Applying the Single REB Review Model for Multi-jurisdictional Minimal Risk Research

Guidance to support the implementation of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)*

Panel on Research Ethics

www.ethics.gc.ca

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Part I: Context

1. Introduction

The single research ethics board (REB) review model for multi-jurisdictional minimal risk research was introduced in the TCPS (2022) to respond to the needs of the research ethics community. The goal of the model is to streamline the research ethics review process where additional ethics reviews are not expected to add greater participant protections. This guidance highlights some of the key elements pertaining to the scope, applicability of, and considerations in selecting the single REB review model. Institutions, REBs, and researchers all have a role to play in adopting and applying the model.

2. Scope of the model

The single REB review model applies to minimal risk research (Chapter 2, Section B for a definition of minimal risk). This model applies to research that falls under the auspices or within the jurisdiction of more than one institution that is, research conducted "by their faculty, staff or students, regardless of where the research is conducted, in accordance with this Policy" (Article 6.1). There are two basic requirements for using the single REB review model: a) the model applies to institutions subject to the TCPS; and b) the REB reviewing the research (known as the reviewing REB) must be affiliated with an institution that is fully eligible to receive and administer funds from one or more of the three federal research funding Agencies (CIHR, NSERC, and SSHRC). This is based on the premise that eligible institutions are subject to the Agencies' shared principles, and accountability mechanisms through the *Tri-Agency Framework: Responsible Conduct of Research*.

Institutions and their REB(s) should consider adopting and selecting this model taking into account existing legislation requiring designated REBs for review in some jurisdictions, other existing harmonization mechanisms, and existing models and agreements (see section 5). REBs may choose to approve and select from multiple streamlining mechanisms for multi-jurisdictional ethics review, as appropriate for the research under review.

3. Why adopt the single REB review model of multi-jurisdictional minimal risk research?

Unless local circumstances merit additional scrutiny, a single ethics review of multi-jurisdictional minimal risk research should confer adequate participant protection, and ethics reviews by additional REBs are unlikely to enhance those protections. This is what the single REB review model of multi-jurisdictional minimal risk research purports, which is in line with a proportionate approach to research ethics review. Streamlining the ethics review process also supports the efficient management of REBs' time and resources where they are more likely to add value to participant protections, while reducing workload for researchers. For example, where there are substantive changes to multi-jurisdictional minimal risk research under this model, only the reviewing REB reviews the changes, while other REBs with jurisdiction over the research – referred to as local REBs – can accept and document the reviewing REB's decision, thereby avoiding unnecessary duplication of reviews, and facilitating the progress of ethical research.

Part II: Guidance

4. What is the single REB review model of multi-jurisdictional minimal risk research?

Where the research is of minimal risk and spans multiple jurisdictions, institutions approving the single REB review model authorize the review of the research by one REB, the reviewing REB. Only REBs affiliated with eligible institutions can undertake the role of the reviewing REB. All other local REBs affiliated with eligible and non-eligible institutions, where the research falls under their auspices or within their jurisdiction, accept the reviewing REB's decision based on a delegated or administrative review of the application materials submitted to and approved by the reviewing REB. Local REBs document their acceptance according to their internal institutional procedures (Application of Article 8.1).

As with other alternative review models outlined in Article 8.1, the single REB review model of multi-jurisdictional minimal risk research is optional and is subject to institutional approval (see section 6). It is of note that the TCPS does not require institutions to enter into official agreements to adopt this model, although they may decide to do so (Application of Article 8.1).

5. Is the single REB review model of multi-jurisdictional minimal risk research appropriate for all situations?

Any process that reduces the number of ethics reviews of multi-jurisdictional minimal risk research, while ensuring adequate participant protection, is appropriate. This may be through the single REB review model, as authorized by institutions, or through the use of existing or new streamlining mechanisms or harmonization efforts. In the absence of such mechanisms, the single REB review model should be considered for the ethics review of multi-jurisdictional minimal risk research.

However, there may be situations in which the single REB review model may not be possible, such as the case where the basic requirements for adopting the model cannot be satisfied. For example, a community or a for profit REB not affiliated with an institution eligible to administer Agency funds currently cannot be selected as the single reviewing REB. In this case, both the community/for profit REB and an REB affiliated with an eligible institution with jurisdiction over the research should review the research. A similar situation arises where an REB is not affiliated with an eligible institution but is most familiar with a special or vulnerable population or culture from which potential participants will be recruited. Ethics reviews by both the REB with relevant expertise as well as an REB affiliated with an eligible institution are required (see scenario 2).

Challenges

Some REBs may be hesitant to adopt the single REB review model as they may view it as an operational burden. This model is intended to simplify, build on existing institutional mechanisms, and streamline the ethics review process rather than add another layer of operational requirements. Institutions should select the simplest administrative path to implement the single REB review model.

Moreover, some institutions may be concerned with potential liability claims. Liability issues are an institutional (not the REB's) responsibility and are unlikely to occur based on the current scope of the single REB review model. REBs should consult with their institutional insurance and risk assessment offices on these issues.

Contextual considerations

Contextual considerations are also important when determining the appropriateness of the ethics review model. In addition to their obligations based on the *Agreement on the Administration of Agency Grants and Awards by Research*, institutions are subject to institutional, regional, and local requirements such as privacy laws or other provincial requirements beyond the ethics review process. For example, some jurisdictions already have intra-provincial mechanisms for streamlining review of certain types of research; while others have legislation that mandates designated REBs to conduct the ethics review. In such contexts, instead of having a single reviewing REB, streamlining may entail a reduction in the number of reviewing REBs. This may vary depending on jurisdiction or institution (see scenario 3).

Examples of existing streamlining mechanisms

Some institutions have already worked together to implement successful streamlining mechanisms and agreements. Examples include Research Ethics BC, the REB Exchange (REBX) (maintained by the University of Calgary and the University of Alberta), Saskatchewan's Provincial Reciprocity Agreement, the Health Research Ethics Board (HREB) in Newfoundland and Labrador, and Quebec's Cadre de référence des établissements publics du réseau de la santé et des services sociaux pour l'autorisation d'une recherche menée dans plus d'un établissement.

6. What role do *institutions* play in streamlining ethics review of multi-jurisdictional minimal risk research based on a single REB review model?

Institutions select and authorize the ethics review models that their REBs may use or participate in (Article 8.1). Typically, the process for selecting and authorizing these models is carried out in consultation with their REBs and, where feasible, builds on existing collaborations between REBs at other institutions. Once an institution authorizes the model that their REB may use, the REB can use its discretion to apply the most suitable review model for the research, without the need for further institutional authorization.

Communicating the institution's authorization

Where institutions have authorized the use of a single REB review model, they should inform their research community. In practice, this may include

incorporating language in institutional policies that indicates that the institution permits the single REB review model for multi-jurisdictional minimal risk research, in accordance with the requirements in the TCPS, and that the REB may accept the ethics review of one of the other local REBs. Other institutions may include their authorization in their standard operating procedures outlining their approved mechanisms for the single REB review model.

Encouraging the sharing of information related to multi-jurisdictional research ethics review

Institutions should strongly encourage their researchers and REBs to share information with and among other local REBs related to the multi-jurisdictional research and the streamlining model in place for the ethics review. This sharing enables institutions, for whom the research falls under their auspices or within their jurisdiction, to effectively exercise their other responsibilities tied to the multi-jurisdictional research or administrative requirements (e.g., to support satisfying their financial obligations and the release of research funds). Communication and sharing of information among REBs contribute to the effective delivery of their mandate of ethics review on behalf of their institution and fulfill their other institutional administrative responsibilities (see section 7).

7. What role do *REBs* play in streamlining ethics review of multi-jurisdictional minimal risk research based on a single REB review model?

REBs have the autonomy to determine which of the review processes/models, authorized by their institution, they will use for each application they receive (Article 8.2).

Selecting the reviewing REB

It is typical, though not mandatory, for the Principal Investigator's (PI) REB to serve as the reviewing REB designated to conduct the ethics review. Where the context of the research suggests the need for a different reviewing REB, the selection of the reviewing REB is determined by the PI's REB based on the PI's justification, and if relevant, existing agreements or mechanisms for multi-jurisdictional ethics review (Application of Article 8.2). This may be the case if the PI's institution is not eligible to administer Agency funds (see section 4), and/or if a different research team member's institution is eligible and has more relevant experience, expertise, and knowledge to review the specific research under

review. In this instance, a local REB can be assigned as the reviewing REB. Other factors such as the REB's familiarity with the potential participant pool, or proximity to the research site, may also be considered when deciding which REB will take on the role of the reviewing REB.

Role of the reviewing REB

In the single REB review model of multi-jurisdictional minimal risk research, the reviewing REB makes the determination on the ethical acceptability of the research. The reviewing REB conducts both the initial and continuing ethics reviews. It develops a plan for how to manage the review of changes to the research as part of the continuing ethics review throughout the life of the research (see section 9).

Typically, the reviewing REB makes the determination on whether the research is of minimal risk. Local REBs should accept this determination unless they have a justification to reject it. If the proposed research is less well known to the local REB, they are encouraged to accept the reviewing REB's determination (see scenario 5).

Role of local REBs

Local REBs with jurisdiction over the research accept the reviewing REB's decision based on a delegated or administrative review of the application material. If a local REB identifies a local circumstance/contextual element that was not considered, or a substantive ethics issue that was missed, the reviewing REB should be notified of these for further consideration. The intention is to keep the reviewing REB as the sole REB that can make changes to the terms of the ethics approval.

Examples of local circumstances that might warrant notifying the reviewing REB for reconsideration include issues that only affect a locally recruited population (e.g., language, culture) or are imposed by unique characteristics of the local site (e.g., remoteness, limited access to necessary resources to support local participants, and issues specific to the local researcher). Other examples include statutory requirements (federal, provincial, or those of the country where the research is being conducted) that would have an impact on how the research is conducted, as well as substantial differences in access to services or standards of care normally followed at the local site.

Local REBs "fulfill their responsibility under Article 6.1 by indicating and documenting their acceptance of the reviewing REB's decision" (Application of Article 8.1). Akin to other alternative review models that are based on official agreements, the delegated reviewer's decision to accept the reviewing REB's approval of the multi-jurisdictional minimal risk research should be reported to their respective REB, on an informational basis (Application of Article 8.1).

Documenting REB decisions

The final package of materials that researchers submit to the reviewing REB, evidence of ethics approval by the reviewing REB, and written confirmation of the local REB's acceptance of the reviewing REB's decision are examples of documentation that local REBs should keep in their records.

The receipt and acceptance of a reviewing REB's decision may be documented in different ways, depending on existing research ethics administrative processes within the local REB's institution. For example, some institutions with online systems may rely on abridged applications that their researchers would use to submit the reviewing REB's materials and that would also document the local REB's acceptance of the external review. These applications would result in local ethics files that could support financial reporting obligations and other institutional requirements.

Communicating among REBs

In the event that a local REB has a concern about an application being reviewed by the reviewing REB, it should contact the reviewing REB to discuss the matter and seek a resolution. REBs are encouraged to communicate among themselves, especially when it pertains to issues that uniquely affect a local population or unique circumstances at the local site(s). Ultimately a local REB may reject the approval of the reviewing REB and conduct its own review if local considerations are not adequately addressed. This is expected to be very uncommon.

8. What role do *researchers* play in streamlining ethics review of multi-jurisdictional minimal risk research based on a single REB review model?

Researchers should consider how the ethics review of their multi-jurisdictional research will be conducted "at the planning and design stage of their research

and should consult with their REBs to facilitate the selection and coordination of the appropriate review model" (Application of Article 8.2). This includes but is not limited to considering circumstances unique to the sites involved, such as specific participant demographics, language, and culture not necessarily present at other sites, and relevant legislation at those sites.

Informing and sharing information with their REB

To support the single REB review model and ensure familiarity with local issues and particular populations "[r]esearchers … should bring to the reviewing REB's attention, particular characteristics of the local population at individual sites, differences in values and cultural norms, or relevant differences in laws or guidelines that may have a bearing on the review" (Application of Article 8.1). Researchers should ensure that the materials submitted to the reviewing REB include contact information for the local REB(s) to facilitate communication among the REBs, where needed.

Once their research is approved by the reviewing REB, the PI and, where applicable, the co-investigators/local researchers should submit the documentation that was approved by the reviewing REB, including evidence of ethics approval, to the local REBs. This will facilitate the local REBs role in (a) accepting the reviewing REB's decision, and (b) documenting that acceptance.

9. How should continuing ethics review be managed for multi-jurisdictional minimal risk research reviewed by a single REB?

"Continuing ethics review of research involving multiple institutions and/or multiple REBs should also be determined at the outset and be consistent with Article 6.14" (Application of Article 8.1). As with all research subject to the TCPS, researchers should report to their REBs any unanticipated issues that may increase the level of risk or have other ethical implications in the research and should submit for ethics review proposed changes to the research as part of the continuing ethics review process (Article 6.16). Multi-jurisdictional research is no exception.

Planning the ethics review of changes to the research

Multi-jurisdictional research may involve the same research activities being carried out at each site/by each co-investigator or different research activities, possibly following different schedules, from one site/co-investigator to the next. "Typically, the reviewing REB would […] conduct the continuing ethics review of the research outlined in Article 6.14" (Application of Article 8.1).

For research lasting more than a year, the reviewing REB should develop a plan for the continuing ethics review process, including how communication will occur with the local REB(s). Normally, research-driven unanticipated issues and substantive changes to the research that have ethical implications or change the level of risk for participants (whether study-wide or site-specific) should be discussed by co-investigator(s) and the PI prior to reporting to the reviewing REB. Once both the PI and co-investigator(s) agree with the change or are aware of the unanticipated issue, the PI should inform the reviewing REB (Articles 6.15 and 6.16). Local REB(s) should inform the reviewing REB of newly arising operational and/or other pertinent local considerations that may have an impact on the review of the research as part of its continuing ethics review process. This will inform the continuing ethics review conducted by the reviewing REB. Researchers and REBs with jurisdiction over the research should be sensitive to the context of the research, the local populations at different sites, and other applicable local laws and requirements (see scenario 4).

REBs are encouraged to streamline the continuing ethics review process, including the review of substantive changes or unanticipated issues. In planning for the continuing ethics review process, the reviewing REB should consider that the research activities and that their review may not occur concurrently for some research. The reviewing REB should acknowledge/consider that some local REBs may ask or need to be involved in the review of certain aspects of the research at the initial and ongoing phases of the research.

Documenting changes to the research

Local REBs should document their acceptance of the reviewing REB's approval of changes and renewals to the research.

Part III: Practical Application

The following scenarios are intended to provide practical application of this guidance. They are examples that may not necessarily apply to the specific

context of certain research. When in doubt, researchers should consult with their REBs, and provide them with available details of the proposed research.

Scenario 1: Research conducted in another country

Context
Collaborative minimal-risk research is conducted by researchers affiliated with three Canadian institutions, all eligible to administer Agency funds. The research is conducted in another country.

Can the single REB review model apply?
If the institutions authorize the single REB review model, their REBs can select one single reviewing REB in Canada. The default is that the PI's REB be the reviewing REB in Canada. The research remains subject to the ethics review process in the other country as well (Article 8.3).

Scenario 2: Eligibility of a community REB to act as the reviewing REB

Context
Minimal risk research involving a community is conducted across multiple jurisdictions. The community's REB and several institutional REBs have jurisdiction over the research. The community REB has the relevant knowledge of the potential pool of participants, but only the PI is affiliated with an institutional REB that is eligible to administer Agency funds.

Can the community REB qualify as the reviewing REB?
If the community REB is eligible to administer Agency funds and has the required knowledge to review the application for its ethical acceptability, the PI can provide justification to their institutional REB and request that the community REB acts as the single reviewing REB. That is provided that the community REB has the capacity to review the application and is willing to take on the responsibility of the ethics review.

If the community REB is currently ineligible to administer Agency funds, the PI must request the ethics review by the institutional REB as well as the community REB (Article 9.3). If there is uncertainty about the REB's eligibility, refer to the CIHR, NSERC, and SSHRC websites for a list of their eligible institutions.

Scenario 3: Research conducted across provinces

Context
Minimal risk research is conducted in multiple Canadian provinces, some of which require the research to be reviewed by a designated REB in the province.

Can the single REB review model apply in this context?
Not all provinces have established streamlining mechanisms or legislation requiring that a designated REB reviews the research. The researcher should submit the research to designated REBs in provinces where this is required. In other provinces, the single REB review model can be applied if authorized by the institution and selected by the REB(s) with jurisdiction over the research. While this does not mean that a single REB reviews the research, it can result in a reduction in the number of reviewing REBs.

Scenario 4: Managing changes to the research under the single REB review model for multi-jurisdictional minimal risk research

Context
Researchers conducting multi-jurisdictional minimal risk research each contribute specialized expertise to the research. The PI's REB acts as the reviewing REB and the other local REBs have accepted and documented the approval of the reviewing REB. During the second year of the research, a co-investigator would like to introduce a substantive change to the research and discusses it with the PI.

What steps should be taken to manage the ethics review of the changes to the research?
If the PI agrees with the change, they should then inform the reviewing REB of the change. From the outset, and as part of the initial review, the reviewing REB should have established a process for continuing ethics review, including the review of changes throughout the life of the research. This plan may include that the reviewing REB would be the sole reviewer of all changes, or that another local REB with expertise in the proposed change may be selected for the review of the change. In any case, the PI/co-investigators or preferably the reviewing REB must inform all other local REBs of the change. They should also be informed

of the decision made by the REB selected to review the change to enable all REBs to accept and document those decisions.

Scenario 5: Importance of communication among REBs

Context
Minimal risk research is conducted by a single researcher affiliated with an eligible institution at which the REB will act as the reviewing REB. The research involves the same activities (i.e., collecting data) at different institutions across Canada, many of which are eligible to administer Agency funds. One of the local REBs disagrees with the level of risk involved in the research and believes it to be more than minimal risk.

What steps should be taken to resolve the disagreement on the level of risk involved in the research?
If the researcher does not have co-investigators at the other institutions, they will need to play an integral role in ensuring that the sharing of information and communication is occurring among REBs to address the disagreement. The researcher should provide the reviewing and local REBs with the name and contact information of all REBs involved to facilitate direct communication between the REBs.

The reviewing REB should take an active role in striving to resolve the disagreement, and should consider if there are any local issues that it may be unaware of. In doing so, consideration should be given to the grounds for disagreement provided by the local REB, and the experience and knowledge of the local REB on the issue. The reviewing REB should also recognize that some REBs with limited experience in the research topic may reach different conclusions by overstating or understating the level of risk involved in the research.

Having the reviewing REB make the determination on the level of risk can give local REBs comfort and reassurance to accept this determination. Normally, local REBs should accept the determination of risk level by the reviewing REB and follow the single REB review model. The local REB that determines that the specific local context dictates a more than minimal risk level for the same research can conduct its own full REB review, but this is not expected to be common practice.

Scenario 6: Different institutional requirements

Context

Minimal risk research is conducted by a team of researchers affiliated with several Canadian institutions that have authorized the use of the single REB review model. However, the institutions involved have different training requirements for researchers leading the research. For example, some institutions require their researchers to successfully complete specific research ethics training before they can start their research, while the institution of the reviewing REB does not. As a result, some of the local REBs may be reluctant to accept the reviewing REB's approval given the differences in the training requirements.

How can REBs address the differences in their institutional requirements in order to adopt the single REB review model?

Local REBs' acceptance of the ethics review of multi-jurisdictional minimal risk research by the reviewing REB builds on trust relationships, collaboration, and communication amongst researchers, REBs and institutions. This is a scenario where advance discussion and planning by the research team, and direct communication and dialogue among REBs can help resolve any concerns regarding the differences in their institutional requirements, including whether those differences are relevant in the context of the research under review.

There are several possible solutions to support differences in ethics training, while recognizing that this is occurring in a minimal risk context:

- The local REB's acceptance of the reviewing REB's approval includes verifying that the local researchers meet the training requirements without extending those requirements to researchers at other sites (including that of the reviewing REB);
- The researchers at the reviewing REB's institution complete the training required by the local REBs in order to facilitate the single REB review process; or
- The reviewing REB requires specified training for all participating researchers at all sites for the research at hand.