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Framework for Public Health and Social Services Institutions to authorize research conducted at more than one site

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INTRODUCTION

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 RUISs conducted extensive consultations with key players in the territories they serve and submitted their proposals to the MSSS in summer 2013 for analysis, the results of which were presented to RUIS representatives and the FRQS in fall 2013. Consensus was reached at the end of this process, and a harmonized system was established for the RSSS public institutions in Quebec.

Any research project conducted at more than one public institution in the RSSS will now undergo a single ethics review by a research ethics board (REB) in the RSSS. These new procedures will come into effect on February 1, 2015, and will replace those in the Mechanism for the Ethical Review and Ongoing Oversight of Multicentre Projects, the "*Mécanisme encadrant l'examen éthique et le suivi continu des projets multicentriques*" from 2008.

One of the main concerns raised by the four RUIS during their consultations involves the REBs' funding. Moving toward a single ethics review must not result in the underfunding of the REBs and, consequently, the loss of their skills and expertise. Thus, considering the various issues and challenges that the REBs will have to face once a single ethics review is conducted for multicentre projects, specific measures will apply during the transition period from February 1, 2015, to March 31, 2016. The existing billing parameters for the ethics review and ongoing oversight of multicentre projects will be maintained. For a multicentre project funded by a private enterprise, institutions with a REB will continue to bill charges that are at least equal to those that currently apply. At the same time, a working group will be set up to establish optimal funding arrangements for the REBs.

During the transition period, adjustments will be made to the process, if required. Although the fundamental approach of a single ethics review will remain, improvements will be considered. This Framework is therefore a transitional document. It currently includes temporary clauses that will be removed once implementation is completed; it will be tested and fine-tuned in the upcoming months. At the end of the transition period, an updated Framework will be distributed throughout the RSSS.

The framework established for multicenter research projects 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 involved 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 boost the competitiveness of Quebec's research system on the national and international scene, as well as its ability to attract the best researchers to Quebec.

CONTEXT

This document describes how the public institutions in the RSSS will coordinate the interactions between the people and committees that oversee the review, authorization and smooth operation of research projects conducted at more than one institution.

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 will enable public institutions in the RSSS to authorize a research project in their institution by recognizing an ethics review conducted by an REB in the RSSS, whether or not it is part of the institution where the research is to be conducted.

The provisions in the Framework relating to the determination of the reviewing REB and its activities apply notwithstanding any incompatible provisions that may be included in the institution's regulatory framework for research activities, mission statement or operating rules of the institution's REB, if it has one, or in an affiliation agreement.

The Framework governs the interactions between the public institutions in the RSSS and their 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 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. This network approach is reflected in the Framework: some provisions are new (e.g. the Statement by the REB that agrees to act as reviewing REB), others already existed but have been formalized (e.g. letter from the person mandated by the institution to authorize research conducted on site).

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:

- adopts a resolution accepting the principle of a single ethics review for the same research project; the review is done by a REB in the network that is not necessarily within the institution; and
- formally designates the person mandated to authorize a researcher to conduct research when the scientific (scholarly) review, ethics review and site-specific assessment for the project at the institution are all positive. The institution is responsible for the operational and organizational conditions under which the formally mandated person executes his mandate.

Responsibility: The institution's liability insurance applies, provided that the REB that conducted the ethics review is a REB established by the board of directors of a public institution in the RSSS or the *Comité central d'éthique de la recherche* (CCER) established by the *Ministère de la Santé et des Services sociaux* (MSSS).

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 research and the method of communicating with him; and
- researchers are informed of the procedure for requesting a site-specific assessment of the project at the institution, obtaining recognition of an ethics review by the REB that agreed to act as reviewing REB and obtaining authorization from the mandated person to conduct the research at the institution.

Network approach in a REB

Communication: The REB acting as the reviewing REB gives top priority to maintaining communications with the researcher and the person who authorized the research at each of the institutions. 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 institutions, the REBs and the administrative support staff take the initiative to participate voluntarily in any other communications aimed at improving the oversight of research activities in the RSSS.

Local population circumstances: The REB performs tasks assigned to the reviewing REB 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 relevant information about local populations and circumstances that may have a bearing on a project's ethical review. It advises the researcher so that documents pertaining to the research project, including the consent form, are presented in a format that can be used at several institutions.

Network approach for a researcher

Local circumstances: Researchers who ask an REB to act as reviewing REB for a multicenter research project shall ensure that the reviewing REB is provided with any relevant information about the local populations and circumstances that may have a bearing on the ethics review of the project.

Specific situation of a sponsor working with several researchers: In general, the Framework applies to a researcher who wishes to carry out a project, with a team under his direction, at several public institutions in the RSSS. It is also possible that many researchers will act individually with a sponsor to work on the same project, each at his own institution. This situation is addressed by the Framework. Among other things, it stipulates that the researcher who asked the REB to act as the reviewing REB shall provide the reviewing REB with follow-up notifications regarding the ongoing oversight of the research project that are applicable at all sites where the project is being conducted or that concern everyone. Researchers responsible for the research at their institution will send to the reviewing REB the ongoing oversight notifications pertaining to their institution.

Network approach for a sponsor

Choice of researcher to request the ethics review: When a sponsor wishes to conduct the same research project with a different researcher at each of the targeted public institutions in the RSSS, the sponsor and one of these researchers must agree to ask a REB in the network to act as reviewing REB. When determining which researcher will request the ethics review and subsequently assume responsibility for filing the follow-up notifications for the entire project, the best interests of all parties should guide the decision, despite the competitive context for the sponsor's other actions associated with this research project.

AN EVOLVING APPROACH

This Framework was developed on the basis of the results of an extensive consultation process conducted in partnership with the FRQS and the RUIS. It includes transitional provisions, and the rules for implementing the various clauses will be re-examined at the end of the transition period to ensure the stated objectives are achieved.

1. DEFINITIONS

[Note: these are in the same order as in the French version of the document]

1.1 **REB**: Research Ethics Board

1.2 **Reviewing REB**: 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. It must have been established by the board of directors at one or more public institutions in the RSSS or at a health and social services agency, or it must be the *Comité central d'éthique de la recherche* (CCER) established by the *Ministère de la Santé et des Services sociaux* (MSSS).

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

1.4 **Researcher**: a person to whom a public institution in the RSSS, university or CEGEP in Quebec has conferred the status of researcher; a person who can demonstrate that he can satisfy the criteria required to hold the status of researcher; a graduate or doctoral student, as defined by a granting agency of the Quebec government or federal government.

1.5 **Public institution**: a public institution, under the *Act respecting health services and social services*, covered by the liability insurance program of the Direction des assurances du réseau de la santé et des services sociaux (DARSSS).

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 an institution, or to the extent determined by by-law of the board, a member of the personnel of that institution appointed to authorize a research project to be conducted at the institution or under its auspices, in accordance with section 169 of the *Act respecting health services and social services.*

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

1.9 **Research**: Must be understood broadly to include any research activity in the health and social services domain that involves the participation of people, including databases and biological materials established for research purposes. Research with people includes that examining personal information, human remains, biological materials of human origin, bodily fluids, cadavers, gametes, embryos, fetuses and information or data derived from biological materials 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 (Health and Social Services Network).

1.11 **Ongoing active oversight**: Ongoing active oversight of a research project requires the assistance of a body that is independent of the researcher and the sponsor to review the conduct of the research and related documents.

1.12 **Ongoing passive oversight**: Ongoing passive oversight of a research project is carried out by a reviewing REB based on the notifications it receives from a researcher or sponsor while the research is under way.

2. SCOPE OF THE FRAMEWORK

Ministerial directive applicable to research conducted at more than one public institution in the RSSS

2.1 This Framework is a ministerial directive that must be applied when research is conducted, in whole or in part, at more than one public institution in the RSSS, according to the definition of the terms "public institution" and "RSSS" as used in this document.

Transitional provisions

2.2 The transitional provisions provided relative to a section of the Framework are in effect from February 1, 2015, to March 31, 2016.

Deadlines: effective April 1, 2015

2.3 The deadlines set out in the Framework become mandatory effective April 1, 2015.

Agreement in principle by the institution's board of directors

2.4 This Framework sets out the terms and conditions for the implementation of the principle that research conducted at more than one public institution in the RSSS gives rise to a single ethics review. To participate in such a research project, the institution's board of directors must accept this principle by resolution, with a copy sent to the MSSS.

This Framework takes precedence immediately

2.5 The provisions in this Framework pertaining to the determination of the reviewing REB and its activities apply notwithstanding any incompatible provision that may be included:

- in the institution's regulatory framework for research activities;
- in the mission statement or operating rules of the institution's REB, if a REB has been established, or
- in an affiliation agreement.

In these documents, the incompatible provisions are immediately replaced by those in this Framework. At a time of their choosing, the institutions may formally integrate this Framework into the documents they have previously adopted.

This Framework replaces the 2008 Multicentre Mechanism

2.6 Effective February 1, 2015, this Framework shall replace the Mechanism for the Ethical Review and Ongoing Oversight of Multicentre Projects that came into effect April 1, 2008.

Research in progress under the 2008 Multicentre Mechanism

2.7 Research projects that are in progress as of February 1, 2015, under the 2008 Multicentre Mechanism will continue to be subject to it, until the research project is completed or until the next annual renewal of approval for the project by the main REB after April 1, 2015. The Framework shall apply to the research project as of the date of this annual renewal and the main REB under the 2008 Multicentre Mechanism shall become the reviewing REB and will perform its functions.

Addition of site(s) to a project that has already been reviewed by several REBs with the easing of rules in the 2008 Multicentre Mechanism

2.8 This Framework may be applied if one or more sites are added to a research project in progress on February 1, 2015, provided that a REB agrees to act as the reviewing REB at the researcher's request. The applicable specific conditions are described in section 6.4.

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

The REBs in the RSSS may act as reviewing REBs provided their method of operation is compliant

3.1 To be able to act as a reviewing REB, the REB must conduct its activities in compliance with the legal and regulatory requirements applicable in Quebec and with 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 reviewing REB must also respect the deadlines prescribed in the Framework as of the date specified in section 2.3.

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

3.2 To establish its compliance, the REB must 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 a reviewing REB. A REB established after February 1, 2015, must file an initial annual report to the MSSS to establish its compliance before being able to act as a reviewing REB.

Specific situation: participation of non-designated REBs

3.3 A REB that is not designated by the MSSS and did not satisfy the reporting requirement to the MSSS in fiscal years 2012-2013 and 2013-2014, as required under the 2008 Multicentre Mechanism, may not act as a reviewing REB before establishing its compliance with the MSSS.

4. DETERMINING WHICH REB THE RESEARCHER WILL ASK TO BE THE REVIEWING REB

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

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

Specific condition: 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 condition: research project requiring the use of a database or bank of biological material established for research purposes

4.3 When the research project requires the use of a database or bank of biological material established for research purposes that is located at more than one public institution in the RSSS, the researcher shall address his request for ethics review to the REB to which the institutions involved have assigned the ethics review and ongoing monitoring of the bank, as indicated in the management framework for this bank. If the bank's management framework assigns responsibility for ethics review and monitoring 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 researcher should be in possession of the positive results of the scientific (scholarly) review of his research project conducted by a person or committee with the necessary scientific expertise, before taking steps with a REB in the RSSS to request that it acts as reviewing REB.

If the scientific (scholarly) review of the project has not yet been done when the researcher asks a REB to act as reviewing REB

5.2 If the researcher has not yet obtained a positive result for a scientific (scholarly) review when he asks a REB to act as reviewing REB, he shall submit the project for professional peer-review assessment at the institution of the REB he is asking to act as reviewing REB. The researcher may also ask the reviewing REB to conduct a scientific (scholarly) review of the project. In order to agree to such a request, the REB should have the necessary scientific (scholarly) expertise and this task should be part of the mandate it has received from the institution that established it.

The reviewing REB confirms to the researcher that it is satisfied the scientific (scholarly) review was conducted by a person or committee with the required scientific (scholarly) 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 of the research project, the reviewing REB shall determine if the project has undergone a scientific (scholarly) 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 supervisor or by a peer review committee at a university or college.

When it conducts the ethics review of the project, the reviewing REB shall also examine the ethical implications of the methods and design of the research.

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

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

6. SUBMISSION OF A REQUEST FOR AN ETHICS REVIEW BY THE RESEARCHER

The researcher shall use the project submission form of the REB he is approaching and attach to it documents requested by the REB

6.1 The researcher files his request for an ethics review using the form intended for this purpose from the REB he is asking to act as reviewing REB. The REBs in the RSSS shall indicate to the researchers which documents must accompany the request to act as reviewing REB and which ones may be filed later.

Documents that must accompany the request to act as reviewing REB

6.2 The list of documents that must accompany a request to act as reviewing REB and those to be supplied by the researcher subsequently is established by the REB by applying the requirements set out by the MSSS and, when they are compatible, instructions from other authorities with regulatory power in the research field in question. At a minimum, the REB must receive the following documents:

- a list of all the public institutions in the RSSS from which the researcher plans to request authorization to conduct the research as well as any relevant information about the local populations and circumstances that may have a bearing on the ethics review;
- the positive result of the scientific (scholarly) review of the project or information as to the steps taken or to be taken by the researcher to obtain a scientific (scholarly) review; and
- the list of all steps taken with other public institutions in the RSSS or other REBs with a view of securing project approval as well as a list of any significant previous decisions by other REBs or regulatory authorities regarding the same project.

Specific situation: research conducted with a sponsor (e.g. a clinical trial)

6.3 When the research project has a sponsor and will be conducted by a different researcher at each of the participating public institutions in the RSSS, the sponsor works with one of the researchers to submit a request for an ethics review. The researcher who asks a REB to act as reviewing REB informs the REB that the research project is being conducted with a sponsor and identifies that sponsor. If possible, he also identifies the researchers who will be responsible for conducting the same project at the other participating institutions.

Specific situation: adding site(s) to a project that has already been reviewed by several REBs in the RSSS with the easing of rules under the 2008 Multicentre Mechanism

6.4 When a researcher wishes to add one or more sites to a project in progress that has already been reviewed by more than one REB in the RSSS, he may ask one of the REBs to act as reviewing REB for the new site(s). If the REB agrees to act as reviewing REB, the terms and conditions in this Framework will apply for conducting the project in the new institution(s).

7. STATEMENT BY THE REB AGREEING TO ACT AS REVIEWING REB

The REB that receives the request from the researcher must reply within five working days

7.1 When a researcher requests that it acts as reviewing REB, the REB promptly establishes whether or not it has the necessary expertise to act as reviewing REB for the project and declares it in writing to the researcher, no later than five working days after receiving the request, the statement needs to include the date on which it will review the project. When the request comes from a researcher in the institution, the REB's statement should be provided immediately.

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 examines 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;
- 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 approached a REB in the RSSS to request that it act as reviewing REB for a research project, no other researcher shall submit this project to another REB in the RSSS to request an ethics review.

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 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 reviewing REB, the REB informs the researcher which additional documents are required, if applicable, for the REB to proceed with the review of the research project 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 in the 30 calendar days following the date on which it agreed to act as reviewing REB.

8. ETHICS REVIEW BY THE REVIEWING REB AND DEADLINES

Full Board review or delegated review

8.1 The reviewing REB does a full Board review of the project, adopting a proportionate approach such that the level of review is determined by the level of risk and taking into account the field of research involved. A transitional provision allows for a delegated review for some types of research.

Transitional provisions for delegated review

8.2 For research projects that do not involve the participation of minors or persons unable to give consent under section 21 of the Quebec Civil Code, a REB may decide that the project undergo a delegated review. In its annual report to the MSSS, the REB must identify those research projects that underwent a delegated review. The data collected by the MSSS on the application of this transitional provision will be used to determine if it is appropriate to conserve it after March 31, 2016.

Network approach to the ethics review

8.3 The ethics review is conducted by the reviewing REB in accordance with the requirements of the MSSS and taking into account instructions from authorities with regulatory powers in the field of research involved.

Considering that more than one public institution in the RSSS will participate in conducting the research, the review by the reviewing REB must, at a minimum, allow it to:

- establish that the researcher requesting the ethics review—and if applicable, each of the researchers who informs the REB that he will be responsible for conducting the same project at an institution in the RSSS (e.g. a clinical study)—has the qualifications for carrying out the research project;
- obtain any relevant information about the local populations and circumstances that may have a bearing on the ethics review.

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

8.4 The reviewing REB sends its comments to the researcher promptly and no later than five working days after the meeting at which it reviewed the project.

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

8.5 The reviewing REB examines the researcher's answers to its comments either in full or select committee. The reviewing REB continues its discussions with the researcher until it is satisfied with the answers to its questions and is ready to receive the researcher's final version of the documents relating to the research.

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

8.6 The final version of the documents pertaining to the research, including the consent form, should be written in a format that makes it easy for several public institutions in the RSSS to use them, 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.

Upon receipt of the final version of the documents, the reviewing REB has five days to respond

8.7 When the reviewing REB receives the final version of the researcher's documents pertaining to the research, it provides the researcher with a letter, no more than five working days later, in which it:

- confirms that it is assured the project has undergone a scientific (scholarly) review with a positive result 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 reviewing REB attaches an appendix with this letter to document how the ethics review has been conducted. It also indicates the procedure to follow when an institution that authorizes research to be conducted asks for purely administrative changes to the documents that had been approved by the reviewing REB.

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

8.8 The reviewing REB that conducts the ethics review of a multicentre research project that is covered by the *Guidance Document For Clinical Trial Sponsors: Clinical Trial Applications* published by Health Canada must produce an attestation to the effect that it commits to carry out its functions in a manner consistent with good clinical practices at each of the sites where the research is being conducted. This form is retained as records by the sponsor.

The reviewing REB shall provide this attestation to the researcher when he requests it on the sponsor's behalf. To prepare this attestation, the reviewing REB shall duplicate Part 3 of the REB Attestation form proposed by Health Canada as many times as necessary to capture all sites addresses. A site is a public institution in the RSSS that, on the date the attestation was signed, sent the reviewing REB a copy of the authorization to conduct research provided to a researcher. The reviewing REB may use its own letter of attestation, provided that it complies with Health Canada requirements for the use of such a document.

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

8.9 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 to 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 formally assigns a member of the personnel of that institution and whose name is submitted to the MSSS the mandate to authorize a researcher to conduct research at the institution or under its auspices that is also being conducted at one or more public institutions in the RSSS. This person must not be subject to apparent, real or potential conflict of interest.

The institution may agree upon operational and organizational arrangements whereby the mandated person fulfills his mandate and responsibilities under this Framework. Persons or bodies currently identified within institutions to receive requests from researchers (e.g. research office, ethics office, clinical research unit) may continue to serve as contacts with researchers for the purposes of authorization.

Whatever arrangements are implemented, the authorization for the research to proceed in the institution is the responsibility of the formally mandated person.

Network approach: whether or not it has a REB, the institution sets out procedures to accommodate researchers conducting multicentre research and 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 for a site-specific assessment of the project as soon as he has in his possession a formal statement 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 a request for a site-specific assessment of the project if additional documents are required;
- 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: research conducted by a different researcher at each institution with the same sponsor (e.g. a clinical trial)

9.3 When a 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 asks the researcher who obtained a statement from a REB that agrees to act as reviewing REB to provide a copy of this statement to each of the other researchers who wish to request authorization from their institution to conduct the same research project, as stipulated in section 9.2. Each of these researchers must promptly:

- identify themselves and their institution to the reviewing REB;
- provide the reviewing REB with documents demonstrating they are qualified for carrying 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

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 he is provided with the results of this review.

Site-specific assessment of the project

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

- 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.

11. AUTHORIZATION FOR THE RESEARCH TO PROCEED IN THE INSTITUTION

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

11.1 The researcher provides the person mandated by the institution to authorize research with a letter in which the reviewing REB:

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

The researcher attaches to this letter:

- documents showing how the ethics review was conducted and relevant exchanges between the researcher and the reviewing REB;
- the final version of the documents pertaining to the research, as approved by the reviewing REB; and
- instructions from the reviewing REB regarding purely administrative changes that may be made by an institution to the approved version of the documents describing the project.

These attachments are not required when the researcher submits his application to the person mandated to authorize research at the reviewing REB's institution.

Specific situation: research carried out by a different researcher at each of the institutions with the same sponsor (e.g. a clinical trial)

11.2 When a sponsor proposes a research project to more than one public institution in the RSSS that is conducted under the responsibility of a different researcher at each institution, it asks the researcher who obtained the letter from the reviewing REB confirming that the research project has undergone a scientific (scholarly) review and ethics review with positive results to provide a copy of this letter, with attachments, to each of the other researchers who are seeking authorization from their institution for the same project.

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

- identify himself and his institution to the reviewing REB;
- provide the reviewing REB with a document detailing his qualifications for carrying out the project; and
- provide the reviewing REB with any relevant information about the local populations and circumstances that may have a bearing on the ethical review.

When the researcher produces documents showing a positive result for the scientific (scholarly) review and ethics review, the institution has five working days to decide whether or not to give authorization for the research to proceed

11.3 When the researcher provides a letter in which the reviewing REB confirms the positive results of the scientific (scholarly) review and ethics review, the person mandated to authorize research at an institution must proceed promptly to:

- obtain from a person or a committee at the institution the result of the site-specific assessment of the project, according to the procedure implemented at least 30 days previously, as stipulated in section 9.2; and
- inform the researcher, within five working days, of its decision whether or not to authorize the project to proceed.

The mandated person authorizes the research to proceed at the institution upon receipt of documents indicating that the scientific review, ethics review and site-specific assessment of the project produced positive results

11.4 The person mandated to authorize the researcher to conduct research at the institution or under its auspices fulfills his responsibility by formally receiving documents to the effect that the research project has undergone a scientific (scholarly) review, ethics review and site-specific assessment which produced positive results.

Format for authorization granted by the institution

11.5 The authorization granted by the public institution for the research to proceed must contain, at a minimum, the aspects mentioned in the explanatory model of reply letter produced by the MSSS.

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

11.6 The authorization given by the institution may be contingent upon purely administrative changes made to the documents describing the research that were approved by the reviewing REB, including the consent form. When it requires such administrative changes, the institution must comply with the reviewing REB's requirements in this area and must inform the researcher which body within the institution will follow up on the requested administrative changes.

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 person mandated to authorize research at the institution sends his decision on whether or not to authorize the research to proceed to the researcher who requested the authorization, with a copy to the reviewing REB and the 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 addressed the letter confirming the positive result of the ethics review, the person mandated to authorize research at the institution also forwards a copy of his authorization to the researcher whose name appears on the letter from the reviewing REB.

Research 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 he has authorized are listed in the institution's research registry and reports annually to the institution's board of directors and the MSSS.

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

11.9 When the institution has a REB that did not act as reviewing REB, the person mandated to authorize research at the institution provides it with a copy of his authorization to the researcher to conduct the research, along with all documents pertaining to the research.

The institution may suspend or revoke authorization provided to the researcher to conduct the research

11.10 When the person mandated to authorize research at the institution receives information likely to challenge its initial acceptance while a project is in progress, he may suspend or revoke the authorization given to the researcher. He then promptly informs the reviewing REB about the measures taken, stating the reasons.

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

Implementing ongoing passive oversight by the reviewing REB

12.1 The reviewing REB determines the degree of ongoing passive oversight that it deems appropriate in compliance with the requirements set out by the MSSS for this purpose and relevant instructions from other authorities with regulatory power in the research field in question.

When an ongoing oversight activity results in changes to a document pertaining to the research, the reviewing REB asks the researcher who filed the notification to submit the new document, along with a copy of the previous version annotated to highlight the changes approved by the reviewing REB, to the person who authorized the research at each of the public institutions in the RSSS participating in the research.

Specific situation: research carried out by a different researcher at each of the institutions with the same sponsor (e.g. a clinical trial)

12.2 When a different researcher at each of the participating institutions is responsible for research being conducted for a single sponsor, the researcher who requested the ethics review sends the reviewing REB the notifications required for ongoing oversight of the project:

- that pertain to the progress of the research at the reviewing REB's institution (e.g. annual report of the reviewing REB's institution, serious adverse reaction (SAR) at the reviewing REB's institution; and
- that are applicable at all sites where the project is being conducted or that concern everyone (e.g. a change to the research project that is other than administrative or notification of a SAR elsewhere than in an institution in the RSSS). When a monitoring activity results in a change to a document pertaining to the research, the researcher who obtains the follow-up decision from the reviewing REB must send the new document as well as a copy of the previous version annotated to highlight the changes that were approved by the reviewing REB to the researchers responsible for conducting the same research project at other public institutions in the RSSS.

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

The reviewing REB may impose requirements for the ongoing oversight of the research 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 their follow-up notifications.

Forms for ongoing oversight

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

Network approach: forwarding the reviewing REB's follow-up decisions promptly

12.4 The reviewing REB sends its follow-up decisions to the researcher who forwarded that notification, with a copy to the person who authorized the research at each of the public institutions in the RSSS involved and to the researchers responsible for conducting the same research at other public institutions with a sponsor, when these decisions affect them. The REB proceeds promptly and renders its follow-up decision within 30 calendar days after receiving the notification. While the research is in progress, the reviewing REB contacts the people who authorized the research at each of the institutions as needed.

Upon reception of a copy of the reviewing REB's follow-up decisions, the institution must endorse them or revoke the authorization granted to the researcher

12.5 The person mandated to authorize the research at the institution receives a copy of the decisions made by the reviewing REB for ongoing oversight of the project and, as needed, acts as contact person with the reviewing REB while the research project is in progress at the institution. These conditions are optional at the reviewing REB's institution.

If the mandated person refuses to endorse a follow-up decision by the reviewing REB, he must suspend or revoke the authorization previously granted to the researcher and inform the reviewing REB.

When there is a REB at the institution that did not act as reviewing REB, this REB is informed of follow-up decisions and may make recommendations to its institution following a review of the annual report submitted by the researcher

12.6 Once the reviewing REB's follow-up decision has been endorsed, the approved documents are sent to the institution's REB by the person mandated to authorize research. This is the case when the institution has an REB that did not serve as the reviewing REB.

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

Network approach: The reviewing REB and each person who authorized the research at an institution must remain in contact while the research is in progress

12.7 While the research project is in progress, the reviewing REB and each person who authorized the project at a public institution in the RSSS must have access to all relevant information on the progress of the research and must share this information in a timely manner.

When the institution has a 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 the research at the institution so it can rely on these resources to act quickly if needed during each of the research projects it has authorized, with the researcher and the reviewing REB.

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

Research projects that involve billing by the institution

13.1 The public institutions in the RSSS may bill the researcher for expenses incurred for services rendered in processing the request for authorization to conduct research at the institution or under its auspices, the ethics review and during the ongoing oversight of a research project. These charges apply only to research projects currently governed by the ministerial circular entitled "*Contribution de l'entreprise privée dans le cadre d'activités de recherche découlant d'un octroi de recherche.*"

Transitional provision: when the institution has a REB, current billing terms remain unchanged

13.2 Until March 31, 2016, each public institution in the RSSS participating in the same research project may, if it has a REB, bill the researcher by applying the same terms as those in effect at the institution prior to February 1, 2015, for research projects currently 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 to consolidate objectives to protect the participants in a study and facilitate implementation of recognition of the ethics review when the same research project is conducted at more than one public institution in the RSSS.

APPENDIX 1: SUMMARY OF PROCEDURE FOR THE RESEARCHER

General procedure for a single researcher and more than one institution	Specific procedure when a sponsor works with a different researcher at each institution	Deadlines (effective April 1, 2015)
1) The researcher identifies the institutions where the participants will be recruited and establishes which REB in the RSSS he will approach (section 4).		
2) The researcher asks a REB in the RSSS to act as reviewing REB (section 6).	After consulting with the sponsor, the research asks a REB in the RSSS to 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 may not be submitted to another REB in the RSSS (section 7.3).	The REB declares within **5 working days** whether or not it agrees to act as reviewing REB. The REB agrees immediately when the request is made by a researcher within the institution. In its statement, the REB indicates to the researcher the date on which the REB will meet for examine the project. This meeting must take place within 30 calendar days following the statement (section 7).
3) The researcher submits the statement by the reviewing REB 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 from the institution (section 9.2).	The sponsor may ask the researcher who obtained the REB's statement that it agrees to act as reviewing REB to provide this statement to other researchers who wish to seek authorization to conduct the same research at their institution. These new researchers must then immediately identify themselves to the reviewing REB and provide it with the information required (section 11.2).	The person mandated to authorize research projects at the institution informs the researcher within **5 working days** if additional documents are required for the site-specific assessment of the project at the institution (section 9.2).
4) The researcher: - receives comments from the reviewing REB on his project; - reply to its requests; when the reviewing REB is satisfied, provides the final version of the documents pertaining with the research (section 8).		The reviewing REB sends its comments to the researcher within **5 working days** following the REB's meeting to review the project (section 8.4).
5) The researcher receives a letter from the reviewing REB confirming the positive outcome of the scientific (scholarly) review and the ethics review (section 8.7).		The reviewing REB sends the results of the ethics review to the researcher within **five working days** following submission of the final version of

General procedure for a single researcher and more than one institution	Specific procedure when a sponsor works with a different researcher at each institution	Deadlines (effective April 1, 2015)
		the documents pertaining to the research.
6) The researcher forwards the letter with the reviewing REB's decision regarding the project to the person who authorizes research at each institution (section 11.1).	The sponsor may ask the researcher who received the letter in which the reviewing REB states its decision on the project to the researchers who which to ask for authorization to conduct the same research at their institution (section 11.2).	The person who authorizes research at the institution 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 refuse the researcher's request to conduct research at the institution (section 11.3).
7) The researcher receives a letter from the person authorizing the research at the institution, indicating that he may begin the project at this site (sections 11.4 – 11.7).	The reviewing REB receives a copy of the authorization to conduct the research granted by each institution. It can complete and sign the REB's attestation form, or the document replacing it, which the sponsor must conserve in its files, as per Health Canada requirements (section 8.8).	
8) During the research project, the researcher provides notifications to the reviewing REB for the ongoing oversight of the project (section 12.1).	The researcher who asked the REB to act as reviewing REB provides it with follow-up notifications that pertain to all the sites and those that pertain to the reviewing REB's institution. Each researcher who was authorized to conduct the same research at his institution provides the reviewing REB with follow-up notifications pertaining to his institution (section 12.2).	The reviewing REB sends its ongoing oversight decisions to the researcher(s), with a copy 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 notification (section 12.4).
9) The researcher provides the reviewing REB with an annual report on the status of the research at each participating institution in the RSSS. If the institution has a REB that did not serve as reviewing REB, this REB receives a copy of the reviewing REB's follow-up decision regarding this annual report. It may make recommendations to the person who authorized research at its institution (section 12.6).	Each researcher responsible for research at an institution submits an annual report to the reviewing REB (section 12.2).	