

# Research Ethics Board Review

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James Ellasus, BA

Ethics Review Intake and Administration,  
Research Ethics Office, MUHC



**Centre universitaire de santé McGill**  
**McGill University Health Centre**

# My Role

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- Act as a contact person between the REO and the REB, liaison with the MUHC, PI, RI, study coordinators and the REB offices of other institutions.
- Look at submissions before ethics review.

# Objectives

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- Facilitate the ethics review process.
- Using the eReviews system efficiently as a submission and communication tool.
- Share the common questions and problems that I receive from Principle Investigators, research assistants and study coordinators.

# New Study Submitted For Ethics Review

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- Notification by e-mail following science review or that a study is exempt from science review.
- Contact with Principle Investigator/Study Coordinator via eReviews.

# Submission

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- Verify for completeness of submission before the review of a study.
- Paper copies required for review (facilitates review for REB members and REB Chairs).

# New Study for Full Board Review

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## What documents are needed?

- Use of “confirmation.doc” from the “Confirmation of New Study Submission” e-mail
- Submission of eReviews documents, protocol, consent, subject recruitment methods (e.g., letters, phone calls, ads, posters etc)
- Original Authorizing Signatures page and the Science Review Decision letter are often forgotten to be included in the collated paper package.

# Original Signatures page



## APPLICATION TO CONDUCT HUMAN SUBJECTS RESEARCH INVESTIGATOR COMMITMENTS AND AUTHORIZING SIGNATURES

*A signed copy of this form must be included your eReviews study submission and kept as part of your study files*

**Study Title:**

**Investigator Name:**

**eReviews ID:**

### Ethics

An application for Research Ethics Board approval to use human subjects in research for conduct in the MUHC jurisdiction requires the following declarations:

- The Principal Investigator (Qualified Investigator) will obtain prior written approval from the REB for any substantive modification to the research, including changes to the study procedures, financial arrangements and/or resource utilization, before initiating the change.
- Unexpected or otherwise significant adverse events, and/or alarming trends that occur during the study will be promptly reported to the REB as per the study protocol, and MUHC policy.
- Any new significant finding emerging during the course of the study that may affect a subject's decision to participate will be reported to the REB, and to all study subjects.
- If the research study is approved it will be subject to quality assurance assessment and to the continuing review and approval of the REB.
- The Principal Investigator will comply with all REB requests to report study information.
- The Principal Investigator will maintain study records according to regulatory requirements.
- *if these conditions are not met, REB approval for the research study may be withdrawn.*

**➡ As Principal Investigator, I have read and agreed to the commitments outlined above.**

**Principal Investigator initials:** \_\_\_\_\_

### Conflicts of Interest

The Principal Investigator must inform the REB of the existence of a financial arrangement or other reward involving all local investigators and/or an immediate family member that creates a conflict of interest, or the appearance thereof.

Please provide details concerning a real or apparent conflict of interest, prior to REB review, in confidential correspondence to the REB Chair, or the Director of the Research Ethics Office.

During the conduct of the study the REB and the Contracts Office must be informed if the Principal Investigator becomes aware of a new financial arrangement involving the Study Sponsor or representative.

# Effectively communicating using the eReviews system

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- Responding to requests for change on eReviews (number of copies needed for review, questions, missing information, document needed before review).
- Importance of addressing the query through the system (by answer questions or confirmation of the task).
- Pending notifications that are not attended to (notifications box in red, e-mail reminders from the system).



# Study Management

Study Management eReview: X

demo.evision.ca/ethicsMcGill/studyList.do

Institut de recherche / Research Institute  
Centre universitaire de santé McGill / McGill University Health Centre

John Smith Home Help Français Logout eREVIEWS

**What do you want to do?**

- Submit COA
- Create a new study
- Manage delegates

### Study Management

**Notifications pending! Please consult your studies list to see which one(s) require(s) your attention**

Pending Authorization Authorized (Ongoing) Archived

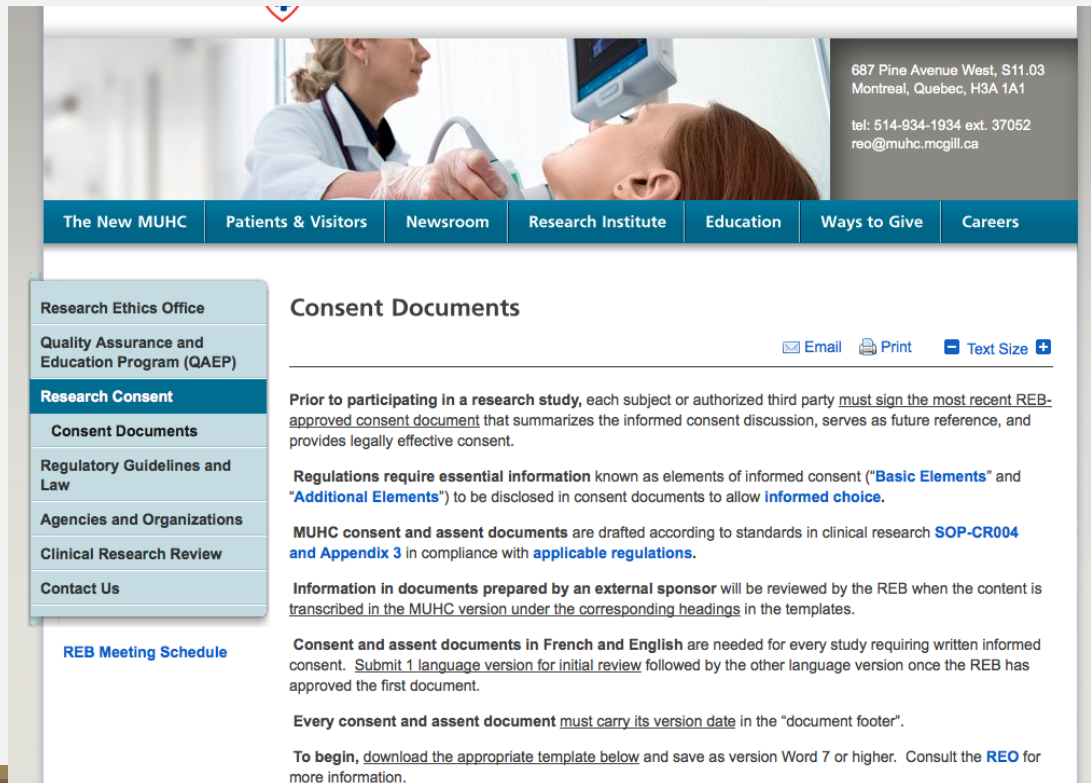
MUHC Study Code:	ID	Study short title	Principal Investigator	Status	Edit	Submit / Track	Manage Delegates	Notifications
	2889	FLD	Smith	Approval in progress				1
	2906		Smith	Not submitted				0
	2907		Smith	Not submitted				0
13-500-BMD	2885	OP-103-B	Smith	Approval in progress				0

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# The Consent Document

- Consent forms need to conform to the MUHC standard.
- Consent and assent document must have a version date in the document footer.

<http://muhc.ca/reo/page/informed-consent>



687 Pine Avenue West, S11.03  
Montreal, Quebec, H3A 1A1  
tel: 514-934-1934 ext. 37052  
reo@muhc.mcgill.ca

The New MUHC | Patients & Visitors | Newsroom | Research Institute | Education | Ways to Give | Careers

Research Ethics Office  
Quality Assurance and Education Program (QAEP)  
**Research Consent**  
Consent Documents  
Regulatory Guidelines and Law  
Agencies and Organizations  
Clinical Research Review  
Contact Us

## Consent Documents

[Email](#) [Print](#) [Text Size](#) [+](#)

**Prior to participating in a research study**, each subject or authorized third party **must sign the most recent REB-approved consent document** that summarizes the informed consent discussion, serves as future reference, and provides legally effective consent.

**Regulations require essential information** known as elements of informed consent ("**Basic Elements**" and "**Additional Elements**") to be disclosed in consent documents to allow **informed choice**.

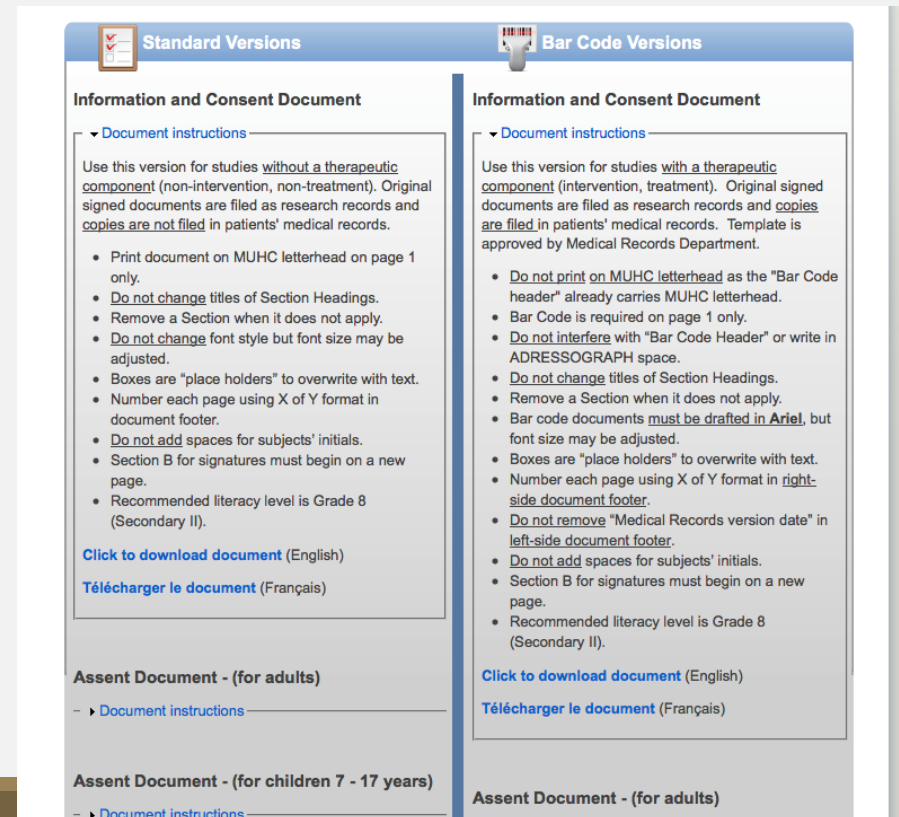
MUHC consent and assent documents are drafted according to standards in clinical research **SOP-CR004 and Appendix 3** in compliance with **applicable regulations**.

Information in documents prepared by an external sponsor will be reviewed by the REB when the content is transcribed in the MUHC version under the corresponding headings in the templates.

Consent and assent documents in French and English are needed for every study requiring written informed consent. **Submit 1 language version for initial review** followed by the other language version once the REB has approved the first document.

Every consent and assent document **must carry its version date** in the "document footer".

To begin, download the appropriate template below and save as version Word 7 or higher. Consult the **REO** for more information.



Standard Versions | Bar Code Versions

### Information and Consent Document

▼ Document instructions

Use this version for studies without a therapeutic component (non-intervention, non-treatment). Original signed documents are filed as research records and copies are not filed in patients' medical records.

- Print document on MUHC letterhead on page 1 only.
- **Do not change** titles of Section Headings.
- Remove a Section when it does not apply.
- **Do not change** font style but font size may be adjusted.
- Boxes are "place holders" to overwrite with text.
- Number each page using X of Y format in document footer.
- **Do not add** spaces for subjects' initials.
- Section B for signatures must begin on a new page.
- Recommended literacy level is Grade 8 (Secondary II).

[Click to download document](#) (English)  
[Télécharger le document](#) (Français)

### Assent Document - (for adults)

→ [Document instructions](#)

### Assent Document - (for children 7 - 17 years)

→ [Document instructions](#)

### Information and Consent Document

▼ Document instructions

Use this version for studies with a therapeutic component (intervention, treatment). Original signed documents are filed as research records and copies are filed in patients' medical records. Template is approved by Medical Records Department.

- **Do not print on MUHC letterhead** as the "Bar Code header" already carries MUHC letterhead.
- Bar Code is required on page 1 only.
- **Do not interfere** with "Bar Code Header" or write in ADDRESSOGRAPH space.
- **Do not change** titles of Section Headings.
- Remove a Section when it does not apply.
- Bar code documents **must be drafted in Ariel**, but font size may be adjusted.
- Boxes are "place holders" to overwrite with text.
- Number each page using X of Y format in right-side document footer.
- **Do not remove** "Medical Records version date" in left-side document footer.
- **Do not add** spaces for subjects' initials.
- Section B for signatures must begin on a new page.
- Recommended literacy level is Grade 8 (Secondary II).

[Click to download document](#) (English)  
[Télécharger le document](#) (Français)

### Assent Document - (for adults)

# Subject Recruitment Methods

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- Who? Where? When? How?
- Population
- Details about the recruitment of subjects.

# New Study for Expedited Review

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## What documents are needed?

- Health Records Research document from eReviews
- Protocol/proposal. Please ensure that there is a date and a version number.
- Original Authorizing Signatures page.
- Ensure DPS approval to access medical records.

# Following initial review of new study:

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- REB correspondence following review - upload PDF copy of the REB correspondence following Initial Review on eReviews.
- Response to the REB - upload revised documents on eReviews.
  - 1) What revised documents are being uploaded?
  - 2) Revised documents must have new version dates with track changes or highlights.
  - 3) Paper copies forwarded to the REB for review.

# Translation validation

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- REB approves revisions to the consent document.
- Notification on eReviews to translate Consent in French.
- Translated version with REB modifications matches the approved English Consent.
- Validation sent to REB translator.
- Clean English Consent and French Consent with track changes uploaded on eReviews.

# On-going studies

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**Continuing review - occurs once a year.**

- Submission should be done in a timely manner (at least 1 month).
- Ensure that the number of subjects is consistent year after year.

# Other on-going events

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- Study Status report - related to subject recruitment (often submitted as a Continuing Review or Study Completion report)
- Revisions to an Approved study (Amendment) - rationale for changes, new version dates, paper copy submission

Documents available via the RI portal in the SOP-CR012-EN03  
The Study Review Policies and Clinical Trial Registration



# Other on-going events

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- Serious Adverse Event
- Protocol Deviation (exception and violation)
- Study Completion report - submit when data analysis is completed

# QUESTIONS?

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