L'Institut de recherche
du Centre universitaire de santé McGill
The Research Institute
of the McGill University Health Centre

Optimizing Use of the eReviews Online Submission Tool

February 6th, 2014

eReviews Software

- Internet-based study review management software
- Launched at the MUHC on April 1, 2011
- System manages:
  - Science review
  - Ethics review
  - Site-specific assessments (pharmacy, resources utilization, contracts, access to medical records)
- Currently over 1000 users and 2000 ongoing studies in the system

System Access

- Only PIs can create account
- Access to system is controlled manually. Allows for verification of:
  - MUHC or McGill staff appointment
  - Valid research privileges
- All other users (students, research staff, residents, fellows) must be delegated a study to access the system

System Access

- User account permissions:
  - Principle Investigator (PI):
    - create studies
    - delegate individuals to studies
    - complete forms
    - sign off on forms
    - submit Confidentiality Disclosure Agreements (CDAs) for review
  - Delegate:
    - complete forms for delegated studies
    - submit (CDAs) for review on behalf of PI

System Access

- Each user is assigned their own username and password
  - MUHC policy and good security practices: **DO NOT SHARE YOUR USERNAMES AND PASSWORDS**

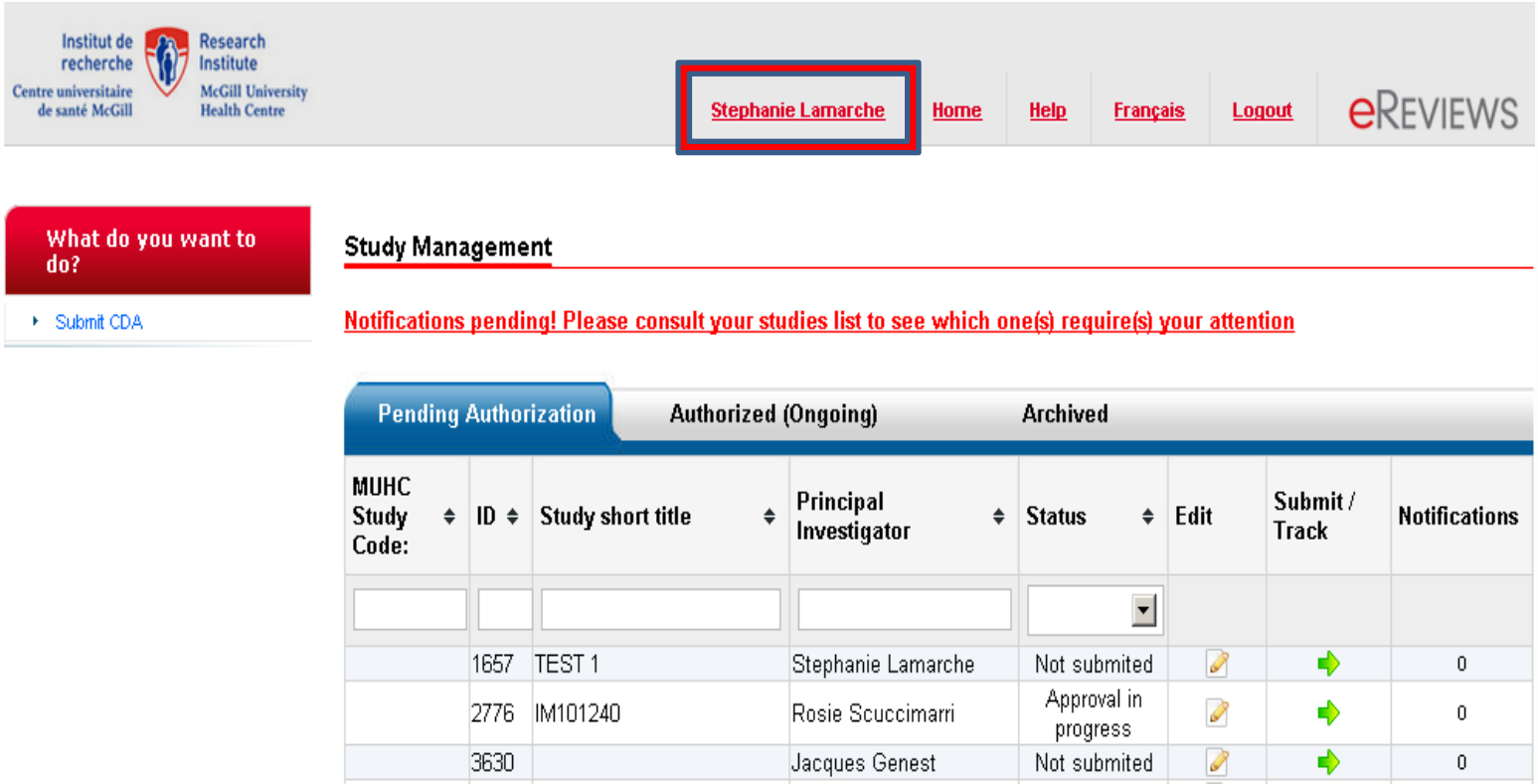
- Each user is responsible for the use of their username, password and the activities conducted in their account.

Password Management

- Password reset function is available on the login screen:

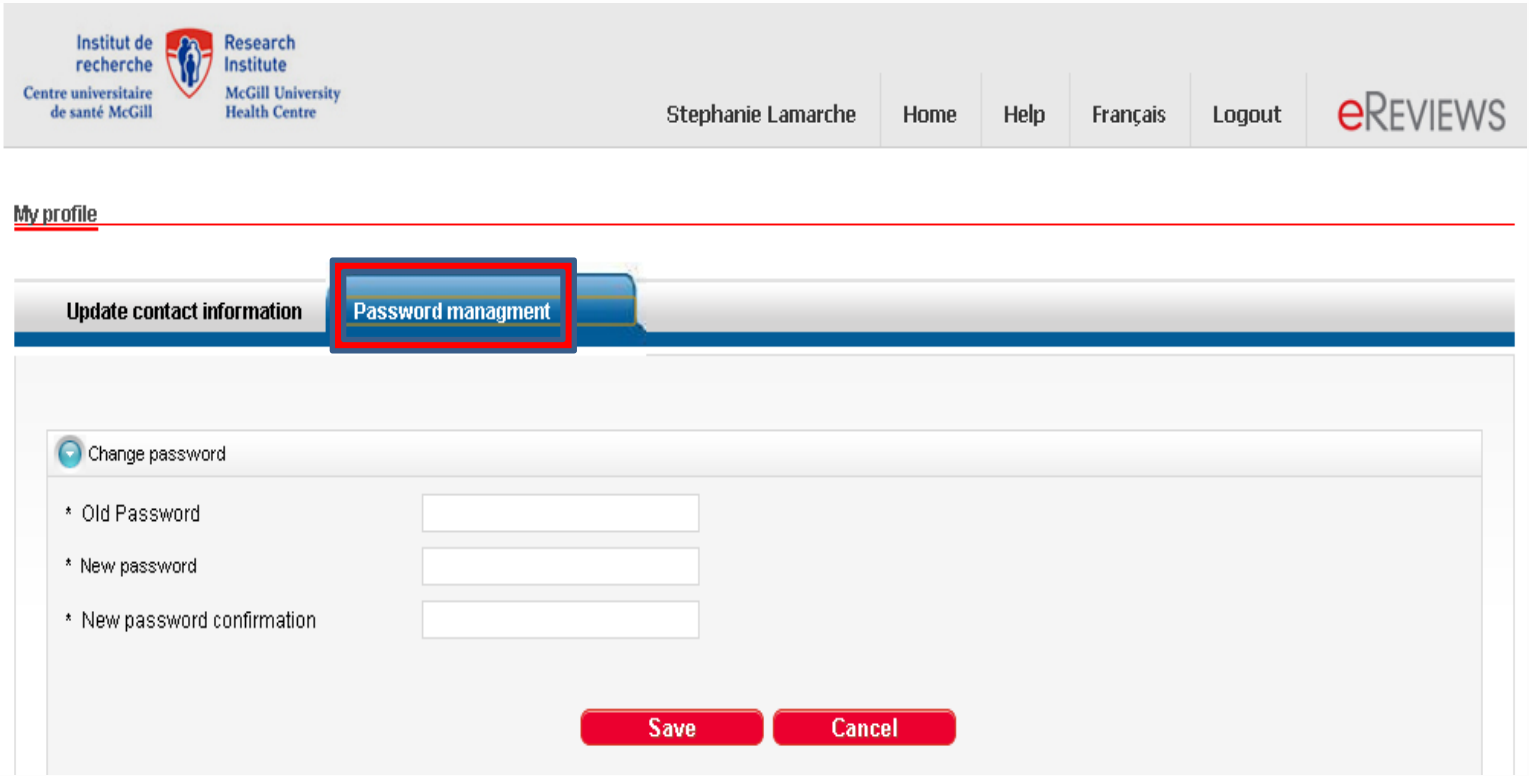
Password Management

- Passwords can be changed once logged in by accessing profile information

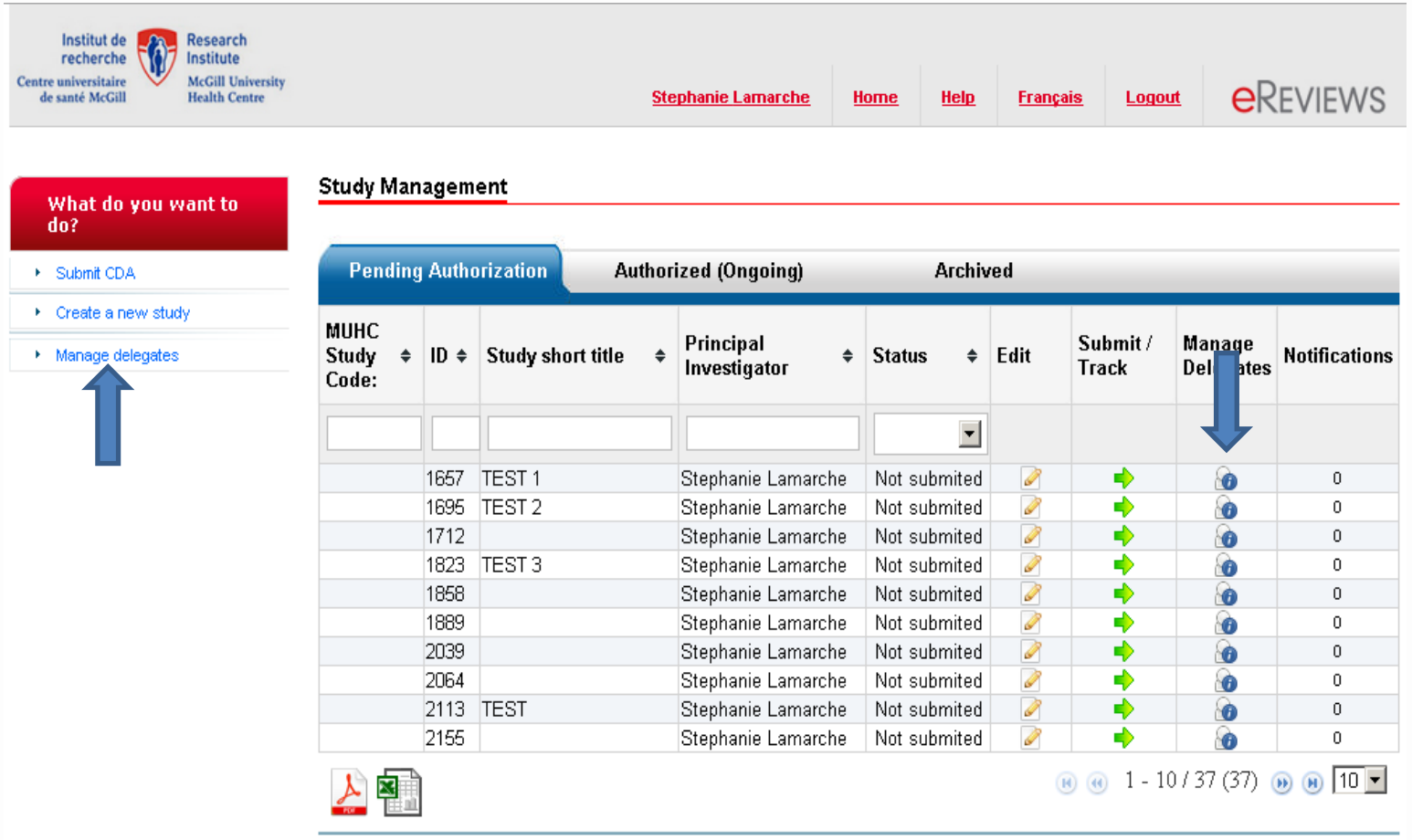


Password Management

- Use the Password management tab



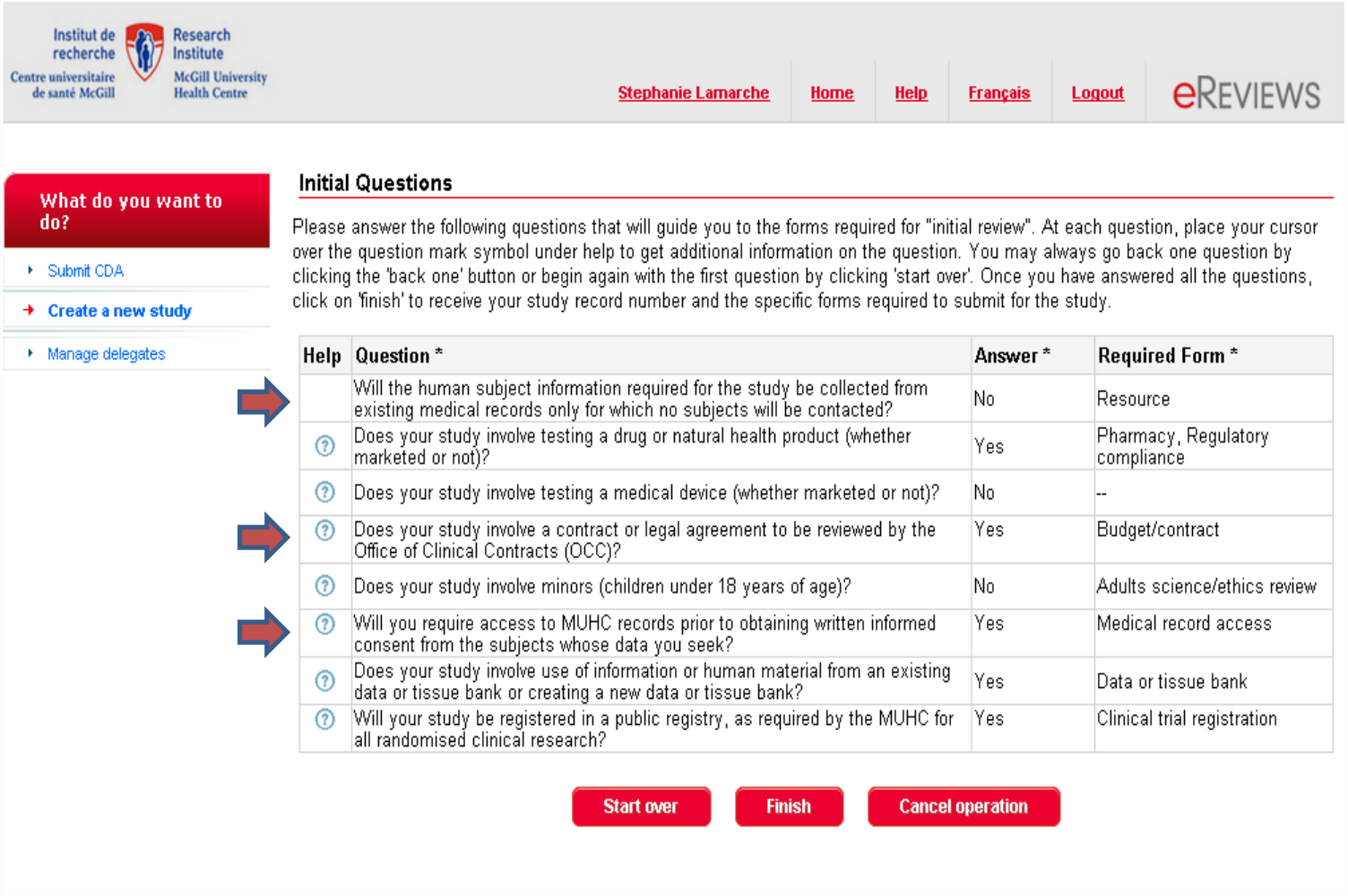
Delegate Management



New Study Creation

- Studies can only be created by PI
- A series of initial questions determine which forms the investigator will need to complete.
- The investigator can delegate the role of form completion to a member of his team only once the study has been created.

New Study Creation



New Study Creation

- **Question:** Will the human subject information required for the study be collected from existing medical records only for which no subjects will be contacted?
  - "Medical Records" not limited to paper charts – includes any information which is part of a patient's medical history
  - Answering Yes generates both the Health Records Research form and the DPS Medical Records Access form.

New Study Creation

❖ Laws governing access to information

- Article 19.1 of *La loi sur les services de santé et les services sociaux*
  - Requirement to obtain informed consent for use of health record information

- Article 125 of *La loi sur l'accès aux documents des organismes publics et sur la protection des renseignements personnels*
  - The requirement for consent may be waived if:
    - The projected use of the data is not frivolous
    - The personal information will be used in a manner which respects its confidential nature

New Study Creation

- In institutions of the health and social services network, the Director of Professional Services (DPS) can authorize use of information for research if conditions outlined in Article 125 are met

- Approval of either the DPS or the REB alone is not sufficient to conduct health records research

New Study Creation

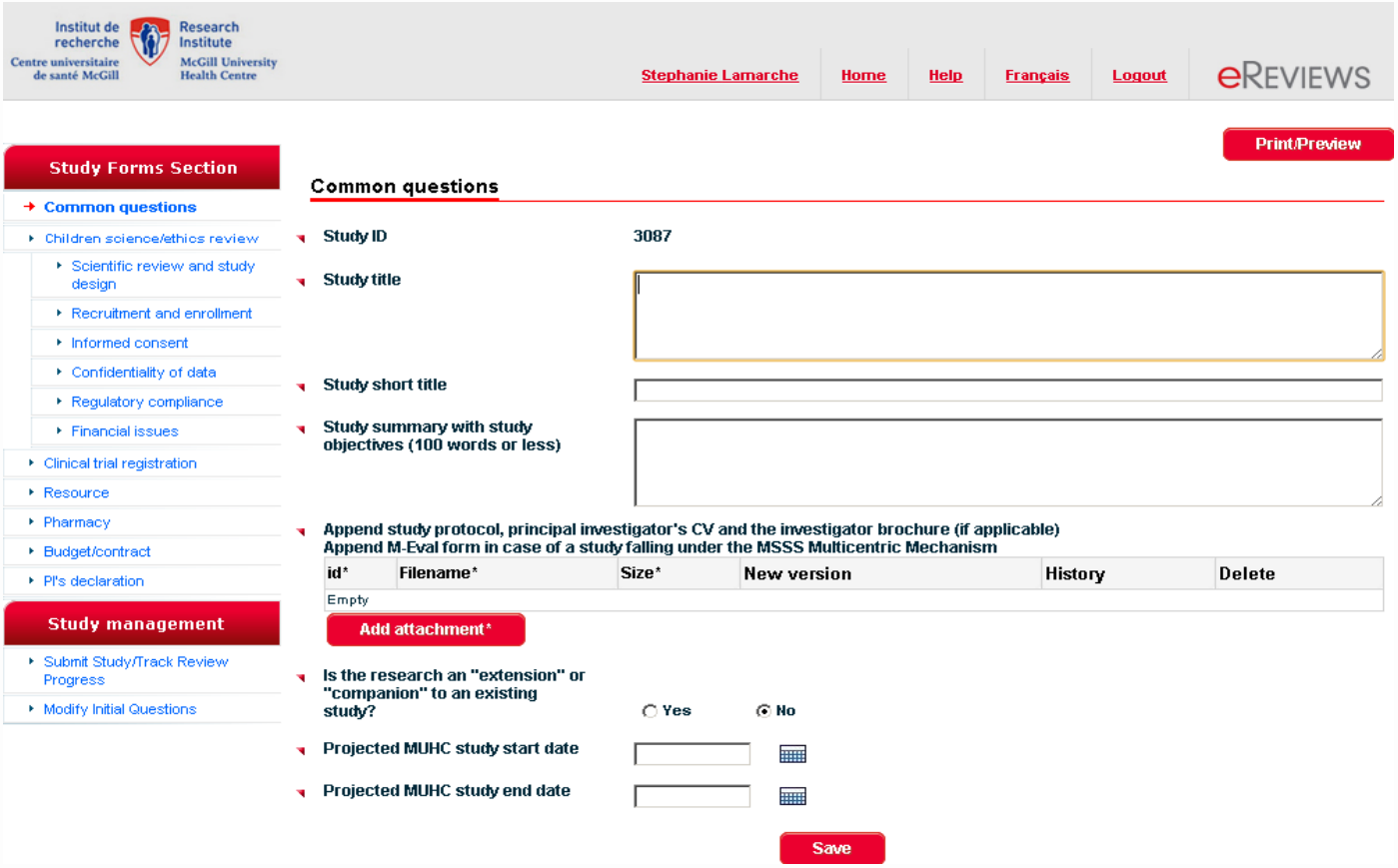
- **Question:** Will you require access to MUHC records prior to obtaining written informed consent from the subjects whose data you seek?
  - Answering Yes will generate the DPS Access to Medical Records form
  - Using medical records to screen for potential participants prior to contacting them
  - No need to answer Yes if only accessing records after participant consent (provisions should be in consent form)

New Study Creation

- **Question:** Does your study involve a contract or legal agreement to be reviewed by the Office of Clinical Contracts (OCC)?
  - Answering Yes will generate the Contract Review Application
  - When is a contract or agreement required?
    - When both parties stand to benefit from a collaboration (benefit can be money, publication rights, data, etc.)
  - Agreements include: Clinical study agreements, inter-institutional agreements, material transfer and data transfer/sharing agreements, etc.

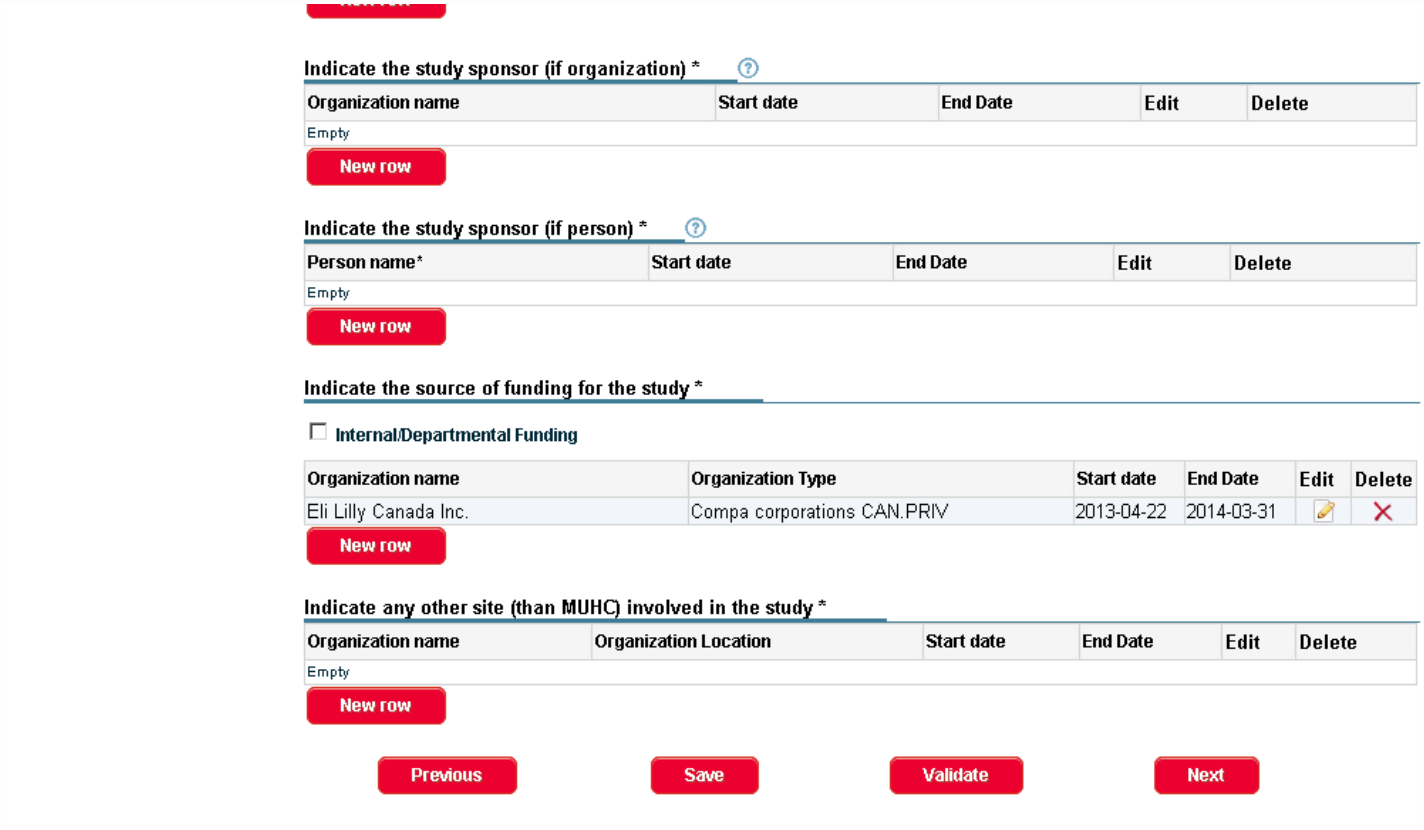
Form Navigation and Validation

- The study forms are listed in the left hand menu



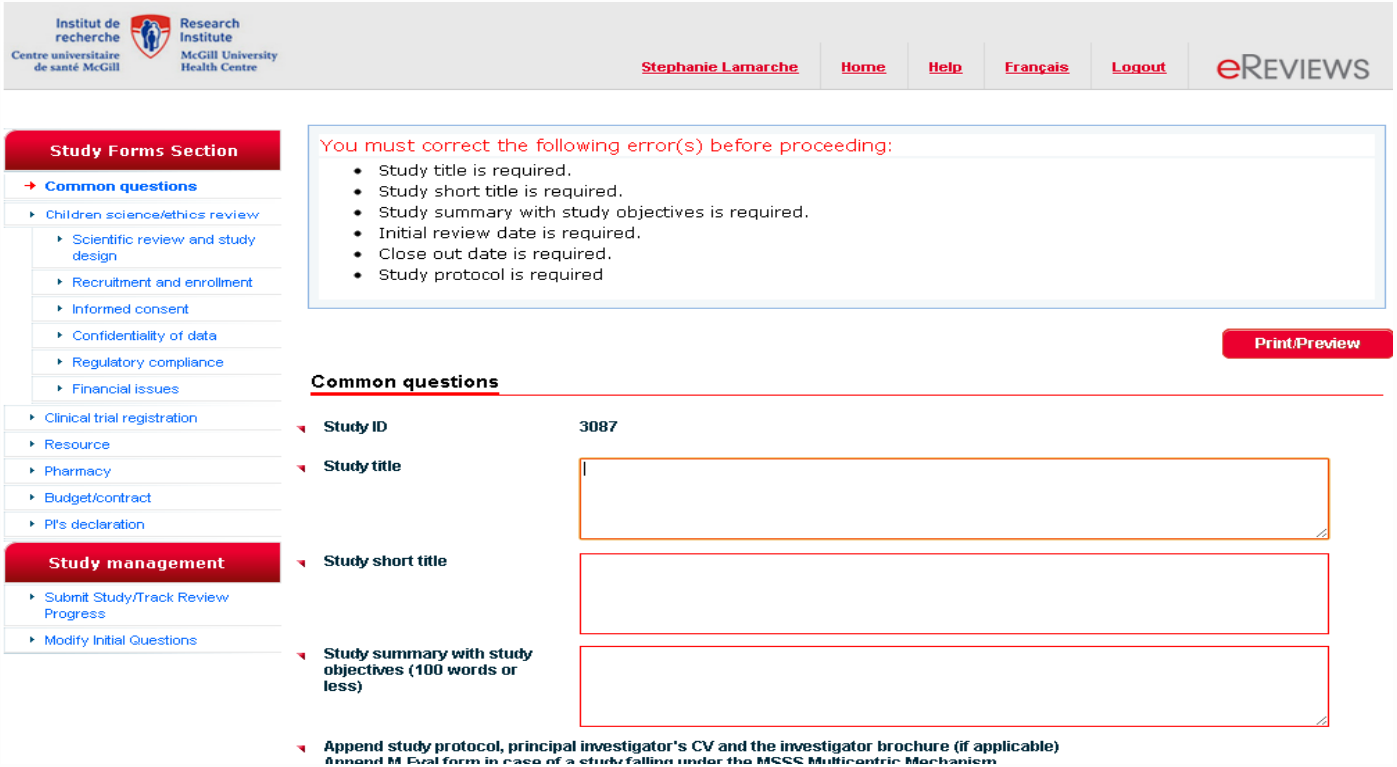
Form Navigation and Validation

- Naviagation tabs at the bottom of the screen guide the investigator through the study application



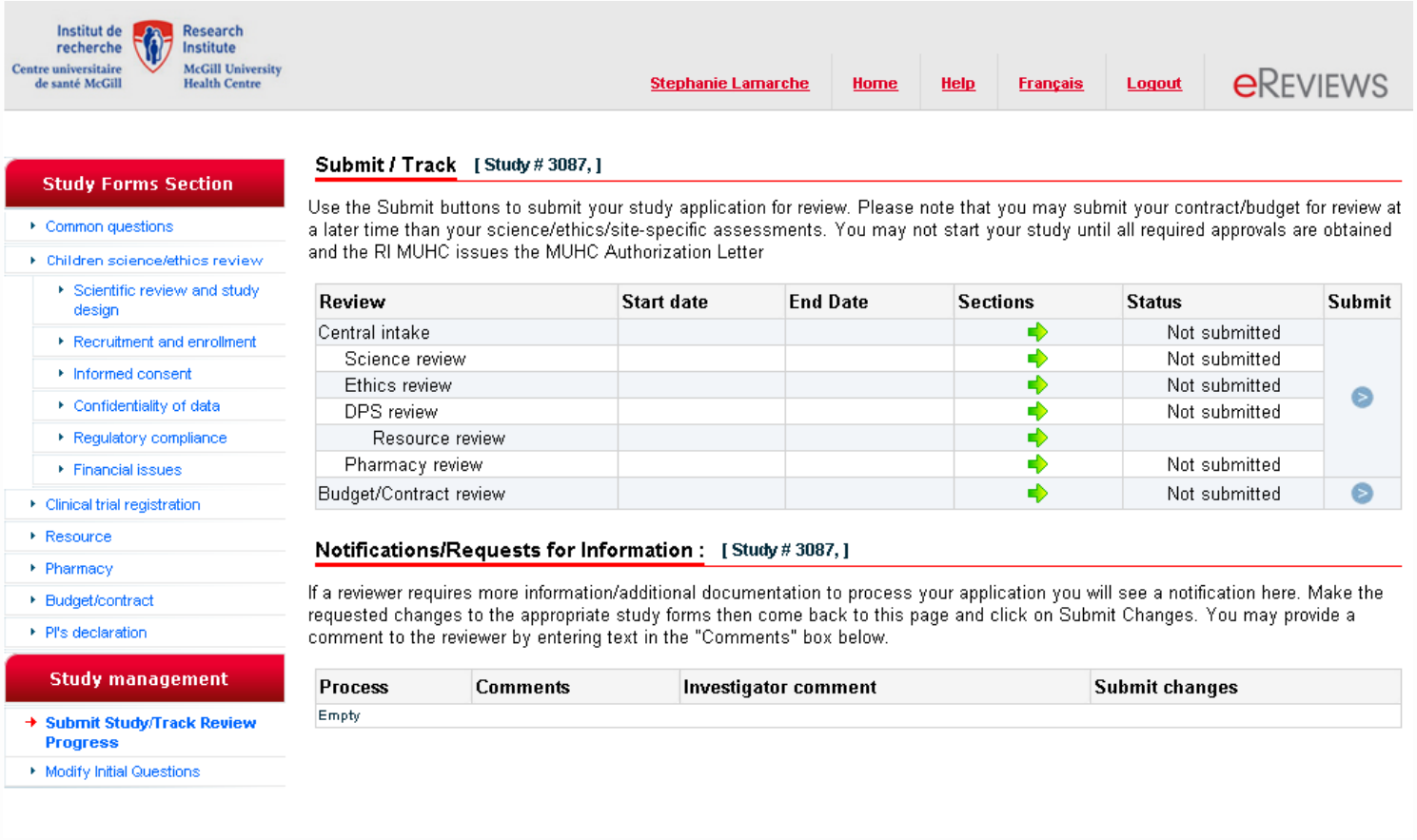
Form Navigation and Validation

- The « Validate » function allows the investigator to verify what information is required to submit the study

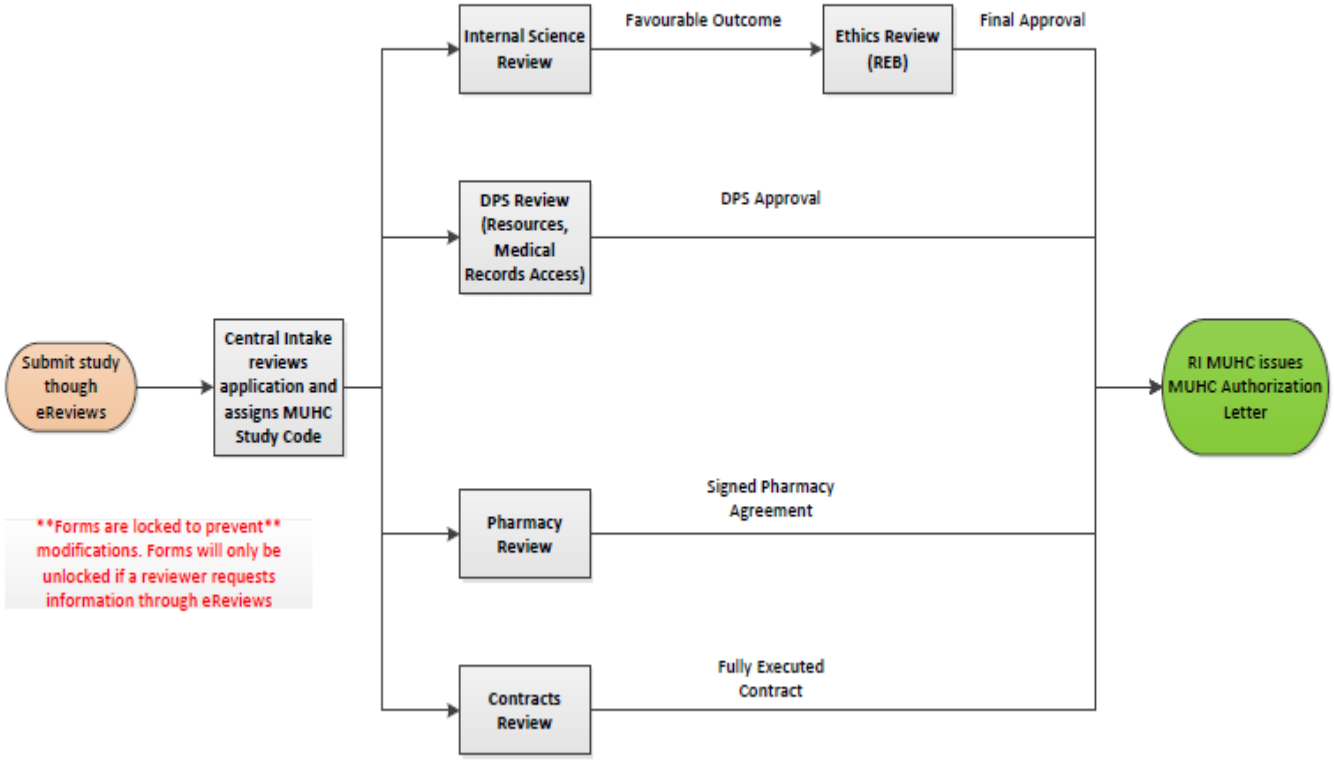


Study Submission

- When ready to submit the study for review, click on Submit



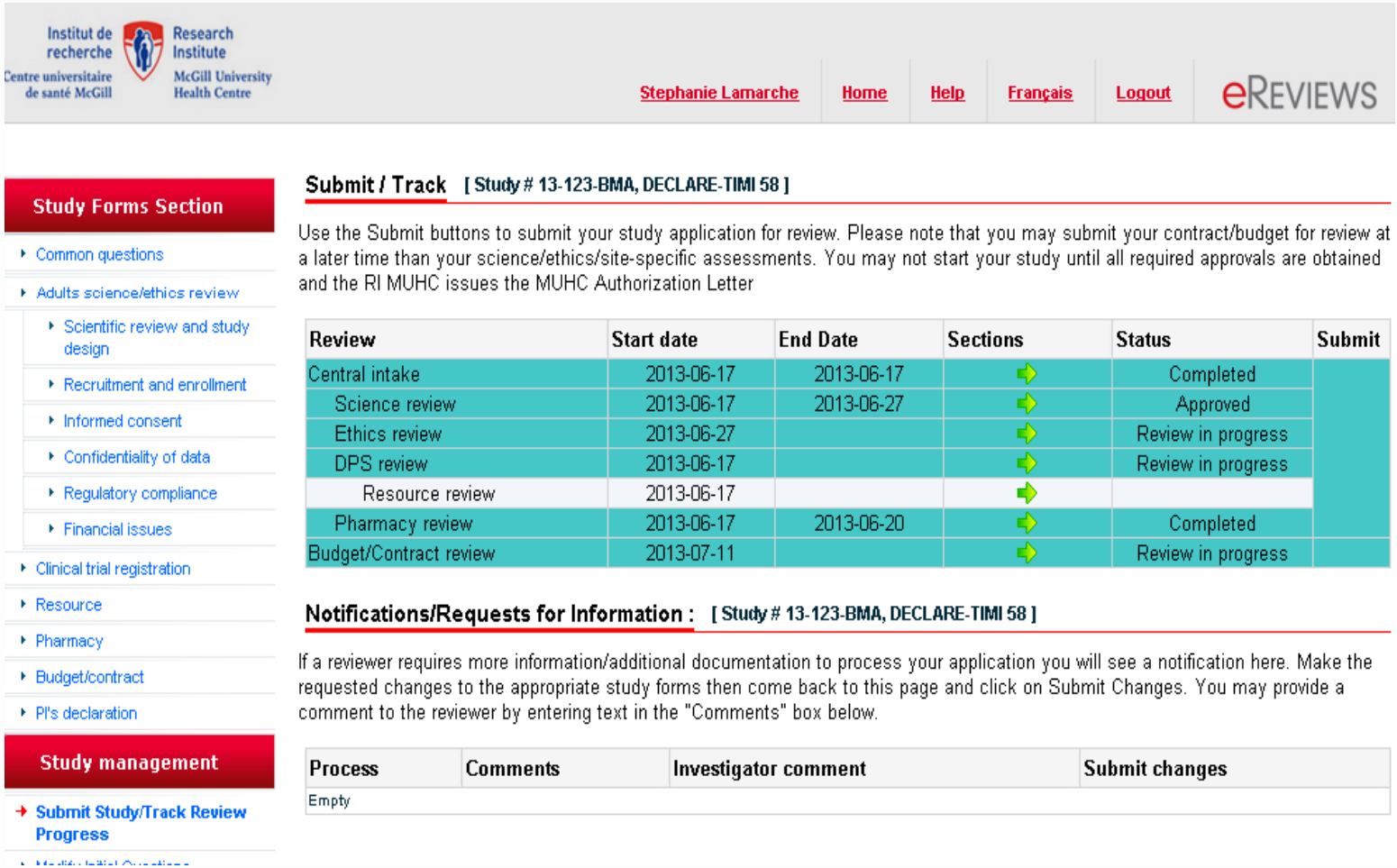
Review Process Overview



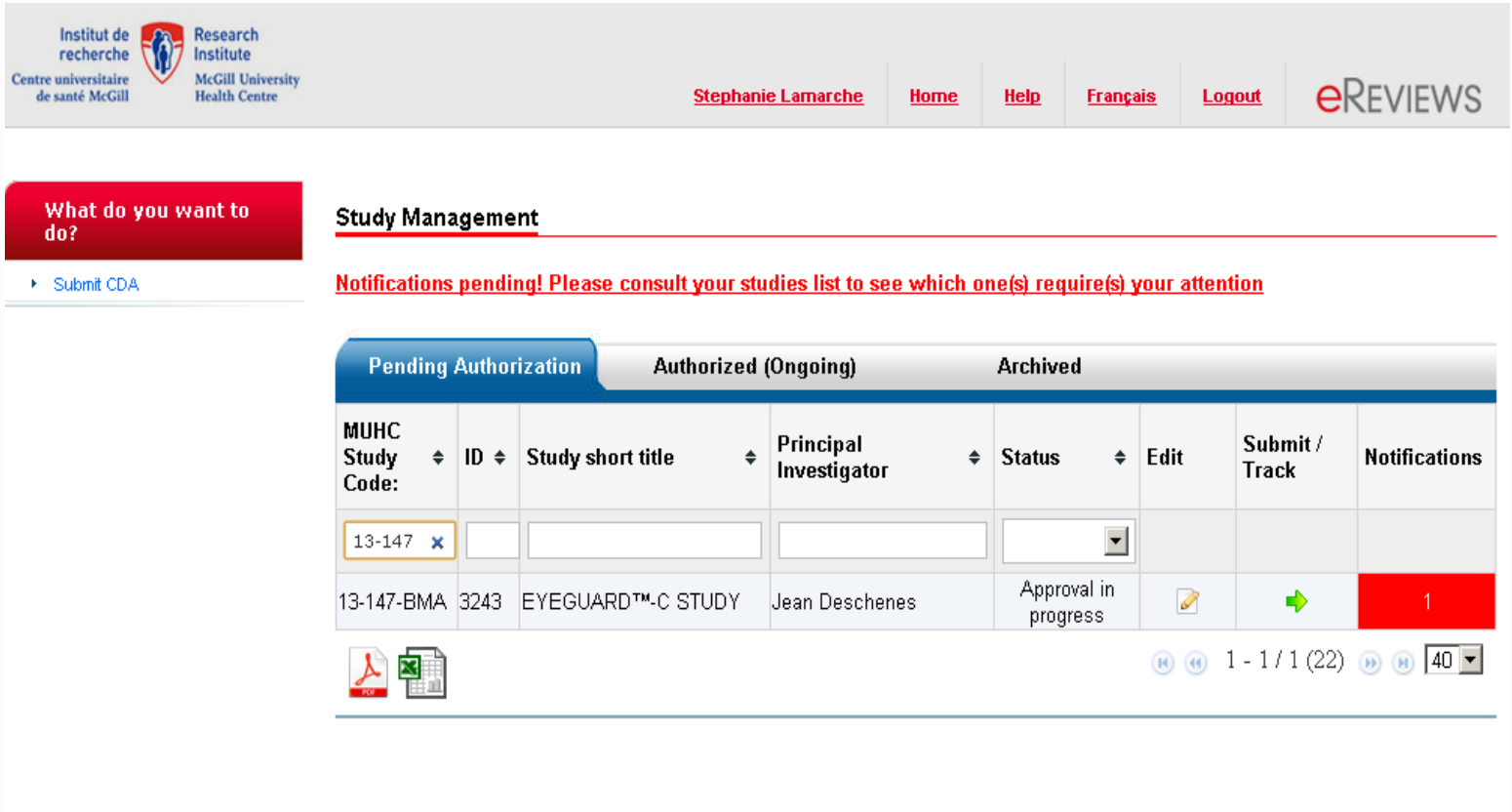
Review Process Tracking

- Clicking on Submit locks the forms to prevent further modification
- To modify forms a reviewer (REB coordinator, contract reviewer, pharmacy manager) has to request information

Review Process Tracking



Review Process Tracking



- PI and delegates will receive copy of notification email

Review Process Tracking

Study Forms Section

- Common questions
- Adults science/ethics review
  - Scientific review and study design
  - Recruitment and enrollment
  - Informed consent
  - Confidentiality of data
  - Regulatory compliance
  - Financial issues
- Clinical trial registration
- Resource
- Medical record access
- Pharmacy
- Budget/contract
- PI's declaration

Study management

- **Submit Study/Track Review Progress**
- Modify Initial Questions

Submit / Track [Study # 13-147-BMA, EYEGUARD™-C STUDY]

Use the Submit buttons to submit your study application for review. Please note that you may submit your contract/budget for review at a later time than your science/ethics/site-specific assessments. You may not start your study until all required approvals are obtained and the RI MUHC issues the MUHC Authorization Letter

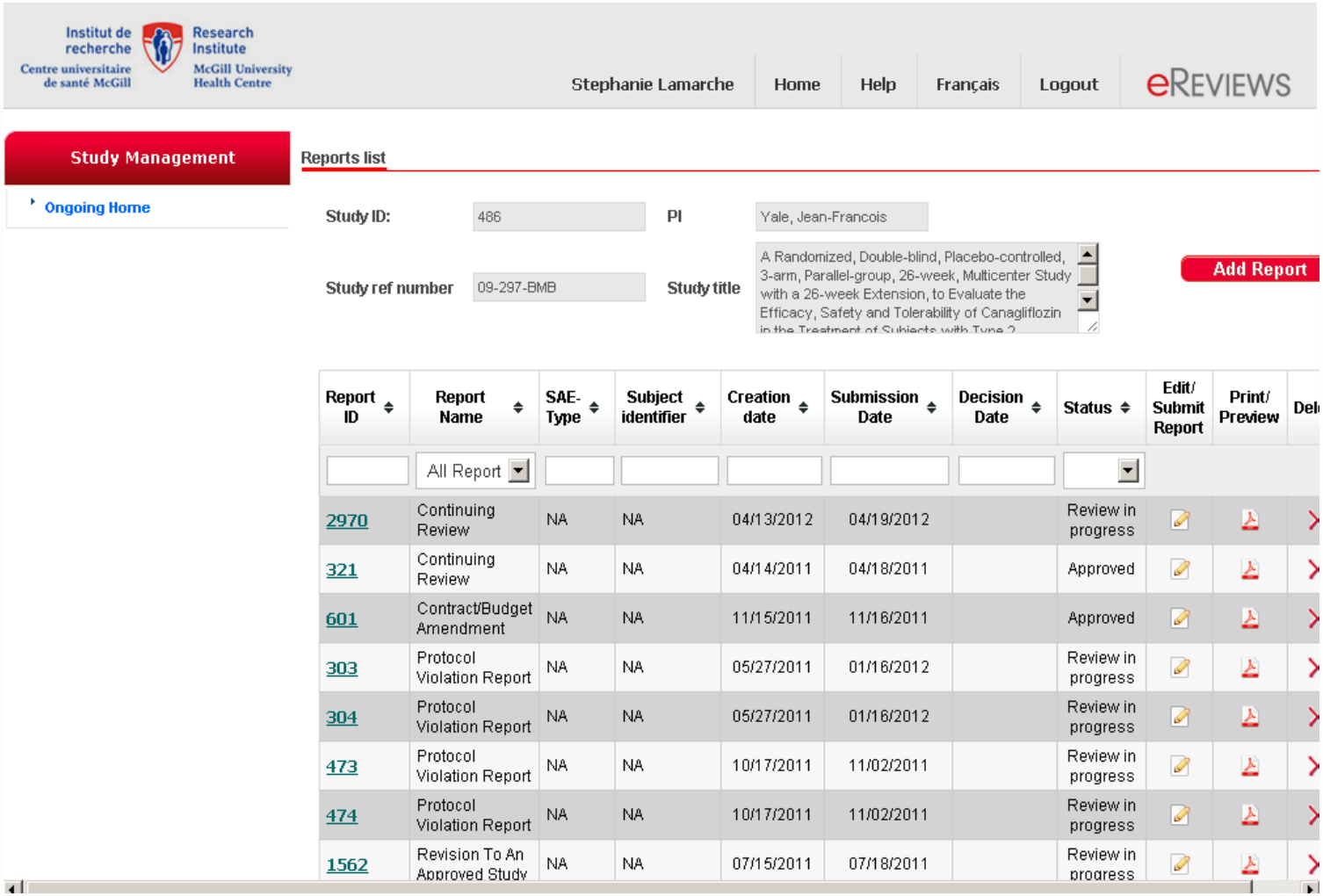
Review	Start date	End Date	Sections	Status	Submit
Central intake	2013-07-05	2013-07-08		Completed	
Science review	2013-07-08	2013-07-15		Approved	
Ethics review	2013-07-15			Modification requested	
DPS review	2013-07-08			Review in progress	
Medical Record Access	2013-07-08				
Resource review	2013-07-08				
Pharmacy review	2013-07-08			Review in progress	
Budget/Contract review	2013-07-19			Review in progress	

Notifications/Requests for Information : [Study # 13-147-BMA, EYEGUARD™-C STUDY]

If a reviewer requires more information/additional documentation to process your application you will see a notification here. Make the requested changes to the appropriate study forms then come back to this page and click on Submit Changes. You may provide a comment to the reviewer by entering text in the "Comments" box below.

Process	Comments	Investigator comment	Submit changes
Ethics review	Dear Dr. Deschenes: Please submit 1 signed original and 9 copies of collated study documents that require ethics review to my attention at S11.08. Please confirm in the eReview comment field that you will do the submission. Thank you! James Ellasus Research Ethics Office-Intake RVH S11.08 x34323		

Ongoing Report Management



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Thank you