RESEARCH ETHICS REVIEW 101

Rebecca MacDonald
Senior Ethics Officer
Coordinator, Research Ethics Committee
St. Mary’s Hospital Center
OUTLINE OF PRESENTATION

- **Part 1**: What types of research require ethics review and why?
- **Part 2**: Overview of the research review process: scientific, ethical and administrative.
- **Part 3**: Basics requirements of the research review submission process.
- **Part 4**: Particular types of research projects and the specific requirements for ethics review (i.e. clinical trials, chart reviews, quality projects).
- **Part 5**: Post-approval requirements: project modifications, reporting serious adverse events, and annual re-approval.
PART 1: WHAT TYPE OF RESEARCH REQUIRES ETHICS APPROVAL AND WHY?

What is human subjects research in the health care context?

✓ Data collection from human subjects or medical charts with the intent to increase scientific knowledge (including prepare an article for publication, or presentation, or a grant application);

✓ Data collection from human subjects of identifiable information, such as name, hospital number, photograph, audio or video recording;

✓ Data collection from staff or trainees, and this data are not part of the regular evaluation of their practice or other professional activities;

✓ A clinician is systematically making observations and testing experimental interventions or approaches in order to improve her/his own practice;

✓ Information from patients and/or additional blood/tissue samples are being collected, including for St. Mary’s quality assurance projects, and analyzed with the intent to further scientific knowledge.

Source: REGULATORY FRAMEWORK FOR THE CONDUCT OF RESEARCH AT ST. MARY’S HOSPITAL CENTER (APRIL 2011)
PART 1: What type of research requires ethics approval and why?

What is **not** considered human subjects research in the health care context...

- a manager is collecting data to evaluate the on-going practice of an employee;
- a manager is collecting information from managers or others about the collective practice in her/his unit management;
- a teacher is collecting information from teachers or others about the collective practice in her/his unit management;
- a clinician is systematically making observations and testing accepted (non-experimental) interventions or approaches in order to more thoroughly understand or improve her/his own practice.

However, should the manager/clinician wish to **publish and any scientific conclusions** reached as a result of the analysis of the data collected from these scenarios, it would be considered research and require ethics review.

Source: REGULATORY FRAMEWORK FOR THE CONDUCT OF RESEARCH AT ST. MARY’S HOSPITAL CENTER (APRIL 2011)
PART 1: What type of research requires ethics approval and why?

**SUMMARY:** If any of these criteria apply, then your project requires Research Ethics Review.

**Why?**
- ✓ In such cases, the researcher stands to benefit from the data collected.
- ✓ The objective of research ethics review is to ensure that the researcher does not take advantage of their subjects, and that subjects are not subjected to unnecessary risk or burdens.
- ✓ Moreover ethics review ensures that participants are recruited in a manner that respect their autonomy and confidentiality.
PART 1: WHAT TYPE OF RESEARCH REQUIRES ETHICS APPROVAL AND WHY?

Types of research that do not require ethics approval

- Data collected is publicly accessible and there is no reasonable expectation of privacy.
  - i.e. official publications of private or public institutions, artistic installations, public events, publications accessible in the public libraries, cyber documents on public pages, newspapers.

- Data collected from Internet research that is non-intrusive, and does not involve interaction between the researchers and the individual.
  - i.e. What are the trending hashtags for health problems on Twitter? #hernia #mybackhurts

- Data is provided by individuals but the individuals themselves are not the subject of the research.
  - i.e. Asking every hospital in Montreal for data on bed availability.

PART 1: WHAT TYPE OF RESEARCH REQUIRES ETHICS APPROVAL AND WHY?

Other types of research that may require ethics

✓ Data collected from publicly accessible sites digital sites where there is a reasonable expectation of privacy. In such cases you should submit to the REB.
  - i.e. Don’t do research on your Facebook friends (unless you have their permission)!

✓ Observing people in public spaces to collect research information is OK if…
  - It does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups;
  - Individuals or groups targeted for observation have no reasonable expectation of privacy; and
  - Any dissemination of research results does not allow identification of specific individuals.

  ➢ Let me tell you about my first breach of research ethics…

✓ Secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information.
  - BUT, in some cases funding agencies may request ethics approval!

PART 1: WHAT TYPE OF RESEARCH REQUIRES ETHICS APPROVAL AND WHY?

GENERAL RULES OF THUMB...

✓ If your study involves collecting information from people (including anonymously) or their medical records... You need ethics review!

✓ If your study involves an intervention (i.e. Drug or vitamin, self-help resources, experimental procedures not done in the context of normal care)... You need ethics review!

✓ If you’ve received funding from an agency or foundation, but your study doesn’t fit the general criteria for ethics review, check with the funding agency to ensure that you don’t need ethics review.

✓ If you want to publish (paper, poster, presentation) and your project hasn’t received ethics review, you should check with the publisher/organization.

There are always exceptions, and we can debate these nuances forever. Therefore, when and doubt it is best to simply ask the Research Ethics Committee!
PART 2: OVERVIEW OF THE RESEARCH REVIEW PROCESS

Three components of the research review process:

- Scientific
- Ethical
- Administrative

The scientific validity of a research project is the essential ‘gear in the machine.’ Without an adequate scientific methodology to attain the study’s objectives, the review cannot go forward.
PART 2: OVERVIEW OF THE RESEARCH REVIEW PROCESS

SCIENTIFIC REVIEW

- Scientific review ensures the validity of the project. A protocol should provide an methodology that collects and analyses data in a manner that **achieves the objectives of the study**. It is **unethical** to conduct a study that is not **scientifically valid or frivolous**.

- A protocol should contain (where applicable):
  - Study objectives and/or hypotheses;
  - Literature review (this need not be exhaustive but should demonstrate familiarity with the most relevant prior work in the field);
  - Description of study population, inclusion and exclusion criteria;
  - Sample size and how it was determined;
  - Research design and description of methodology;
  - Measurements and study instruments (including questionnaires, data collection forms, etc);
  - Data analysis plan;
  - A list of references in acceptable scientific format.

- If you need help preparing your protocol, **come see us** at the Research Centre.

PART 2: OVERVIEW OF THE RESEARCH REVIEW PROCESS

Scientific review – who does it?

- Scientific review = peer review
- If you have funding from a government organization you already have scientific review (i.e. CIHR, FRQS).
- If you have funding from a foundation you (should) already have scientific review (i.e. Alzheimer's society, Diabetes Québec, CARE).
- Doctoral or master’s students project, must provide a letter from their supervisory committee ensuring the scientific integrity.
Private industry studies are usually peer reviewed, but due to potential C.O.I. they are usually reviewed a second time. Sometimes we will obtain the scientific review from the another hospital (MUHC).

Sometimes residents supervised by physicians require scientific review because their supervisor may not have the right expertise.

Sometimes we get “fresh” studies that haven’t been peer reviewed at all.

In any of the above cases, someone with the proper expertise will be appointed as the independent scientific reviewer. This could be someone from the REC, the research centre or someone outside of St. Mary’s (i.e. McGill professor in the area of expertise).
PART 2: OVERVIEW OF THE RESEARCH REVIEW PROCESS

Ethical – The Research Ethics Committee

- Ethical aspects of the study will be assessed by the Mary’s Research Ethics Committee (REC).
- The REC’s mandate is to protect the welfare of research participants under the auspices of St. Mary’s. This includes ensuring the risk/benefit ratio, consent and recruitment methods are appropriate. The REC also examines conflict of interests.
- The REC follows policies and procedures established by the federal and provincial government.
- The REC reports annually to the MSSS.
- The REC is “designated” by the MSSS to review projects involving minors and incompetent participants.
- Current REC roster includes 2 physicians, 2 laypeople, a pharmacist, a lawyer, a clinical ethicist, a psychologist, a nurse, a chaplain, and a recent law graduate with a bachelor’s in philosophy/ethics. And myself, the coordinator, although I am not a voting member.
- REC meets on a monthly basis.
Some studies may involve administrative aspects, such as:

- **Contract with a company (typical for clinical trials).**
  - Contracts are reviewed by Hospital lawyers and research center management. Contracts must be between the hospital and the funding agency. All contracts must be signed by Dr. Joshi.

- **Budgets (typical for any study with funding).**
  - Researchers with expenses incurring at St. Mary’s should prepare a budget and justification for submission.

- **Hiring of personnel (i.e. research assistants).**
  - New personnel needs to be approved by the Research Center, and in the case of personnel in direct contact with participants, authorization from Linda Bambonye is required.

- **Space requirements (i.e. office space and computers).**
  - Use of office space requires approval from the Research Centre or local department.

- **Resource use (i.e. labs, pharmacy).**
  - If you plan on using any hospital resources you need written permission from the head of that department.

The contact person for administrative aspects is **Zahoor Chughtai (ext. 5068).**
PART 3: BASICS REQUIREMENTS OF THE RESEARCH REVIEW SUBMISSION PROCESS.

To register your protocol in the research review office, you need at the minimum....

A complete protocol

A complete Form A: Research protocol registration form
**PART 3: BASICS REQUIREMENTS OF THE RESEARCH REVIEW SUBMISSION PROCESS.**

Section A: Administrative Information

**Scenario 1:** You’ve been asked by a researcher at another institution to be the St. Mary’s local Site Investigator (SI).

You should complete the Form A along with the Principal Investigator (PI). You should be listed as the local St. Mary’s Site Investigator.

Sometimes PIs are sponsoring doctoral students or residents (referred to as trainees).

The Form A can be downloaded at http://smhc.ca/en/research/research-review/register-your-project

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<table>
<thead>
<tr>
<th>Administrative Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Principal Investigator:</strong> Sheldon Cooper, PhD</td>
</tr>
<tr>
<td><strong>Title/Position:</strong> Neuroscientist</td>
</tr>
<tr>
<td><strong>Institution:</strong> McGill University</td>
</tr>
<tr>
<td><strong>Department:</strong> Neuroscience</td>
</tr>
<tr>
<td><strong>SMHC Department Head/ Admin. Supervisor:</strong> N/A</td>
</tr>
<tr>
<td><strong>Mailing Address:</strong> 1000 University Avenue, Office 2727</td>
</tr>
<tr>
<td><strong>Tel:</strong> (514) 555-1555</td>
</tr>
<tr>
<td><strong>Fax:</strong> (514) 555-1444</td>
</tr>
<tr>
<td><strong>Email:</strong> <a href="mailto:sheldon.cooper@mcgill.ca">sheldon.cooper@mcgill.ca</a></td>
</tr>
<tr>
<td><strong>Postal Code:</strong> H4A1A1</td>
</tr>
<tr>
<td><strong>Project Coordinator email:</strong> <a href="mailto:will.wheaton@mail.mcgill.ca">will.wheaton@mail.mcgill.ca</a></td>
</tr>
</tbody>
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| **Name of trainee:** Will Wheaton |
| **Program of study:** Neuroscience |

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| **SMHC Site Investigator (if PI is not a SMHC staff member):** Amy Farrah Fowler, MD |
| **Title/Position:** Psychiatrist |
| **SMHC Department Head/ Admin. Supervisor:** Dr. Suzanne Lamarre |
| **Tel:** (514) 354-3511 |
| **Fax:** (514) 555-5656 |
| **Email:** amy.farrah.fowler.chsm@ssss.gouv.qc.ca |

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| **Complete protocol title:** Chimps vs Humans in Understanding Morals, Philosophy and Science (The CHUMPS study) |
| **Brief protocol title:** CHUMPS |

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| **6. Is this protocol an add-on or continuation of a previously approved protocol?** No ☐ Yes ☑ |

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**Scenario 2:**

You are the Principal Investigator of the study and you are affiliated with St. Mary’s. You should list yourself as **Principal Investigator** and there will be no site investigator.

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**Section A: Administrative Information**

<table>
<thead>
<tr>
<th>Field</th>
<th>Information</th>
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<tbody>
<tr>
<td>Principal Investigator</td>
<td>Amy Farrah Fowler, MD</td>
</tr>
<tr>
<td>Title/Position</td>
<td>Psychiatrist</td>
</tr>
<tr>
<td>Institution</td>
<td>St. Mary’s Hospital Center</td>
</tr>
<tr>
<td>Department</td>
<td>Mental Health</td>
</tr>
<tr>
<td>SMHC Dept. Head/Admin. Supervisor</td>
<td>Dr. Suzanne Lamarre</td>
</tr>
<tr>
<td>Mailing Address</td>
<td>3830 avenue Lacombe Room 3220</td>
</tr>
<tr>
<td>Postal Code</td>
<td>H3T1M</td>
</tr>
<tr>
<td>Tel.</td>
<td>(514) 345-3511</td>
</tr>
<tr>
<td>Ext.</td>
<td>3698</td>
</tr>
<tr>
<td>Fax.</td>
<td>(514) 555-1444</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:amy.farrah.fowler.chsm@ssss.gouv.qc.ca">amy.farrah.fowler.chsm@ssss.gouv.qc.ca</a></td>
</tr>
</tbody>
</table>

**Complete protocol title:**

**Chimps vs Humans in Understanding Morals, Philosophy and Science (The CHUMPS study)**

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The Form A can be downloaded at http://smhc.ca/en/research/research-review/register-your-project
PART 3: BASICS REQUIREMENTS OF THE RESEARCH REVIEW SUBMISSION PROCESS.

Section A: Administrative Information

3. Name of trainee: ___________________________ Program of study: ___________________________
   Name of supervisor (if different from PI): ___________________________
   Title/Position: ___________________________ Institution: ___________________________
   Tel: ___________________________ Ext.: ___________________________ Fax: ___________________________ Email: ___________________________

4. SMHC Site Investigator (if PI is not a SMHC staff member): N/A
   Title/Position: ___________________________ Department: ___________________________
   SMHC Department Head/ Admin. Supervisor: ___________________________
   Tel: ___________________________ Ext.: ___________________________ Fax: ___________________________ Email: ___________________________

5. Complete protocol title: Chimps vs Humans in Understanding Morals, Philosophy and Science (The CHUMPS study)
   Brief protocol title (70 characters max): CHUMPS

6. Is this protocol an add-on or continuation of a previously approved protocol? ☐ No ☐ Yes [if yes, indicate which below]
   Protocol #: 11-56 Title: Perceptions of morals, philosophy and science in humans: a pilot study

7. Projected Start Date (yyyy/mm/dd): 2013-01-01  Projected End Date (yyyy/mm/dd): 2015-02-01

8. Does your study involve any of the following SMHC resources? Check those that apply below and write a brief description. Include letters of support or signatures from corresponding department heads (see section G).
   - Equipment ☐ No ☐ Yes: Storing of blood tests prior to shipment to MUHC for analysis
   - Labs ☐ No ☐ Yes: Nurses for blood procurement
   - Pathology ☐ No ☐ Yes: Pharmacy ☐ No ☐ Yes: Radiology ☐ No ☐ Yes: Other ☐ No ☐ Yes: Office in research centre, computer

It is very important to indicate which resources you need.

This can also include hospital manpower like the Quality Assessment Unit or Statisticians.
PART 3: BASICS REQUIREMENTS OF THE RESEARCH REVIEW SUBMISSION PROCESS.

Section A: Administrative Information / Section B: Financial Information

9. Does your project require access to medical records? □ No 〇 Yes [if yes, check one of below]
   - Access will be requested with a patient consent form
   - Patient consent will not be requested [in this case, Director of Professional Services signature required in section F #4]

B. Financial Information:

1. Funding source (check one and specify):
   - Not funded [skip to section C]
   - Government granting agency: Canadian Institutes for Health Research (CIHR)
   - Industry:
   - Other private source (including foundations):
   - Other:

2. (a) Amount: $150,000.00
   (b) This amount is: 〇 Total 〇 Per patient
   (c) This amount has been:
      - Already awarded [include copy of approval/award letter]
      - Requested [promptly inform the Research Review Office of funding decision, when made]

3. Funding/grant period from (yyyy/mm/dd): 01-Oct-2012 to 01-Feb-2016
   □ Not Applicable

4. Indicate where the funds will be held:
   - St. Mary's Hospital Center [if SMHC, include a detailed budget and justification]
   - McGill University
   - Other (specify):

5. Will any project expenses be incurred at SMHC? □ No 〇 Yes [if yes, include a detailed budget and justification]

6. Does your project involve a contract? □ No 〇 Yes [if yes, submit a copy]

* New policies at the McGill OSR.

➢ Medical records: Patient permission or director of professional services?
➢ Funding? Projects with funding will need a budget if expenses are incurred at St. Mary’s. If resources are used here the hospital will need to be reimbursed with research funds. For studies involving McGill PI’s, the funds are normally kept at McGill and transferred here – you need a budget for that. Some funds are held exclusively at St. Mary’s.
➢ If there is contract it should be submitted to Zahoor Chughtai as early as possible to ensure it can be reviewed in a timely manner.
PART 3: BASICS REQUIREMENTS OF THE RESEARCH REVIEW SUBMISSION PROCESS.

Section C: Personnel Information

Section D: Scientific Information

- If you are hiring new staff you need to forward their CVs and licences (if applicable) to the Research Review Office. Any new staff in direct contact with patients needs to be approved by Linda Bambonye (in writing).

- Did your project already undergo scientific review? If yes, provide the information and evidence in writing.
## Section F: Research Ethics Information

### F. Research Ethics Information:

1. Type of research (check all that apply):
   - [ ] No human subjects involved  **[if no human subjects, proceed to question #5]**
   - [ ] Analysis of previously collected research data
   - [ ] Data collection from pre-existing records or databases (e.g. chart review)
   - [ ] New data collection from human subjects: minimal risk
   - [ ] New data collection from human subjects: more than minimal risk
   - [ ] Phase I, II or III clinical trial (safety / efficacy drug studies): **Choose Phase from Drop Down Menu**
   - [ ] Other clinical trial, specify intervention:
   - [ ] Other study, specify:

2. If your study involves a clinical trial, have you registered it with ClinicalTrials.gov?  
   - [ ] No
   - [ ] Yes
   - [ ] Not applicable

3. (a) How many subjects do you plan to recruit and/or how many charts do you plan to review across all study sites?
   - Number of research subjects: 250
   - Number of chart reviews: 100

   (b) How many subjects do you plan to recruit and/or how many charts do you plan to review at SMHC?
   - [ ] Not applicable [if N/A, skip to question #3]
   - Number of SMHC research subjects: 250
   - Number of SMHC chart reviews: 100

3. (c) What type of subjects and from which departments do you plan to recruit at SMHC (check all those that apply)?
   - [ ] Inpatients  Department(s): Mental Health, Family Medicine, Oncology
   - [ ] Outpatients  Department(s): Mental Health, Family Medicine, Oncology
   - [ ] Staff  Department(s):
   - [ ] Other (specify):

4. Does this study involve (check one)?  
   - [ ] Children
   - [ ] Mentally incompetent adults
   - [ ] Neither
Although the form indicates to only submit REB approvals that required major modifications, it is a good idea to submit all other approval letters because it gives your study some “back-up.”
Researchers shall disclose in research proposals they submit to the REB any real, potential or perceived individual conflicts of interest, as well as any institutional conflicts of interest of which they are aware that may have an impact on their research. Upon discussion with the researcher, the REB shall determine the appropriate steps to manage the conflict of interest. (TCPS 2, art. 7.4)

“Perceived vs. Real”
PART 3: BASICS REQUIREMENTS OF THE RESEARCH REVIEW SUBMISSION PROCESS.

Section E: Signatures

E. Signatures of Principal Investigator and Site Investigator (if applicable):

1. Investigator declaration:

I have reviewed this form and approve the attached research protocol entitled

Chimps vs Humans in Understanding Morals, Philosophy and Science (The CHUMPS study)

I agree to carry out and will be responsible for this research according to policies and procedures described in the St. Mary's Hospital Center Regulatory Framework in Health Research.

Amy Farrah Fowler, MD
Principal Investigator
N/A
SMHC Site Investigator

2. Signature of supervisor of trainee (if applicable):

I am the supervisor of the trainee and I approve the above-mentioned protocol to be conducted at SMHC.

Supervisor of trainee

3. Signature of the PI's or SMHC site investigator's administrative supervisor:

I have been fully informed of the above research and I support it. I have reviewed and approved the following (check all that apply):

- Protocol
- Budget
- Human Subjects Review Summary (methods of recruitment)
- Use of hospital resources
- Involvement of hospital staff
- Contract (e.g. clinical trial agreement)
- Consent form

I have reviewed the CV of Amy Farrah Fowler, MD and feel that he/she is scientifically competent to conduct the above-mentioned protocol at SMHC.

Dr. Suzanne Lamarre

When approaching an administrator, you should provide a cover letter and copies of the protocol documents and the investigators’ CVs.

It is important that this signature page is properly completed. If the PI is from outside St. Mary’s, than the SI’s administrative supervisor must sign section E3.

... in the normal alphabet E comes before F
PART 3: BASICS REQUIREMENTS OF THE RESEARCH REVIEW SUBMISSION PROCESS.

Section G: Resource Signatures

<table>
<thead>
<tr>
<th>Approval of the Vice President of Professional Services for access to medical records needed for this study</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have been fully informed of the research protocol entitled CHUMPS and grant access to medical records as described in the Human Subjects Review Summary:</td>
</tr>
<tr>
<td>Vice President of Professional Services</td>
</tr>
</tbody>
</table>

G. Resource Approvals:

1. I have been fully informed of the research protocol entitled Chimps vs Humans in Understanding Morals, Philosophy and Science (The CHUMPS study) and authorize use of my department resources for the protocol.

| Equipment (specify) respective chief of dept. | Signature | Date (yyyy/mm/dd) |
| Dr. Joe Dylewski | |
| Chief of Laboratories | Signature | Date (yyyy/mm/dd) |
| Ms. Linda Bambonye | |
| Vice President of Nursing & Operations | Signature | Date (yyyy/mm/dd) |
| Chief of Pharmacy | Signature | Date (yyyy/mm/dd) |
| Chief of Radiology | Signature | Date (yyyy/mm/dd) |
| Chief of Pathology | Signature | Date (yyyy/mm/dd) |
| Other (Specify) respective chief of dept. | Signature | Date (yyyy/mm/dd) |

- Approaching a department head of resource use always come prepared! (cover letter, CV and protocol docs).
- You don’t need all resource approval to register... but it’s highly recommended!
PART 4: PARTICULAR TYPES OF RESEARCH PROJECTS AND THE SPECIFIC REQUIREMENTS FOR ETHICS REVIEW

- Observational studies
- Clinical Trials
- Anonymous Questionnaire
- Chart Review
- Quality Assurance
Form C: Human Subjects Review Summary

Submitted as a separate document, please provide the following details about your study:

1) Study goals / objectives
2) Description of subjects
3) Method of recruitment
4) Type of involvement
5) Interventions
6) Informed Consent Procedures
7) Risks
8) Benefits
9) Quality of Data
10) Ongoing ethics monitoring

More details are available on the complete form.

The Form C can be downloaded at http://smhc.ca/en/research/research-review/register-your-project
PART 4: PARTICULAR TYPES OF RESEARCH PROJECTS AND THE SPECIFIC REQUIREMENTS FOR ETHICS REVIEW

Form D: Consent form checklist

You must submit a completed and signed consent form checklist for each consent form you submit.

We also have consent form templates available to help you write a consent form.

The **Form D** can be downloaded at http://smhc.ca/en/research/research-review/register-your-project
**Form I: Budget Justification Template**

**PART 4: PARTICULAR TYPES OF RESEARCH PROJECTS AND THE SPECIFIC REQUIREMENTS FOR ETHICS REVIEW**

For funded studies you must **prepare a budget**. The Budget justification template provides an outline on how to formulate a proposed budget. It is best to contact Zahoor Chughtai early on to obtain guidance for preparing the budget. Budgets must be approved by Hospital Admin (chief accountant, VP corporate & support, REC Chair, VP academic affairs... etc)

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**FORM I - BUDGET JUSTIFICATION TEMPLATE**

Principal Investigator: _____________________________
SMHC Site Investigator (if applicable): _____________________________
Protocol No.: _____________________________
Full title of the protocol: _____________________________

1. **Research Assistant:**
The study coordinator will perform the following tasks on the research protocol:

2. **Hospital patient costs:**
Example:
   a. Pharmacy stock management = $99/patient X 99 patients = $X.XXX
   b. Patient transportation costs (taxi) = $9 each way X 9 ways X 99 patients = $XXX

3. **Office supplies:** $XXX
4. **Delivery and courier:** $XXX
5. **Photocopies:** $XXX
PART 4: PARTICULAR TYPES OF RESEARCH PROJECTS AND THE SPECIFIC REQUIREMENTS FOR ETHICS REVIEW

Observational studies

- Involves the collection of new data from subject.
- Data is usually collected from an interview or questionnaire.
- There is no intervention.
- Normally requires written consent (for exceptions see TCPS 3.12)

Form A: Research Protocol Registration

Form C: Human Subjects Review Summary

Form D: Consent form Checklist

Consent form

Form I: Budget Justification

Funding approval letter

Contract

Investigator CVs

CVs & licenses of RAs/co-investigators

Scientific review ltr

Other REC approvals

Questionnaires

Others...
PART 4: PARTICULAR TYPES OF RESEARCH PROJECTS AND THE SPECIFIC REQUIREMENTS FOR ETHICS REVIEW

Clinical trial

- Involves an **intervention** (something is administered such as a drug or activity).
- Additional **data is usually** collected from an interview, questionnaire or other medical tests such as blood tests or even CT scans.
- Almost always requires a clinical trial agreement or **contract** and budget.
- Almost always funded by **industry or government**

Form A: Research Protocol Registration

Protocol

Form C: Human Subjects Review Summary

Consent form

Form D: Consent form Checklist

Investigator CVs

Form I: Budget Justification

Funding approval letter

Contract

CVs & licenses of RAs/co-investigators

Scientific review ltr

Other REC approvals (i.e. McGill IRB)

Questionnaires

Ads, ID cards, pamphlets...
Anonymous questionnaire

- Data is collected **anonymously via questionnaire.**
- Typical method of data collection for **Quality Assessment (QA)** studies.
- All anonymous questionnaires should state at the top of the page: “Your participation in this study is voluntary and anonymous. You may skip any questions on this questionnaire.”
- Consent is implied by the **completion** of the questionnaire.
- Ideally, participants can return the **questionnaire anonymously**, i.e. in a locked box, or by mail.
Quality Assurance studies

- Quality Assessment or QA studies are projects developed by the hospital staff concerned with evaluating care of patients and services.
- QA projects must be registered with the QA Unit. The QA staff member will usually develop and review the protocol with the investigator.
- The QA staff members will complete the QA project proposal form and QA Unit Ethics Screening form with the investigator. Should they determine the project requires REC approval, they will forward the form and relevant documents to the Research Review Office.
- The majority of QA projects requiring REC approval involve anonymous questionnaires.

QA project proposal + Quality Assessment Unit Ethics Screening form + Protocol + Questionnaire (Eng + Fre) + Investigator CVs
PART 4: PARTICULAR TYPES OF RESEARCH PROJECTS AND THE SPECIFIC REQUIREMENTS FOR ETHICS REVIEW

Chart review studies

- Some research studies rely exclusive on data from medical records, often referred to as “Chart reviews” or “la recherche sur dossiers.”
- Access to patient’s charts for research purposes needs to be provided either by the patient or the Director of Professional Services (DPS).
- The past, the DPS has been able to provide ethics approval and chart access, however, the Québec government now requires ethics approval.

For more information: http://ethique.mssss.gouv.qc.ca/site/145.0.0.1.0.0.phtml
PART 4: PARTICULAR TYPES OF RESEARCH PROJECTS AND THE SPECIFIC REQUIREMENTS FOR ETHICS REVIEW

How do I submit?

- By mail or email (email is preferable).
- It is helpful to submit word documents of consent forms, then if there are minor changes I can send them back to you easily.

When should I submit? Are there deadlines?

- Most studies are minimal risk, therefore they do not require a full board review and can be given expedited review by the REC Chair or a delegated REC member. In such cases, there are no particular deadlines for submissions.
- In cases of studies that are more than minimal risk, i.e. clinical trial for a new drug, involvement of children, mentally incompetent or other vulnerable populations as research subjects, the protocol must go to full board review. In such cases, the investigator should be sure to respect the submission deadlines for full board review posted on the website.
- Link: http://smhc.ca/en/research/research-review/research-review-committee
What happens after I submit?

- I will review the documents and verify that the submission is complete (all the documents are there and the forms are filled out properly).
- I will notify you within 1-3 working days of any missing documents or any questions I may have.
- Once the submission is complete I give the file to Zahoor Chughtai for administrative review (contract, budget and human resources). Zahoor will follow up regarding any administrative issues.
- I meet with the REC Chair weekly. I will present the file to the Chair at our next meeting. The Chair will decide if the protocol will go to Full REC review or expedited review.
- If there is no prior scientific review the project will be sent to a scientific reviewer.
- If the protocol goes to Full REC it will be mailed out to the REC two weeks prior to the meeting date.
- If the protocol is expedited, the Chair will take a few days to review it herself or delegate it to another committee member.
- Once all admin aspects and ethical aspects have been approved, a full institutional approval letter will be signed by the Chair of the REC and VP of academic affairs.
How long will it take for me to get the approval letter?

The following are some stats concerning the average time between the date of registration and the date of full institutional approval.

Sample: All projects register on or after January 1, 2010 that were eventually approved. (N=145)

Average review times for....

- **ALL PROJECTS** (N=145) : 38 days
- Projects undergoing **EXPEDITED REVIEW** (N=137): 32 days
- Average review time for projects undergoing **EXPEDITED REVIEW**, with **NO BUDGET OR CONTRACT** (N=109) : 22 days
- Projects with **BUDGETS** but no contract (N=34): 84 days
- Projects with **CONTRACTS & BUDGETS** (N=11): 92 days
- Projects receiving **FULL REC REVIEW** (N=8): 140 days
- Projects with **McGILL IRB APPROVAL** (N=54): 18 days
WHY DOES THIS TAKE SO LONG??!!

- Incomplete Form A. A project cannot be registered unless the Form A is complete.
- The consent form was not properly completed using the Form D: Consent form checklist. HOWEVER... since Dr. St-Cyr implemented the mandatory completion of the consent form checklists in January 2012, the average review time for expedited projects was cut in half from 30 days in 2011 to 15 days in 2012.
- The human subjects review summary isn’t properly completed. Then if the ethics committee has questions, there’d be some back and forth which could be timely.
- Waiting for signatures of department heads. That’s why it’s a good idea to get the signatures before you submit for ethics review. It saves time to approach the department head with a cover letter and all the necessary documents. We’ve seen delays in negotiating and approving office space as well.
- Contract negotiations. Unfortunately this is something we have little control over, so make sure to get your contract to Zahoor ASAP! Also note that Dr. Joshi needs to sign the contract prior to the study commencing.
- Budget approval. One things that has caused significant delays is that the investigator didn’t realize he needed a budget. Combine this with the fact that 6 people need to sign off on the budget...
WHAT DO I GET ONCE IT'S APPROVED?

Thank you for your application.

A letter signed by the Chair and VP of Academic Affairs!

Julie St-Cyr, MDCM
Chair, Research Ethics Committee

Susan Law, Ph.D.
Vice President of Academic Affairs

Copies of the stamped consent forms!

An ID Card!

A Cost Center!

79994
PART 5: POST-APPROVAL REQUIREMENTS
WHAT AM I EXPECTED TO DO ONCE I HAVE APPROVAL?

You will be expected to follow the conditions of approval as outlined in the Full Institutional Approval letter:

- Notifying the REC of any protocol modifications, serious adverse events or accidents.
- Reporting annually to the REC.
- Maintaining a research subject log of all patients recruited on the study (or all charts reviewed).
- Filing the consent form and consent form cover sheet in the participant’s chart (for intervention studies).
- Make arrangements to keep your data for a minimum of 5 years (25 for intervention studies).
- Ensuring all new personnel submit their CV (and credentials if applicable) to RC management and obtain at St. Mary’s ID badge.
- Use stamped versions of the approved consent form within the walls of St. Mary’s.
- Cooperate with the Research Ethics Monitor.
- Make arrangements with the medical records team to access charts.
- Completion of a termination report form upon study completion.
- Finally, all researchers and staff are expected to make a sincere effort to protect and maintain the confidentiality of their research participants.
A serious adverse event (experience) or reaction in any untoward medical occurrence that at any dose:

- results in death,
- is life-threatening

Note: The term “life-threatening” in the definition of “serious” refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

- requires inpatient hospitalization or prolongation of existing hospitalization,
- results in persistent or significant disability/incapacity, or
- is a congenital anomaly/birth defect.

Examples:

- A patient on an oncology trial suffers a stroke due to blood clots.
- A patient in an exercise study suffers a heart attack during the exercise intervention.
- A patient in a mental health study threatens to commit suicide during a study related interview.
Non-life threatening accidents and occurrences should also be reported to the REC. The MSSS Unité d’éthique defines these types of events as follows: « Un accident s’entend d’un événement fortuit ou imprévisible, survenu pendant le déroulement du projet, qui a eu ou pourrait avoir des conséquences sur l'état de santé ou le bien-être d’un sujet de recherche. »

**Examples:**
- A participant in a tele-home care rehabilitation study slips and falls, injuring her back.
- A participant in a mental health study claims that participating in the study is making him relive painful events and it has been making him more depressed.
- A participant faints during a study related blood draw.
- A participant develops anemia in a clinical trial for vegan vs. omnivore diet.
PART 5: POST-APPROVAL REQUIREMENTS

Serious adverse events and untoward medical events can be reported via the **Form E: Immediate Reporting and Amendment form.**

Form E can be downloaded from the website: [http://www.smhc.qc.ca/en/research/research-review/post-approval-requirements](http://www.smhc.qc.ca/en/research/research-review/post-approval-requirements)
PART 5: POST-APPROVAL REQUIREMENTS.

Modifications / Amendments / New Documents

- Any **modifications** you make to the protocols, consent forms, questionnaires, advertisements, or other protocol documents need to be submitted to the Research Review Office for REC approval.
- Special consideration should be paid to changes to the risks and benefit ratios of a research study. It is very important that information about changes in the risks and benefits of a study are communicated to current participants, because consent is an **ongoing process**. In cases where the risk / benefit ratio has changed, it is necessary to re-consent or inform the current participants of the changes.
- In cases where the consent form is modified you will receive a **stamped version** of the new consent form.
- Amendments/modifications can be reported using the **Form E** (same form as for serious adverse events).

Form E can be downloaded from the website: http://www.smhc.qc.ca/en/research/research-review/post-approval-requirements
PART 5: POST-APPROVAL REQUIREMENTS.

Annual re-approval / Interim report

- Standard approval time is **1 year** (this will be indicated on the full institutional approval letter).
- A progress report to the REC must be submitted on an annual basis. This is done by completing the **Form F: Interim report form**.
- The Interim report form should be submitted at least **1 month** before the full approval expiry date.
- If you forget to renew and your protocol expires you will be hearing from me...

Form F can be downloaded from the website: [http://www.smhc.qc.ca/en/research/research-review/post-approval-requirements](http://www.smhc.qc.ca/en/research/research-review/post-approval-requirements)
PART 5: POST-APPROVAL REQUIREMENTS.

Termination report

Once the study is complete the final report must be submitted to the REC along with any resulting publications/reports.

Form G can be downloaded from the website: http://www.smhc.qc.ca/en/research/research-review/post-approval-requirements
PART 5: POST-APPROVAL REQUIREMENTS.

A very special note on McGill IRB approvals and studies reviewed using the MSSS multicenter mechanism.

➢ If your study was previously approved by the McGill IRB, your study automatically qualifies for expedited approval (unless the study involves minors or incompetent adults). All subsequent reporting (i.e. modifications, annual renewals, reporting of SAEs & accidents) is directly to the McGill IRB and the decision is subsequently communicated to the local RECs. If you are doing a study in more than 1 McGill affiliated (i.e. JGH, MUHC, Children’s) hospitals, you may want to look into submitting the McGill IRB first.

➢ If your study will consist of 5+ sites (including the home site) in the Québec health network, you are required by the MSSS to use the MSSS multicenter mechanism. Like the McGill IRB review mechanism, after the initial approval, you only need to report to the main REC for modifications or annual reports.

➢ For both these review mechanisms you will still be required to submit local serious adverse events to the St. Mary’s REC.

➢ If either of these mechanism applies to your study, please come see me.
PART 5: POST-APPROVAL REQUIREMENTS.

Active Monitoring Program

St. Mary’s currently has an active monitoring program. Active monitoring relies on a third party individual – the Research Ethics Monitor (REM) - who is assigned tasks by the Research Ethics Committee (REC) to verify investigator and research team adherence to ethical guidelines. The current monitor is Chant Keropian.

*Types of Active monitoring:*

**Level A – consent form monitoring**
- Verifying that the stamped consent form is being used.
- Verifying that the consent form has been properly completed.
- For intervention studies, checking if the consent form cover sheet has been filed along with the consent form in medical records.
- Checking that the research subject log is up to date.

**Level B – office spot checking**
- Ensuring that confidential information is being kept in a secure area.
- Only for investigators with office at St. Mary’s Hospital.
- Procedure currently under development.
Types of Active monitoring (continued):
Level C – Consent process monitoring
- The REM observes the consent process and takes notes that are reported to the REC.
- The REM looks for criteria of the informed consent process – i.e. did the consent administrator give the participant adequate time to ask questions?
- The REM does not intervene and must leave if the participant objects to his presence.

Level D – Patient interviews
- Patients are interviewed by the REM after their initial consent.
- The REM will ask questions about the informed consent process and report back to the REC.
- The participant can refuse to participate.
- This procedure is currently under revision and will be merge with Level C.
Resource list

St. Mary’s Research Review Office
http://smhc.ca/en/research/research-review

Québec government Ethics Unit
http://ethique.msss.gouv.qc.ca

Federal government Ethics Unit (TCPS 2)
http://www.pre.ethics.gc.ca

McGill IRB
http://www.mcgill.ca/medresearch/ethics

McGill Office of Sponsored Research:
http://www.mcgill.ca/research/researchers

Complete St. Mary’s Hospital Regulatory Framework available from the Research Review Office
CONTACT LIST

Research Center – ext. 5060

Research Review & Research Ethics Committee – Rebecca MacDonald – ext. 3698

Protocol development – Alina Dyachenko – ext. 3362

Research Administration (budget, contracts, human resources) – Zahoor Chughtai ext. 5068.

Research Ethics Monitor – Chant Keropian – ext. 5073

Quality Assurance – Marc Pineault – ext. 6586

McGill IRB – Ilde Lepore - (514) 398-8302
A very special note...

We are always looking to **improve** the research review process. We are currently working on a **handbook** for researchers at St. Mary’s.

Any **comments or suggestions** you have about the process, the forms or this presentation will be greatly appreciated.

Rebecca MacDonald - ext. 3698
rebecca.macdonald.chsm@ssss.gouv.qc.ca
THANK YOU

It's QUESTION TIME!!