Centre intégré
universitaire de santé
et de services sociaux
de l'Est-de-
l'Île-de-Montréal
Québec

April 12th, 2024

Subject: Budget related to Clinical Research Studies at CIUSSS de l'Est-de-l'Île-de-Montréal (CIUSSS-EMTL)

Dear partner,

As required by the Québec Ministry of Health and Social Services (*Ministère de la Santé et des Services Sociaux (MSSS)*), the CIUSSS-EMTL has endorsed and implemented a mandatory billing schedule intended for services provided to private companies for the review and approval of research projects conducted by the CIUSSS-EMTL.

Enclosed you will find the MSSS billing schedule ***(Annex 1)*** that is indexed on April 1st of each year.

All administrative and operational cost are indispensable and essential to clinical research protocols and must be included in the research project budget. When the project is financially supported by a private company, the 30% overhead is applicable to all fees enumerated below with the exception of the billing schedule (*Annex 1*).

Note: Related review and approval fees for a research project will be invoiced directly to the sponsor by the CIUSSS-EMTL.

Exceptions to the MSSS Scale:

As seen in the "Application Field" billing scale issued by the MSSS, the CIUSSS-EMTL applies the following two (2) billing situation, permitted by the MSSS:

1- When the amount allocated to the budget of a project (or the total of successive versions of the same research project presented to the institution during the same year) does not exceed $18 557:
   - CIUSSS-EMTL is the REB evaluator a one-time fee $2,500
   - CIUSSS-EMTL is not the REB evaluator a one-time fee $1,500

and

2- When the project for which the researcher does not yield his intellectual property to the private company and the only involvement of the private company consists of making a financial contribution and does not give the rights to the progress of the research:
   - CIUSSS-EMTL is the REB evaluator: No billing
   - CIUSSS-EMTL is not the REB evaluator a one-time fee $ 1,500

Costs Associated with Clinical Research:

1. Administrative Fees: *(30% Overhead Applicable)*

- Start up Fees
- Annual Maintenance Fees
- Closeout Fees

See **annex 2** below for details effective date: April 1st, 2024

2. Medical Imaging Fees: *(30% Overhead Applicable)*

The cost for each study is established after being evaluated by the Imaging Department.

It may include, but is not limited to:

- Exam fees
- Reading fees
- Anonymized image copy fees

The costs reflect the amount to be paid out to CIUSSS-EMTL if the study requires procedures in medical imaging. The CIUSSS-EMTL guarantees medical imaging procedures will be conducted according to the project protocol and include any particular reading, for example, according to RECIST standards.

3. Pharmacy Fees: *(30% Overhead Applicable)*

The cost for each study is established after evaluation by the Pharmacy Department. All medication related in any clinical research protocol must be stored at the research pharmacy.

It may include, but is not limited to:

- Set up and coordination fees
- Closeout fees
- Preparation/coordination fees for regulatory audit or quality assessment (sponsor)
- Preparation and training fees- protocol amendment/pharmacy manual
- Storage of refrigerated and frozen medication
- Annual maintenance fees
- Transmission of study logs by fax/email

Additional Management Fees: Any additional management tasks not planned in the initial estimate, but not limited to, additional online training regarding a procedure, reception or additional management of study medication.

Fees per Patient: These fees cover the time allocated for the dispensing of the study medication (randomization, teaching, completion of patient logs preparation of medications). This amount varies depending on the complexity of the preparation of the medication and could be established for each service or each treatment cycle (modality will be specified if necessary) according to suggested categories in the chart below.

Pharmacy Fees (Continued):

Category 1	Verification of concomitant medication prior to starting study treatment or during screening
Category 2	Medication dispensed without conditioning (ex. oral medication dispensed in their original packaging…)
Category 3	Medication dispensed with simple conditioning (ex. liquid medication, injectable medication, injectable medication with simple reconstitution, multipack oral medication or dose calculation or dose adjustment)
Category 4	Medication with complex manipulation (ex. injectable medication with reconstitution including calculation of volume to be injected in infusion bag, follow-up/adjustment of dose according to renal function, repackaging of capsules, injectable medication to be prepared to maintain a blind)
Category 5	Medication with very complex manipulation (ex.: treatment involving 2 or more medications with different dosages, chemotherapy protocols)
Category 6	Medication with particular manipulation with/without frequent dose adjustments by the pharmacy
Category 7	Cost per patient: Total cost for all services throughout the study. These costs will be determined after agreement with the PI. These costs will be billed following the first dose of the first visit for each patient randomized in the study.

Pharmacy Availability and Call-back Fees

- Business hours for the research pharmacy:

  Regular office hours Monday to Friday, from 8:30 AM to 4:30 PM Eastern Standard time, excluding Holidays established by CIUSSS-EMTL.

- On-call fees*:

  An on-call service can be provided for all studies in need of randomization outside of regular office hours. The on-call periods are established with the study coordinator and/or the study PI before each study initiation.

- Travelling fees*

**Fees are established according to the convention of the MSSS.*

4. Laboratory Fees: *(30% Overhead Applicable)*

Research team will provide costs associated with laboratory analyses and procedures applicable to clinical research protocol to the CRO/Sponsor.

Note: *These costs are not negotiable.*

5. Billing Administrative Fees: *(30% Overhead Applicable)*

- Dry ice
- Non scheduled visit
- Preparation time in view of an audit or inspection visit
- Administration fees for implementing and amendment with changes to the Information and Consent form
- Preparation for REB's annual re-approval
- Completion of the Serious Adverse Events (SAEs) report and submission to REB
- Reimbursement of fees to patients that come from remote areas
- Additional training during the study
- Investigator meeting during the study
- Some specific tasks requested by protocol can be invoiced

Personnel Hourly Rate*	Minimal $ / hour
Study Nurse	$77.00
Study Coordinator	$77.00
Study Assistant	$61.00
Doctor	$190.00

** Prices may vary according to specialties*

We hope this information will help you and our research teams reduce the time spent on planning and negotiating budgets.

Please don't hesitate to contact us at 514-252-3400 ext 3724 should you have any questions or concerns.

Best regards,

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Deputy Director – Research Division
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Annex 1

SCHEDULE FOR THE USE BY PUBLIC INSTITUTIONS IN THE HEALTH AND SOCIAL SERVICES NETWORK (RSSS) FOR THE BILLING OF SERVICES PROVIDED TO PRIVATE COMPANIES FOR THE REVIEW AND APPROVAL OF RESEARCH PROJECTS

Effective date: April 1st, 2024

Basic exemption amount for billing services	**As of April, 1 st, 2024$****
The public institution in the health and social services network (RSSS) may refrain from billing the private company for the following services for any research activity arising from a research contract or a lower grant amount than the one established	18 557 $

Services invoiced to private companies for the same research project:			**As of April, 1 st, 2024$****
	Research conducted in a unique public institution* of the RSSS	**Research conducted in more than one public institution of the RSSS**	
1. Fees for the **SCIENTIFIC REVIEW** if done by a Committee of the institution.	Only one scientific review per project.*** Public institutions in the RSSS recognize the scientific review performed by another public institution within the network or by an established peer-reviewcommittee.		618 $
2. Fees for the **ETHICAL REVIEW** if done by a Committee of the institution.	Only one ethic review per project.**** Public institutions in the RSSS recognize the ethical review performed by another public institution REB in the RSSS.		6 187 $
3. Total amount for all **ONGOING ETHICAL MONITORING** during the year, other than major changes. Only one REB conducts the Ongoing Ethical Monitoring and bills for services to one or more institutions.	Total amount invoiced on the anniversary date of the REB letter giving positive outcome to the ethical review.	The total amount invoiced for the year is multiplied by the number of public institutions in the RSSS involved in the research, up to a maximum of 10. The renewal of Ethics approval must be carried out on the same date for all participating institutions. For an institution added during the year, monitoring is carried out by the REB for less than 12 months but full amount is charged.	618 $ per year X number of participating institutions.
4. Costs for the **ETHIC REVIEW** by the REB for a **MAJOR CHANGE** to the project.	It falls to the REB performing the ongoing ethical monitoring to establish whether the change is major or not. Accumulation of minor changes in a given year can be considered a major change.*****		618 $ each major modification
5. Fees for **AUTHORIZATION** process to carry out research in a public institution in the RSSS.	Amount invoiced by the public institution in the RSSS to conduct a Site-Specific assessment of the project, establish the contract and produce the letter authorizing the investigator to conduct the research. Amount invoiced by each public institution within the RSSS with a BoD. The institution may choose to invoice that amount when issuing the letter authorizing the investigator to conduct the research project, or to charge from the beginning of the project start-up for the portion covering the site-specific assessment review and the preparation of the contract.		Each participating institution invoices 1 856 $ regardless of the number of participating institutions and/or merged facilities that are involved.
6. Fees for the **ANNUAL FOLLOW-UP** by the **INSTITUTION** of the **AUTHORIZATION** to conduct the research.	Amount invoiced by the public institution of the RSSS when receiving the renewal of Ethics Approval by the REB.	Amount invoiced by each participating public institution of the RSSS, on receipt of the decision of renewal of Ethics Approval by the REB. Prorating for the 1st renewal if the authorization follow-up was done during less than 12 months.	618 $ per year. Each participating institution invoices this amount.

7. Fees related to withdrawal of a research prior proponent signing the contract.	The public institution in the RSSS charges the private company costs for the examinations made until the project withdrawal date, according to the “user pays” principle.	In each participating institution.

* A merged institution which is administered by an integrated center for health and social services is not considered as a separate institution of this integrated center.

** On the 1st of April of each year, the amounts shown here are indexed to the Pension Index established in accordance with Article 117 of the Act respecting the Québec Pension Plan (chapter R-9). The indexation rate applicable for 2024 is 4.4%.

*** The addition of a new experimental drug during the project requires a new scientific review.

**** In the context of basket, umbrella or platform trials, the different cohorts can be considered as individual projects.

***** The addition of a cohort to a basket, umbrella or platform trial can be considered as a new request for a separate project.

Annex 2

Effective date: April 1st, 2024

	Monocenter	Multicenter for which the REB-of the CIUSSS-EMTL does not act as reviewing REB	Multicenter for which the REB-of the CIUSSS-EMTL act as reviewing REB
Start-Up Fees	**5 100$ (<u>Mandatory fees)</u> *minimum, non deductible):** ▪ Evaluation of the protocol by the Principal Investigator (feasibility); ▪ Budget negotiation; ▪ Preparation and signatures of Regulatory Documents (QIU, CVs etc.); ▪ Initiation and selection visits; ▪ Submission and feedback with the REB until final approval; ▪ Submission and feedback of the protocol with the “Comité scientifique et de la convenance institutionnelle” until the final approval by the authorized appointed person; ▪ Communications with CRO/Sponsor; ▪ Recruitment strategies (meeting); ▪ Preparation of source documents; ▪ Internal advertising; ▪ Validation and calibration of equipment; ▪ Training; ▪ Investigator’s meeting; ▪ Hourly rate for staff	**5 100$ ((<u>Mandatory fees)</u> *minimum, non deductible) :** ▪ Evaluation of the protocol by the Principal Investigator (feasibility); ▪ Budget negotiation; ▪ Preparation and signatures of Regulatory Documents (QIU, CVs etc.); ▪ Initiation and selection visits;Submission and feedback of the “Comité scientifique et de la convenance institutionnelle” until the final approval of the protocol by the institution’s formally mandated person. ▪ Communications with CRO/Sponsor; ▪ Recruitment strategies (meeting); ▪ Preparation of source documents; ▪ Internal advertising; ▪ Validation and calibration of equipment; ▪ Training; ▪ Investigator’s meeting; ▪ Hourly rate for staff.	**8 200$ (Mandatory fees) *minimum, non deductible) :** ▪ Evaluation of the protocol by the Principal Investigator (feasibility); ▪ Budget negotiation; ▪ Preparation and signatures of regulatory documents (QIU, CVs etc.); ▪ Initiation and selection visits; ▪ The researcher associated to the reviewing REB assumes the responsibilities for the initial approval of the research project concerning all institutions where the project is being conducted. ▪ Submission and feedback of the protocol with the REB until final approval by the authorized appointed person; ▪ Submission and feedback with the “Comité scientifique de la recherche et de la convenance institutionnelle”; until the final approval by the authorized appointed person ▪ Communications with CRO/Sponsor;

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	Monocenter	Multicenter for which the REB-of the CIUSSS-EMTL does not act as reviewing REB	Multicenter for which the REB-of the CIUSSS-EMTL act as reviewing REB
Start-Up Fees	*The amount may vary depending on the complexity of the study and time of the employees. An assessment will be done by each research team for each research protocol.	*The amount may vary depending on the complexity of the study and time of the employees. An assessment will be done by each research team for each research protocol.	▪ Recruitment strategies (meeting); ▪ Preparation of source documents; ▪ Internal advertising; ▪ Validation and calibration of equipment; ▪ Training; ▪ Investigator's meeting; ▪ Hourly rate for staff. *The amount may vary depending on the complexity of the study and time of the employee. An assessment will be done by each research team for each research protocol.

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	Monocenter	Multicenter for which the REB-of the CIUSSS-EMTL does not act as reviewing REB	Multicenter for which the REB-of the CIUSSS-EMTL act as reviewing REB
Maintenance Fees	**3 775$ per year (applicable 1 year after the signature of the contract)** ▪ Communications with CRO/Sponsor; telephone calls, emails, fax; ▪ Management of queries; ▪ Managing documents corresponding to the studies; ▪ REB correspondences; ▪ Provide clinical information required and answer the CRO/sponsor's requests (represents 1 week a year of work for a study nurse); ▪ Monitoring visits*; ▪ Management of administrative changes (CRO change, new database etc.) ▪ Investigator's meetings and/or conference calls; ▪ Additional training during study These fees are recommended *Fees of 250$ are applicable to any Monitoring visit made outside the monitoring plan foreseen by the sponsor.	**3 775$ per year (applicable 1 year after the signature of the contract)** ▪ Communications with CRO/Sponsor; telephone calls, emails, fax; ▪ Management of queries; ▪ Managing documents corresponding to the studies; ▪ REB correspondences; ▪ Provide clinical information required and answer the CRO/Sponsor's requests (represents 1 week a year of work for a study nurse); ▪ Monitoring visits*; ▪ Management of administrative changes (CRO change, new database etc.) ▪ Investigator's meetings and/or conference calls; ▪ Additional training during study These fees are recommended *Fees of 250$ are applicable to any Monitoring visit made outside of the monitoring plan foreseen by the sponsor.	**5 100$ per year (applicable 1 year after the signature of the contract)** ▪ Communications with CRO/Sponsor; telephone calls, emails, fax; ▪ Management of queries; ▪ Managing documents corresponding to the studies; ▪ REB correspondences; ▪ Provide clinical information required and answer the CRO/Sponsor's requests (represents 1 week a year of work for a study nurse); ▪ Monitoring visits*; ▪ Management of administrative changes (CRO change, new database, etc.) ▪ Investigator's meetings and/or conference calls; ▪ Additional training during study

Annex 2

	Monocenter	Multicenter for which the REB-of the CIUSSS-EMTL does not act as reviewing REB	Multicenter for which the REB-of the CIUSSS-EMTL act as reviewing REB
Maintenance Fees			▪ The researcher associated to the REB, assumes the responsibilities of submitting to the same REB any relevant notifications for the project's ethical monitoring and in regards to all institutions where the project is being carried out or concerning the conduct of the research in its institution. These fees are recommended *Fees of 250$ are applicable to any Monitoring visit outside of monitoring plan foreseen by the sponsor.

Annex 2

	Monocenter	Multicentrique dans laquelle le CÉR-du CIUSSS-EMTL n'agit pas comme CÉR évaluateur	Multicentrique dans laquelle le CÉR-du CIUSSS-EMTL agit comme CÉR évaluateur (CÉRÉ)
Close-Out Fees	**2 550$ (Mandatory fees) :** ▪ Management of queries; ▪ Correspondance with the REB; ▪ Communication with CRO/sponsor; ▪ Close-out visit and completion of regulatory documents; ▪ Preparation of the study documents for archiving and data imaging conservation; ▪ Return of material or equipment to CRO/sponsor; ▪ Financial review of study and final invoicing; ▪ Archiving fees.	**2 550$ (Mandatory fees):** ▪ Management of queries; ▪ Communication with CRO/sponsor; ▪ Close-out visit and completion of Regulatory Documents; ▪ Preparation of the study documents for archiving and data imaging conservation ▪ Return of material or equipment to CRO/Sponsor; ▪ Financial review of study and final invoicing; ▪ Archiving fees.	**3 775$ ((Mandatory fees) :** ▪ Management of queries; ▪ Correspondance with the REB; ▪ Communication with CRO/sponsor; ▪ Close-out visit and completion of Regulatory Documents; ▪ Preparation of the Study documents for archiving and data imaging conservation; ▪ Return of material or equipment to CRO/Sponsor; ▪ Financial review of study and final invoicing; ▪ Archiving fees; ▪ Assumes responsibilities for the researcher associated to the reviewing REB.