

<b>Title</b>	Billing for services provided by the MUHC Research Ethics Board (REB) to private enterprises
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<b>N2/CAREB SOP CODE</b>	NON-APPLICABLE – MUHC REB only
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## 1 PURPOSE

This Standard Operating Procedure (SOP) describes how the Research Ethics Board (REB) implements the "*Barème à l'usage des établissements publics du réseau de la santé et des services sociaux pour la facturation des services fournis à l'entreprise privée pour l'examen et l'autorisation des projets de recherche*", Annexe à la Directive ministérielle 2023-016 (hereafter, the "Fee Schedule").<sup>1</sup>

## 2 SCOPE

This SOP applies to the REB of the McGill University Health Centre (MUHC), which reviews research projects conducted with human participants at the MUHC and/or in an establishment of the Health and Social Services Network (HSSN), in accordance with applicable regulations and guidelines.

## 3 RESPONSIBILITIES

The Researcher and all staff involved in the procedure for billing for REB services are responsible for ensuring that the requirements of this SOP are met.

More specifically, the Researcher is responsible for accurately reporting the circumstances of the research project, as described below. This includes:

- Declaring all sources of funding for a research project at the time of submission for REB review;
- Triggering the contract review process when the contract is pending negotiation or signature; and
- Submitting a notice to the REB when closing or abandoning the research project (as per the applicable REB SOP).

The REB support staff is responsible for:

- Identifying and tagging billable research projects;
- Consulting the REB Chair as needed;
- Identifying the REB's billable items and ensuring these are transmitted for billing;
- Producing a cumulative report of billable items over a fiscal year and reporting it to the competent authorities of the MUHC and the Montreal Neurological Institute (MNI).

The leadership of the Centre for Applied Ethics (CAE) is responsible for:

- Determining with the Research Institute of the MUHC (RI-MUHC) the allocation of any revenue generated by the REB but not required for the CAE operating budget.

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<sup>1</sup> *Facturation à l'entreprise privée des services fournis par les établissements publics de santé et de services sociaux lors de l'examen et de l'autorisation d'un projet de recherche*, 2023-04-20.



The REB Chair is responsible for:

- Making decisions that take into account the interests of the MUHC, the RI-MUHC, and the MNI.

#### 4 DEFINITIONS

- **Billable item:** any REB review provided for in the Fee Schedule, regardless of the decision rendered.<sup>2</sup> The amounts to be billed per item are provided in the Fee Schedule, which is regularly indexed.

The REB considers as 'major' (see terminology in the Fee Schedule) any amendment that meets one of the following criteria:

- Any full-board review;
  - Any modification to the protocol, including the addition of a sub-study;
  - Any modification to an information and consent form ("ICF") or another document intended for the participant;
  - Any new ICF or participant-facing document;
  - Any modification to the Investigator's Brochure;
  - Any site addition.
- **Billable project:** a project funded, in whole or in part, by private enterprise for which REB review and the authorization activities of the Formally Mandated Person (FMP) will be billed in accordance with the Fee Schedule, taking into consideration, at minimum, the exemption amount found in the Fee Schedule. This includes, notably:
    - Projects funded, in whole or in part, by private enterprise(s) where the portion of funding from one or more private enterprises exceeds the exemption amount;
    - Clinical trials funded and sponsored by a pharmaceutical company, medical device company, software company, or any other therapeutic product;
    - Investigator-initiated clinical trials with private or mixed (private and public) funding for which the sponsor is the RI-MUHC.

Signature of a contract is not required for a project to be considered billable; for instance, when the REB review process has been initiated but the project is abandoned before a contract is fully executed.

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<sup>2</sup> As per the *Policy on the approvals and institutional authorization required to conduct research involving human participants under the auspices of the McGill University Health Centre (MUHC)*, the REB conducts the science review of the project, unless one has already been conducted by a recognised peer review committee.



- **Private enterprise:** for the purposes of this SOP, a private enterprise is any enterprise that is privately owned. This includes all legal persons governed by private law (as opposed to public and parapublic bodies), including business corporations, general partnerships, not-for-profit organizations, etc.
- **Tags (billing):** markers used by REB support staff to identify billable projects, non-billable projects, or those for which billing status must be validated.

## 5 PROCEDURES

### 5.1 Required Information When Submitting a Research Project

- 5.1.1 The Researcher must identify the source of funding for the project in the research project submission form. If there is no source of funding, the corresponding option must be selected.
- 5.1.2 When the research project is funded in whole or in part by private enterprise, the Researcher must provide the information requested at the time of submission, including the corresponding contact information of the private enterprises and the budgets.
- 5.1.3 If the required billing contact information is not provided at the time of submission, the Researcher must follow up with the contracts office and/or the finance department of the RI-MUHC.

### 5.2 Determination of a Research Project's "Billable" vs. "Non-Billable" Status

- 5.2.1 Only the REB support staff may add or modify a billing tag.
- 5.2.2 Upon receipt of the research project, the REB support staff reviews the source of funding declared by the Researcher and adds one of three billing tags:
  - "Billable" if the project meets the definition of a billable project;
  - "Non-billable" if the project does not meet the definition of a billable project;
  - "Billing to be confirmed" if the information provided by the Researcher does not allow a clear determination of the project's billable or non-billable status.
- 5.2.3 Projects tagged as "Billing to be confirmed" are reviewed by the REB Chair.

### 5.3 Extraction of Billable Items

- 5.3.1 The REB determines which items are billable.
- 5.3.2 All REB actions that occur before confirmation by the REB of project closure are billable.
- 5.3.3 Designated support staff generate lists of billable items, according to the applicable format and based on the information entered by the Researcher in the Nagano platform.



#### 5.4 Validation of Billable Projects and Items

- 5.4.1 At each billing cycle, the REB support staff validates the “billable” vs. “non-billable” status of all projects reviewed in that cycle.

Before modifying a “billable” tag, the REB support staff confirms the absence of private enterprise funding with the relevant contracts office. Any complex case is referred to the REB Chair.

- 5.4.2 At each billing cycle, REB support staff verifies that all billable items appear on the billable items list of that cycle.
- 5.4.3 When the result of the validation carried out by the REB support staff requires updating the source of funding that was declared by the Researcher, the REB support staff must inform the Researcher and the project in Nagano updated accordingly.

#### 5.5 Communication of Billable Items to the Appropriate Finance Department

- 5.5.1 For each financial period, the REB support staff sends the list of billable items to the appropriate finance department for billing purposes.
- 5.5.2 If the REB support staff notices that billable services have not been billed (notably following the late addition of a billing tag or when an error is detected), the identified billable items must be sent immediately to the billing department via an interim list of billable items.

#### 5.6 Correction of Project Tags Following a Decision

- 5.6.1 Upon receipt of the list of projects whose billable status has been validated by the REB Chair, the REB support staff adjusts the billing tags accordingly.
- 5.6.2 When the REB Chair’s decision also requires updating the source of funding declared by the Researcher, the REB support staff must inform the researcher and the project in Nagano updated accordingly.

#### 5.7 Preparation of a “Cumulative Report” of Billable Items

- 5.7.1 The REB support staff maintains, for each fiscal year (April 1 — March 31), a cumulative list of all billable items sent to the finance department, and updates this list at each billing cycle.
- 5.7.2 Every quarter, the REB support staff prepares an updated cumulative list showing the total amount of all billable items. The CAE management communicates this list to the relevant finance department.
- 5.7.3 At fiscal year end, the cumulative report of billable items compiled by the CAE is reconciled with the amounts collected by the finance departments involved. The allocation of any amount not required to cover the CAE’s operating budget will be determined with the participation of CAE leadership.

At fiscal year end, the REB support staff prepares the cumulative list of billable items of the FMP for studies taking place at the MNI; transfer of funds to the CAE will occur within 60 days.

## 5.8 Revisions to this SOP

5.8.1 The REB support staff ensures this SOP is kept up to date.

5.8.2 The REB support staff ensures dissemination of this SOP to researchers, sponsors, and the personnel of the relevant finance departments, notably via the MUHC REB webpage.

## 6 REFERENCES

- Directive ministérielle 2023-016. [Facturation à l'entreprise privée des services fournis par les établissements publics de santé et de services sociaux lors de l'examen et de l'autorisation d'un projet de recherche](#). 2023-04-20.
- Directive ministérielle 2023-015. [Contribution de l'entreprise privée dans le cadre d'activités de recherche découlant d'un contrat de recherche ou d'une subvention](#). Updated 2024-02-25.

## 7 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
REB-SOP 350.001	2020-03-20	Original version
REB-SOP 350.002	2025-10-07	Clarification of billable projects and items; Typo corrections; Removal of the "validation committee"; Reference updates

## 8 APPENDICES