSSS regulation) and the researcher's home academic institution.

Table 1: TCPS2 (2014) definitions of independent, delegated and reciprocal research ethics review models (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada and Social Sciences and Humanities Research Council of Canada 2014, 99-100)

Model	TCPS2 definition
Independent	The REB involved at each participating institution conduct an independent research ethics review and provide their separate decisions, either concurrently or sequentially. The level of ethics review for research that involves multiple REBs and/or institutions shall be proportionate to the risk involved in the research (see Article 6.12).
Delegated	Institutions may allow research on specialized content or research methods to be reviewed by an external, specialized or multi-institutional REB, where such a body exists. External, specialized or multi-institutional REBs may be established regionally, provincially/territorially or nationally, as necessary. Two or more institutions may choose to create a single joint REB, or to appoint an external REB, to which they delegate research ethics review. This delegation of review may be based on geographical proximity or other considerations such as resources, volume of reviews or shared expertise... In the official agreement between the selected REB and the institutions submitting research for ethics review, the external, specialized, or multi-institutional REB shall agree to adhere to this Policy.

Reciprocal	Multiple institutions may enter into official agreements under which they will accept, with an agreed level of oversight, the research ethics reviews of each other's REBs. This might involve specific agreements between institutions for sharing their workload. Alternatively, institutions may decide that reciprocity agreements should be established for the ethics review of each relevant research proposal on a case-by-case basis... In either case, researchers shall 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. The reviewing REB might call upon local REBs to provide information in addition to that provided by the researchers.

This HRA focuses on the 2015 reform to the provincial MSSS policy for hospital-affiliated research. Under this reform all research involving humans conducted at more than one health institution within the Réseau de la Santé et des Services Sociaux (RSSS) network undergoes a single, delegated review by a leading Board of Record. The Board of Record's decision applies to, and is legally recognized among all sites named in the study that are part of the RSSS network (MSSS 2016). The reform was significant for two reasons. First, it signalled one of the first province-wide transitions to a delegated model of research ethics review for hospital-affiliated research in Canada. Second, the reform does not apply to health research conducted at Québec academic institutions, or to hospital-based research collaborations outside the province of Québec. The implications of this omission, and its impact on collaborative multi-site health research will be explored in depth. This HRA provides an overview of the political, social and economic factors motivating the MSSS reform, and the ways in which it coheres with a broader movement towards collaborative science, especially with respect to the data-intensive science disciplines such as genetics/genomics. That other provincial and international jurisdictions are streamlining processes for ethics approval is indicative of ethics policy evolving in tandem with the scientific innovations it aims to govern.

2 ETHICS REVIEW POLICY AND THE BIOMEDICAL RESEARCH CONTEXT

Scientific collaboration across centres (in some instances, across borders) has grown dramatically, and is indeed essential to biomedical innovation in the data-intensive sciences such as genetics and genomics. Innovations in ethics governance, in contrast, are experiencing considerable lag. In this era of globalized biomedical research and bio-economies (Dove and Özdemir 2015), the independent, or institution-by-institution model of ethics review poses a multitude of practical challenges for researchers and research ethics boards alike. While

the independent model preserves direct local (institutional) oversight of research activities, it invites inconsistencies in the review process as a whole for multi-site studies (Dove *et al.* 2013), exacerbates project delays (Al-Shahi Salman *et al.* 2014) and, at worst, may cost patient lives (Whitney and Schneider 2011).

The delegated model was proposed as one viable alternative to address these review challenges and better meet the collaborative needs of contemporary biomedical research in Canada (Abbott *et al.* 2008; Martz *et al.* 2012) and internationally (Dove *et al.* 2016). Improvements in the efficiency of multi-site/multi-national reviews are among the many benefits afforded by the delegated model, and was a motivating factor of its adoption in the province of Québec. Newfoundland and Labrador (Pullman 2005) as well as Alberta (Alberta Health Innovates n.d.; Health Research Ethics Board of Alberta n.d.) have also adopted a form of delegated review at the provincial level, while two provinces are currently in the process of enacting similar reforms (British Columbia and Nova Scotia). In addition, Clinical Trials Ontario (CTO)(Clinical Trials Ontario n.d.) and the Ontario Cancer Research Ethics Board (OCREB)(Chaddah 2008) apply the delegated review model for discipline-specific research in the province of Ontario. That is, the CTO recognizes REBs qualified to review multisite clinical trials in Ontario, and cancer-related studies specifically may apply to OCREB for review.

In the MSSS policy, a delegated review approval negates the need for a full board review at the local level. Local ethics boards are responsible, however, for actively monitoring the study at their respective sites (e.g., through data safety monitoring committees or through an industry sponsor). The sections that follow detail the specifics of the MSSS reform, explore explicit and implicit motivations for its adoption, and posit how future policy analysis may determine how similarly streamlined models of review can be implemented and studied across Canada.

3 GOALS OF THE REFORM

3.1 Stated

An official framework for authorizing multi-site research was released in December 2014. It outlines a "network approach" for governing the roles and responsibilities, reorganization and inter-institutional communication of research ethics review bodies within the RSSS network. The framework outlines the following priorities of the new delegated process of research ethics review and its primary stakeholders:

- Users of public institutions in the RSSS can safely participate in a larger number of high-quality research activities.
- Researchers are well accommodated and supported by the public institutions in the RSSS network whether or not these institutions have their own REB.
- The expertise of the REBs established by the public institutions in the RSSS network benefits the entire network (MSSS 2014).

One of the major procedural changes of the reform was to supplant full board review at each participating institution. Instead, a newly created "Authorization" representative authorizes the proposed research on behalf of the institution and under the conditions as approved by the nominated Board of Record. Figure 1 details this process. The MSSS further asserted in the framework that a more streamlined review process is key to enhancing Québec's competitiveness within the biomedical research enterprise by attracting top investigators to locate their research at Québec health institutions: "Thanks to contributions from all stakeholders, this approach [single ethics review] will boost the competitiveness of Quebec's research system on the national and international scene, as well as its ability to attract the best researchers to Quebec" (MSSS 2014, 1). The MSSS reform also intended to create a knowledge-sharing platform in which existing REB expertise could be made available to other public institutions under the MSSS umbrella (Laflamme 2015).

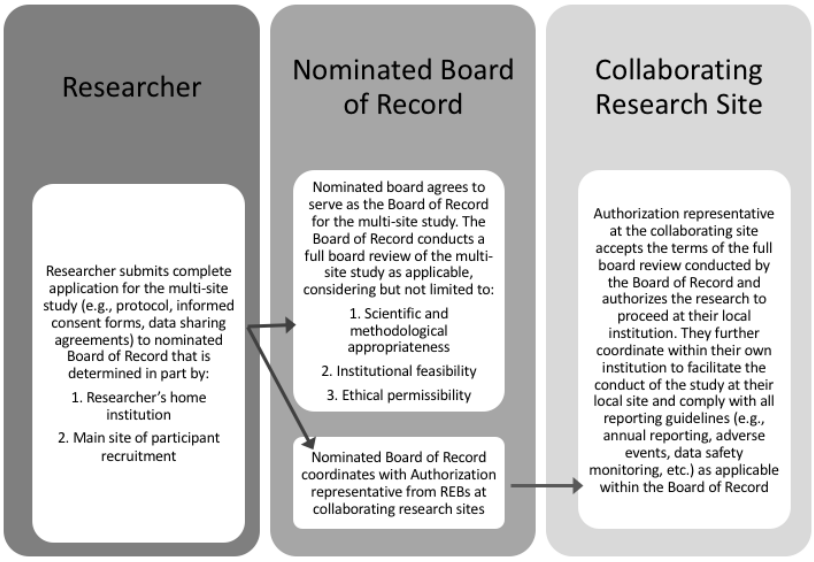

Figure 1: Multi-site research ethics review application process within the Réseau de la Santé et des Services Sociaux (RSSS) network

3.2 Implicit

The prior independent model of multi-site reviews required substantial financial and human resources. In addition to reducing administrative burdens, the transition to a delegated

review model should (theoretically) lower costs proportionate with the fewer full-board reviews necessary to approve multi-site studies, and reduce the overall time from submission to approval. The latter is especially critical in order to ensure large collaborative studies begin on time and can meet funding deadlines. Cost savings is therefore an implicit, albeit significant motivation for transitioning to a delegated model. Empirical evidence demonstrates the extent of such cost savings in the United States (Wagner *et al.* 2010), but similar evaluations have not yet been conducted in Canada.

The reform also implicitly mandates communication between existing institutional REBs for coordination purposes. It is the charge of a nominated Board of Record to communicate their decision to all participating sites, and coordinate the necessary authorizations. Such networking and coordination was nearly absent prior to the reform given that REBs operated independently of each other, and required institutionally-specific submission and consent forms.

4 FACTORS THAT INFLUENCED THE REFORM

Influential factors leading to the 2015 reform to research ethics review in Québec are summarized in Table 2 using the Lavis *et al.* (2012) framework. They are furthermore described in specific relation to how the reform was achieved, implemented and evaluated in greater detail in the sections below.

Table 2: Factors that influenced policy decision-making about research ethics review mechanisms in Québec based on the Lavis *et al.* (2012) framework

Key factors	Institutions
Government structures	• TCPS2 requires research ethics review for all protocols involving humans as a condition of federal funding. Provincial legislations regulate the composition, operation and activities of research ethics review boards that are complementary to the TCPS2. • Québec Civil Code mandates ethics review for all research involving human subjects. • Minister of Health and Social Services (MSSS) is authorized to make key decisions regarding the formation of research ethics committees, their composition and operating conditions, as well as monitoring activities.

Policy legacies	• MSSS left open the possibility for a truly delegated model when it adopted the 2008 edition of the framework. • The 2008 multi-site framework underscored the importance of multi-site, collaborative research, and set out an organizational structure for how such reviews would take place among the institutions within the Réseau de la Santé et des Services Sociaux (RSSS) network. • Bill 10 consolidated 180 health institutions into 34, which laid the organizational blueprint for how REBs would be organized in the 2015 framework.
Policy networks	• Approximately 40 REBs comprise the RSSS network. • MSSS shares responsibilities with 18 regional authorities that oversee the organization of services in their respective territories. • The Réseaux universitaires intégrés en santé (RUIS) consults key stakeholders in their service area, and submits proposals for policy amendments to the MSSS.

Key factors	Interests
Interest groups	• Health researchers currently conducting research involving humans in the province are required by law to submit their protocol for review prior to commencing their research; researchers who are drawn to conduct health research in the province due to the streamlined review process. • REB chairs acting on behalf of institutional administrations, and may exhibit protectionist attitudes towards reviewing protocols that implicate their own researchers or potential participants; institutions favour independent review namely out of concern for managing liability, ensuring quality of review and maintaining administrative oversight over all research activities occurring at the institution. • Community members and prospective research participants who must be assured of adequate ethics protections (i.e., privacy, consent, and minimized harms).
Civil society	• Lay community is represented by at least one mandatory community representative on each REB in the province.

Key factors	Values
Values	• Significant social and scientific value is placed on the translation of clinical research into practice. • Protections for humans involved in research are internationally codified in the United Declaration on Human Rights, Declaration of Helsinki and Council of International Organizations of Medical Sciences (CIOMS), for example. • Respect for persons, concern for welfare, beneficence and justice are dominant ethical principles in the conduct of research involving humans. • Privacy protection, data security, and data sharing are contemporary concerns of biomedical research participants and researchers. • Scientific and ethical imperative to collaborate in research requires similar degrees of collaboration among REBs and other forms of ethics governance. • Procedural efficiency of ethics review enables timely clinical innovation and translation. • Publication is the disciplinary currency of professional success in academia. Thus collaborative research can challenge the individualist notion of scientific discovery/contribution.
Research evidence	• Quantitative, qualitative and commentary articles from the literature highlight inefficiencies and procedural burdens associated with independent models of review for collaborative, multi-site studies. • New research consortia have been funded to ensure translation of research knowledge (e.g., Public Responsibility in Medicine and Research). • Privacy and data security platforms have been proposed by legal scholars and bioinformaticians which support collaborative health, and in particular biomedical, research.

Key factors	External factors
Major reports	The following reports identify the logistical and theoretical challenges of existing research ethics review mechanisms: • U.S. Department of Health and Human Services. 1998. *Institutional Review Boards: A Time for Reform.* • *Strategy for Patient Oriented Research Report (SPOR): An Overview of Research Ethics Harmonization in Canada: Strategy for Patient-Oriented Research Streamlining of Health Research Ethics Review*
Technological change	• Sophistication of genome sequencing tools which are now regarded as the primary scientific tools used for biomedical research • Realization of great statistical and computational power needed to ensure scientific soundness of empirical studies using whole genome/exome sequencing • Routinization of collaborative science in data-intense disciplines • Federal and provincial funding agencies mandate research collaboration in eligibility criteria • Creation of online REB submission platforms
Media coverage	• Press releases • Institutional announcements • Emails • Board of Governors Annual Reports

5 HOW THE REFORM WAS ACHIEVED

The new framework outlined in the 2015 *Mécanisme encadrant l'examen éthique et le suivi continu des projets multicentriques* was the culmination of numerous stakeholder consultations with representatives from the Réseaux universitaires intégrés en santé (RUIS) and personnel from the nearly 60 REBs it consolidated across the province (Jean and Pari 1991). The Ministry of Health, in partnership with the Fonds de recherche du Québec (FRQ-S) began stakeholder consultations in January 2013, and formally announced the policy would come into effect in late 2014 (subsequently modified to January 2015). Each of the four RUISs consulted ethics review leaders and hospital administrators in their respective territories and submitted their recommendations for moving towards a single review system to the MSSS in the summer of 2013. The collective findings were presented to RUIS representatives and the FRQ-S in fall of 2013, and a consensus was reached on the harmonized

system (thus ruling out independent as well as reciprocal systems) that would apply to all public hospitals in Québec by the end of 2013. The MSSS also proposed a feasibility timeline for implementing the reform based on the framework. The reform was rolled out in the following stages:

- *Summer 2014*: A number of institutions within the RSSS network piloted the delegated review model, developing training activities and determining optimal funding arrangements to support single review.
- *September 2014*: Four information meetings took place among members of the MSSS, the four RUIS, presidents and coordinators of research institutions within the network in order to finalize the policy framework.
- *October and November 2014*: Information meetings and training sessions were held with key stakeholders, including institutional REBs and researchers.
- *November 2014*: The 2015 MSSS framework was disseminated across the network.
- *1 December 2014*: The 2015 MSSS framework entered into force. A transitional period ensued and lasted until March 2016. A working group was also struck to provide financial support for existing institutional REBs that were to be phased out by the reform.
- *31 March 2016*: Transition period ended.
- *Spring and Summer 2016*: Initial reform evaluation began (MSSS n.d.).

The impetus for a province-wide revision to research ethics review organization and procedures dovetailed with pan-Canadian reports citing governance-related barriers to multisite research collaboration (Abbott *et al.* 2008). Although not explicitly related to research ethics review, Bill 10 provided a structured template for how the MSSS would reorganize ethics review bodies within the network. Bill 10 consolidated 180 health institutions into 34, many of which maintained research ethics boards of their own. This reduced by default the coordination burden of the new MSSS policy, facilitating its roll-out from initial implementation through to the end of the transition period in March of 2016.

6 EVALUATION

The MSSS reform took full effect across all Québec health institutions on 1 April 2015. Subsequent revisions to the original framework were proposed to accommodate human resource and administrative needs of REB staff, researchers and hospital administrations following the reform's transition period (ending in March 2016). The MSSS has engaged in ongoing community discussions to revise the underlying policy framework as necessary, and used preliminary analysis of REB administrative data to substantiate these revisions (MSSS 2016). Although too soon to conduct an evaluation of the new system's performance, the forced coordination among RSSS REBs is generating rich data that can be used to monitor (and compare) its performance to approval mechanisms before the reform. There is wide debate in the literature, however, how health services and policy researchers should measure

REB performance and quality. Costs associated with the approval process notwithstanding, metrics for assessing the "quality" of reviews—including measures of how well an REB protects research participants and ensures ethical treatment—as well as the trade-offs (if any) for review efficiency have not been adequately addressed in the literature.

The MSSS plans to conduct a more formal evaluation of the procedures, outcomes and reporting structures following the reform for quality improvement purposes once additional administrative data have been collected. To this end, the MSSS could benefit from the approach Alberta adopted to evaluate a pilot reciprocal model of ethics review (*Plan, Do, Study, Act*) (*The Alberta Health Research Ethics Harmonization Initiative Reciprocity Pilot Evaluation Report* 2011).

7 STRENGTHS, WEAKNESSES, OPPORTUNITIES AND THREATS

The provincial experience in transitioning to a delegated review model in Québec provides important insight into the processes and contexts that facilitate the model's more widespread adoption across Canada. The procedural disadvantages of the independent model in facilitating collaboration in research (most notably in fields of research that require multi-site collaboration), underscored the scientific rationale for reform from the researcher's perspective. The MSSS framework presents one major limitation, however. Because health and academic institutions fall under the purview of different provincial Ministries (Health and Education, respectively) the MSSS reform only applies to health institutions governed by the former. As a result, Québec maintains a dual (duplicative) ethics review governance system: one at health institutions separate from a parallel system of review at Québec academic institutions. It is too early to determine if the promises of a more efficient review system incentivizes researchers to pursue ethics approval from institutions that adopt delegated or reciprocal models. Yet, preserving this dual system may be a missed opportunity to foster true reciprocity and mutual recognition in ethics review across provincial and national boundaries. In contrast to other provincial policies—such as the Health Research Ethics Act of Newfoundland and Labrador—the new MSSS affords the benefits of the delegated model only to multi-site research studies conducted within the province of Québec, and then only to hospital-affiliated research in Québec. In effect, this stipulation narrows the pool of possible delegated agreements among research institutions (academic or otherwise), which should ideally include as many institutions and jurisdictions as possible to maximize the virtues of mutual recognition underpinning the delegated and reciprocal models. By imposing this intra-provincial stipulation, the MSSS may inadvertently (and counterproductively) discourage the inter-provincial research collaborations it intended to facilitate. Table 3 highlights the features of the delegated model that render it conducive to reviewing multi-site protocols from the perspectives of the REB (whose role is to represent the interests of participants in research) and researchers.

Table 3: Strengths, Weaknesses, Opportunities and Threats of adopting a delegated review model of research ethics review from the perspective of researchers and research ethics boards

Strengths	Weaknesses
• Streamlined approval process • Reduces delays, costs and inconsistencies • Enables (inter)national research collaboration • Harmonized ethics documents (e.g., consent)	• Indirect institutional oversight • Reliance on strong inter-institutional agreements and communication • Requires significant time and human resources
Opportunities	**Threats**
• Improved mechanism for REB reporting • Attracts more researchers • Increased funding for collaborative projects • Source of provincial revenue • Improved training and education in using data sharing tools	• Institutional liability • Lack of local oversight • Decline in quality of review when efficiency takes priority • Lack of methodological or other expertise • Sociocultural factors specific to local site not reflected in REB decisions

This reform analysis furthermore highlights the political and economic motivations that favoured the delegated over the existing independent model of ethics review in the province. The MSSS makes clear in its stated goals for reform that the delegated review model gives Québec a competitive research edge, and purports to attract leading clinical researchers to locate their research in the province. Already a leader in gross federal funding for health research (Canadian Institutes of Health Research n.d.), an efficient model of ethics review can help Québec remain a national leader. Upon analysis of the available public documents, one consistent message for reform was clear: the MSSS sought to improve the duplicative (bureaucratically-wrought) research ethics review process in order to encourage innovation, while still maintaining high standards of research protections.

An examination of the Québec reform goals and implementation history revealed that consolidating bureaucratic structures and addressing liability concerns at the local institutional level presented the greatest challenges toward realizing the full potential of the delegated (or reciprocal) review model. Therefore, the complexity of existing bureaucracies associated with REBs could predict the future implementation success of either model in other Canadian jurisdictions. Pullman, a major contributor to research ethics review

reform in Newfoundland and Labrador agrees, "The key lesson here is that establishing a comprehensive governance structure involves multiple institutions, and multiple levels of bureaucracy within those institutions" (2005, 78). Concerns of institutional liability, the quality of locally specific reviews and general oversight of internal activities substantiate—and sometimes for good reason—why institutions might continue to favour the independent model over its delegated or reciprocal counterpart (Townend *et al.* 2016). Fluid and timely communication between REBs at participating research sites is essential if the delegated and/or reciprocal review models can ensure adequate participant protections.

Both the United States (National Institutes of Health and the Department of Health and Human Services 2016) and Australia (Boult *et al.* 2011) enacted single-REB policies for multi-site collaborative research. Furthermore, the Ethics Review Equivalency Task Team of the Global Alliance for Genomics and Health released a practical policy guidance document for promoting mutual recognition at the international level. The globalization of research—and the collaborative partnerships forged as a result—means even jurisdictional specificities in ethics governance have international implications. That reforms to ethics review policies and procedures in otherwise vastly different healthcare jurisdictions appeal to similar principles of mutual recognition, however, points to at least some international consensus on the value added of centralized ethics review for facilitating collaborative research, data sharing and innovation (Rahimzadeh and Knoppers 2016).

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