JOINT GROUP HEALTH CENTRE / SAULT AREA HOSPITAL
RESEARCH ETHICS BOARD

Application Guide For Researchers

Mail Box #90
Sault Area Hospital
750 Great Northern Road • Room G1062
Sault Ste. Marie, Ontario P6B 0A8
Phone: 705.759.3434 x 4238 • Fax 705.256.3493
Email: reb@sah.on.ca

Table of Contents

Part 1

Introduction

The REB: Who, What, Where, When, and Why

The Research Ethics Board (REB) oversees research involving humans and their related information to ensure that the research meets the highest scientific and ethical standards, in accordance with the spirit of the *Tri-Council Policy Statement (TCPS)* and other commonly-accepted regulations and guidelines in order to protect patients, investigators, and institutions.

To facilitate research and collaboration, the Group Health Centre (GHC) and Sault Area Hospital (SAH) have a joint REB, with an office at SAH serving as the administrative gateway for both organizations. The REB meets over an extended lunch hour on a bi-monthly basis from September to June of each year.

Of utmost concern to the REB is that research occurring at GHC and/or SAH ensures the safety and welfare of study participants. To this end, the REB consists of local physicians and pharmacists, but also community members, such as lawyers, spiritual leaders, and privacy experts. These non-medical members ensure that all legal, religious, and psycho-social issues are considered and protected during the course of each research project.

As described in *TCPS*, the REB believes in Respect for Persons, Concern for Welfare, and Justice - ethical principles that are commonly-held and valued by diverse research disciplines.

Functions of the Research Ethics Board

- to approve, reject, propose modifications to, or terminate any proposed or ongoing research;
- to review and make recommendations for approval of all proposed human participant research involving GHC and/or SAH patients, staff, physicians, students, residents, and/or hospital information; *and*
- to educate, support, and mentor researchers regarding the process of ethical review.

REB Review

Prior to a REB meeting, members receive copies of all submitted study protocols, informed consent forms, protocol amendments/addenda, and any other materials to be distributed to study participants. The members review these materials individually, in advance of the REB meeting, and then present any questions or concerns at the REB meeting.

Therefore, it is imperative that researchers adhere to submission deadlines to allow sufficient time for the REB membership to carefully review all submitted materials.

During the REB Meeting

Researchers are required to present an oral, 5-minute overview of their proposed research study (see Appendix 1). Most presentations shall be made in person at the REB meeting at an appointed time; if required,

teleconferencing may be arranged in advance through the REB office. The REB office will contact researchers with their exact appointment time, as well as any specific presentation requirements (as applicable).

Generally, the presentation to the REB will be made by the study's Principal Investigator (PI), though a Co-Investigator or Study Coordinator may make the presentation if the PI is unavailable. This alternate presenter must be fully informed about the study methodology, consent process, and potential risks to participants.

A question-and-answer period between the REB members and the presenter will follow the oral presentation. Typical questions include clarification of medical terms, information on other available treatments, further explanation of potential risks, etc. The presenter then will be asked to leave the meeting to allow the REB members to discuss the project and to finalize the Board's decision on the research proposal.

Decision of the REB

After carefully considering a research project proposal, the REB may make one of the following decisions:

- **Approval With No Revision Required**: an official approval letter shall be issued by the REB to the PI. This letter shall include a unique project identification number, which must be referenced in all future correspondence to the REB. Upon receipt of this letter, the PI may begin the research project immediately.

- **Conditional Approval With Minor Revisions**: an official letter shall be issued by the REB to the PI with details concerning the required minor revisions and resubmission directions. This letter shall include a unique project identification number, which must be referenced in all future correspondence to the REB. Final REB approval is delegated to the REB Chair, pending acceptable revisions. Upon receipt of the Chair's delegated approval letter for the submitted revisions, the PI may begin the research project immediately.

- **Conditional Approval With Major Revisions**: an official letter shall be issued by the REB to the PI with details concerning the required major revisions and resubmission directions. This letter shall include a unique project identification number, which must be referenced in all future correspondence to the REB. Full REB review is required for the revised application, and the PI may be required to attend a second REB meeting to discuss the revisions. Upon receipt of the approval letter for the submitted revisions, the PI may begin the research project immediately.

- **Decision Deferred**: an official letter shall be issued by the REB to the PI with details concerning the reason for the deferral and, if possible, a new date for review. This letter shall include a unique project identification number, which must be referenced in all future correspondence to the REB. The REB's decision may be deferred if there is a lack of quorum at the meeting, or if insufficient information is provided by the researchers in the application (i.e. concerning study methodology, the informed consent process, potential risks, etc.).

- **Not Approved**: an official letter shall be issued by the REB to the PI with details concerning the rejection; the PI may request clarification, and will be given the opportunity to respond in person or in writing.

Part 2

The Initial Application

Application Information

Researchers are required to submit an **original signed and dated paper copy** of the completed *Application* to the REB office; the *Application* must be signed by the PI and dated **on pages 1 and 5**. In order to meet submission deadlines, a faxed or emailed copy will be accepted temporarily, but the REB approval letter will be held until a signed and dated original copy is received.

Materials must be submitted **by 4:00 p.m. at least fourteen (14) calendar days before the scheduled REB meeting**. Submissions made after this cut-off date will not be reviewed by the REB until the next scheduled meeting in approximately two months.

Incomplete applications will not be accepted for review, and will be sent back to the researchers for revision.

Required Documents

- a completed REB *Application* (must be an original signed [on pages 1 and 5] and dated copy)
- the research proposal and/or study design/methodology/protocol
- a *TCPS2: Course on Research Ethics* completion certificate for each investigator and study team member
- approval from the SAH/GHC departmental manager/director where the research will be conducted
- Declaration of Conflict of Interest forms for each investigator (must be original signed and dated copies)
- institutional approval from SAH/GHC to conduct on-site research
- all informed consent documents

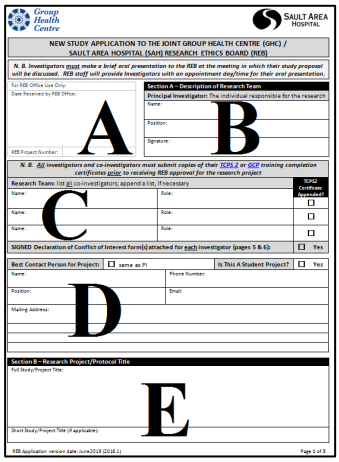
Supplemental Documents (Where Applicable):

- product monographs or investigator brochures [for investigational product(s)]
- Health Canada No Objection Letters [for investigational product(s)]
- data collection tools (i.e. surveys, data abstraction forms, interview guides, etc.)
- any amendments to the initial study protocol and/or consent form(s) (both clean and tracked changes)
- participant recruitment materials (i.e. posters, brochures, scripts of radio/television announcements, etc.)
- correspondence to participants (i.e. information letters, notifications, etc.)

Completing the Application Form

Researchers are required to complete each section of the *Application* in full. The next several pages offer tips and guidance for completing the REB *Application*; for more information or assistance with completing the form, contact the REB office.

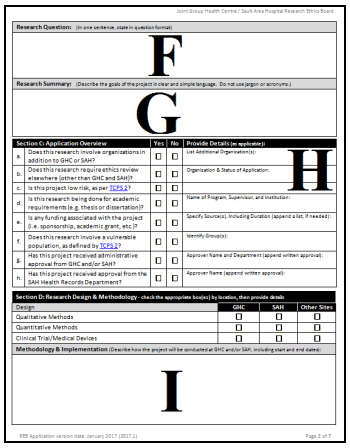
PAGE ONE



Submitted applications will be date-stamped by the REB upon receipt, and will be assigned a unique project number to be referenced in all future correspondence with the REB (**A**). The PI must sign the application and indicate his/her work-related position (i.e. medical student, physician, professor, etc.) (**B**). All members of the research team must be listed (**C**) and must submit a copy of their *TCPS 2: Course on Research Ethics* training completion certificate; the REB approval letter will be held until these certificates are received from all investigators.

The contact person (**D**) must be fully informed about the research project. Provide complete mailing information to facilitate REB correspondence. Indicate whether this is a student project (i.e. part of academic requirements). The full project title (**E**) must be listed, and it must match all other documentation for this study (i.e. protocol name, clinical trial registry, etc.). Indicate whether the study has a nickname or is more commonly referred to by a shortened title.

PAGE TWO

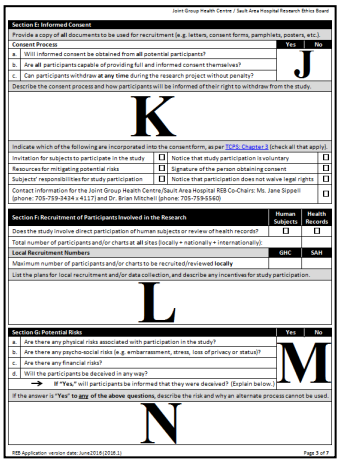


Indicate the research question (**F**) in one sentence. Explain the reason (**G**) for the research (i.e. to determine safety, efficacy, etc.). Not all members of the REB are clinicians, so medical terminology and jargon must be clearly defined.

Refer to *TCPS* for information on "Minimal Risk" and "Vulnerability" (**H**). Any vulnerable groups targeted by the research must be identified. Ensure that prior approval has been granted from the department in which the proposed research will take place and from SAH Health Records.

Detail how research activities taking place at GHC and/or SAH will be implemented (**I**), including the acquisition of institutional and/or departmental permission to conduct the research on site. If possible, provide an itemized timeline from start to finish, including dates for recruitment, intervention, and analysis; ensure that timeframes are realistic and allow for unforeseen delays.

PAGE THREE

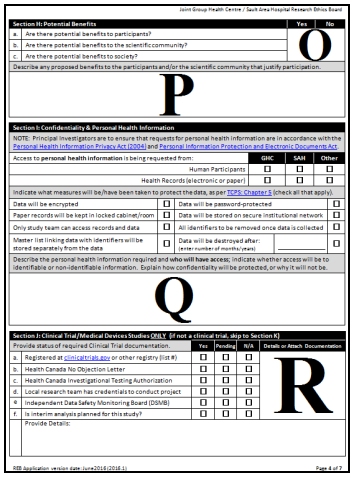


Explain how consent will be obtained (**J**). Participation must be voluntary and informed consent must be given freely. Legal rights must not be waived and patient care must not be impacted by a decision not to participate. Contact details for the researchers and REB Co-Chairs must be listed on the consent. Detail the withdrawal process, any risks it may pose, and contingencies for when it is no longer feasible (**K**).

Indicate actual numbers of participants and/or charts to be reviewed globally and locally. List methods for recruitment at GHC and/or SAH, including full inclusion/ exclusion criteria, and append a copy of any recruitment letters, posters, etc. (**L**)

Refer to Chapter 2 of *TCPS* for information on potential risks (**M**), both physical (i.e. pain or nausea) and psychological (i.e. stress or anxiety). Risks must be minimized, and measures (i.e. intervention or counselling) must be in place to mitigate any negative impact (**N**).

PAGE FOUR

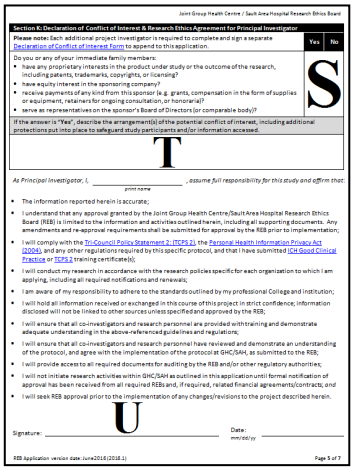


Indicate whether the research will result in potential benefits for the participants, the scientific community, and/or society (**O**); provide complete details (**P**). If there are no foreseeable benefits, justify why the research is going to be conducted. **N. B.** Cash reimbursement for participation is **not** considered a benefit.

Refer to Chapter 5 of *TCPS* for details on data confidentiality (**Q**). Explain how collected information will be kept secure during and after the research and analysis period. Electronic data must be stored on a password-protected server or portable device (i.e. laptop, flash drive, etc.) that is both encrypted and password-protected.

If the research involves a medical device or clinical trial, ensure that all supporting documents (i.e. Health Canada No Objection Letters, etc.) are appended (**R**). Discuss the need for any interim analyses.

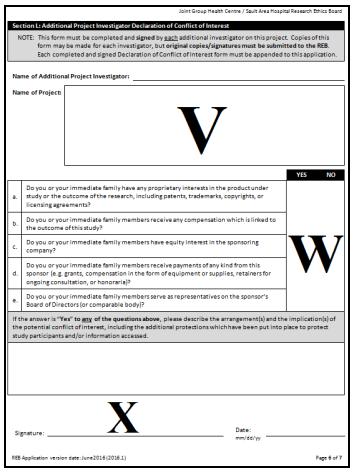
PAGE FIVE



The PI must complete all areas on this page (**S** and **T**), and **sign** and date the form (**U**). This form must be submitted to the REB office as part of the initial application package for each research project. Applications received without a signed Declaration Conflict of Interest will not be considered and will be returned to the PI for signing and resubmission.

An original copy of this page must be provided to the REB office; a faxed or emailed copy will be accepted temporarily to meet submission deadlines, but the official REB approval letter will be held until the original copy is received.

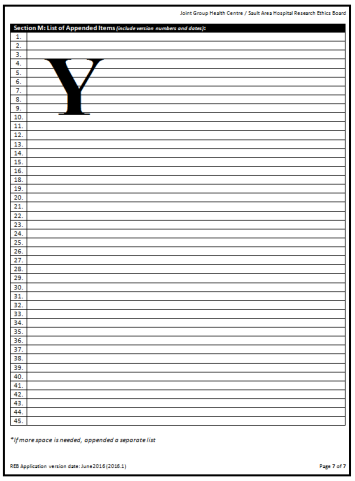
PAGE SIX



Each co-investigator must complete all areas on this page (**V** and **W**), and **sign** and date the form (**X**). These forms must be submitted to the REB office as part of the initial application package for each research project. This page may be copied as needed for additional researchers to complete and sign.

An original copy of this page must be provided to the REB office for each co-investigator; faxed or emailed copies will be accepted temporarily to meet submission deadlines, but the official REB approval letter will be held until the original copy is received.

PAGE SEVEN



Joint Group Health Centre / Sault Area Hospital Research Ethics Board

Section M: List of Appended Items *(include version numbers and dates):*

1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	
11.	
12.	
13.	
14.	
15.	
16.	
17.	
18.	
19.	
20.	
21.	
22.	
23.	
24.	
25.	
26.	
27.	
28.	
29.	
30.	
31.	
32.	
33.	
34.	
35.	
36.	
37.	
38.	
39.	
40.	
41.	
42.	
43.	
44.	
45.	

**If more space is needed, appended a separate list*

REB Application version date: June2016 (2016.1) Page 7 of 7

All documents submitted for REB review and approval must be listed on this page (**Y**), along with any applicable version numbers and/or dates. If submitting tracked changes of any document(s), this also must be indicated, and a clean copy must also accompany the submission. If more space is required, appended a separate page.

An official REB receipt will be issued for all documents submitted with the Application, both in hard copy by mail and digitally via email, along with the REB approval letter.

For assistance with completing the Application, contact the REB Office at reb@sah.on.ca. Completed application packages (with any supplemental materials) may be submitted via email to reb@sah.on.ca, by fax to 705-256-3493, or via mail to:

The Joint Group Health Centre/Sault Area Hospital Research Ethics Board
Sault Area Hospital - Mail Box #90
750 Great Northern Road
Sault Ste. Marie, Ontario
P6B 0A8

Part 3

Continuing Ethics Review

What Happens After A Research Project Is Approved

Once a project is approved, the REB must confirm that researchers follow the approved protocol and ensure subject safety. The REB annually reviews each project, and only grants approval for a period of one year; in certain cases, more frequent review may be required. The approval period will be clearly defined in the official REB approval letter that is issued to the PI.

Annual Renewal

To continue research beyond one year, the PI must apply for renewal of REB approval **before the current REB approval period expires**. Failure to comply may result in a suspension or termination of REB approval. Upon approving the annual renewal of a research project, the REB Chair shall issue an official letter confirming the approval to the PI; the new approval expiry date will be indicated in this letter.

The *Annual Renewal Application* must be submitted for REB review **at the meeting immediately preceding the current expiry date**. As the REB meets bi-monthly, the meeting immediately preceding the current expiry date may be up to two months' before the actual expiry date listed on the original REB approval letter. The unique project identification number (provided on the original REB approval letter) must be included on the *Annual Renewal Application.*

The PI or authorized designee must sign and complete the *Annual Renewal Application* and submit an original copy of the form to the REB; faxed or emailed copies will be accepted temporarily to meet submission deadlines, but the official REB annual renewal approval letter will be held until the original copy is received.

As with the original *Application*, the *Annual Renewal Application* must be submitted **by 4:00 p.m. at least fourteen (14) calendar days before the scheduled REB meeting**. It is the PI's responsibility to meet these deadlines; submissions made after the cut-off date will not be reviewed by the REB until the next scheduled meeting.

Amendments to the Original Submission

During the course of a research project, the PI may need to make changes to the originally-approved project. In most cases, REB approval is required prior to the implementation of the amendment. However, when an amendment is required to minimize immediate risk to study participants, it may not be possible to obtain prior approval. In this situation, the research team must submit a written report to the REB as soon as possible after implementation. This report must clearly describe the required amendment(s) and the immediate risk(s) to participants; it also must reference the unique project identification number (provided on the original REB approval letter) and must be submitted with a *Deviation Report.*

Minor administrative changes (i.e. a new office fax number or mailing address) do not require REB approval, but the REB must be duly informed in writing, using the *Notification Report* form. The unique project identification number (provided on the original REB approval letter) must be included on the *Notification Report.*

Non-urgent procedural amendments require prior REB approval when changes are made to:

- ✓ the research title, objectives, and/or design/protocol (i.e. sample size, inclusion/exclusion criteria, intervention, procedures, etc.)
- ✓ the list of risks to research participants
- ✓ the research documentation (i.e. information/consent forms, interview scripts, questionnaires, etc.)
- ✓ recruitment methods and/or materials used to publicly promote the project (i.e. letters, posters, etc.)
- ✓ the Principal Investigator(s) and/or the Co-Investigators

Note: this list is not exhaustive. Contact the REBC for more information regarding study amendments.

For non-urgent changes, the *Amendment Application* must be completed and submitted, and must include the unique project identification number provided on the initial REB approval letter. The *Amendment Application* and any revised document(s) must be submitted to the REB for approval **prior to implementation of the change(s)**. A receipt will be issued for all submitted documents, and a letter will be sent to the PI to confirm the REB's decision. Once approved, the PI is required to duly update the study design/protocol with new dates and version numbers, where applicable.

Serious Adverse Events (SAEs)

As per the *International Conference on Harmonisation – Good Clinical Practice*, SAEs occur when a research participant unexpectedly experiences any of the following acute negative reactions to a study drug, therapy, or device:

- requires hospitalization or prolongation of existing hospitalization;
- results in persistent or significant disability or incapacity;
- causes a congenital anomaly or birth defect;
- is life-threatening, *and/or*
- results in death.

External safety reports issued by a study sponsor must be promptly reviewed by the local PI and submitted to the REB for notification purposes only using the *Notification Report* form and must include the unique project identification number (provided on the original REB approval letter).

However, locally-occurring SAEs must be reported promptly to the REB using the *Notification Report* form and must indicate the unique project identification number (provided on the original REB approval letter. Local SAEs must include:

- a description of the local event, including whether the event reaction was mild, moderate, or severe;
- identification number of the affected participant;
- details as to whether the event occurred initially or in follow-up (indicate which number) and date; *and*
- a copy of the sponsor's completed SAE report (if applicable).

Reportable Protocol Deviations/Violations

A protocol deviation or violation occurs when a researcher does not comply with the REB-approved research design/protocol, consent form(s), and/or addenda. Such instances which jeopardize subject safety, study efficacy, or data integrity, and/or constitute a breach of subject privacy must be reported promptly to the REB. Examples of deviations/violations include, but are not limited to, the following events:

- changes to remove apparent immediate hazards to subjects without prior REB approval
- modification of inclusion/exclusion criteria to mitigate any newly-identified risks
- improperly-obtained or not-obtained informed consent
- enrollment of subjects who do not meet eligibility criteria or who were not pre-approved by the sponsor
- incorrect administration of study drug/dosage that increases the risk of harm to the subject

A *Protocol Deviation Report* must be submitted to the REB promptly after the occurrence, even if an *Amendment Application* is later submitted for approval of new study procedures, treatment plans, and/or safety precautions that result from the deviation. The *Protocol Deviation Report* must include the following:

- ✓ the date(s) of the deviation(s) and when the PI and the sponsor (if any) were made aware of the deviation
- ✓ a brief description of the issue which led to or caused the deviation(s);
- ✓ a description of any impact to the participant's safety and/or privacy;
- ✓ the corrective action(s) taken locally to resolve the issue(s); *and*
- ✓ the unique project identification number indicated on the initial REB approval letter.

Study Completion Reports

A project is considered complete when researchers require no further involvement with, or access to, study subjects, their health records, the sponsor (if any), and the host institution (if applicable). If there may be a need to access records for data verification (i.e. to publish study results), REB approval must be renewed to allow for continued access. Students should seek REB renewal until their projects have been accepted by their school.

When a study is finished, discontinued, or terminated, the PI must submit a *Study Completion Report* to the REB, using the unique study identification number from the initial REB approval letter; a signed, original copy must be submitted. Once a *Study Completion Report* is submitted, researchers will no longer have access to study data. A copy of any abstract(s), publication(s), poster(s), PowerPoint(s), etc. that were prepared/presented/published to disseminate study results also must be submitted to the REB for information purposes.

Other Reports

Any other information which is to be reported to the REB, but does not require REB approval, may be submitted with a *Notification Report* form, along with any relevant attachments, including, but not limited to:

- study publications (abstracts, posters, PowerPoints, etc.), both interim and post-project completion
- Data Safety Monitoring reports and summary reports
- information about accrual closure
- updated product monographs or investigator brochures

Appendix 1

Oral Presentation To The REB

What to Expect When Making The Oral Presentation

An integral part of the application process is a brief (5 to 10 minutes) oral presentation to the REB by the PI, Co-Investigator, or Study Coordinator. The presenter must be fully informed about the study methodology, consent process, and potential risks, and must be able to answer any questions the REB may have. **The oral presentation is mandatory**, and should include the following:

a) Background Information

A brief overview of the research should be provided, including a description of the medical condition or illness to be researched. For clinical trials, the current standard treatments, likelihood of recurrences after standard treatment, and mortality rates should also be discussed. It is also important to note who created the study (i.e. a sponsor, a research organization, a medical student as part of his/her educational requirements, etc.), and whether it is to be local, or part of a greater provincial, national, or international research project.

b) Rationale: Explain The Reason For Conducting The Study

Researchers should provide the REB with a summary of their goals for the project and an explanation of why the study is to be conducted. If a new drug, therapy, device, or procedure is to be used, the research team must detail any potential benefits that participation in the study could offer (i.e. symptom control, pain management, increased mobility, etc.).

c) Participants: Eligibility Criteria & The Setting(s) In Which Data Is To Be Collected

It is important to clearly describe the desired participants (i.e. those with a particular type of illness or disability; a certain age group; patients living in remote communities, etc.) so that the REB may assess the validity of the research. Measures to be used to protect confidentiality must be explained; if confidentiality is to be breached, describe the circumstances and the reasoning.

d) Intervention(s): Describe The Intended Treatments For Each Group

Relevant information about the dosage(s), route(s) of administration, and duration of any study intervention(s) must be provided; it is also important to note whether the study will be blinded and/or randomized. Participant surveys and interviews must also be explained, as well as any surgical procedures.

e) Foreseeable/Known Risks

Of utmost concern to the REB is the safety and well-being of research participants. Any potential physical, emotional, and/or psycho-social risks must be thoroughly explained so that the REB can determine whether the foreseeable/known risks outweigh the benefits of research, and to ensure that all due social concerns will be met by the research team during the course of the study.

Appendix 2

Informed Consent Form (ICF)

Requirements For The ICF And/Or Participant Information Letter

In accordance with *TCPS*, prospective participants and/or authorized third parties must be provided with all of the information necessary to make an informed decision. For consent to be informed, prospective participants must be given adequate time and opportunity to review the information, pose any questions, and consider whether to participate in the research.

An ICF must be written in plain language at a grade 6 reading level (as per the Flesch-Kincaid Readability Test), without any jargon, acronyms, or technical terms. All ICFs must be on official letterhead of the institution(s) where the study will be conducted, and should include a version date and page number. The ICF must include:

a) notice of the invitation to participate in the research

b) a description of the research purpose, procedures, and data to be collected

c) the identity of the researcher/PI and the funder/sponsor (if any)

d) a description of all reasonably-foreseeable risks and potential benefits arising from participation

e) notice of real, potential, or perceived conflicts of interest for researchers, institutions, and/or sponsors (if any)

f) a description of how results may be disseminated or commercialized, and whether participants will be identified directly or indirectly

g) an indication of who will have access to information collected about the identity of participants, and a description of how confidentiality and privacy will be protected (refer to *TCPS*)

h) notice of who may have a duty to disclose collected information and to whom disclosures could be made

i) information about payments, including any offered incentives, reimbursements, and/or compensation

j) notice that participants have not waived any rights to legal recourse in the event of research-related harm

k) the identity and contact information of a qualified, designated representative who can explain scientific or scholarly aspects of the research

l) the identity and contact information for the REB Chair whom participants may contact regarding possible ethical issues involved with the research

m) the expected duration and nature of participation, and an assurance that participants:

- are under no obligation to take part in the research activities
- are free to withdraw at any time, without prejudice to pre-existing entitlements
- will be given information relevant to their decision to continue or withdraw from the study

n) for clinical trials: the rules of stopping and details as to when researchers may remove participants from a trial