



Policy on the approvals and institutional authorization required to conduct research involving human participants under the auspices of the McGill University Health Centre (MUHC) ¹	
Related Procedure: <i>Modes opératoires normalisés des diverses évaluations impliquées</i>	Associated SNC-O&M Policy and Procedure (if applicable):
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Summary : The purpose of this policy is to describe the approvals and authorization required before initiating research activities that involve human participants and that take place under the auspices of the McGill University Health Centre (MUHC).	

(Refer to MUHC Policies and Procedures Manual)

¹ This policy contains the following standards from the *Cadre de référence ministériel*: Standard 2 (*triple examen*) and Standard 3 (*autorisation*; 2.3.1, 2.3.2, 2.3.4).



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I. Purpose

The purpose of this policy is to describe the approvals and authorization required before initiating research activities that involve human participants and take place under the auspices of the McGill University Health Centre (MUHC).

II. Impacted Individuals / Sectors

2.1 Scope

This policy applies to all MUHC researchers and to all team members conducting research involving human participants. It also applies to all individuals involved in the triple review or institutional authorization processes.



2.2 Responsibilities

In accordance with the *Cadre de référence ministériel pour la recherche avec des participants humains* (hereinafter the *Cadre de référence ministériel*), the institution must be able to establish and maintain an organizational culture that values research, ethics, and responsible conduct of research. To this end, it must implement a regulatory research framework².

The institution, the research directors (RI and MNI), the *personne formellement mandatée* ("formally mandated individual"), and the Centre for Applied Ethics are responsible for the implementation of this policy and must ensure, at a minimum, that it is disseminated, and, if necessary, that adequate support is provided to the teams involved.

III. References / Definition of terms

- Civil Code of Québec, CQLR, c. CCQ-1991
 - Notice entitled *Avis sur les conditions d'exercice des comités d'éthique de la recherche désignés ou institués par le ministre de la Santé et des Services sociaux en vertu de l'article 21 du Code civil*, Gazette officielle du Québec, Part I, vol. 35, 1998, p. 1039
- Act respecting health services and social services, CQLR, c. C-4.2
 - Circular 2016-029 (Québec, Ministère de la Santé et des Services sociaux, 2016b);
 - Circular 2003-012 (Québec, ministère de la Santé et des Services sociaux, 2003a);
 - *Cadre de référence ministériel pour la recherche avec des participants humains*, October 2020;
 - *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*, Government of Québec, Ministère de la Santé et des Services sociaux, 2016
- Act respecting Access to documents held by public bodies and the Protection of personal information, CQLR c. A -2.1
- Food and Drugs Act, R.S.C., (1985), c. F-27
 - Food and Drug Regulation, C.R.C., c. 870
 - Good Clinical Practice, International Conference for Harmonization, GCP – ICH E6(R2)
- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS2 (2018);

IV. Policy

In accordance with the *Cadre de référence ministériel*, any research project involving human participants must first be subject to a triple review (see process in Appendix 1) and must have obtained a final authorization following favourable decisions in regard to³:

- the science and ethics reviews carried out by the Research Ethics Board of the MUHC (MUHC REB) or by another REB part of the health and social services network (RSSS); and
- the research feasibility reviews carried out by the MUHC, the Montreal Neurological Institute (MNI), and the Research Institute of the MUHC (RI), if applicable.

Without these approvals:

- No intervention or interaction can be carried out on or with individuals who would participate in research, including recruitment.

² [Cadre de référence ministériel pour la recherche avec des participants humains](#), Government of Québec, Ministère de la Santé et des Services sociaux, October 2020, p. 1 and standard 1, hereinafter *Cadre de référence ministériel*.

³ *Cadre de référence ministériel*, standards 2 and 3.



- No collection of personal information can be initiated (for example in a database or from a user's medical chart).
- No biological material can be collected or analyzed.

4.1 Research that must be reviewed

Research that involves human participants and is carried out under the auspices of the MUHC⁴ must be reviewed before it is initiated, regardless of the level of risk⁵.

For the purposes of this policy, research involving human participants includes:

- Any research activity that involves human participants, including the creation or the use of a database or biobank;
- Any research project that uses personal information;
- Any research project that uses biological material of human origin or the data derived from such material, regardless of whether or not it is possible to identify the person from whom they originated.

4.2 Activities that do not require review

No REB approval is required for:

- Quality assurance and quality improvement studies; program evaluation activities and performance reviews; testing within normal educational requirements when used exclusively for assessment, management, or improvement purposes⁶;
- Public health surveillance activities⁷;
- The initial exploration phase during which researchers make contact with individuals or communities with the purpose of establishing research partnerships or informing the design of a research project⁸. This can include the installation of equipment.

4.3 Proportionality principle

The triple review adopts the principle of proportionality. The measures implemented must take into account the institution's level of involvement in a research project with regard to its objectives⁹. The three types of reviews adapt the proportionality principle to their respective area of focus.

4.4 Platform for the review of research projects

Research projects are submitted for the required reviews through a single portal by completing a submission form on the MUHC Nagano web platform; the platform is also used for all related communications.

The reviews and decisions are recorded in and communicated via the MUHC Nagano web platform.

⁴ Policy on the McGill University Health Centre (MUHC) Research Ethics Board (REB), 2021-09-20, art. 4.4.1 and 4.4.2.

⁵ Tri-Council Policy Statement 2 – Interagency Advisory Panel on Ethical Conduct of Research, 2018, art. 2.1, hereinafter TCPS2; *Cadre de référence ministériel*, section 1.5 and 2.2; *REB SOP 102.001*, MUHC.

⁶ TCPS2, art. 2.5; *Cadre de référence ministériel*, section 1.5.

⁷ *Cadre de référence ministériel*, section 1.5.

⁸ TCPS2, art. 6.11.

⁹ See *Cadre de référence ministériel*, section 2.2.4.



4.5 Scientific review

4.5.1 Procedure

The first step of the review process is the scientific review. Unless the project already underwent a scientific review by a recognized peer committee¹⁰, the project will have to be reviewed by the REB; the principle of proportionality set out in article 4.5.2 of this policy will be applied¹¹. The REB's Standard Operating Procedures (SOPs) are applicable when it conducts the scientific review of a project.

During a scientific review, the REB ensures:

- the research project is relevant and valuable;
- the literature review is adequate;
- the hypotheses are clear;
- the study population is well chosen;
- the sample size is justified;
- the data collection tools are adequate;
- the statistical analysis methods are adequate;
- the study duration is adequate;
- the project is safe (including dose choice and use of placebo, if applicable);
- the research team is qualified;
- the project's potential outcome is relevant.

4.5.2 Decision-making power

The REB has the authority to approve, to approve conditionally, or to disapprove the research project. This decision must be made within a reasonable timeframe. If issues must be addressed before a decision can be made, the REB may postpone/defer its decision¹².

4.6 Ethics review

4.6.1 Procedure

Unless the project was already subject to the review of another research ethics board part of a public institution within the RSSS, it will have to be reviewed by the MUHC REB¹³.

The REB reviews the ethical acceptability of research projects.

For the purpose of the ethics review, the REB assesses, among others¹⁴:

- the relevance and value of the project;
- the rationale for selecting the population to be studied;
- the procedures for selecting and recruiting participants;
- the management of risks;
- the proportionality of risks versus benefits;
- the rationale for the use of placebo or deception, if applicable;
- the plan and commitments related to the protection of privacy and data confidentiality¹⁵;

¹⁰ *Cadre de référence ministériel*, section 2.2.1.

¹¹ TCPS2, art. 2.7; *Cadre de référence ministériel*, section 2.2.1.

¹² See REB SOP 401.001, MUHC.

¹³ In application of the ministerial provisions regarding multicentric research: *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*, Government of Québec, Ministère de la Santé et de Services sociaux, 2016, hereinafter *Cadre de référence pour la recherche dans plus d'un établissement*.

¹⁴ For the minimum criteria for research project approval, refer to REB SOP 403.001, MUHC.

¹⁵ The REB is not responsible for ensuring data safety.



- the management framework of databases or biobanks,¹⁶ which must specify:
 - which REB performed the initial ethics review and provides ongoing ethics oversight;
 - which REB will perform the ethics review and provide ongoing ethics oversight of research projects for which the bank will be used;
 - the respective roles of institutions that are housing the bank, when there are more than one.
- the process, and all documents, related to participant consent;
- the ethical acceptability of the project and any other ethical issue (e.g., financial conflicts of interest or other) that would compromise the safety or well-being of participants, or the integrity of data of the research project.

4.6.2 Proportionality of the ethics review¹⁷

Ethics reviews are carried out at a full-board meeting. If the project's level of risk is considered minimal, the project can receive a delegated review¹⁸.

4.6.3 Decision-making power

The REB has the authority to approve, to approve conditionally, or to disapprove the research project. This decision must be made within a reasonable timeframe. If issues must be addressed before a decision can be made, the REB may postpone/defer its decision¹⁹.

The REB also has the power to suspend or terminate the ethics approval of the research²⁰. It must then immediately contact the *personnes formellement mandatées* who authorized the project within their respective institutions to inform them of the reasons of the decision and of the actions being undertaken.

4.7 Institutional feasibility review

4.7.1 Procedure

The feasibility review is conducted in parallel with the scientific and ethics reviews, as described in Appendix 1.

The feasibility review aims to make sure the research is feasible locally.

The MUHC, the RI, and the MNI are responsible for different feasibility reviews. Feasibility reviews are generally initiated and recorded in the Nagano web platform. Other feasibility reviews, such as the review done by the McConnell Brain Imaging Centre (BIC) of the MNI, are carried out outside of Nagano but are documented in it. When a project requires a feasibility review that was not planned, the *personne formellement mandatée* must make sure the necessary approvals are obtained.

As per the *Cadre de référence ministériel*, the following, among others, must be assessed as part of each feasibility review²¹:

¹⁶ Refer to MUHC Policy on Biobanks and Databases (BBDB) for research Purposes, 2018-06-15; *Cadre de référence ministériel*, section 2.5.5.

¹⁷ See definition REB SOP 402.001, MUHC.

¹⁸ TCPS2, art. 2.9 and 6.12; REB SOP 402.001, MUHC.

¹⁹ REB SOP 401.001, MUHC. See also TCPS2, art. 6.3; GCP, 3.1.2.

²⁰ REB SOP 407.001, MUHC; GCP, sect. 3.1; TCPS2, art. 6.3.

²¹ *Cadre de référence ministériel*, section 2.2.3; *Cadre de référence pour la recherche dans plus d'un établissement*, section 10.2.



- the availability of the institution's facilities, equipment, and human resources required by the project [carried out by the relevant sectors];
- the financial and contractual aspects as well as their impact on the institution's resources, in particular by making sure that all direct costs of the research project are adequately budgeted for [carried out by the Contracts Office of the RI, the Contracts Office of McGill University, the MUHC Financial Services];
- the research project's liability insurance coverage [carried out by the Contracts Office of the RI, the Contracts Office of McGill University];
- the reasonable and non-abusive solicitation of the individuals targeted by the research project [carried out by Department Heads];
- the procedures for medication management [carried out by Pharmacy];
- the alignment between the research project and the MUHC's vision and mission, as well as the institution's capacity [carried out by *personne formellement mandatée* upon request of the REB or feasibility reviewers];

Based on specific needs, a feasibility review could also be required for the following elements:

- biosafety;
- potential, real, or perceived conflicts of interest reported to the REB, suggesting appropriate actions to solve or manage those conflicts [carried out by any individual that may be aware of such a situation];
- research privileges of the researcher responsible for the project at the MUHC [carried out by the RI and MNI leadership];
- for projects that are reviewed by another REB part of the RSSS, the adequacy of the documentation to build a complete study record and the local versions of the documents that will be given to study participants [carried out by the *personne formellement mandatée*].

New feasibility reviews may be added according to the needs and evolution of the research.

4.7.2 Feasibility reviewers and persons responsible of feasibility workflows

For every feasibility workflow (e.g., pharmacy, laboratories, nursing, contracts, etc.), a person is in charge of each project's review. For each of the feasibility workflows, the person responsible can be assisted in his/her functions.

The general feasibility review process (i.e., flow and system components) is under the responsibility of the following individuals, depending on the site:

- For the MUHC: the DQEPE Director
- For the RI: the RI Director
- For the MNI: the MNI Director

4.7.3 Decision-making power

The feasibility reviewer has the authority to approve, to request modifications or to deny the involvement of his/her sector in the research project. This decision must be made within a reasonable timeframe. The feasibility reviewer also has the power to suspend or terminate the approval of his/her sector. The feasibility reviewer must then inform, as soon as possible, the REB and the *personne formellement mandatée* who authorized the research of the reasons for the decision and of the actions being undertaken.



4.8 Institutional authorization to conduct research at the site

4.8.1 Procedure

Before it is initiated, a research project to be conducted within the institution or under its auspices must be authorized by the *personne formellement mandatée*²².

The *personne formellement mandatée* must make sure the research project was subject to a scientific, ethics, and feasibility review with positive results²³.

For projects reviewed by the REB based at another institution within the RSSS, the *personne formellement mandatée* must also make sure that:

- the applicant complies with criteria set out in article 4.4.3 of the *Policy on the Research Ethics Board of the McGill University Health Centre*;
- the documentation on file is complete.

The authorization to conduct research within the institution will be automatically renewed annually, on the renewal date of the ethics approval by the evaluating REB²⁴, unless the *personne formellement mandatée* intervenes. If the evaluating REB does not use Nagano, the researcher must make sure that the evaluating REB's ethics renewal is communicated to the *personne formellement mandatée*.

4.8.2 Administrative affiliation and nomination of the *personne formellement mandatée*

The *personne formellement mandatée* is either the President and Executive Director of the institution or, upon delegation of the latter, a staff member of the institution whose nomination has been confirmed by the Board of Directors²⁵.

4.8.3 Decision-making power

The *personne formellement mandatée* has the power to authorize or withhold the authorisation of research projects. This decision must be made within a reasonable timeframe. The *personne formellement mandatée* can also suspend or remove the authorization granted to the researcher. The individual must then inform the evaluating REB, as soon as possible, of the reasons for the decision and the actions being undertaken²⁶.

4.9 Privately-funded research

When a research project is funded by a private entity, the RI and the MNI must bill for the three reviews²⁷ and for the institutional authorization. The billing must comply with the billing schedule of the *Ministère de la Santé et des Services sociaux* and it must use the rates in effect at the time the billable activity was carried out.

Furthermore, the RI and the MNI must make sure the research budget provides for a contribution to the payment of the research project's indirect costs (infrastructure, administrative services, REB, facilities, equipment, etc.), which are calculated using the project's total direct cost²⁸.

²² Cadre de référence ministériel, section 2.3.

²³ Cadre de référence pour la recherche dans plus d'un établissement, section 11.4.

²⁴ Cadre de référence pour la recherche dans plus d'un établissement, section 11.4.

²⁵ Act respecting health services and social services, c. S-4.2, art. 169.

²⁶ Cadre de référence pour la recherche dans plus d'un établissement, section 11.10.

²⁷ Circular 2016-029 (Québec, Ministère de la Santé et des Services sociaux, 2016b); REB SOP 350-001

²⁸ Circular 2003-012 (Québec, Ministère de la Santé et des Services sociaux, 2003a)



4.10 Required service agreements and approvals

An institution can enter into a formal agreement with another RSSS institution or with an external organization to provide a research-related service (e.g., laboratory tests, sequencing, biostatistician services) if it complies with ministerial provisions²⁹.

The institution receiving the service is the institution that must authorise the conduct of research.

The institution that provides the service is not required to perform an ethics review of the research project³⁰ or authorize it, provided the agreement does not have an impact on the institution's civil liability and insurance coverage.

4.11 Research project registry

The *personne formellement mandatée* makes sure that measures are implemented so that the research projects that were authorized by him/her are documented within the institution's research project registry. The research project registry is kept on the Nagano web platform.

At a minimum the following information must be kept³¹:

- title of the research project;
- name of the researcher responsible for the project;
- name of the REB that performed the ethics review and that ensures ongoing ethics oversight, regardless of whether the REB is part of the institution or not;
- date on the REB letter that contains the positive result of the ethics review as well as the date of the annual ethics renewals;
- date on the letter that authorizes the conduct of research within the institution;
- date on which the REB acknowledges the end of the research project or the date on which the project was suspended;
- the agreements that the MUHC, the RI, or the MNI entered into to obtain a service related to the research project (via the project's file in Nagano).

For databases and biobanks created for research purposes, the minimal information within the registry includes:

- title of the bank;
- name of the bank's director;
- date on the REB letter that confirms the positive result of the ethics review performed at the time of the bank's creation;
- date of the bank's most recent annual ethics renewal;
- date at which the bank ceased its activities;
- the type of content (data, biological material) and the types of research projects for which it is used.

Research projects are kept within the registry for a minimum of 7 years after the end of the research, unless the project is a clinical trial regulated by Health Canada, in which case the information is kept within the registry for a minimum of 25 years after the research has ended³².

The registry is accessible to individuals authorized by the institution, for internal management, surveillance, or verification purposes, as well as to any person authorized by law.

²⁹ According to Circulars 2014-005 and 2014-009.

³⁰ *Cadre de référence ministériel*, 2.3.1 and 2.5.3

³¹ *Cadre de référence ministériel*, section 2.3.4.

³² *Cadre de référence ministériel*, section 2.3.4; Food and Drug Regulation, C.R.C., c. 870, art. C.05.012 (4).



V. Special Considerations

N/A

VI. Relevant Forms

All relevant forms related to the policy are available on the Nagano platform (<https://nagano.muhc.mcgill.ca/login>).

VII. Revision History

Revision Date	Revision Summary
2021-08-13	Revision of sections that are relevant to the triple review and to the final authorization of the "Regulatory framework in health research at the MUHC" and inclusion of a specific and distinct policy. Update to reflect the 2020 <i>Cadre de référence ministériel</i> .

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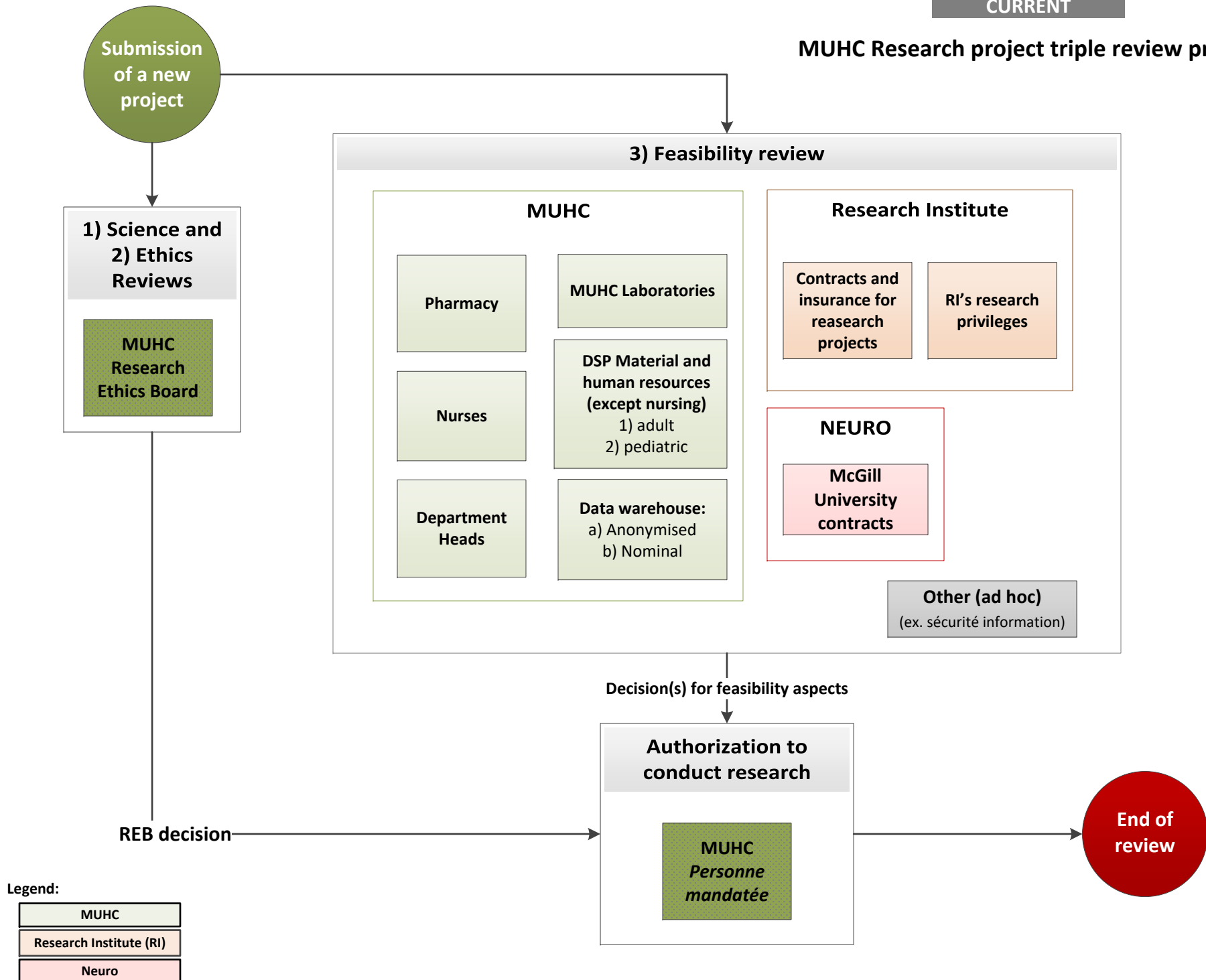
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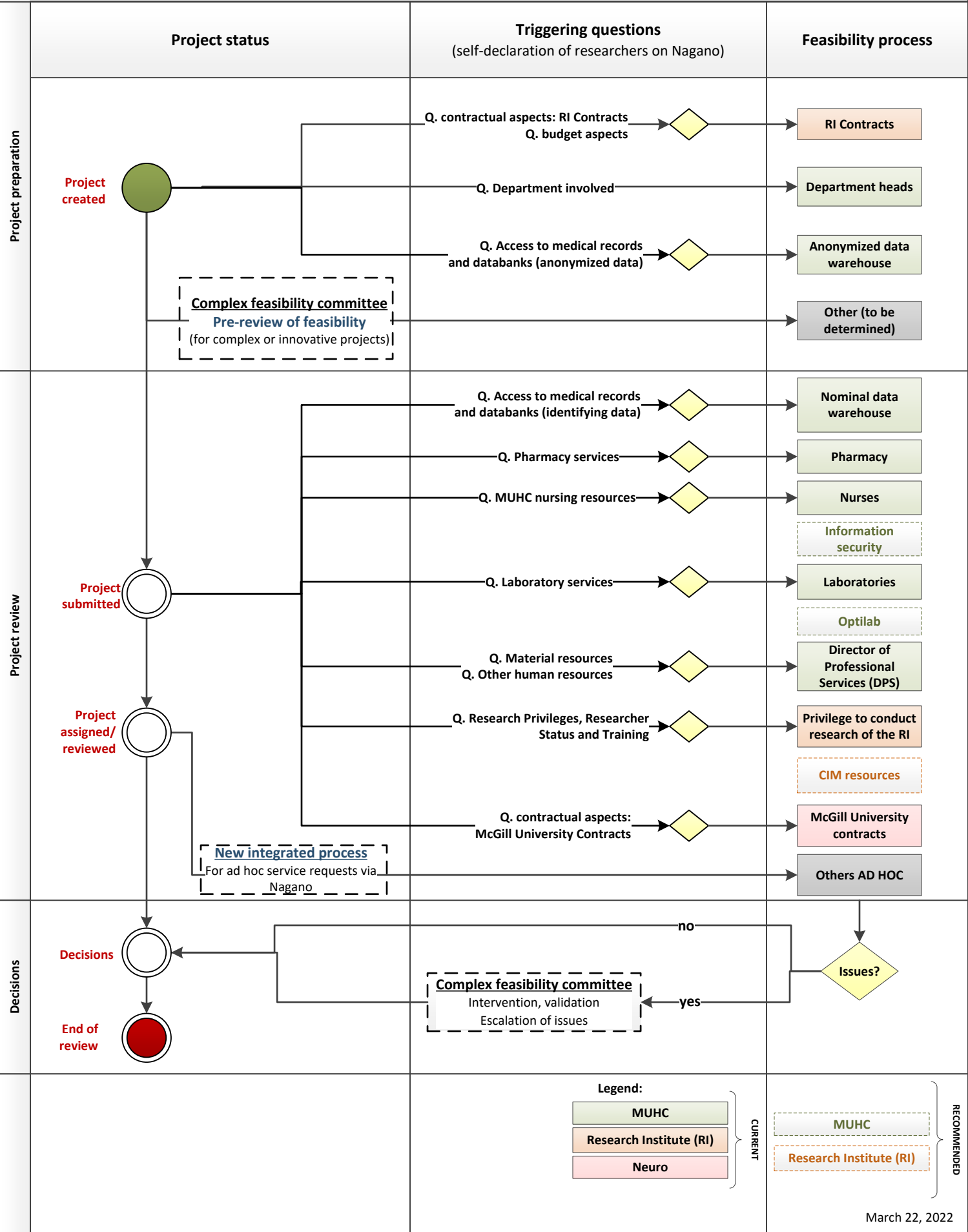
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MUHC Research project triple review process



Feasibility review process - RECOMMENDED



Organizational chart of the responsibilities within the MUHC research project review process

