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Framework for 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

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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[1] therefore undergoes only one ethics review by a research ethics board (REB) in the RSSS. In application since February 1, 2015, the *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* (the Framework) describes the new procedures. The Framework replaces the "Mécanisme encadrant l'examen éthique et le suivi continu des projets multicentriques" that came into effect April 1, 2008 (the "2008 Multicentre Mechanism").

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, except for the one that maintains, until June 30, 2016, the parameters for invoicing industry sponsor 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 at the RSSS institutions designated under art. 88-91 of the Act Respecting Health Services and Social Services. The changes do not substantially alter the previous version of the Framework. They are mostly intended to clarify procedures.

There are, however, two requirements that must be met by July 1, 2016: the use of the revised template for the Letter of Institutional Authorisation (Appendix 3) and the new guidance to REBs and individuals authorizing the conduct of research pertaining to the transmission of documents to stakeholders (Articles 6, 8, 11 and 12).

In summary, the April 1, 2016 additions are the following:

- Details on the context, particularly the network concern for public institutions, REBs, researchers and sponsors;
- Clarifying how to apply the Framework when institutions are added to projects already under way or when they start contributing to an existing dataset and/or biobank as of February 1, 2015 (sec. 2.3, 2.4, 2.5);

[1] A research project conducted in more than one facility and/or grouped institution administered by the board of directors of an integrated center is deemed to be conducted in a single RSSS public institution.

- Clarifying how to apply the Framework when creating a data and/or biobank for research purposes after February 1, 2015, or when contributing to such a data or biobank after February 1, 2015 (sec. 6.5, 9.1, 10.2 and 11.5);
- Clarifying how the REB of Record should apply the Framework when a sub-study is added to a research project already under way. In particular, how to issue a statement that will be presented by the researcher to each participating public institution calling for a site-specific assessment of the sub-study, which must 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);
- Stating how the researcher and the REB of Record should fulfill 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);
- Stating how the researcher is to be informed of the closing out of his or her ethics request by the REB of Record if answers are not provided to REB's comments (sec. 7.5 and 8.3);
- Issuing new guidance to the person mandated by the institution to authorize research regarding 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 letter), follow-up on changes made to a consent form (12.5) and annual follow-up on the authorization by the institution (sec. 11.5, 11.10);
- Issuing new guidance to the REB of Record for providing documents to industry sponsors (sec. 6.3, 8.5, 11.2), and to all parties issuing its declaration (sec. 6.3) as well as in support of its ethics review (sec. 8.5) and ongoing oversight decisions (sec. 12.4);
- Adding an appendix to outline the procedure for industry sponsors who work with a different researcher at each public institution in the RSSS;
- Adding an appendix to include a modified version of the template letter that the public institution in the RSSS shall use to authorize research at the institution or under its auspices.

The Framework is aimed both at protecting the participants in the research and fostering the excellence and vitality of research in the RSSS. It allows a 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 the public institutions in the RSSS will harmonize their procedures, thus allowing the individuals and the committees responsible for the review and authorization of multicentre research projects to better coordinate their actions.

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 a REB in the RSSS, whether or not it 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 a 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 so as to take into account that other RSSS institutions are involved in the same research project and so as to be aware of the effect this has throughout the network.

Network approach in a public institution

Governance: In all the public institutions in the RSSS that wish to host multicentre research projects, the board of directors:

- Identifies, 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.
- Adopts the necessary changes to the institution's regulatory framework for research activities, when warranted for the application of the Framework.

Institution's civil liability: In order to comply with the terms and conditions of the civil liability insurance of the public institutions in the RSSS, the ethics review of a research project must be conducted by a REB that was formed by the board of directors of a public institution in the RSSS, or by the central research ethics board (CCER) established by the Minister of Health and Social Services.

Hosting researchers: The public institution that wishes to participate in research projects that will also be conducted at other public institutions in the RSSS ensures that:

- the parties concerned, including the MSSS, are provided with the name of the person formally mandated to authorize the conduct of research projects at the institution and the method of communicating with this person; and
- researchers are informed of the procedure for requesting a site-specific assessment of the project at the institution, for obtaining confirmation of an ethics review completed by the REB of Record and for obtaining from the mandated person the authorization to conduct the research at the institution.

Network approach in a REB

Communication: The REB of Record gives top priority to maintaining communications with the researcher who requested the ethics review and with the person who authorized the research at each institution. When the REB at an institution did not serve as the REB of Record, the REB of Record 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 REB performs tasks assigned to the REB of Record in the Framework, taking into account the fact that the research project extends beyond the REB's institution. It requires the researcher to provide any useful information about local populations and circumstances that may have a bearing on the REB's review. It 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 (SOPs); they must be able to account for the integrity of their methods. When the REB acts as REB of Record, it makes its expertise available to all researchers and all public institutions in the RSSS who wish to participate in the same project. Since the REB of Record'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 with an industry sponsor and responsibility is assigned to a different researcher at each participating public institution in the RSSS. A researcher who requests an ethics review and shares the results of his discussions with the REB of Record with other researchers shall not be placed in a situation in which he is required to substitute for the researchers at the other institutions when performing tasks.

Network approach for a researcher

One researcher's responsibility for conducting a multicenter research or multiple researchers responsible for the same project each in their own institution: When the same research project is conducted at several public institutions in the RSSS, there are two different scenarios. A single researcher responsible for a project but supported by a team of collaborators may conduct the same research at several public institutions in the RSSS. This situation differs from the one in which several researchers act individually

with an industry 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 an industry sponsor, for which each participating institution signs a separate contract with a sponsor and a researcher.

Both of these scenarios 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 REB of Record or uses a copy of a declaration or ethics approval from a REB of Record, 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.

Datasets and biobanks used for research purposes: At a public institution in the RSSS, the use of datasets 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 dataset or biobank located at a public institution in the RSSS other than his own, or one that involves contributing public institutions other than the institution that created it, the Framework shall apply if the dataset or biobank was set up after February 1, 2015. Section 2 sets forth optional provisions regarding datasets or biobanks established before February 1, 2015.

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

When research projects involve creating a dataset or biobank, the researcher shall ensure that the documents used to obtain participants' consent allow the REB of Record to be satisfied that the future participants have been properly informed and that a clear distinction is made between consent to research and consent to the banking of data or biological materials for research purposes. Before establishing whether it is appropriate to use separate consent information and 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 an industry sponsor wishes to conduct the same project with a different researcher responsible at each of the public institutions in the RSSS, the sponsor and one of these researchers shall agree to ask a REB in the network to act as REB of Record.

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 REB of Record's declaration, the letter from the REB of Record 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 REB of Record.

Document format: The industry 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 REB of Record 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

(Note: same order as in the French document)

1.1 **REB**: Research Ethics Board

1.2 **REB of Record**: a 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 Minister of Health and Social Services.

1.3 **CCER**: Comité central d'éthique de la recherche formed by the Minister of Health and Social Services

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 (RSSS) having a Board of Directors (integrated centres may include grouped public institutions administered by the same Board of Directors), which is covered by the civil 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**: Executive Director of an institution or a member of the personnel of that institution, as determined by by-law 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 private industry or public organization in charge of funding a research project. The definition includes an organization or person that the industry 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 with human participants in the field of health services and social services, including datasets and biobanks used 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 measures for REB ongoing oversight:** those carried out by a body that is independent of the researcher and the sponsor that reviews the conduct of the research and related documents.

1.12 **Passive measures for REB ongoing oversight**: those carried out by a REB of Record based on notifications it receives from a researcher or sponsor while the project is under way.

2. SCOPE OF THE FRAMEWORK

Mandatory directive, applicable as of February 1, 2015, to new research projects (or addition of a sub-study to these projects) 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 added sub-study) conducted as of February 1, 2015, in whole or in part, at more than one public institution in the RSSS (an integrated centre where the Board of Directors administers grouped institutions is deemed to be a single RSSS public institution), 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 to an existing project is handled in the same way as a review for any new research project. If requested by the researcher, the REB of Record 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 principal REB shall become the REB of Record and perform its duties beginning with the first annual renewal of the project's ethics approval after April 1, 2015. The main REB that thereby becomes the REB of Record sends a copy of its ongoing ethics review 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 ethics 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 REB of Record for the new institution. The REBs are not bound to accept this request. Once a REB has agreed in writing to act as REB of Record for the project, a researcher may not obtain declarations from the other REBs.

The REB that agrees to act as REB of Record 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 ethics 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 REB of Record for a new institution shall act as REB of Record for any public institutions added subsequently. The other REBs that have granted their ethics approval for the same

project prior to February 1, 2015 continue to conduct ongoing ethics oversight of the project at their institution, according to the originally established terms and conditions.

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 REB of Record and to provide a declaration to this effect. The REB is not bound to accept this request.

The REB that agrees to act as REB of Record 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 ethics 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 institution.

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

Adding a contributing institution to a dataset or a biobank existing at February 1, 2015, in the RSSS

2.5 The researcher who wishes to contribute data or biological material to a dataset 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 ethics oversight of the dataset or biobank to act as REB of Record, under this Framework.

The REB is not bound to accept this request. The REB that agrees to act as REB of Record 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 contributing institution. It provides the researcher with a copy of the ethics approval of any changes made to the data or biobank, as well as any other relevant document so that the researcher can request authorization to contribute to the dataset or biobank under the auspices of his or her institution.

3. REBs IN THE RSSS THAT CAN ACT AS REBs OF RECORD

Compliant REBs in the RSSS may act as REBs of Record

3.1 To be able to act as REB of Record, 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 clinical practices that may apply in the field of research in question.

The REB of Record 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 the MSSS feels this report does not satisfactorily establish the REB's compliance, it shall inform this REB and its institution and set out the conditions to be fulfilled before this REB can act as REB of Record. A REB established after February 1, 2015, shall provide the MSSS with a first annual report to establish its compliance before being able to act as REB of Record, 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 REB OF RECORD

4.1 To determine which REB will be asked to act as REB of Record, 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 a 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 a 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 REB of Records based on the sole fact that the project's participants will not be recruited at its institution.

Specific condition: When there is an inter-institutional 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 REB of Record shall be the joint REB or the REB mentioned in the inter-institutional agreement, except when it contravenes section 4.1. The provisions in the inter-institutional agreement shall apply, unless they are incompatible with those in the Framework, in which case the provisions of the Framework shall prevail.

Specific condition: Using datasets or biobanks for research purposes

4.3 When the researcher will use for research purposes a dataset or a biobank that is 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 ethics oversight, as stated in the management framework for this dataset or biobank. If the management framework assigns responsibility for ethics review and ongoing ethics oversight to more than one REB, the REB that will act as REB of Record 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 REB of Record

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 REB of Record, 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 REB of Record to conduct the scientific review. The REB shall not agree to such a request unless this task is part of the mandate it has received from the institution that established it and its members have the scientific expertise required to review the project.

The REB of Record informs the researcher that it is satisfied that the project has undergone a scientific review conducted by a person or committee with the required scientific expertise, 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 REB of Record 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 REB of Record 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 REB of Record shall:

- confirm that the project has undergone a scientific review, conducted by a person or committee with the required scientific expertise, that produced positive results; 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 requesting a declaration from an REB for the ethics review of a new project or the addition of a sub-study 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 REB of Record and which may be filed prior to the REB's meeting, on the date indicated in the declaration by the REB of Record.

The researcher who obtained the REB of Record'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 REB of Record to provide the date on which it will conduct the ethics review and submit this declaration to the participating public institutions so that each 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 REB of Record or be provided prior to its meeting

6.2 The list of documents that must accompany a request to act as REB of Record 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 will take into account, when they are compatible, guidelines from other authorities with regulatory power in the research field in question.

Specific condition: Research conducted with industry sponsor involving a different researcher at each participating institution

6.3 When the research project will be conducted by a different researcher acting with the same industry sponsor at each of the participating public institutions in the RSSS, the sponsor comes to an agreement with one of the researchers who is then designated as the only one who will ask a REB to act as REB of Record. 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 REB of Record'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 REB of Record and to provide proof of competency, if required by the REB.

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

6.4 When requested by a researcher, the REB that conducted the ethics review of a research project as the REB of its institution shall provide a declaration stating that it agrees to act as REB of Record for other public institutions where the same project will be carried out. The REB is bound to agree to act as REB of Record 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 REB of Record. 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 REB of Record provides the researcher with a written declaration and, if applicable, a copy of the REB's ethics 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 condition: Adding a contributing institution to a dataset or a biobank created after February 1, 2015

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

To obtain a copy of these documents, the researcher presents a request to the REB designated in the management framework for the data or biobank, or otherwise, to provide ongoing ethics oversight of the data or biobank. Unless otherwise stipulated in the management framework for the REB of Record or biobank, the REB named therein shall provide the researcher with a declaration that it will act as REB of Record or a copy of this declaration if the REB is already acting as REB of Record for other public institutions in the RSSS.

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

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 REB of Record, the REB shall promptly establish whether it has the expertise to act as REB of Record 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 REB of Record a sub-study to be added to a project already under way, he may ask the REB of Record to produce a declaration indicating the date on which it will conduct the ethics review of the sub-study and submit this declaration to the participating public institutions so that each can begin a site-specific assessment of the sub-study before receiving the positive results of the ethics review.

Points to consider before agreeing to act as REB of Record

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 within 30 calendar days from the date it agreed to act as REB of Record.

When the REB is able to act as REB of Record, 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 REB of Record 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 REB of Record for a research project, no other researcher may ask another REB in the RSSS for an ethics review of the project.

If the REB of Record cannot respond within the specified timeframe

7.4 If the REB of Record cannot respond within the specified timeframe, the researcher may address his request to another REB.

If the file is incomplete, the REB is not required to conduct the ethics review within the timeframe.

7.5 When it states that it agrees to act as REB of Record, the REB informs the researcher which, if any, additional documents required 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. If the researcher fails to respond to the REB's requests within the specified timeframe, the REB may inform the researcher how much more time it will allow for the submission of the documents, after which time 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 REB OF RECORD 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 review of the research project, the consent form in French and requests relating to the ongoing ethics 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 REB of Record 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 REB of Record provides its comments to the researcher in the five days following its meeting

8.2 The REB of Record sends its comments to the researcher promptly and no later than five working days following the meeting where the project was reviewed.

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

8.3 Upon receipt of the researcher's answers to its comments, the REB of Record selects the level of review (full board or delegated) in keeping with a proportionate approach. The REB of Record 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 related 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 time 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 written 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 REB of Record 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 consent form is the date of the letter from the REB of Record giving the positive results of the ethics review, unless the REB of Record has given the researcher a different date.

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

8.5 Once the REB of Record 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 a copy to the sponsor if there is one, in which it:

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

The REB of Record shall attach an appendix to the letter in order to document the outcome of the ethics review and shall specify its requirements for ongoing ethics oversight, including submission of an annual report on the project's progress.

In the case of clinical trials: the REB's attestation form required by Health Canada

8.6 When the REB of Record 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, the REB of Record shall provide to the sponsor an attestation listing each of the RSSS public institutions that, up to that time, have sent the REB of Record a copy of its institutional authorization to conduct the research. Along with this authorization that was issued to the researcher, the REB of Record will provide a copy of the consent form used by this researcher 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 REB of Record's decision

8.7 The researcher may ask a REB of Record to reevaluate its decision on the project's ethical acceptability. If this first step is unsuccessful, he may appeal the REB of Record's decision before an REB that is 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 formally mandates a person to authorize research conducted at the institution, or under its auspices, and that is also being conducted at one or more public institutions in the RSSS. This person has an employment relationship with the institution and his/her name must be submitted to the MSSS. This person's authorization is also required for a researcher to create a data and/or biobank for research purposes or to contribute to an existing data 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 institution may agree upon operational and organizational arrangements whereby the mandated person fulfills his mandate and responsibilities under this Framework.

Whatever arrangements 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 a REB, the institution sets out procedures for multicentre research and makes its requirements known within five days when receiving a request for the authorization process to be initiated.

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 REB of Record 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 condition: research conducted with an industry sponsor and under the responsibility of a different researcher at each institution

9.3 When an industry sponsor proposes the same research project to more than one public institution in the RSSS, conducted under the responsibility of a different researcher at each institution, it determines with the researcher who obtained a declaration from a REB that has agreed to act as REB of Record how a copy of this declaration will be provided to each of the other researchers who wish to request authorization from their institution to conduct the same research project, as stipulated in section 6.3.

Each of these researchers shall promptly:

- identify themselves and their institution to the REB of Record;
- provide the REB of Record with documents demonstrating they are qualified to carry out the research project; and
- provide the REB of Record 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 establishes how to gain access to the results of this review.

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;
- the ways medication is to be managed, if applicable;
- the possibility of a misalignment with the institution's policy directions;
- the impact of the institution's contribution to the data and/or biobank that will be established for research purposes, if applicable.

11. AUTHORIZATION TO CONDUCT RESEARCH GRANTED BY THE INSTITUTION

The researcher provides the institution with the documents from the REB of Record confirming that the project has undergone a scientific (scholarly) review as well as an ethics review, and was approved

11.1 The researcher provides the person mandated by the institution to authorize research with the approval letter and attachments, in which the REB of Record:

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

The researcher includes:

- the final version of the documents pertaining to the research project as approved by the REB of Record, including the consent form in French, where, in the spaces provided by the REB of Record, the administrative elements required for each institution are inserted.

Specific condition: Research carried out by a different researcher at each public institution, with the same industry sponsor

11.2 When an industry sponsor proposes the same project to more than one public institution in the RSSS with a different researcher responsible for the project at each institution, it receives a copy of the approval letter from the REB of Record, along with attached documents. It provides a copy to each other researcher who wishes to request authorization from their institution for the same project.

If not already done at the time of submission of the declaration from the REB of Record, each researcher must then:

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

When the researcher provides written confirmation by the REB of Record 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 REB of Record 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 REB of Record, 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 necessary documents for 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 should be satisfied that the results of the scientific review, ethics review and site-specific assessment of the project are all positive

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 attesting, through an authorization letter, that the research project has undergone a scientific review, an ethics review and a site-specific assessment with positive results.

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 model of authorization letter issued by the MSSS. The model letter is appended to this document.

When authorizing a researcher to create a data and/or a biobank, or to contribute to a data or biobank, the institution shall add the terms and conditions to the model letter accordingly and 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 REB of Record's ethics approval. Upon receipt of this decision from the REB of Record, 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 in its authorization letter to the researcher and the sponsor.

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 project that were approved by the REB of Record. The consent form to be used at the institution shall correspond to the form approved by the REB for use in the RSSS network, 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 REB of Record, clearly identified in the institution's authorization letter and documented in attachments to the authorization letter sent to the REB of Record. If the REB of Record 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 ethics approval of the project at this institution if it feels it is necessary.

On the consent form used at the institution, the date of the authorization letter issued by the institution may be added along with the date of the ethics approval by the REB of Record of the network version of the form.

The institution informs the researcher(s), the REB of Record and the industry 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 REB of Record and to the industry sponsor, if there is one. If the researcher who receives authorization to conduct the research at the institution is not the person to whom the REB originally 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 REB of Record.

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 REB of Record. This is 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 REB of Record and to the industry 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 REB of Record 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 ethics approval of the project at this institution if it feels it is necessary.

Research projects registry 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 registry and that reports are made annually to the institution's Board of Directors and the MSSS.

When the institution has a REB that did not act as REB of Record

11.9 When the institution has a REB that did not act as REB of Record, the person mandated to authorize research at the institution may provide the institution 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 REB of Record as needed while the research is in progress at the institution. A follow-up of the authorization given to the researcher should be done annually at a minimum, upon receipt of the REB of Record's decision to renew the ethics approval.

While a research is in progress in the institution, 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 then promptly informs the REB of Record of the measures taken, stating the reasons.

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

Implementing ongoing passive ethics oversight by the REB of Record

12.1 The REB of Record establishes the passive means it feels are appropriate for the ongoing ethics oversight of the research, by applying MSSS requirements and, when compatible, taking into account guidelines from other authorities with regulatory jurisdiction in the research field in question.

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

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

Specific condition: Same research carried out by a different researcher at each of the institutions, with an industry sponsor

12.2 When a different researcher at each participating institution is responsible for a research being conducted with an industry sponsor, the researcher who requested the ethics review submits to the REB of Record the notifications required for ongoing ethics oversight of the project that:

- pertain to the progress of the research at the REB of Record's institution, e.g. annual report by the REB of Record's institution, serious adverse reaction (SAR) at the REB of Record's institution; and
- impact the progress of the research at all the institutions where the project is being conducted (e.g.: other than an administrative change made to the project or the request for annual renewal of the ethics 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 REB of Record, notification of a SAR at the institution), the ongoing ethics oversight notification is submitted to the REB of Record by the researcher responsible for the project at the institution involved. The REB of Record's decision following these notifications is sent to the researcher who submitted the notification.

The REB of Record may impose requirements for the ongoing ethics 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 REB of Record shall clearly distinguish, in the approval letter or in the 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 institutions in the RSSS. These requirements are essential, especially with respect to the content and deadlines of the scheduled annual reports.

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

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

Forms for ongoing ethics oversight

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

Network approach: Promptly forwarding the REB of Record's oversight decisions

12.4 The REB of Record forwards its decisions pertaining to the ethics review of the research, along with documents deemed useful:

- to the researcher who requested the ethics review;
- to the industry sponsor;
- 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 institutions, when these decisions affect them.

When an ongoing ethics review results in changes to a document pertaining to the research, the REB of Record 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 REB of Record acts promptly and renders its decision within 30 calendar days of receiving the request for ethics review. When the ethics review concerns a change to the consent form, the REB of Record acts promptly so that the new version of the form is accessible to all those involved and that the protection of the participants is maintained.

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

12.5 The person mandated to authorize research at the institution receives a copy of the REB of Record's decisions in the ongoing ethics review of the project. It shall endorse them or revoke the authorization given to the researcher. When refusing to endorse an ethics review decision and suspending or revoking the authorization previously granted to the researcher, the mandated person shall inform the REB of Record, citing the reasons.

When an ethics review decision by the REB of Record 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 REB of Record gave its ethics approval, as well as a copy of the previous version indicating the changes made. The following steps shall be promptly completed at each institution where the research is carried out:

- Upon receipt of the REB of Record's review decision, the person mandated to authorize research at the institution determines whether the researcher conducting the research has already provided an amended version of the consent form showing where changes have been made and administrative elements inserted. . If this has not been done, the person sets a deadline for the researcher to produce the document;
- When the researcher provides the final version of the new consent form to be used at the institution, along with a copy of the previous version indicating the changes made, the person mandated to authorize research at the institution should be satisfied that the changes to the network version of the consent form are administrative in nature and, if requested, should issue to the researcher a written confirmation with the authorization date for use of the new consent form in the institution;
- The person mandated to authorize research in the institution sends the new consent form to be used at the institution to the REB of Record and the sponsor, if applicable, along with a copy indicating the changes made and the administrative elements added to the network version of the form.

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

When the institution has a REB that did not act as REB of Record

12.6 After endorsing a review decision issued by the REB of Record, 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 REB of Record. 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 REB of Record's review decision that was forwarded to the institution's REB pertains to the approval of the annual report provided by the researcher to the REB of Record, 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 for implementation of active oversight measures at the institution.

Network approach: While the research is under way, the REB of Record must liaise with the person who authorized the research to proceed at each participating institution.

12.7 While the research is under way, the REB of Record and the person mandated to authorize research 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 ethics bureau, a research office or an REB that did not act as REB of Record, a direct line of communication should be established between these resources and the person formally mandated to authorize research at the institution. This is so the mandated person can rely on their expertise to promptly take action with the researcher and the REB of Record, 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 during the scientific review, ethics review and ongoing ethics oversight of a research project. The billing takes place when processing the request for authorization to conduct research under the auspices of the institution and at the time of annual review 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 players

14.2 The MSSS strongly encourages any initiative by the various players that would foster dialogue, develop shared forms and standardize the REBs' operating rules or requirements, and the conduct of the ethics review, so as to consolidate objectives to protect study participants and facilitate the 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 : - one researcher in charge, and -several RSSS public institutions	Special case : - an industry sponsor, and - one researcher in charge at each RSSS public institution	Deadlines
1) The researcher identifies the institutions where the participants will be recruited and establishes which REB in the RSSS will be approached (section 4).		
2) The researcher asks a REB in the RSSS to declare that it agrees to act as REB of Record (section. 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 REB of Record (section 6.3). Once a researcher has approached a REB in the RSSS to ask it to act as REB of Record, 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 REB of Record. 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 (section 7).
3) The researcher submits the REB of Record'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 agreeing to act as REB of Record 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 REB of Record and provide it with 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 REB of Record: • receives the REB of Record's comments on the project; • replies to its requests; and • when the REB of Record is satisfied, provides the final version of the documents pertaining to the research, including a network version		The REB of Record sends its comments to the researcher within **five working days** following the REB's meeting to review the project (section 8.2).

General procedure : **- one researcher in charge, and** **-several RSSS public institutions**	**Special case :** **- an industry sponsor, and** **- one researcher in charge at each RSSS public institution**	**Deadlines**
of the consent form in French (section. 8).		
5) The researcher receives a letter from the REB of Record confirming the positive results of the peer scientific review and its ethics review (section 8.5).		The REB of Record 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 REB of Record 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 provides a copy of the REB of Record's letter with the result of the ethics review, along with attached documents, to the other researchers who will request the authorization to conduct the same project at their institution (section 11.2). Researchers add the administrative elements to the network version of the consent form as required so the form can be used in their 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 the 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 at the institution (review 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 REB of Record, on behalf of the sponsor, to provide an attestation, with the list of institutions that provided it 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 REB of Record with the notifications required for the ongoing ethics review and oversight (section. 12.1) When a sub-study is added, the REB of Record proceeds as if it were a new research project.	For ongoing ethics review and oversight, the REB of Record: • receives from the researcher who asked it to act as REB of Record the notifications that pertain to all the sites and those that pertain to the REB of Record'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).	For ongoing ethics oversight, the REB of Record sends its decisions to the researcher(s) concerned, to any sponsors and to the person who authorized the research at each of the institutions affected by the decision, **promptly and no later than 30 calendar days** after receiving the request for an ethics oversight (section 12.4).
9) The researcher provides the REB of Record with an annual	The REB of Record renews ethics approval for all participating	

General procedure : - one researcher in charge, and -several RSSS public institutions	Special case : - an industry sponsor, and - one researcher in charge at each RSSS public institution	Deadlines
progress report on the research project (section 12).	institutions on the anniversary date of the letter giving the result of the ethics review. Each researcher responsible for research at an institution complies with the conditions determined by the REB of Record for the submission of an annual report (section 12.2). If not, ethics approval for this institution is suspended by the REB of Record.	