This document was originally published in French under the title "*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,* by the *Ministère de la Santé et des Services sociaux* (MSSS) in Quebec. The MSSS does not assume responsibility with regards to the English translation and for any damages, losses or prejudices that may result. In the event of contradiction between the English and the French text, the latter prevails.

Framework for Quebec Public Health and Social Services Institutions to Authorize Research Conducted at More Than One Institution

Ministère de la Santé et des Services sociaux

Updated April 1, 2016

The original French version of this document was prepared by:
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The masculine form is employed throughout this document for purposes of legibility; no discrimination is intended.

The English translation of the document was commissioned by RUIS McGill.

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INTRODUCTION TO THE APRIL 1, 2016, UPDATE

In January 2013, the Ministère de la Santé et des Services sociaux (MSSS), in association with the Fonds de recherche du Québec – Santé (FRQS) and the four integrated university health networks (RUIS), embarked on a process for the recognition of ethics reviews within the public institutions of the Health and Social Services network (RSSS). The goal of this process was to have any research project conducted at more than one public institution in the RSSS undergo a single ethics review that would be recognized by the other institutions involved in the project.

The four RUIS conducted extensive consultations with key players in the territory they serve, and their proposals were submitted to the MSSS in the summer of 2013. The proposals were studied, and the results were presented to RUIS and FRQS representatives in fall 2013. Consensus was reached at the end of this process, and a harmonized system was established for all public health and social services institutions in Quebec.

Any research project conducted at more than one public institution in the RSSS under the jurisdiction of a board of directors therefore undergoes only one ethics review by a research ethics board (REB) in the RSSS. The new procedures are described in *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*. They came into effect on February 1, 2015, thus replacing the "Mécanisme encadrant l'examen éthique et le suivi continu des projets multicentriques" introduced in 2008 (the "2008 Multicentre Mecanism").

This Framework is intended to be an evolving document and will be updated periodically. The version dated November 21, 2014, contained transitional provisions that are no longer included in the version dated April 1, 2016, excepting the one that maintains, until June 30, 2016, the parameters for invoicing private companies that were applied by the institutions prior to February 1, 2015. Section 13.2 was thus amended to extend the status quo until the standardized fee schedule for the public institutions in the RSSS comes into effect when it is released as a ministerial circular.

The wording of some sections in the Framework was revised, and clarifications were added to reflect the questions and comments received as well as data collected during the follow-up process completed with the cooperation of REBs in RSSS institutions designated as university centers. The changes do not substantially alter the previous version of the Framework. They are mostly intended to clarify procedures.

There are, however, two new requirements applicable starting July 1st, 2016: the use of the revised template for the Letter of Institutional Authorization to conduct the research (Appendix 3) and the new guidance to REBs and persons mandated by the institution to authorize research pertaining to the transmission of documents to stakeholders (Articles 6, 8, 11 and 12).

In summary, the additions made in April 1st, 2016 will clarify:

- The context in which Quebec public institutions and their REBs work as a network with all stakeholders.
- How to apply the Framework when institutions are added to projects already under way (sec. 2.3 and 2.4) and when requesting the authorization for banking data or biological materials for research purposes (sec. 2.5).
- How to apply the Framework when creating data sets or biobanks for research purposes after February 1, 2015, or when contributing to such a data set or biobank (sec. 6.5, 9.1, 10.2 and 11.5).

- How the reviewing REB will apply the Framework when a sub-study is added to a research project already under way. The REB will issue a statement with the date of the ethics review of the sub-study. This statement will be presented by researchers to their public institution with the request that the site-specific assessment of the sub-study be started by the institution before receiving the positive result for the ethics review of the sub-study (sec. 2.1, 6.1, 7.1).
- How the researcher and the reviewing REB should attend to their obligations under the French Language Charter, with respect to filing and reviewing the consent form in French (sec. 6.2, 8.1, 8.4, 8.5 and 11.1).
- How the reviewing REB will terminate the procedure after a waiting period when the researcher fails to provide an answer to REB's comments on the project (sec. 7.5 and 8.3).
- How the person mandated to authorize research to be conducted in the institution will apply the new guidance pertaining to the documents that must accompany the authorization letter, specifically the consent form in French to be used at the institution (sec. 11.6, 11.7 and template in Appendix 3), will provide the reviewing REB with the consent form used in the institution (12.5) and will follow-up, at least annually, on the authorization given by the institution (sec. 11.5, 11.10).
- How the reviewing REB will apply the new guidance for the provision of documents to the stakeholders, including the sponsor if requested: statement as reviewing REB (6.3), ethics review (8.5, 11.2) and ethics oversight decisions (12.4).
- How the sponsor will proceed when acting with more than one researcher in order to conduct the same research in more than one public institution (Appendix 2).
- How the person mandated to authorize research in the institution will use the new template provided for the Authorization letter (Appendix 3).

The Framework is an agreement between public institutions and is aimed both at protecting the participants in the research and fostering the excellence and vitality of research in the RSSS. It allows an REB to put its expertise to use not only for the institution it reports to but also for the other public institutions in the RSSS participating in the same research project. This approach has become possible because the REBs have consolidated their expertise over the years and established trust beyond the confines of their own institution. Thanks to contributions from all stakeholders, this approach will make the public health and social services institutions more competitive nationally and internationally, as well as boosting their ability to attract top researchers to Quebec.

CONTEXT

This document describes how public institutions in the RSSS will harmonize their procedures in order to facilitate the interactions between stakeholders when reviewing, authorizing and conducting multicentre research projects.

This Framework introduces a network approach to the authorization of multicentre research projects so that:

- 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, whether or not these institutions have their own REB;
- the expertise of the REBs established by the public institutions in the RSSS benefits the entire network.

A network approach to authorizing research projects

The Framework sets out the rules that enable public institutions in the RSSS to authorize research projects at their institution or under their auspices by recognizing an ethics review conducted by an REB in the RSSS, whether or not the REB is located in the institution where the research will be conducted.

The Framework governs the interactions between the public institutions in the RSSS and the REBs, researchers and sponsors. Other staff members at the institutions whose work supports an REB or who work in an ethics office or research centre also contribute to the smooth operation of research activities. Their role is not governed by this Framework, but they still make a valued contribution. Their expertise should continue to be sought so that the research activities in the RSSS are not reduced to perfunctory interactions but rather, reflect a genuine concerted effort.

The terms and conditions in this Framework will require researchers, institutions and their REBs to adjust their interactions to take into account the fact that other RSSS institutions are involved in the same research project and to be aware of the effect this has throughout the network.

Network approach in a public institution

Governance: The board of directors of a public institution where multicentre research projects are conducted will:

- Identify in the institution's by-laws the person who is formally mandated to authorize a researcher to conduct research at the institution or under its auspices. This person shall ensure that the scientific review, ethics review and site-specific assessment for the project are all positive before granting authorization to the researcher. The operational and organizational procedures used by the formally mandated person are under the institution's jurisdiction.
- Adopt the changes required in the institution's regulatory framework for research activities when needed for the application of the Framework.

Institution's liability: In accordance with the terms and conditions of their liability insurance policy, the public institutions will recognize an ethics review only when provided by an REB acting under the jurisdiction of the board of directors of a public institution in the RSSS, or provided by the Comité central d'éthique de la recherche (CCER) formed by the Ministère de la Santé et des Services sociaux.

Hosting researchers: Public institutions conducting multicenter research projects will provide the following information to the researcher:

- The name of the person formally mandated to authorize research to be conducted in the institution and how to communicate with this person. This information will also be provided to the MSSS.
- The procedure for requesting a site-specific assessment of the project at the institution and obtaining recognition of the ethics review and the authorization to conduct the research under the jurisdiction of the institution.

Network approach for a reviewing REB

Communication: The reviewing REB gives top priority to maintaining communications with the researcher who requested the ethics review and the person who authorized the research at each institution. When the REB at an institution did not serve as the reviewing REB, the reviewing REB agrees to cooperate to resolve any problems, at the request of the person who authorized the research at this institution. The Framework sets out communications channels, so that the required authorizations can be provided within the required timeframe. These channels will function even better if the researchers, the people authorizing research at the institutions, the REBs and the administrative support staff take the initiative to participate voluntarily in any other communications aimed at improving oversight of research activities in the RSSS.

Local populations and circumstances: The reviewing REB takes into account the fact that the research project extends beyond the institution where the REB is located. It requires the researcher to provide any useful information about local populations and circumstances that may have a bearing on the ethics review. The reviewing REB also advises the researcher so that the documents pertaining to the research project, including the consent form, are presented in a format that can be used at several institutions.

Administrative procedures: The REBs of the public institutions in the RSSS shall adopt best ethical practices for research, for example, by applying standard operating procedures (SOP); they must be able to account for the integrity of their methods. When the REB acts as reviewing REB, it makes its expertise available to all researchers and all public institutions in the RSSS who agree to participate in the same project. Since the reviewing REB's actions are not limited to the institution it is attached to, these administrative procedures must allow for discussion and circulation of documents with other institutions in the network that are participating in the same project, whether or not these institutions use IT platforms. Special attention must be paid when the same project is conducted by a sponsor with several researchers, each one in charge of the project in his or her own institution. A researcher who asks for an ethics review for the benefit of all researchers conducting the same project in their own institution should not be placed in a situation in which he or she is required to substitute for the researchers at the other institutions when performing tasks.

Network approach for a researcher

One or several researchers for the same multicenter research: When the same research project is conducted at several public institutions in the RSSS, there are two different cases. A single researcher responsible for a project and supported by a team of collaborators may conduct the same research at several public institutions in the RSSS. This situation differs from that in which several researchers act individually with a sponsor to conduct the same research, each at their own institution and with sole

responsibility for the project. This is generally the situation with clinical trials funded by a private sponsor, for which each participating institution/researcher signs a contract with a sponsor.

Both cases are covered by the Framework and, where applicable, guidelines are provided.

Local populations and circumstances: When a researcher seeking authorization to conduct research at a public institution in the RSSS asks a REB to act as reviewing REB or uses a copy of a declaration or ethical approval from a reviewing REB, he also provides this REB with any information about local populations and circumstances that may have a bearing on the ethics review of the project.

Banking data or biological materials for research purposes: At a public institution in the RSSS, the creation and use of data sets and/or biobanks for research purposes shall be managed in accordance with the institution's regulatory framework for research activities. When a researcher wishes to contribute to a data set or biobank located at a public institution in the RSSS other than his own, or one that involves the contribution of more than one public institution the Framework shall apply if the data set or biobank was set up after February 1, 2015. Section 2 sets forth optional provisions regarding data sets or biobanks established before February 1, 2015.

When one or more public institutions in the RSSS start contributing to a data set or biobank established after February 1, 2015, the REB responsible for the ongoing ethical oversight of the data set or biobank becomes the reviewing REB for the newly contributing public institution(s), unless the management framework for the data set or biobank specifies otherwise.

When a research project involves banking data or biological materials, the researcher shall ensure that the documents used to obtain participants' consent allow the reviewing REB to be satisfied that the participants have been properly informed and that a clear distinction is made between consent to participate to the research project and consent to the banking of data or biological materials. In order to establish whether it is appropriate to use separate consent forms, the researcher shall find out in advance about the practices and policies in effect at the public institutions that might take part in the project.

Network approach for a sponsor

Choosing which one of the researchers will request the ethics review: When a sponsor seeks to conduct the same project with several researchers each one of them being responsible for the conduct of the research at his or her own institutions, the sponsor and one of these researchers shall agree to ask a REB in the network to act as reviewing REB.

The researcher who is designated to request the ethics review shall agree with the sponsor on how to proceed so that the other researchers with whom the sponsor wishes to work on the same project at public institutions in the RSSS can easily access the documents they need to request this authorization, including the reviewing REB's declaration, the letter from the reviewing REB with the result of the ethics review, the network version of the consent form in French and the final version of the documents pertaining to the project approved by the reviewing REB.

Document format: The sponsor plays an important role in ensuring that the documents relating to the research project, including the consent form in French, are written to reflect the fact that they will be used at more than one public institution in the RSSS. The consent form approved by the reviewing REB should therefore be formatted in a way that makes it easy to identify where each of the researchers can fill in the administrative information required for the use of the form at a specific institution.

1. DEFINITIONS

1.1 **REB**: Research Ethics Board.

1.2 **Reviewing REB**: An REB that, after determining if it meets the requirements, agrees to review a research project that will be conducted at more than one public institution in the RSSS. The REB shall be established by the board of directors at one or more public institutions in the RSSS or be the Comité central d'éthique de la recherche (CCER) formed by the Ministère de la Santé et des Services sociaux.

1.3 **CCER**: Comité central d'éthique de la recherche formed by the Ministère de la Santé et des Services sociaux.

1.4 **Researcher**: A person whom a public institution in the RSSS recognizes as a researcher or to whom it grants research privileges under the conditions specified in the *Act respecting Health Services and Social Services*. For the purposes of a specific project, the public institution may also recognize the status the researcher obtained at another public institution, university or CEGEP in Quebec, or that has already been recognized by a funding agency of the provincial or federal government.

1.5 **Institution**: A public institution in the health and social services network (integrated centres may include grouped institutions all administered by the same board of directors), which is covered by the liability insurance program of the Direction des assurances du réseau de la santé et des services sociaux (DARSSS) and governed by the *Act respecting Health Services and Social Services* and the *Act to modify the organization and governance of the health and social services network, in particular by abolishing the regional agencies*.

1.6 **MSSS**: Ministère de la Santé et des Services sociaux.

1.7 **Person formally mandated by the institution to authorize research**: The executive director of a public institution, or a member of the personal of that institution as determined by by-law of the board under section 169 of the *Act respecting Health Services and Social Services,* mandated to authorize a research project to be conducted at the institution or under its auspices.

1.8 **Sponsor**: A natural or legal person, a public or private institution or organization in charge of funding a research project. The definition includes an organization or person that the sponsor has contracted to perform one or more tasks or functions tied to the research project.

1.9 **Research**: Must be understood broadly to include any research activity in the health and social services domain that involves human participants, including banking of data or biological materials for research purposes. Research activity with human participants must be understood broadly to include personal information, human remains, biological material of human origin, body fluids, cadavers, gametes, embryos, foetuses and information or data arising from biological material of human origin that may or may not serve to identify the person with whom they are associated.

1.10 **RSSS**: Réseau de la santé et des services sociaux.

1.11 **Active means for ethics ongoing oversight:** The review of the conduct of the research and related documents carried out by a body that is independent of the researcher and the sponsor.

1.12 **Passive means for ethics ongoing oversight**: The review carried out by the REB based on notifications it receives from a researcher or sponsor while the project is under way.

2. SCOPE OF THE FRAMEWORK

Ministerial directive, mandatory as of February 1, 2015, applicable to new research projects (or sub-study added to an on-going project) conducted at more than one public institution in the RSSS

2.1 This Framework is a ministerial directive that shall apply to any new research project (or sub-study added to an on-going project) conducted as of February 1, 2015, in whole or in part, at more than one public institution (integrated centres may include grouped institutions administered by the same board of directors) in the RSSS, according to the terms "research," "public institution" and "RSSS" as used in this document. This Framework does not, however, apply to research governed by the *Act respecting clinical and research activities relating to assisted procreation.*

The review of a sub-study added to an existing project is handled in the same way as a review for any new research project. If requested by the researcher, the reviewing REB may provide a declaration indicating the date on which it will review the sub-study, as indicated in section 7.1.

This Framework replaces the 2008 Multicentre Mechanism

2.2 Effective February 1, 2015, this Framework shall replace the Mécanisme encadrant l'examen éthique et le suivi continu des projets multicentriques that came into effect April 1, 2008. For research projects already in progress that are governed by the 2008 Multicentre Mechanism at February 1, 2015, the REB acting as main REB shall become the reviewing REB and perform its duties beginning with the first annual renewal of the project's ethical approval after April 1, 2015. The main REB that thereby becomes the reviewing REB sends a copy of its ongoing ethical oversight decisions, along with documents deemed useful to support these decisions, to the person mandated to authorize research at each of the participating institutions.

Adding a participating institution to a project reviewed by several REBs with easing of rules in the 2008 Multicentre Mechanism

2.3 This Framework may apply when one or more institutions are added to a research project already under way at February 1, 2015, whose ongoing ethical oversight is currently provided by several REBs in the RSSS. The researcher wishing to conduct the same research at an additional public institution may ask one of these REBs to act as reviewing REB for the new institution. The REB is not bound to accept this request. Once a REB has agreed in writing to act as reviewing REB for the project, a researcher may not obtain declarations from the other REBs.

The REB that agrees to act as reviewing REB provides the researcher with a written declaration, under conditions it feels are appropriate, specifically with respect to the prior submission by the researcher of the consent form to be used at the new participating institution and disclosure of local circumstances. As needed, it gives the researcher a copy of the REB's ethical approval of the project and approval of any changes made to the initial project, along with any other relevant documents so the researcher can request authorization to conduct research at the institution.

The REB that agrees to become reviewing REB for a new institution shall act as reviewing REB for any public institutions added subsequently. The other REBs that have granted their ethical approval for the same project prior to February 1, 2015 continue to conduct ongoing ethical oversight of the project at their institution, according to the 2008 Multicentre Mechanism.

Adding a participating institution to a research project already under way at a single public institution in the RSSS at February 1, 2015

2.4 The researcher wishing to conduct research already under way at February 1, 2015, at a different institution may ask the REB that conducted the ethics review of this project to act as reviewing REB and to provide a declaration to this effect. The REB is not bound to accept this request.

The REB that agrees to act as reviewing REB provides the researcher with a written declaration, under conditions deemed appropriate, specifically with respect to the prior submission by the researcher of the consent form to be used at the new participating institution and disclosure of local circumstances. As needed, the REB provides the researcher with a copy of the ethical approval of the project and approval of any changes made to the initial project, along with any other relevant documents so that the researcher can request authorization to conduct research at the new institution.

The REB that agrees to become reviewing REB for a new participating institution shall act as reviewing REB for any public institutions added subsequently

When a new institution seeks to contribute to a data set or a biobank existing at February 1, 2015, in the RSSS

2.5 The researcher who seeks to contribute data or biological materials to a data set or a biobank established for research purposes by one or more public institutions in the RSSS prior to February 1, 2015, or in which one or more public institutions in the RSSS participated at February 1, 2015, may ask one of the REBs providing ongoing ethical oversight of the data set or biobank to act as reviewing REB, under this Framework.

The REB is not bound to accept this request. The REB that agrees to act as reviewing REB provides the researcher with a written declaration, under conditions deemed appropriate, specifically with respect to the prior submission by the researcher of the consent form to be used at the new contributing institution. It provides the researcher with a copy of the ethical approval of the data set or biobank and the approval of any changes made, as well as any other relevant document so that the researcher can request authorization to contribute to the data set or biobank under the auspices of his or her institution.

3. REBs IN THE RSSS THAT CAN ACT AS REVIEWING REBs

Compliant REBs in the RSSS may act as reviewing REBs

3.1 To act as reviewing REB, the REB shall conduct its activities in compliance with the legal and regulatory requirements applicable in Quebec and according to the directives of the MSSS, which take precedence over directives issued by other authorities with regulatory powers. During the ethics review of a research project, the REB shall also comply with the standards, guidelines, standard operating procedures and good practices that may apply in the field of research in question.

The reviewing REB shall also respect the deadlines prescribed in the Framework.

To establish its compliance, the REB reports on its activities to the MSSS

3.2 To establish its compliance, the REB shall report on its activities to the MSSS every year, using the online report form produced by the MSSS. If this report does not, according to the MSSS, establish the REB's compliance, the MSSS shall inform this REB and its institution and set out the conditions to be fulfilled before this REB can act as reviewing REB. A REB established after February 1, 2015, shall provide the MSSS with a first annual report to establish its compliance before acting as reviewing REB, unless it results from a merger with at least one REB that has established its compliance.

4. DETERMINING WHICH REB THE RESEARCHER WILL ASK TO ACT AS REVIEWING REB

4.1 To determine which REB will be asked to act as reviewing REB, the researcher shall take the following elements into consideration:

When the person holds the status of researcher:	The researcher addresses the request for ethics review:
With one or more institutions in the RSSS	› To the REB of one of the institutions where the researcher has been granted the status of researcher, if participants will be recruited at the institution; if not, to the REB at one of the institutions where participants will be recruited. › To the REB of an institution where the researcher has been granted the status of researcher, if none of the institutions where the researcher intends to recruit participants has an REB. › To the CCER, when neither the institutions where the researcher intends to recruit participants nor those where the researcher has been granted the status of researcher have an REB.
With a Quebec university, college, government or paragovernmental organization	› To the REB at one of the public institutions in the RSSS where participants will be recruited. › To the CCER, if there is no REB at these institutions.

An REB at a public institution in the RSSS may not refuse to act as reviewing REB based on the sole fact that the project's participants will not be recruited at its institution.

Specific situation: When there is an inter-institution agreement for ethics review

4.2 When the researcher plans to recruit participants at an institution that has established a joint REB or has a formal agreement with another public institution in the RSSS regarding ethics reviews for research projects, the REB that will act as reviewing REB shall be the joint REB or the REB mentioned in the inter-institution agreement, except when it contravenes section 4.1. The provisions in the inter-institution agreement shall apply, unless they are incompatible with those in the Framework, in which case the provisions of the Framework shall prevail.

Specific situation: Using data sets or biobanks for research purposes

4.3 When seeking to use for research purposes a data set or a biobank located at more than one public institution in the RSSS, the researcher shall address the request for ethics review to the REB to which the institutions involved have assigned the ethics review and ongoing ethical oversight of the database or bank, as stated in the management framework for this data set or biobank. If the management framework assigns responsibility for ethics review and ongoing ethical oversight to more than one REB, the REB that will act as reviewing REB shall be the REB at the institution where most of the data or samples will be used.

5. SCIENTIFIC (SCHOLARLY) REVIEW OF THE RESEARCH PROJECT

It is preferable for the scientific review to be conducted before the researcher asks a REB to act as reviewing REB

5.1 The scientific review of a research project is conducted by a person or committee having the necessary scientific expertise. The researcher may refer to the scientific committee of a public institution in the RSSS or a scientific committee recognized by the institution. Before taking steps with a REB in the RSSS to ask it to act as reviewing REB, the researcher shall have obtained the positive results of the scientific review of the project or be able to provide this result to the REB prior to its meeting date.

When the researcher is unable to obtain a scientific review from a peer committee

5.2 If the researcher is unable to obtain a professional peer-review assessment, he may ask the reviewing REB to conduct the scientific review. The REB shall not agree to such a request unless this task is part of the mandate the REB has received from the institution that established it and its members have the scientific expertise required to review the project.

The reviewing REB confirms to the researcher that the requirement for a scientific review by a person or committee with a scholarly expertise is satisfied, and also reviews the ethical implications of the methods and design of the research as part of the research ethics review.

5.3 Before proceeding with the ethics review, the reviewing REB shall determine if the project has undergone a scientific review by a person or committee with the required scientific (scholarly) expertise or, in the case of a student research project, by the student's research director or a scientific committee at a university or college.

As part of research ethics review, the reviewing REB shall review the ethical implications of the methods and design of the research.

In the letter it provides to the researcher once the ethics review has been completed, the reviewing REB shall:

- confirm that a scientific review that produced positive results was conducted by a person or committee with the required scholarly expertise; and
- provide the result of the project's ethics review.

6. REQUEST BY THE RESEARCHER FOR A DECLARATION THAT THE REB AGREES TO CONDUCT THE ETHICS REVIEW OF A PROJECT

When asking an REB to act as reviewing REB for a new project or a sub-study added to a project under way, the researcher uses the forms and includes the documents as indicated by this REB.

6.1 The REBs in the RSSS shall indicate to the researchers:

- which forms to be completed to obtain a declaration;
- which documents must be included with the request to act as reviewing REB and which may be filed prior to the REB's meeting, on the date indicated in the declaration by the reviewing REB.

The researcher who obtained the reviewing REB's declaration provides the REB with a request for an ethics review when any sub-study is added during the course of the research project. The researcher can then ask the reviewing REB to provide the date on which it will conduct the ethics review. Upon receipt of the REB`s declaration, the participating public institutions can begin the site-specific assessment of the sub-study before receiving the positive results of the ethics review.

Documents that must accompany the request to act as reviewing REB or be provided prior to its meeting

6.2 The list of documents that must accompany a request to act as reviewing REB shall be limited to those that will enable the REB to establish that it has the competency required to conduct the ethics review of the project. The list of documents to be provided to the REB prior to its meeting shall include the consent form in French and shall be established by applying the requirements of the MSSS and take into account, when they are compatible, guidelines from other authorities with regulatory power in the research field in question.

Specific situation: Research conducted with sponsor with a different researcher in charge at each participating institution

6.3 When a sponsor seeks to conduct the same project with several researchers, each one of them being responsible for the conduct of the research at his or her own institutions, the sponsor and one of these researchers shall agree to ask a REB in the network to act as reviewing REB. When requesting the REB's declaration, the researcher identifies the sponsor. If the researcher makes the request and provides contact information for the sponsor, the REB shall forward the sponsor a copy of the declaration.

If able to do so, the researcher requesting the declaration identifies the researchers who will be responsible for the same project at the other participating institutions. This information is provided to the REB as an indication only. It is up to each researcher, when using a copy of the reviewing REB's declaration and/or letter giving the result of the ethics review to request authorization to conduct the same project at their institution, to promptly identify themselves to the reviewing REB and to provide proof of competency, if required by the REB.

Specific situation: Adding institutions to a project started after February 1, 2015, at a single institution in the RSSS, without the REB declared as reviewing REB

6.4 When a researcher in charge of a project approved by the REB and under way at his or her own institution seeks to conduct the same project in more public institutions, the REB that conducted the ethics review of the project shall provide a declaration stating that it agrees to act as reviewing REB for the other public institutions. The REB is bound to agree to act as reviewing REB if the project for which it conducted the ethics review was presented to it after February 1, 2015.

The REB shall inform the researcher of the conditions under which it agrees to become reviewing REB. Among other things, the REB shall require the submission of a consent form that complies with the form originally approved by the REB, except for administrative changes so that the form can be used at other public institutions taking part in the same research project.

The REB that thereby agrees to act as reviewing REB provides the researcher with a written declaration and, if applicable, a copy of the REB's ethical approval of the project and approval of any changes made to the initial project, as well as any other relevant document so that the researcher can request authorization to conduct the research at other institutions.

Specific situation: Adding a contributing institution to a data set or biobank created after February 1, 2015

6.5 In order to obtain authorization from a public institution in the RSSS to contribute under its auspices to a data set or biobank created after February 1, 2015 by, or involving, one or more public institutions in the RSSS the researcher shall provide the person mandated to authorize research at his or her own institution with the documents that confirm that the data set or biobank has undergone an ethics review with positive results and that it is subject to ongoing ethical oversight by an REB acting under the jurisdiction of the board of directors of a public institution in the RSSS.

The researcher will contact the REB in charge of the ethical review and oversight of the data set or biobank, as stipulated in its management framework or otherwise, in order to have access to the documents needed to obtain the authorization at his or her institution. Unless otherwise stipulated in the management framework for the dataset or biobank, the REB named therein shall provide the researcher with a declaration that it will act as reviewing REB or a copy of this declaration if the REB is already acting as reviewing REB for other public institutions in the RSSS.

7. DECLARATION BY THE REB THAT IT AGREES TO ACT AS REVIEWING REB

Upon receiving the request from a researcher, the REB must reply within five working days.

7.1 When a researcher requests that it act as reviewing REB, the REB shall promptly establish whether it has the expertise to act as reviewing REB for the project and declare it in writing no later than five working days after receiving the request, indicating to the researcher the date on which it will review the project. The date for the REB's ethics review shall be within 30 calendar days of the date of the declaration.

When a researcher submits to a reviewing REB a sub-study to be added to a project already under way, he may ask the reviewing REB to produce a declaration indicating the date on which it will conduct the ethics review of the sub-study. Upon receipt of the REB`s declaration, the participating public institutions can begin the site-specific assessment of the sub-study before receiving the positive results of the ethics review.

Points to consider before agreeing to act as reviewing REB

7.2 To respond to the researcher's request, a member of the REB or its secretariat considers the following points:

- whether the research involves minors or persons of full age incapable of giving consent, under section 21 of the Quebec Civil Code, in which case the REB must be designated or formed by the Minister of Health and Social Services;
- whether the REB's members include persons with relevant expertise pertaining to the population targeted by the research, the method, discipline or field of research related to the proposed project; and
- whether the REB is able to hold a meeting for the ethics review of the project in the 30 calendar days following the date on which it states that it agrees to act as reviewing REB.

When the REB is able to act as reviewing REB, it is bound to accept. Any exemption under this section must be reported by the REB in its annual report to the MSSS.

Once a reviewing REB has agreed to conduct the ethics review, no other REB in the RSSS may conduct an ethics review of the same project

7.3 Once the researcher has asked a REB in the RSSS to act as reviewing REB for a research project, no other researcher may ask another REB in the RSSS for an ethics review of the project.

If the reviewing REB cannot respond within the specified timeframe

7.4 If the reviewing REB cannot respond within the specified timeframe, the researcher may address his or her request to another REB.

When documents are missing, the REB is not required to conduct the ethics review within the timeframe.

7.5 When it states that it agrees to act as reviewing REB, the REB informs the researcher which, if any, additional documents it needs to conduct the ethics review and the timeframe within which these documents must be provided.

If the researcher fails to provide the documents within the specified timeframe, the REB is not bound to proceed with the ethics review at the date stipulated in its declaration. When the researcher fails to respond to the REB's requests within the specified timeframe, the REB informs the researcher how much more time it will allow for the submission of the documents, after which the file will be closed. The researcher who provided a copy of the REB's declaration to other researchers shall then inform them that the declaration is no longer valid and that the REB has closed the file.

8. ETHICS REVIEW BY THE REVIEWING REB AND DEADLINES

Full Board review or delegated review

8.1 In keeping with a proportionate approach to research ethics review, the selection of the level of REB review (full board or delegated) for the examination of the research project, the consent form in French and requests relating to the ongoing ethical oversight of the project (including addition of a sub-study or changes to documents relating to the project) shall be determined by the level of foreseeable risks to participants, and the reviewing REB will also take into account standards in effect in Quebec as well as guidelines from authorities with regulatory jurisdiction in the research field in question.

The reviewing REB provides its comments to the researcher in the five days following its meeting

8.2 The reviewing REB sends its comments to the researcher promptly and no later than five working days following its meeting to review the project.

Review by the reviewing REB of the researcher's answers to its comments

8.3 Upon receipt of the researcher's answers to its comments, the reviewing REB selects the level of examination (full board review or delegated review) in keeping with a proportionate approach. The reviewing REB continues its discussions with the researcher until it is satisfied with the answers to its questions and is ready to receive from the researcher the final version of the documents relating to the research.

If the researcher does not respond to the REB's comments, it is up to the REB to inform the researcher of the additional time allowed to provide answers, after which the file will be closed. The researcher who provided a copy of the REB's declaration to other researchers shall then inform them that the declaration is no longer valid and that the REB has closed the file.

Network approach: The researcher presents his documents in a format that can be easily used by several institutions

8.4 Since the research project will be proposed to more than one public institution in the RSSS, the final version of the documents pertaining to the project shall be prepared accordingly. The consent form must be in French and may be accompanied by a translation into another language. It shall be presented in a format that makes it easy for several public institutions in the RSSS to use it, taking into account the fact that each of the institutions has its own complaints commissioner and insofar as possible, appending administrative data that may vary from institution to institution. The consent form approved by the reviewing REB shall be formatted to make no reference to a specific institution and shall clearly indicate the places where administrative elements may be inserted so that the form can be used by each of the institutions taking part in the same project.

The approval date for the final version of the documents and network version of the consent form is the date of the letter from the reviewing REB giving the positive results of the ethics review, unless the reviewing REB has given the researcher a different date.

When it is satisfied with the final version of the documents, the reviewing REB shall issue the letter stating the result of the ethics review within five days.

8.5 Once the reviewing REB has informed the researcher it is satisfied with the final version of the documents pertaining to the project, including the consent form in French, it has five working days to provide the researcher with a letter, with copy to the sponsor if one has been identified, in which it:

- confirms that the project has undergone a scientific review with positive results and that it was conducted by a person or committee with the necessary scholarly expertise; and
- provides the results of its ethics review.

The reviewing REB shall attach an appendix to this letter to document how the ethics review was conducted and shall specify in the letter its requirements for ongoing ethical oversight, including submission of an annual report on the project's progress.

Specific situation: The REB's attestation form required by Health Canada for clinical trials

8.6 When the reviewing REB conducts the ethics review of a project covered by Health Canada *Guidance Document for Clinical Trial Sponsors: Clinical Trial Applications*, it shall provide the researcher and/or sponsor with the required attestations, upon request.

If requested by the sponsor, the reviewing REB shall identify each of the public institutions in the RSSS that, on the date the attestation is signed, provided the reviewing REB with a copy of the authorization to conduct the research in the institution and a copy of the consent form used to conduct the research at the institution. Upon request, the REB shall issue an update of this attestation when additional institutions have authorized the project.

Request for reevaluation and appeal of a reviewing REB's decision

8.7 The researcher may ask a reviewing REB to reevaluate its decision on the project's ethical acceptability. If this first step is unsuccessful, he may appeal the reviewing REB's decision with a REB authorized to hear appeals.

9. RESEARCHER'S SUBMISSION OF A REQUEST FOR AUTHORIZATION TO CONDUCT RESEARCH AT A PUBLIC INSTITUTION IN THE RSSS

A person is duly mandated by the institution to authorize research to be conducted

9.1 The board of directors of a public institution where multicenter projects are conducted formally mandates a person who has an employment relationship with the institution and whose name is submitted to the MSSS to authorize a researcher to conduct research at the institution or under its auspices. This authorization is also required when banking data or biological materials for research purposes or when the researcher wishes to contribute to an existing data set or biobank under the institution's auspices.

This person shall not be in a position of conflict of interest, whether apparent, actual or potential.

The authorization is granted according to the Framework and the operational and organizational procedures are under the institution's jurisdiction.

Whatever procedures are implemented, authorizing the research to proceed at the institution is the responsibility of the formally mandated person. If the administrative support for the REB and the person authorizing research is provided by the same employees at the institution, clear terms and conditions shall be established so that employees clearly understand to whom they are accountable for completing the various tasks.

Network approach: Whether or not it has an REB, the RSSS institution sets out procedures for granting authorization to conduct a research under its jurisdiction and, upon reception of such a request, makes its requirements known within five days.

9.2 The person mandated to authorize research at the institution or under its auspices ensures that the required supervision is set up at this institution so that a researcher:

- Can ask the institution for a site-specific assessment of the project by providing the mandated person with a formal declaration from a REB that it has agreed to act as reviewing REB for this project.
- Is informed promptly and no later than five working days after filing the request if additional documents are required for the institution to begin the site-specific assessment of the project.
- In cases where a researcher does not hold researcher status with a public institution in the RSSS, provides the institution with a statement to the effect that he will comply with the same requirements as those applicable to researchers who have status with a public institution in the RSSS (e.g. consent to provide information that would identify him to the competent authorities in the event that an alleged breach of responsible research conduct involving him turned out to be well founded).

Specific situation: Multicentre research conducted with a sponsor and under the responsibility of a different researcher at each institution

9.3 When a sponsor seeks to carry out the same multicentre project with several researchers, each one of them being responsible for the conduct of the research at his or her own institutions, the sponsor and one of these researchers agree to ask a REB in the network to act as reviewing REB and they determine how a copy of the REB's declaration will be provided to each of the other researchers who will request authorization from their institution to conduct the same research, as stipulated in section 6.3.

Each of these researchers shall promptly:

- identify themselves and their institution to the reviewing REB;
- provide the reviewing REB with documents demonstrating they are qualified to carry out the research project; and
- provide the reviewing REB with any relevant information about the local populations and circumstances that may have a bearing on the ethics review.

10. SITE-SPECIFIC ASSESSMENT OF THE PROJECT AT THE INSTITUTION

The institution engages the resources required to conduct a site-specific assessment of the project

10.1 The person mandated to authorize research at the institution ensures that a site-specific assessment of the project is conducted with due care at the institution and that the results of this assessment are promptly made available to him or her.

Site-specific assessment of the project

10.2 The project's site-specific assessment must cover, at a minimum, the following points:

- The impact of conducting the study in the context of the other research activities under way at the institution, specifically the institution's concern for avoiding over-solicitation of its users.
- The availability of the institution's facilities, equipment and human resources required for the project.
- The suitability of the local research environment for the proposed project.
- The contractual and financial aspects of the project.
- How medication, if any, is to be managed.
- Whether or not the project is in harmony with the institution's policy directions.
- Impacts of the institution's contribution to the banking of data or biological materials for research purposes, if applicable.

11. AUTHORIZATION TO CONDUCT RESEARCH GRANTED BY THE INSTITUTION

The researcher provides the institution with the documents from the reviewing REB confirming the project has undergone a scientific review and ethics review, with positive results

11.1 The researcher provides the person mandated by the institution to authorize research with the letter and its appendices, in which the reviewing REB:

- confirms that a scientific review that produced positive results was conducted by a person or committee with scholarly expertise in the research field in question; and
- provides the positive results of its ethics review, documents the content and sets out its requirements for ongoing ethical oversight of the project.

The researcher includes:

- the final version of the documents pertaining to the research project as approved by the reviewing REB, including the consent form in French where he has entered in the spaces provided the administrative elements required for the network version of the form to be used at his or her own institution.

Specific situation: Multicentre research conducted with a sponsor and under the responsibility of a different researcher at each institution

11.2 When a sponsor has been identified for a multicenter project conducted under the responsibility of a different researcher at each institution in the RSSS, it receives from the reviewing REB a copy of the letter confirming the project has undergone a scientific review and ethics review with positive result, along with attached documents. It provides a copy to each other researcher who wishes to request authorization from their institution for the same project.

Each researcher must then, if it was not done previously when submitting to their institution the declaration from the reviewing REB:

- identify themselves and their institution to the reviewing REB;
- provide the reviewing REB with documents demonstrating they are qualified to carry out the research project; and
- provide the reviewing REB with any relevant information about the local populations and circumstances that may have a bearing on the ethics review.

When the researcher provides confirmation by the reviewing REB that the scientific review and ethics review were positive, the institution shall reply to the researcher within five working days

11.3 When the researcher provides the letter in which the reviewing REB confirms the positive results of the scientific review and ethics review, along with the final version of documents pertaining to the research as approved by the reviewing REB, the person mandated to authorize research at an institution shall proceed promptly to:

- obtain, from a person or a committee at the institution, the result of the site-specific assessment of the project ; and
- inform the researcher, within five working days, of the decision on whether to authorize the project or, if applicable, delay the decision because the contract required between the institution, the researcher and the industry sponsor has not yet been signed.

The five-day period is a strict deadline:

- if 30 calendar days have passed since the date the researcher provided the institution with the documents needed to conduct the site-specific assessment of the project, as stipulated in section 9.2; and
- when a contract (if required), with an industry sponsor has been signed.

Before authorizing the research, the mandated person makes sure the positive results of the project's scientific review, ethics review and site-specific assessment are documented

11.4 The person mandated to authorize researchers to conduct research at the institution or under its auspices fulfills his or her responsibility by formally receiving documents to the effect that the research project has undergone a scientific review, ethics review and site-specific assessment with positive results, and stating so in an authorization letter.

Format for authorization granted by the institution and annual follow-up

11.5 The authorization granted to the researcher by the public institution shall contain, at a minimum, the points mentioned in the template issued by the MSSS. The template for the authorization letter is appended to this document (Appendix 3).

When authorizing a researcher to create a data set or biobank, or to contribute to a data set or biobank, the institution shall include in the letter the terms and conditions deemed necessary as a result of the site-specific assessment of the project, if applicable.

The authorization to conduct research at the institution shall be renewed annually, on the renewal date of the reviewing REB's ethical approval. Upon receipt of this ethical oversight decision from the reviewing REB, the mandated person may endorse or refuse it. If the institution does not act, the authorization to conduct the research shall be renewed *de facto*. If the institution wishes to set up more formal renewal procedures for renewing its authorization to conduct research, it shall indicate this to the researcher and the sponsor in the authorization letter.

Administrative changes to the documents used to conduct research at an institution

11.6 The documents submitted by the researcher to the person authorizing research at an institution shall correspond to the final version of the documents pertaining to the research that were approved by the reviewing REB. The consent form to be used at the institution shall correspond to the network version of the form approved by the REB, to which the researcher has added administrative elements in the places indicated.

Any other administrative changes to the documents pertaining to the research shall be brought to the attention of the reviewing REB, clearly identified in the institution's authorization letter and documented in attachments to the copy of the authorization letter sent to the reviewing REB. If the reviewing REB feels the changes are not administrative in nature, it promptly informs the researcher and the person who authorized the research at the institution. It may suspend ethical approval of the project at this institution if deemed necessary.

On the consent form used at a specific institution, the date of the authorization letter issued by the institution may be mentioned, with the date of the ethical approval by the reviewing REB of the network version of the form.

The institution informs the researcher(s), the reviewing REB and the sponsor of its decision whether or not to authorize the research to proceed

11.7 The letter from the institution authorizing or not the research to proceed is addressed to the researcher who requested the authorization, with a copy to the reviewing REB and the sponsor, if a sponsor has been identified. If the researcher who receives authorization to conduct the research at the institution is not the person to whom the REB addressed the letter confirming the positive results of the ethics review, the person mandated to authorize research at the institution also forwards a copy of the authorization to the researcher whose name appears on the letter issued by the reviewing REB (attachments are optional).

The researcher provides the person who authorizes research at the institution with the final version of the consent form to be used at the institution as well as a version showing the administrative changes made to the network version approved by the reviewing REB. He does the same for any other administrative changes made to the documents pertaining to the research.

When sending a copy of the authorization letter to the reviewing REB and the sponsor, the person who authorizes research attaches the required documents to show the administrative changes made to the consent form and, if applicable, any other documents pertaining to the research. If the reviewing REB feels the changes are not administrative in nature, it promptly informs the researcher and the person who authorized the research at the institution. It may suspend ethical approval of the project at this institution if deemed necessary.

Research projects register and reporting

11.8 The person mandated to authorize research at the institution ensures that the required procedures are implemented so that the research projects authorized by the institution are listed in the institution's research project register and that reports are made annually to the institution's board of directors and the MSSS.

When the institution has an REB that did not act as reviewing REB

11.9 When the institution has an REB that did not act as reviewing REB, the person mandated to authorize research at the institution may, for information purposes, provide it with a copy of the authorization letter along with all documents pertaining to the research. The aim is to ensure that the institution's REB has access to the documents required to respond to the researcher's request to obtain advice while the research is being conducted at the institution. When the public institution has several REBs, a suitable procedure is implemented by the mandated person.

The institution follows up on the authorization granted to the researcher and may suspend or revoke it

11.10 The person mandated to authorize research at the institution liaises with the reviewing REB as needed while the research is in progress at the institution. An internal follow-up of the authorization given to the researcher should be done at minimum annually, upon receipt of the reviewing REB's decision to renew the ethical approval.

While a research is in progress, the person mandated to authorize research at the institution may suspend or revoke the authorization given to the researcher upon receiving any information likely to challenge its initial acceptance. He or she then promptly informs the reviewing REB of the measures taken, stating the reasons.

12. ONGOING OVERSIGHT BY THE REVIEWING REB, IN LIAISON WITH THE INSTITUTION

Ongoing passive ethical oversight by the reviewing REB

12.1 The reviewing REB establishes the passive means for the ongoing ethical oversight of the research according to MSSS requirements and, when they are compatible, taking into account guidelines from other authorities with regulatory jurisdiction in the research field in question.

The REB's requirements for ongoing ethical oversight, including the deadline for filing an annual progress report on the project, are provided to the researcher in the letter giving the results of the ethics review or attached to this letter. For the filing of an annual report, the reviewing REB shall clearly indicate to the researchers that ethical approval shall be suspended if deadlines are not respected.

While the research is in progress, the reviewing REB liaises with the person who authorized the research at each of the participating institutions, as needed.

Specific situation: Multicentre Research conducted with a sponsor and under the responsibility of a different researcher at each institution

12.2 When a research project is conducted with a sponsor, under the responsibility of a different researcher at each participating institution, the researcher who requested the ethics review sends to the reviewing REB the notifications required for ongoing ethical oversight of the project:

- pertaining to the progress of the research at the reviewing REB's institution, e.g. annual report by the reviewing REB's institution, serious adverse reaction (SAR) at the reviewing REB's institution; and
- impacting the progress of the research at all the institutions where the project is being conducted (e.g.: a change other than administrative made to the project or the request for annual renewal of the ethical approval on the same date for all participating institutions).

In other cases (e.g. annual progress report on the project at an institution, if required by the reviewing REB, notification of a SAR at the institution), the ongoing ethical oversight notification is sent to the reviewing REB by the researcher responsible for the project at the institution involved. The reviewing REB's decision following these notifications is sent to the researcher who submitted the notification.

The reviewing REB may impose requirements for the ongoing ethical oversight of the project on each of the researchers authorized to carry out the research at a public institution in the RSSS and may propose arrangements for coordinating the submission of the required notifications. Since the research is conducted under the responsibility of a different researcher at each institution, the reviewing REB shall clearly distinguish, in the letter giving the result of the ethics review or in attachments to this letter, the requirements addressed to the researcher who requested the ethics review and those addressed to each of the researchers conducting the same research at another institution in the RSSS. All necessary information should be provided to the researchers, especially with respect to the content of the annual report they are expected to submit and deadlines for producing it.

The reviewing REB's ethical approval is renewed every year on the same date for all participating institutions, under the conditions set by the reviewing REB for each of the institutions. The reviewing REB may revoke ethical approval for one of the institutions if the conditions are not respected. The reviewing

REB shall then inform the researcher in question, the sponsor and the person who authorized the research at this institution.

Forms for ongoing ethical oversight

12.3 The forms used for the ongoing oversight shall be those of the reviewing REB.

Network approach: Promptly forwarding the reviewing REB's oversight decisions

12.4 The reviewing REB forwards its decisions pertaining to the ethical oversight of the research, along with documents deemed useful:

- to the researcher who requested the ethical oversight;
- to the sponsor, when a sponsor has been identified;
- to the person who authorized the research at each of the public institutions in the RSSS; and
- if applicable, to the researchers who are responsible for the same research project at other participating public institutions, when these decisions affect them.

When an ongoing ethical oversight results in changes to a document pertaining to the research, the reviewing REB shall send its decision to the above-mentioned people, along with the new document and an annotated copy of the previous version indicating the changes made.

The reviewing REB acts promptly and renders its decision within 30 calendar days of receiving the request for ethical oversight. When the ethical oversight concerns a change to the consent form, the reviewing REB acts promptly so that the new version of the form is accessible to all those involved and that protection of the participants is maintained.

When receiving a copy of an ethical oversight decision, the institution endorses it or revokes the authorization granted to the researcher. If the ethical oversight by the reviewing REB results in changes to the network consent form, the new version to be used at the institution shall be provided to the reviewing REB.

12.5 The person mandated to authorize research at the institution receives a copy of the reviewing REB's decisions in the ongoing ethical oversight of the project and shall endorse them. If not, the authorization given to the researcher has to be suspended or revoked. When refusing to endorse an ethical oversight decision and suspending or revoking the authorization previously granted to the researcher, the mandated person shall inform the reviewing REB, citing the reasons.

When an ethical oversight decision by the reviewing REB involves a change to the consent form, a copy of the modified network version of the consent form is appended to the decision, with the date on which the reviewing REB gave its ethical approval, as well as a copy of the earlier version annotated so the changes to the consent form are evident. The following steps shall be promptly completed at each institution where the research is carried out:

- Upon receipt of the reviewing REB's oversight decision, the person mandated to authorize research at the institution determines whether the researcher conducting the research has already provided an amended consent form and a copy of the earlier version annotated so the changes to the consent form and the administrative elements added are evident. If this has not been done, the person sets a deadline for the researcher to produce the document.
- The researcher provides the new consent form to be used at the institution, along with a copy annotated so that the administrative elements added to the network version of the consent form are evident and the person mandated to authorize research at the institution can see that the changes to the network version of the consent form are administrative in nature. The researcher may request a written confirmation with the date the new consent form is to be used at the institution.
- The person mandated to authorize research at the institution sends the new consent form to be used at the institution, along with a copy annotated so that the administrative elements added to the network version of the consent form are evident, to the reviewing REB and the sponsor, if a sponsor has been identified.

If the reviewing REB feels the changes made to the network version of the consent form are not administrative in nature, it may suspend ethical approval of the project at this institution.

When the institution has an REB that did not act as reviewing REB

12.6 After endorsing an oversight decision issued by the reviewing REB, the person mandated to authorize research at the institution may forward the documents pertaining to the decision to the institution's REB, if there is one, and if it did not act as reviewing REB. The aim is to ensure that the institution's REB has access to the documents required to respond to the researcher's request to obtain advice while the research is being conducted at the institution. When the public institution has several REBs, a suitable procedure is implemented by the mandated person.

When the reviewing REB's oversight decision forwarded to the institution's REB pertains to the approval of the annual report provided by the researcher to the reviewing REB, the institution's REB may examine the content of this annual report and make recommendations to the person mandated to authorize research at the institution for the continuation of the project or implementation of active oversight measures at the institution.

Network approach: While the research is in progress, the reviewing REB must liaise with the person who authorized the research to proceed at each participating institution

12.7 While the research is under way, the reviewing REB and the person mandated to authorize research to proceed at each participating public institution in the RSSS shall have access to all relevant information on the progress of the research and shall share this information in a timely manner.

When the institution has an REB that did not act as reviewing REB, an ethics bureau or a research office, a direct line of communication should be established between these resources and the person formally mandated to authorize research at the institution so this person can rely on their expertise to promptly take action with the researcher and the reviewing REB, if needed while an authorized research is under way at the institution.

13. CHARGES FOR SERVICES RENDERED BY PUBLIC INSTITUTIONS AND THEIR REBs

Research projects that involve billing by the institution

13.1 The public institutions in the RSSS shall bill for the services rendered to private companies: scientific review, ethics review and ongoing ethical oversight of a research project, processing of the request for authorization to conduct research under the auspices of the institution (including the site specific assessment) and annual oversight of this authorization. The fee schedule, which takes into account the number of public institutions that participate in the project, is published in a ministerial circular.

These fees apply only to research projects covered by the ministerial circular on research costs entitled "Contribution de l'entreprise privée dans le cadre d'activités de recherche découlant d'un octroi de recherche."

Transitional provision: Billing procedures currently in effect remain unchanged until June 30, 2016

13.2 Until June 30, 2016, each public institution in the RSSS participating in the same research project may, if it has a REB, continue to apply the same terms as those in effect at the institution prior to February 1, 2015, for services rendered for the review and authorization of a research project governed by the ministerial circular entitled "Contribution de l'entreprise privée dans le cadre d'activités de recherche découlant d'un octroi de recherche."

14. NETWORK APPROACH

Basic oversight that can be improved through voluntary initiatives for collaboration

14.1 This Framework establishes which terms and conditions must at a minimum apply when the same research project is conducted at more than one public institution in the RSSS. Researchers who work on the same project are nonetheless encouraged to propose initiatives to enhance this basic oversight at their own institution and increase the efficacy of research activities in the RSSS.

Encouraging dialogue among stakeholders

14.2 The MSSS strongly encourages any initiative by the stakeholders that would foster dialogue, develop shared forms and standardize the REBs' operating rules or requirements, and the conduct of the ethics review to consolidate objectives to protect participants in a study and facilitate implementation of recognition of the ethics review when the same research is conducted at more than one public institution in the RSSS.

APPENDIX 1

Summary of procedure for the researcher

General procedure : Only one researcher in charge and several participating public institutions	Special situation : Multicentre project conducted with a sponsor and under the responsibility of a different researcher at each public institution	Deadlines
1) The researcher identifies the institutions where the participants will be recruited and establishes which REB in the RSSS he or she will approach (art. 4).		
2) The researcher asks an REB in the RSSS to declare that it agrees to act as reviewing REB (art. 6).	Sponsor agrees with one of the researchers, who will then be the one asking a REB in the RSSS to declare that it will act as reviewing REB (section 6.3). Once a researcher has approached a REB in the RSSS to ask it to act as reviewing REB, the project cannot be presented to another REB in the RSSS (section 7.3).	The REB declares within **five working days** whether it agrees to act as reviewing REB. In its declaration, the REB provides the researcher with: • the date it will meet to review the project (within 30 calendar days of its declaration); and • the date by which it must receive the documents pertaining to the research so that the meeting can take place on the chosen date (art. 7)
3) The researcher submits the reviewing REB's declaration to the person mandated to authorize research at each of the institutions where he plans to recruit participants and requests a site-specific assessment of the project at the institution (section 9.2).	The researcher who has obtained the REB's declaration that it agrees to act as reviewing REB arranges with the sponsor to have a copy of this declaration sent to other researchers who wish to have the same project authorized at their institution (section 6.3). These new researchers shall then immediately identify themselves to the reviewing REB and provide the required information (section 9.3).	The person mandated to authorize research at the institution informs the researcher within **five working days** if additional documents are required for the site-specific assessment at the institution (section 9.2).
4) The researcher who asked the REB to act as reviewing REB: • receives the reviewing REB's comments on the project; • replies to its requests; and • when the reviewing REB is satisfied, provides the final version of the documents pertaining to the research, including a network version of the consent form in French. (art. 8).		The reviewing REB sends its comments to the researcher within **five working days** following the REB's meeting to review the project (section 8.2).

General procedure : Only one researcher in charge and several participating public institutions	Special situation : Multicentre project conducted with a sponsor and under the responsibility of a different researcher at each public institution	Deadlines
5) The researcher receives a letter from the reviewing REB with the positive result of the ethics review. The positive result of the peer scientific review is also mentioned (section 8.5).		The reviewing REB provides the result of the ethics review to the researcher within **five working days** following submission of the final version of the documents pertaining to the project.
6) The researcher provides the person who authorizes research at each of the institutions (including his own) with the letter from the reviewing REB giving the result of the ethics review, along with the appendices and the final version of the documents pertaining to the research, including the consent form in French to be used at the institution (section 11.1).	The sponsor makes sure a copy of the reviewing REB's letter with the result of the ethics review, along with attached documents, is provided to the other researchers so they can request the authorization to conduct the same research at their institution (section 11.2). Each researcher adds the administrative elements to the network version of the consent form in order to use it in his or her own institution.	When the documents required for the site-specific assessment were provided more than 30 calendar days beforehand and, if applicable, when the contract with an industry sponsor has been signed, the person mandated to authorize research has **five working days** to: • obtain the result of the site-specific assessment of the project (started at step 3); and • authorize or not the researcher to conduct research at the institution (section 11.3).
7) The researcher receives a letter from the person mandated to authorize research at the institution, indicating that the project may begin under the auspices of the institution (sections 11.4 – 11.7.	To meet Health Canada requirements, the researcher may ask the reviewing REB, on behalf of the sponsor, to provide an attestation listing all institutions that provided the reviewing REB with a copy of their authorization letter along with the consent form used at their institution (section. 8.6).	
8) While the research is in progress, the researcher provides the reviewing REB with the notifications required for the ongoing ethical oversight (section 12.1) When a sub-study is added, the reviewing REB proceeds as if it were a new research project.	For ongoing ethical oversight, the reviewing REB: • Receives from the researcher who asked for the ethics review the notifications that pertain to all the sites and those that pertain to the reviewing REB's institution. • Receives from each researcher who was authorized to conduct the same research at his institution the notifications pertaining to his or her institution (section 12.2).	The reviewing REB shall **promptly and no later than 30 calendar days** after receiving the request for an ethical oversight, send its oversight decision to the researcher(s) concerned, to the sponsor if a sponsor has been identified, and to the person who authorized the research at each of the institutions affected by the decision (section 12.4).
9) The researcher provides the reviewing REB with an annual progress report on the research project (art. 12).	The reviewing REB renews ethical approval for all participating institutions on the anniversary date of the ethics approval.	

General procedure : Only one researcher in charge and several participating public institutions	Special situation : Multicentre project conducted with a sponsor and under the responsibility of a different researcher at each public institution	Deadlines
	Each researcher responsible for research at an institution complies with the conditions determined by the reviewing REB for the submission of an annual report (section 12.2). If not, ethical approval for this institution is suspended by the reviewing REB.	

APPENDIX 2

Summary of procedure for multicenter projects conducted with a sponsor and under the responsibility of a different researcher at each institution

Industry Sponsor	Researcher requesting the ethics review	Researchers in charge of the project in institutions other that the reviewing REB's institution
1) Declaration from a reviewing REB The sponsor agrees with one of the researchers with whom it plans to conduct the research to: • ask the REB at his institution to act as the reviewing REB; • to inform the REB which other researchers and RSSS institutions plan to take part in the research, if known; and • to make sure other researchers who wish to be authorized to conduct the same research at another institution will promptly be provided with a copy of the REB's declaration that it agrees to act as the reviewing REB (section 6.3).	This researcher asks the REB at his institution to act as the reviewing REB (section 6.3). Upon receiving the REB's declaration, this researcher proceeds according to what was agreed upon with the sponsor to ensure that the REB's declaration is provided to the other researchers who wish to conduct the same research at their institution (section 6.3).	Each researcher to whom the sponsor proposed the project receives a copy of the reviewing REB's declaration. These researchers identify themselves to the reviewing REB, provide proof of their credentials, if required, and inform the REB of local circumstances, if applicable (section 9.3).
2) Presentation of the project to each institution to obtain a site-specific assessment The sponsor ensures that each researcher with whom it wishes to conduct the research: • receives the documents describing the research and the declaration by the reviewing REB; • submits the project to the person who authorizes research at the institution to obtain a site-specific assessment; and • begins contract negotiations with the institution, if required. (art. 9)	This researcher ensures that the person who authorizes research at his institution receives the declaration from the reviewing REB and the documents required for the site-specific assessment of the project at his institution. If a contract with the institution is required, negotiations are started between interested parties.	At each institution, the researcher provides the person who authorizes research with: • the declaration by the reviewing REB, and • all documents required for the site-specific assessment. If a contract with the institution is required, negotiations are started between interested parties.
3) Recognition of the ethics review The sponsor makes sure the researchers who wish to do the same research at their institution will be provided with: • The letter (and appendices) in which the reviewing REB gives the positive results of the ethics review and confirms that a scientific peer review has given a positive result. • The final version of the documents describing the research, as approved by the reviewing REB. • The consent form in French, approved by the reviewing REB, presented in a format that indicates where each institution can insert	This researcher ensures that the person who authorizes research at his or her institution receives: - the ethics approval letter from the reviewing REB, with appendices; - the final version of the documents describing the research; and - the consent form in French, to which he or she has added the administrative elements required for use at the	At each institution, the researcher provides the person who authorizes research with: • the ethics approval letter from the reviewing REB, with appendices; • the final version of the documents describing the research; and • the consent form in French, to which he or she has added the administrative elements

Industry Sponsor	Researcher requesting the ethics review	Researchers in charge of the project in institutions other that the reviewing REB's institution
administrative elements (section 8.4).	reviewing REB's institution.	required for use at his or her institution (sec. 11.2). If not already done, these researchers identify themselves to the reviewing REB, provide it with proof of their credentials, if required, and inform it of local circumstances, if applicable (section 11.2).
4. <u>Authorization to start the research at each of the institutions</u> The sponsor receives a copy of each of the authorization letters issued by a public institution, with a copy of the consent form that will be used at the institution (section 11.7). If a contract is required between the sponsor, the researcher and the institution, the authorization letter will be issued after the contract has been signed.	At the reviewing REB's institution, the researcher may start with the research upon reception of the authorization letter issued by the institution.	At each institution, researchers may start with the research upon reception of the authorization letter issued by their own institution. If the reviewing REB finds that changes other than those of an administrative nature have been made to the consent form or to documents describing the research, it shall suspend its ethics approval (sections 11.6, 11.7).
5. <u>Addition of a sub-study</u> The sponsor asks the researcher who initially requested the ethics review of the project to submit the sub-study to the reviewing REB (sections 2.1, 6.1, 7.1). The sponsor informs researchers who are doing the same research at other public institutions.	Same procedure as that for obtaining an ethics review and issuance of an authorization letter from the institution to conduct the research to which the sub-study is being added.	Same procedure as that for obtaining recognition of the ethics review and issuance of an authorization letter from the institution to conduct the research to which the sub-study is being added.

Industry Sponsor	Researcher requesting the ethics review	Researchers in charge of the project in institutions other that the reviewing REB's institution
6. Modification of documents pertaining to the research The sponsor asks the researcher who initially requested the ethics review of the project to submit to the reviewing REB all changes and obtain ethics approval of the final version of the modified documents. The sponsor informs the researchers who are conducting the same research at other public institutions. The sponsor (previously identified to the REB), receives a copy of the reviewing REB's decision, with the attachments (section 12.4).	This researcher receives the reviewing REB's decision, along with the attachments (section 12.4). If the consent form has been modified, this researcher adds to the network version of the consent form the administrative elements required for use in his institution.	Each researcher receives a copy of the reviewing REB's decision, along with the attachments (section 12.4). If the consent form has been modified, each researcher adds to the network version of the consent form the administrative elements required for use in his or her own institution.
7. Requests for ongoing ethics oversight (including those in 5 and 6) The sponsor ensures that each one of the researchers with whom it is conducting the study is provided with the documents that are submitted to the reviewing REB for the ongoing ethics oversight of the research, as was set by the REB in its letter giving the result of the ethics review or in the attachments to this letter.	This researcher submits to the reviewing REB the requests for ongoing ethics review on matters: • that have an impact on conducting the research at all the institutions; • that pertain to conducting the research at his or her institution. (section 12.2)	Each one of the researchers submits to the reviewing REB the requests for ongoing ethics review on matters that pertain to conducting the research at his or her own institution (section 12.2).
8. Annual renewal of ethics approval Requirements pertaining to the annual report are set by the REB in its letter giving the result of the ethics review or in the attachments. The sponsor provides researchers with the information needed to submit such report on the date and according to the conditions specified by the REB.	This researcher receives from the reviewing REB a letter informing him that the ethics approval has been renewed for one year, on the anniversary date of the REB's initial ethics approval.	Each researcher receives a copy of the letter from the reviewing REB indicating that the ethics approval has been renewed for one year, on the anniversary date of the REB's initial ethics approval. If the reviewing REB requested that an annual report be submitted for each of the institutions, researchers who fail to provide this report shall receive a notice from the reviewing REB indicating that ethics approval for their institution has been suspended.

Industry Sponsor	Researcher requesting the ethics review	Researchers in charge of the project in institutions other that the reviewing REB's institution
9. Follow-up of institutional authorization at each participating public institutions	Depending on what was stated in the letter of authorization issued by this institution, the authorization is renewed: • *de facto* following renewal of the ethics approval; or • upon issuance of a formal notice to the researcher with copy to the sponsor (section 11.5).	Depending on what was stated in the letter of authorization issued by the institution, the authorization is renewed: • *de facto* following renewal of the ethics approval; or • upon issuance of a formal notice to the researcher with copy to the sponsor (section 11.5).

APPENDIX 3

Template: Letter for the institution to authorize research on its premises or under its auspices

…	*Date*
…	*Name of researcher requesting authorization*
…	*Address*
SUBJECT: Authorization to conduct the following research	*Adapt the letter when the researcher requests an authorization for banking data or biological material for research purposes (section 11.5)*
…	*Project title*
…	*Identification number assigned to the project by the reviewing REB*
…	*Identification number assigned to this authorization by the institution and contract number, if there is one*
…	*Dear Sir or Madam:*
1. We are pleased to authorize you to conduct the research identified in the title above, under the auspices of …	I*dentify the public institution of the RSSS. When a research involves a grouped institution administered by the CA of an integrated centre (CISSS), the authorization letter is issued by the integrated centre.*
2. This authorization allows you to conduct research at the following locations …	*Identify the locations for which a site-specific assessment has been completed, with positive results.*
3. In granting you this authorization, our institution recognizes the ethics review conducted by …,	*Identify the reviewing REB*
• which is acting as reviewing REB for this project, in accordance with the framework for Public Health and Social Services Institutions to Authorize Research Conducted at More Than One Institution (the Framework);	
• which has confirmed, in its letter dated …, the positive result of the scientific review and ethics review of the project; and	*Enter the date of the letter issued by the reviewing REB.*
• which approved the network version of the consent form in French used for this project.	*If the reviewing REB feels the changes made in the network version of the consent form affect the ethics of the project, it will suspend its ethics approval for the institution (art. 11.6.).*
We acknowledge receipt of the consent form you have prepared for our institution based on the network version and we are attaching it to the copy of this authorization that will be sent to the reviewing REB. The date of this authorization can be included on this consent form.	
4. You are granted this authorization provided that you agree to:	
• comply with the provisions in the Framework that apply to your research;	

- comply with our institution's regulatory framework for research activities, including the research participants identification mechanism;
- use the documents pertaining to the research as approved by the reviewing REB, with administrative changes only, and the modifications, if any, clearly indicated so the reviewing REB can view them; and
- comply with the requirements set by the reviewing REB for ongoing ethics oversight of the research.

When sending the copy of this authorization letter to the reviewing REB, attach the documents required to indicate changes, if any (sections 11.6, 11.7)

Formulated by the reviewing REB in its letter giving the result of the ethics review and/or in the attached documents (section 12.1)

5. Your authorization to conduct the research under the auspices of our institution:

Check or select one

[…] will be renewed without any other procedure on the date indicated by the reviewing REB in its decision to renew its ethics approval of this research.

See section 12.2.

or

[…] will be renewed on the date indicated by the reviewing REB in its decision to renew its ethics approval of this research, and our institution will also send you a formal confirmation of this renewal.

6. The person to contact for any question regarding this authorization or its renewal or on the subject of any administrative changes made to the network version of the documents pertaining to the research that was approved by the reviewing REB, is …

Indicate "the undersigned" or other name with the telephone number and email address.

Sincerely,

Or other closing formula

…

Signature of the CEO or
Person mandated by the institution to authorize research

encl.:

- Consent form that will be used to conduct the research at the institution (final version and version showing administrative changes)
- Other documents pertaining to the research that have undergone administrative changes (final version and version showing administrative changes)

The authorization date given by the institution may appear on the form.

Attach, if applicable.

cc: Chair, REB …

Name of chair of reviewing REB

…

Sponsor [if there is one].

…

If the researcher who receives authorization is not the one to whom the reviewing REB addressed its letter with the result of the ethics review, name of researcher to whom the reviewing REB's letter was addressed.