Research Ethics Board Review

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Ethics Review Intake and Administration,

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My Role

- 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

- 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

- 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

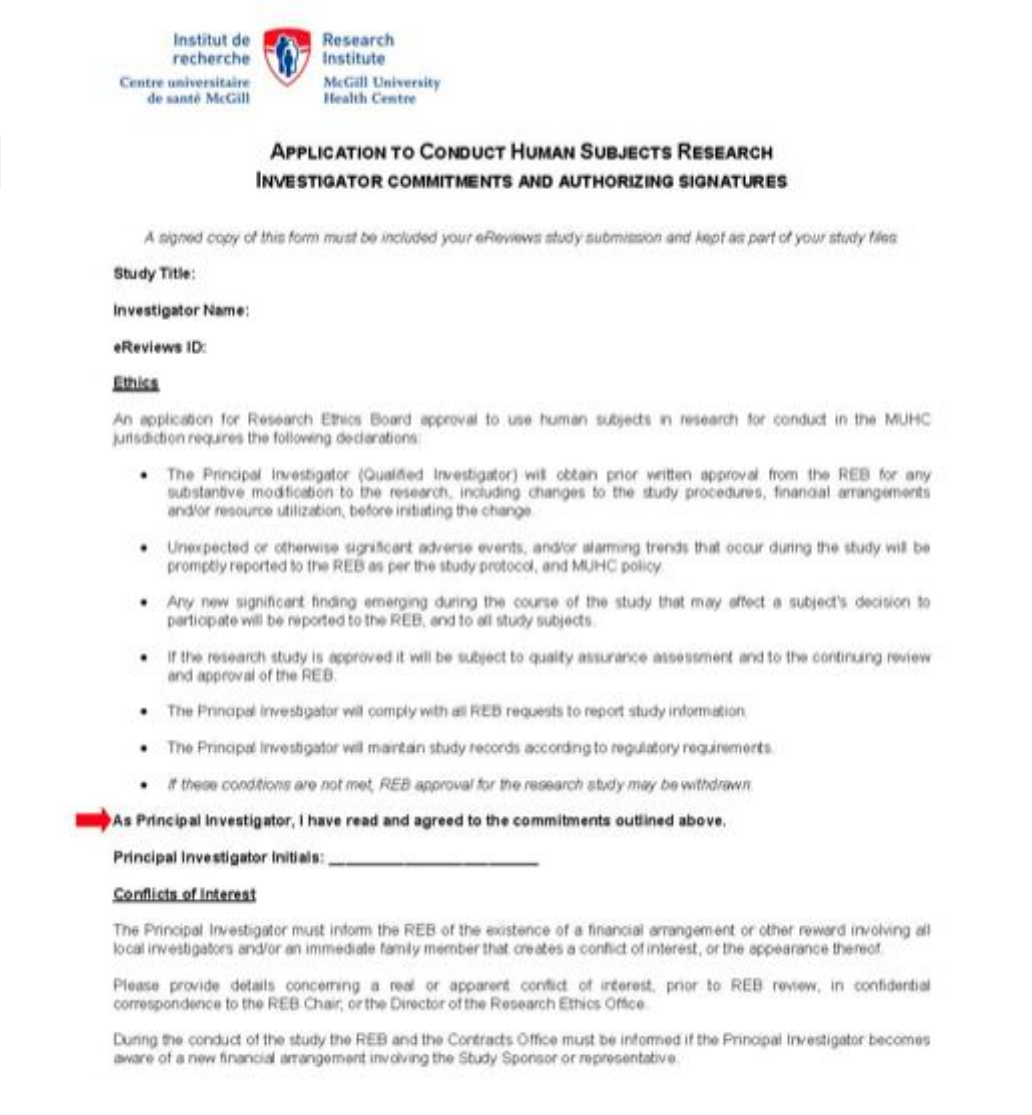
- Verify for completeness of submission before the review of a study.
- Paper copies required for review (facilitates review for REB members and REB Chairs).

New Study for Full Board Review

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



Institut de recherche
Centre universitaire de santé McGill

Research Institute
McGill University Health Centre

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.

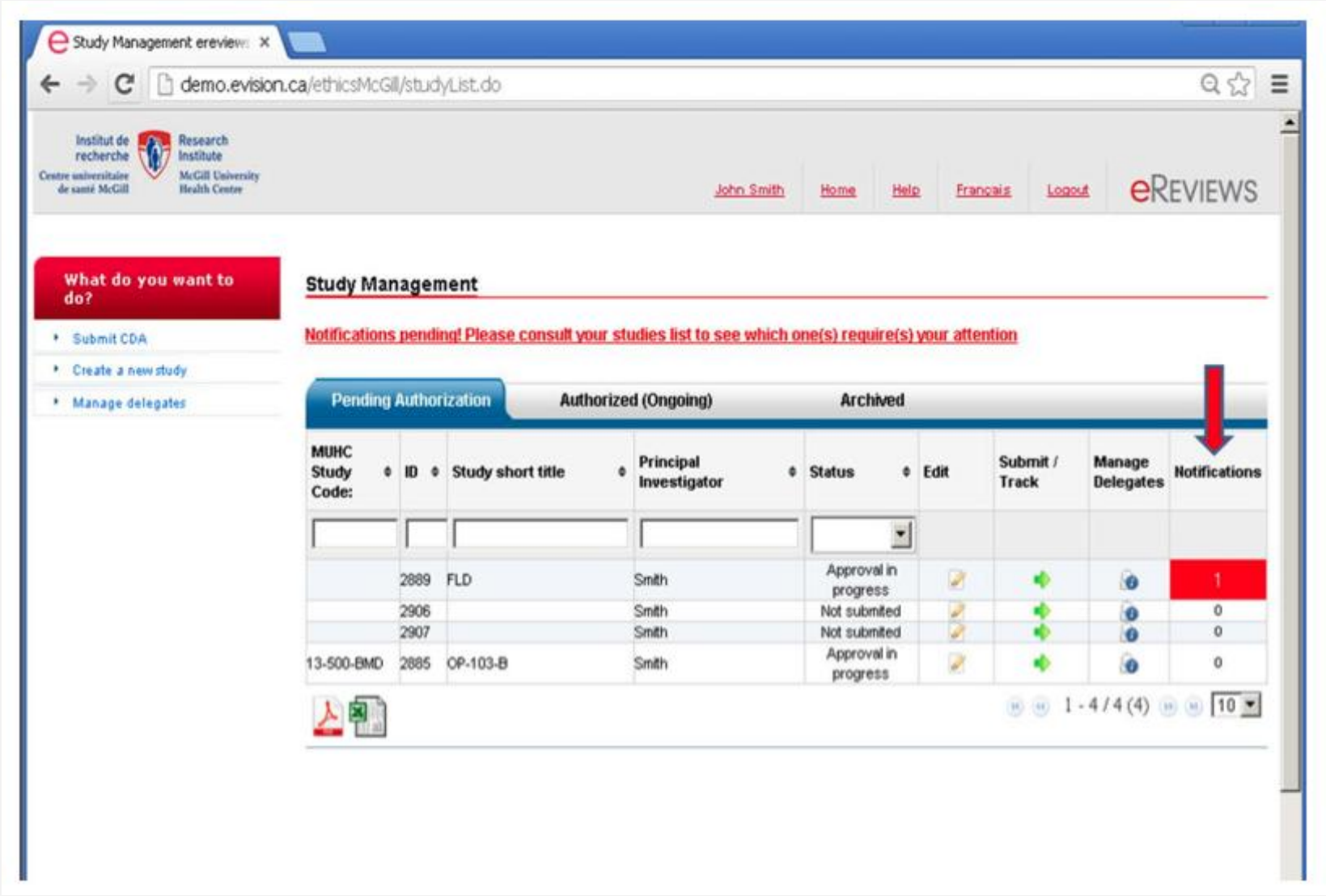
Please provide details concerning a real or apparent conflict of interest, prior to REB review, in confidential correspondence to the REB Chair, or the Director of the Research Ethics Office.

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

- 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).

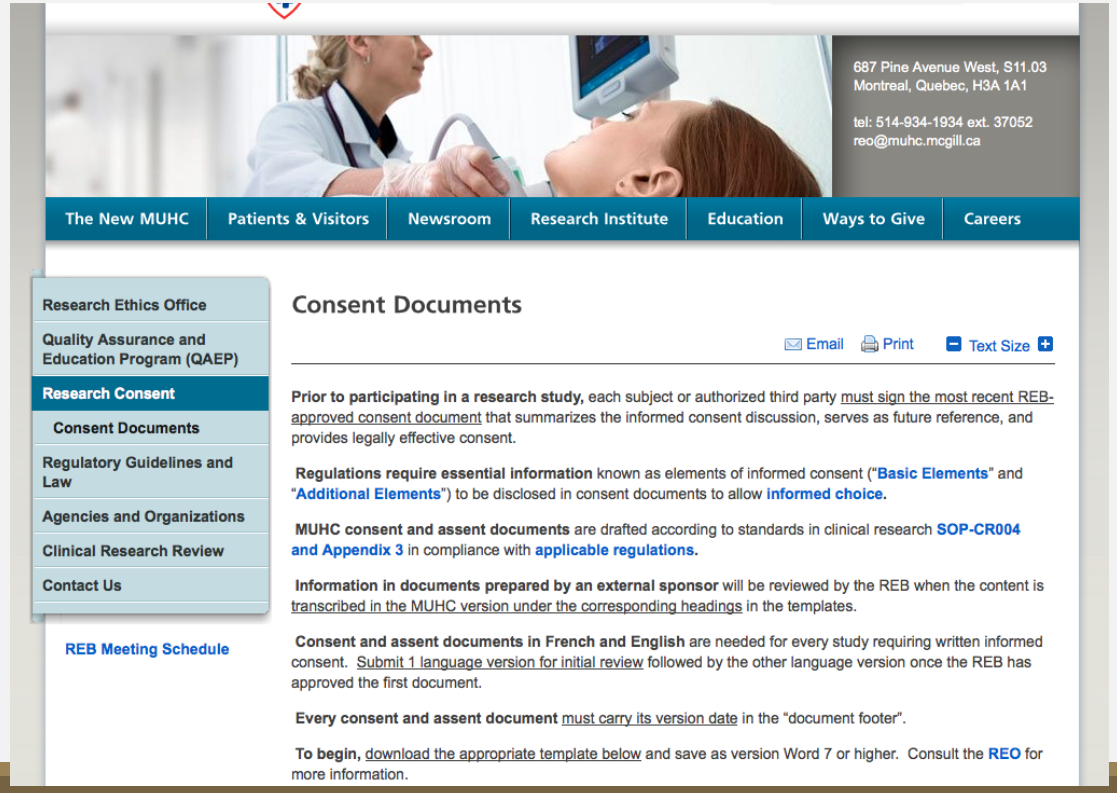
Study Management

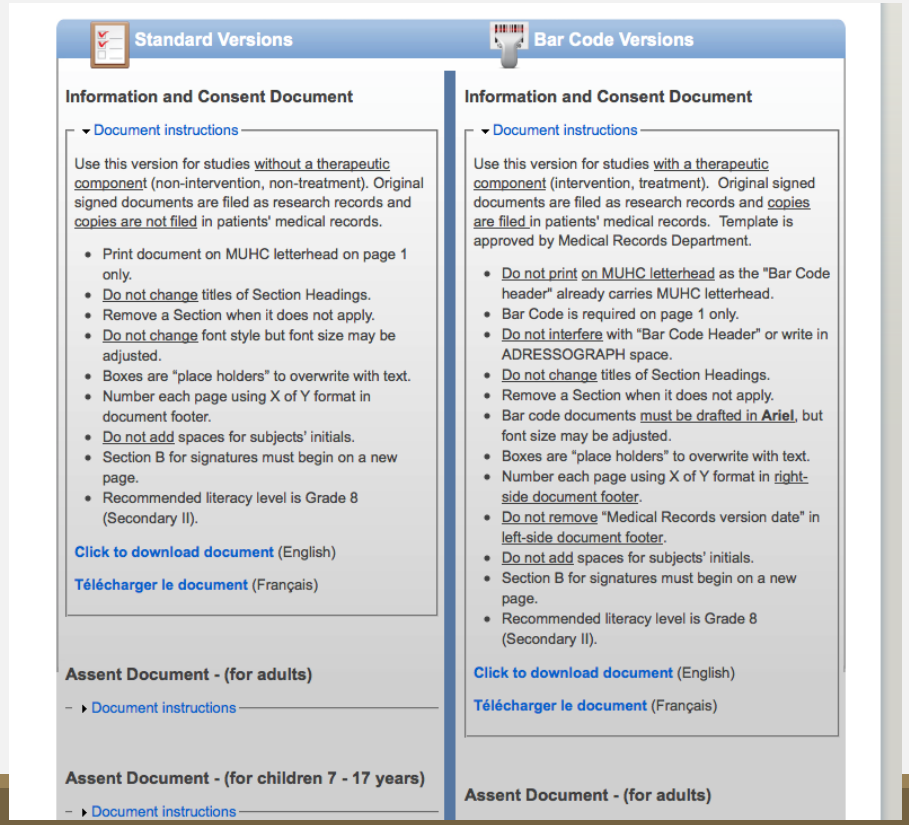


The Consent Document

- 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





Subject Recruitment Methods

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

New Study for Expedited Review

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:

- 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

- 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

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

- 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

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

QUESTIONS?