Dalhousie Research Ethics Boards

Guidance for Submitting an Application for Research Ethics Review – Undergraduate Students

Research Ethics
Hicks Academic and Administration Building, Suite 231
6299 South Street
Halifax, NS, B3H 4R2

Updated: August 2012

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SUBMISSION INSTRUCTIONS:
Applications are accepted at any time during office hours. The monthly deadline dates are available on the Research Ethics website and these dates constitute the deadline each month for research that requires review at a Board meeting. Note: no REB review is available in August.

The submission form and associated attachments must be submitted in two formats, both of which must be received for the submission to be considered complete:

1. A hard copy of the completed, signed submission form, including appendices, must be submitted to:
   Dalhousie Research Ethics
   Henry Hicks Academic Administration Building, Suite 231
   6299 South Street, Halifax, NS, B3H 4R2 by **4:30 pm on the deadline day.**

   The submission must have pages numbered sequentially and may be double-sided.

   AND

2. An electronic copy of the complete submission package (submission form and appendices) must be submitted as a **single** electronic file in MS Word or in PDF format. This single file should be named: REB Submission (Student last name) and submitted by electronic mail attachment or Dalhousie File Exchange (https://filedrop.dal.ca/) to: ethics@dal.ca

Incomplete applications will not be reviewed.

What to include*:*
Your submission must include a hard copy and an electronic copy of the submission form as well as the following appendices (if applicable); each appendix must be clearly labeled:

- Recruitment Documents (posters, verbal scripts, online postings, invitations to participate, etc.)
- Screening Documents
- Consent Forms
- Research Instruments (questionnaires, surveys, interview or focus group questions, etc.)
- Debriefing Forms
- Permission Letters (Aboriginal Band Council, School Board, director of a long-term care facility)

All pages in the application must be numbered sequentially from start to finish including any appendices submitted with the application. This enables the reviewers to reference their comments, making revisions easier.

Text must be in a font size that is no smaller than 11 pts.

Complete all sections of the application form. If a section is not relevant to your proposed research, please indicate “not applicable”.

How to learn more about research ethics*:*

Researchers should consult the Tri Council Policy Statement *Ethical Conduct for Research Involving Humans (*2nd edition) (http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default) and are strongly encouraged to complete the Course on Research Ethics (CORE) tutorial (http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/)

Research at IWK Health Centre, CDHA or Horizon Health Network*:*

Researchers who intend to use IWK Health Centre, Capital District Health Authority or Horizon Health Network facilities or data, or recruit their patients, must contact the ethics offices in these institutions first to determine whether a submission should be made to their Research Ethics Boards, rather than to Dalhousie University.

Research approved by the Research Ethics Boards at these hospitals does not additionally require Research Ethics Board approval at Dalhousie University. However, research approved by the Dalhousie Research Ethics Board *will* additionally require REB approval by these institutions.

Section 1. ADMINISTRATIVE INFORMATION

Determining which Research Ethics Board (REB) to submit to: Dalhousie University has two Research Ethics Boards and the assignment of which Board will review a particular project is done according to the subject matter of the research.

Health Sciences REB – reviews research dealing with medical, dental or health and mental health related topics
Social Sciences and Humanities REB – reviews research dealing with social, behavioural and cultural research in non-medical contexts

Researchers are encouraged to indicate the Board to which they believe their submission should be directed, however the final determination of which Board will review which research rests with the director and/or Board chairs.

1.1 Student Researcher

Students are considered to be Principal Investigators for their thesis research projects. This section asks for contact information and for signed agreement by the student researcher to conduct their research in an ethically sound manner, consistent with the Tri Council Policy Statement *Ethical Conduct for Research Involving Humans* (TCPS) and University Policy.

1.2 Supervisor

As part of the review process, the Board must ascertain whether there is sufficient scholarly merit to the research; in other words, is this a valid piece of research? For this reason, it is important that the student's ethics proposal be carefully reviewed and approved by the student's supervisor prior to submission. A well-conceived and carefully presented research project will pass through the ethics review process more quickly than one that has not received adequate input from the student's supervisor.

The supervisor signature attests that the supervisor has personally reviewed the scientific/scholarly methods of the research project that is described in the ethics application, and believes they are sound and appropriate. Also, the supervisor has personally reviewed the ethics application prior to its submission for ethics review. The supervisor commits to ensuring that the research is conducted following the principles of the Tri Council Policy Statement *Ethical Conduct for Research Involving Humans* and that the research will be undertaken and supervised as per the University *Policy on the Ethical Conduct of Research Involving Humans*.

1.3 Department/unit ethics review

Minimal risk undergraduate research may be reviewed and approved by the department-level research ethics committee. Minimal risk undergraduate thesis research must further be reviewed and approved by the Research Ethics Board, but will undergo a streamlined delegated process when the department research ethics committee has granted department-level approval. This section should be completed by the department research ethics committee (if applicable).

Section 2. PROJECT DESCRIPTION

2.1 Introductory Summary

In lay language, briefly describe the rationale, purpose, study population and methods. Limit this section to approximately 500 words.

2.2 Research Question

Some studies are intended to test hypotheses or to address specific research objectives, while others are more exploratory or inductive, guided by research questions. Whichever is appropriate should be described.

2.3 Recruitment

2.3.1 Justification should be provided for the sample size sought. For quantitative research this may mean power calculations, for qualitative work, a rationale for the estimated number of participants needed.

2.3.2 Researchers should describe how they, or others on their behalf (e.g., staff of a community service provider distributing recruitment brochures, IT managers circulating an email) will be using these recruitment methods. Researchers should be careful to address issues surrounding recruitment that might relate to the voluntariness of participation. For example, TAs wishing to involve students as participants in research must clearly demonstrate how they have mitigated any undue or coercive influences (see TCPS 3.1).

Recruitment instruments include such items as posters, media advertisements, brochures, email text or letters, etc., copies of which should be appended to the application. Where oral recruitment is proposed, scripts guiding this process should be presented. Whatever participants see or hear must be presented to the REB to review.

The description of the study population should include any and all characteristics or attributes of potential participants that are relevant to the research. Specific attention should be paid to those attributes that would suggest a level of vulnerability in the potential participants; e.g., literacy limitations, mental or physical impairment, extreme youth or age.

Specific inclusion and exclusion criteria (e.g., age, profession, medical condition) should be stated, and if results are intended to be generalizable broadly, exclusion of population groups should be justified.

Where screening methods are used to select participants, these should be described, along with how the data from these measures will be used, stored and destroyed.

External factors, such as the cultural or socio-political environment that could affect the potential participants, should be described. For example, where a study is investigating a source of community conflict, the nature of the conflict needs to be described so that its ramifications of the study on the safety of participants can be assessed. Where the cultural context is relevant to the methodology, consent process or risks that might be posed to participants, these should be discussed.

2.4 Methods and Analysis

2.4.1 The **physical location** of the study (e.g., where testing will be conducted, or interviews held) must be described. It is important to provide sufficient detail so that any limitations to confidentiality, or any safety concerns, can be identified.

A description of the **procedures, tasks or activities** that research participants will be asked to take part in must be presented so that the Board can clearly understand what they will experience. Where many procedures are planned, a stepwise flow-chart or table (indicating procedures and their duration) may be helpful. This is especially important where multiple interactions are planned with some or all of the participants.

The researcher should **estimate the time** that participants will be asked to commit to the study. This will include travel time, time to review the consent form, time to complete the study measures, and any post-data collection activities, such as member-checking or data verification. The researcher should provide a total time for participation as well as a time estimate for each task.

The researcher should describe **what data will be collected** and how it will be done. All **research instruments** should be described and/or appended (e.g. questionnaires, focus group/interview guides, psychometric tests) along with their validity and reliability (where appropriate).

Ethical principles require that researchers only collect the data needed to address the research questions. Therefore, where a number of instruments or demographic questionnaires are to be used, each must be justified in relation to the objectives of the study. Where video recording or audio recording is planned, the researcher should describe why this is necessary and how it will be done. Any plans to re-contact participants need to be described, where applicable. Any safety measures should also be described.

The researcher should describe the way in which blinding or randomization will be used for data collection and analysis (if applicable).

Participants should be given ample opportunity to withdraw from the study with no negative consequences. The researcher should discuss how participants may withdraw, and at what point this may no longer be possible (e.g. after study results are analyzed). The limits on withdrawal should be made clear to potential participants, including what will happen with their data should they withdraw part way through the study.

2.4.2 Describe your specific role in the research study. Members of the research team should have the appropriate qualifications to carry out their duties in the study and these should be described (e.g. professional experience, methods courses, fieldwork or other experience).

2.4.3 A brief description of the plans for data analysis (including any software and statistical tests that will be used) should be described. Describe how the proposed data analysis addresses the study's primary objective.

2.4.4 If **misdirection or deception** will be used in the study, this should be justified, indicating why it is essential in order to achieve the study objectives (see TCPS article 3.7). Similarly, if information will be withheld from participants (e.g., the full intent of the study), this must be discussed along with the rationale for doing so. Where deception/misdirection/non-disclosure is used, the researcher should normally **debrief** participants regarding the true circumstances surrounding their research participation. This would include disclosing what the deception or misdirection consisted of along with explaining the reasons for it. Similarly, information that has been withheld should be disclosed. A short written communication can be used, however, participants should be given the opportunity to withdraw themselves and their data from the study. A debriefing form must be included in the application as an appendix.

2.4.5 It is not necessary to offer **compensation, incentives or reimbursement** to participants for their participation in your research. However, when offered, compensation for research participation is generally considered to be an honorarium or gesture of appreciation for the effort or inconvenience experienced by the participant. It is not intended to represent a payment in the sense of employment. Compensation or incentives should not represent an undue influence that would induce a participant to accept significant risks that they otherwise would not (see TCPS 3.1).

2.5 Informed Consent Process

The conduct of research involving human participants requires that participants be provided with the opportunity to give informed consent prior to their participation in research. The process of obtaining this consent can be carried out in a number of ways, and where warranted, should be revisited during the research (where the research takes place over a protracted period, or where information emerges during research that might influence a participant's decision to remain in the study).

Informed consent is commonly documented using a **written consent form** that the researcher reviews with participants prior to the start of the research. This document must provide research participants with sufficient information about the research to ensure that they understand the procedures, tasks or activities in which they will be involved, and the risks and potential benefits of the research. It must also inform them of their rights with respect to participation, i.e., that research participation is voluntary and that they have the right to withdraw at any time. Researchers should provide the consent form to participants in advance of whatever activity they will be involved in (i.e., focus group, testing) so that potential participants have a chance to consider their participation prior to engaging in research activity.

The researcher should describe the consent process that will be used, including who will engage in it, when it will be done (in relation to when the research will take place) and where it will be done.

Where different groups of participants will be involved in different aspects of the study, a **consent form specific to each group's participation** should be developed, to avoid confusion or misinterpretation.

Written and signed consent forms are not always appropriate, or may constitute a risk to

research participants. In these cases, **non-written consent** may be appropriate and the process to be used in obtaining it and documenting it should be described in the application. The TCPS (article 3.12) requires researchers to document the non-written consent in some manner (e.g., audio recording, field notes). It may also be appropriate to leave the participants with a statement of information about the project and contact information for the researcher and the Research Ethics office.

In accordance with the TCPS (article 3.7), there are specific situations where the REB may **waive the requirement for obtaining informed consent** for minimal risk studies. The conditions listed in the TCPS must be met (minimal risk, impracticable, no therapeutic intervention, adverse effects unlikely, and debriefing if possible). If a researcher would like to waive the requirement for obtaining informed consent, s/he must describe how the proposed research meets each of these conditions.

Where it is not clear that potential participants have the **capacity** to provide informed consent, or if the research participants are of a population recognized as lacking the capacity to provide informed consent (e.g., young children, persons with a significant cognitive impairment), informed consent must be obtained from an individual who bears responsibility for decisions concerning the well-being of the participant (e.g. parent, guardian, caregiver). Where this impairment is temporary, researchers should describe how consent will be obtained from the participant when they are deemed to have regained decisional capacity. Where a participant lacking decisional capacity is able to provide assent for the research (i.e., demonstrate their willingness to cooperate with the researcher and take part in the research), this should also be sought. Researchers should provide a description in the application of the criteria that they will use to judge assent or dissent of a participant. With children, there is no age of consent for research in Nova Scotia, thus capacity is assessed on a case-by-case basis. The more invasive the study, the more it may make sense to have parental consent and youth assent. With less invasive studies, it is often appropriate to have youth consent, simply informing parents.

The **process of consent** is not limited to the initial discussion and signature of the consent form. During the course of the research, new information about the study, or knowledge regarding the risks of study procedures may be learned that should be disclosed to participants. It is the responsibility of the researcher to ensure that this is done. This would be achieved through submitting an amendment to the Research Ethics Board describing the changes to the recruitment or consent process; informing and reconfirming consent of those currently involved in the study; and modifying the consent process and/or consent form for new participants.

In some circumstances (e.g., Aboriginal research) it may be important to seek **consent from the community** as a whole in addition to getting consent from individual participants. It is the responsibility of the researcher to determine whether or not this is needed, and if so, to describe how such consent will be sought.

If the permission of organizations is needed (e.g., Aboriginal Band Council, School Board, director of a long-term care facility) for the researcher to be able to conduct recruitment and research activities, these should be described and letters of permission included in an appendix to the submission. Organizational permission is not always appropriate, particularly for critical inquiry (see TCPS article 3.6).

Participants should be given ample **opportunity to withdraw** from the study with no negative repercussions. The researcher should discuss how participants may withdraw, and at what point this may no longer be possible (e.g. after study results are analyzed). The limits on withdrawal should be made clear to potential participants, including what will happen with their data should they withdraw part way through the study.

2.6 Privacy and Confidentiality

2.6.1 Researchers have a responsibility to ensure that all data received from research participants is maintained in a confidential manner. Where the data is of a personal or sensitive nature, the Board may require the researcher to demonstrate significant confidentiality safeguards, including at a minimum the use of password protection and encryption of electronically-stored data. The researcher should clearly describe the kinds of information that will be collected. This is equally important where secondary use of data collected previously is being conducted; for example, by accessing client files, or personal records.

Where (and in what format) the **data will be stored** should be described, along with who will have access to it. If there are codes to be used that link the data from various sessions or sources, or to information that could identify participants (names, addresses etc.), security of these codes should be described. If there is to be remote transmission (e.g., electronic) from one location to another, this should be described as well as any security that pertains to this transmission. How data will be reported (e.g., as aggregate statistics, personal narratives) and what the implications of this are with respect to participant identification and data confidentiality should be described. If a transcriptionist or translator has access to the data, s/he should be required to sign a simple confidentiality agreement, a copy of which should be appended to the ethics submission.

The researcher should state how long the data will be retained. Data may be retained indefinitely, but this needs to be clear to participants. Also, the researcher should state how the data will ultimately be either rendered anonymous or destroyed.

2.6.2 Where there are limits to confidentiality due to legal obligations (i.e., duty to disclose suspected child abuse or neglect, or the abuse or neglect of an adult in need of protection) or professional codes of ethics, this must be stated (when applicable to the study). A simple description of what the researcher will do in such a situation should be provided. This is advisable for research that may, inadvertently, cause such disclosures to be made, and it is imperative for research that specifically deals with issues of sexual or child abuse, domestic violence or elder abuse.

2.6.3 If you propose using a survey company (e.g., Survey Monkey) or software to help you collect, manage, store, or analyze data that is personally identifiable and accessible from outside of Canada, you must describe that use here. It is recommended that student researchers make use of the Opinio survey tool available through the University`s Information Technology Services department, which meets the Board`s expectations with respect to electronic security.

Researchers must comply with the University *Policy for the Protection of Personal Information*

from Access Outside Canada that defines the responsibilities of all members of the University community with respect to handling of personal information. "Personal information" means recorded information about an identifiable individual, including, but not limited to:

- name, address, telephone, email (personal not business);
- race, ethnic origin or religious political beliefs or associations;
- age, sex, sexual orientation, marital status or family status;
- any identifying number or symbol (examples: Dalcard ID, SIN, credit card, health insurance, drivers' license);
- fingerprints, blood type, or inheritable characteristics;
- medical or personal history;
- educational, employment, financial, or criminal history;
- personal views or opinions.

These responsibilities relate to the collection, storage, analysis and management of personal data about identifiable individuals, and apply in various ways to different practices:

- When purchasing non-Canadian software
- When renewing service and trouble-shooting maintenance agreements for existing non-Canadian software
- When seeking to transfer data within Canada
- When transporting data outside of Canada
- When wishing to share the data with colleagues outside of Canada
- When hiring a Canadian survey company using non-Canadian software
- When hiring a non-Canadian survey company

Researchers should consult the full University policy for assistance in determining which provisions of this policy might apply to their research and what actions (if any) they must take to satisfy them. These should be reported briefly in this section of the application.

2.6.4 If the researcher plans to use **quotations from research participants** in results or presentations of the data, this should be stated. How this will be done without disclosing the identities of participants (unless participants agree to attribution) should be described. If willingness to be quoted is a condition of participation, this should be made clear in the consent forms or any oral consent process.

If the researcher wishes to attribute quotes by name, a justification for this should be provided. Participants identifiable by quotations should be given the opportunity to approve or withdraw their quotes.

Participants are often given the opportunity to see the **results of the study**, once it has been completed. This may be done in a number of ways, e.g., by giving a group presentation, sending a simple written summary to participants, providing the results on-line, using a website. Participants who undergo testing as part of their research participation may wish to see the **results of their tests**. This may or may not be feasible, when measures to preserve confidentiality require that identifying information is removed from individual results, rendering them de-identified, or when data aggregation takes place prior to analysis. Also, there may be concerns (depending upon the nature of the tests conducted) related to the potential for misinterpretation (e.g., where the results require expert interpretation) or misuse of individual results. Where it is appropriate and possible to give participants individual results, this should

be done in such a manner as to enable clear interpretation by the participant, either independently, or with the assistance provided by the researcher.

Where data collected from a research participant indicates that the participant might be at risk (e.g., is demonstrating distress, may have a previously unknown physiological condition) the researcher has an ethical obligation to inform the participant that appropriate follow-up is available and/or advisable, and to provide some information to assist in this.

2.7 Risk & Benefit Analysis

2.7.1 Conducting a risk assessment of the proposed research is a vital part of the ethics submission. Researchers should be thorough but realistic in describing and estimating risks that are posed to participants in the study. Because of the inherent uncertainty in the conduct and outcomes of research, it is not appropriate to claim that there are 'no risks'. Risks may be minor or significant; however the researcher is responsible for mitigating any anticipated research-related risks to the best of his/her ability. In all cases, the researcher must disclose to participants whatever risk, discomfort, or inconveniences the research might pose, including all **known adverse effects** (including physical, emotional, psychological, social or economic) to the participant, and any anticipated or **potential risks** or stressors (physical, emotional, psychological, social or economic) to the participant.

It is useful if the researcher integrates the concept of 'minimal risk' into the description of risk. The definition of minimal risk used in the TCPS (p. 23) is: "research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research."

Risk has two components: harm and the **probability of that harm**. In describing potential risks, the researcher should discuss both, such as "there is a high probability that participants will feel emotional distress…" or "there is one chance in 10,000 that participants could experience cardiac arrest …" Where possible these should be substantiated by references to prior research or to the literature.

Researchers should describe what steps are taken to **mitigate the risks** posed. These could include specific safety precautions, screening protocols, or ameliorating actions (e.g., contact information for support services).

Sometimes the research poses **risks at the level of communities**. For example, there can be the risk of stigmatization linked to the exploration of negative characteristics. The researcher should seek to identify such risks when they exist, and to determine whether or not there are any mitigating actions that could be taken. This is not to suggest that critical research should not be undertaken, rather that the assessment of risk should consider communities, as well as individuals, and the researcher should address these either through mitigation (where possible) or disclosure where it is not possible to mitigate these risks.

2.7.2 Direct benefits and indirect benefits should be described. **Direct benefits** are those benefits that participant receives as a direct result of his/her participation in the research. Only those benefits that can be assured should be described (often there are none). For example, a

free fitness test might be a direct benefit if it is provided to all participants. Anticipating that participants might learn about research methods, or have a positive self-reflective experience is not something that can be guaranteed, nor is this obviously a benefit to them. Care should be taken not to overstate direct benefits.

The **indirect benefits** of the study arise from the new knowledge, information, or insights that result from the research. Because the REB assesses whether the risks to participants are justified by the benefits of the research, the Board must be convinced that the research will yield some benefits. Indirect benefits may be framed in terms of new knowledge that will be gained as well as any benefits that might accrue to study participants.

2.8 Conflict of Interest

Conflicts of interest may arise in the form of **relationships between researchers and participants** (see TCPS 7.4). For example, when a researcher who is also an instructor or TA wishes to recruit students from his/her own class into a research project, supervisor wishes to recruit employees under his or her supervision. The researcher should describe how these conflicts will be mitigated and/or managed.

SECTION 3. APPENDICES

3.1 Appendices Checklist

Append all relevant material to this application. This may include:

- Recruitment Documents (posters, verbal scripts, online postings, invitations to participate, etc.)
- Screening Documents
- Consent Forms (see section 3.2 below)
- Research Instruments (questionnaires, surveys, interview or focus group questions, etc.)
- Debriefing Forms
- Permission Letters (Aboriginal Band Council, School Board, Director of a long-term care facility)

3.2 Consent Form

Where it is clear that research participants have the capacity (i.e., decision making capability) to provide informed consent, the researcher must ensure that the information provided to research participants is presented in such a manner as to be easily and comprehensively understood. The language and terminology used in describing the research must clearly convey the objectives and methodology of the research project, and the risks and benefits to the research participant. It is recommended that consent forms be written for a **Grade 8 level of reading comprehension**.

A template of a consent form is included in the submission form to assist student researchers in developing this important document. The template may be adapted as appropriate to the

proposed research.

The Research Ethics Boards use the following as a guide when reviewing a consent form:

Format

- Is the consent form appropriately **headed** (i.e. letterhead)?
- Identification of document as **Consent Form**
- Is the consent form simply written (**Gr. 8** comprehension level, no technical jargon)?
- Is it appropriately **formatted**: font size (min 11 pt), headings, page numbering?
- Is a **title** for the study included on the **first** page and on the **signature** page?

Invitation to Participate in Research

- Is there an introduction explaining that this is a research study, and that **participants are invited to participate in research**?
- Is there a statement that assures **voluntariness and right to withdraw** without repercussions?

Who Is Conducting the Research Study

- **Identity and affiliation** of researchers

Purpose and Outline of the Research Study

- Is the **purpose** of the study clearly described?
- Is the **study design** clearly described and how many **participants** are involved?

Who Can Participate in the Research Study

- Are **inclusion and exclusion** criteria described?

What Participants Will Be Asked to Do

- Are the participants appropriately told what they will be **asked to do** based on the description in the protocol?
- Are the **procedures or tasks** that the participants will be asked to carryout described?
- Is the **time** that participation will involve described?
- Is any **special clothing or other requirements** on the part of participants explained?

Possible Benefits, Risks and Discomforts

- Are **direct benefits** (if any) to participants (other than compensation) explained?
- Are **indirect benefits** of the study (e.g. contribution to new knowledge) explained?
- Are the foreseeable **risks** identified? Are their **probabilities** estimated? Are the means to **mitigate the risks** described?

Compensation / Reimbursement

- If the participants are to be **compensated**, are the conditions and amount of compensation described?

Privacy and Confidentiality

- Is there a statement regarding the **confidentiality** of participant data (e.g., storage of data, access, method of publication)
- Is there a statement regarding how the identity of the participant will be safeguarded?

- Are any **limits on confidentiality** (if applicable) described (e.g., duty to disclose abuse or neglect)?
- If participants will be **quoted** in reports from the data, is this addressed in the consent form (e.g., whether they will see quotes in advance and whether quotes will be attributable)?

Participant Withdrawal

- Are participants given information about the opportunity to **withdraw participation**?
- Are they given information about the opportunity to **withdraw data**? Is the information appropriate?
- Are those providing consent informed about how **assent** of participant will be sought when third parties give consent?

Sharing Research Findings with Participants

- Description of how participants will **review transcripts of interviews**, if applicable
- Description of how **study results** will be provided to participants

Questions

- Is there information about **whom** the participant may contact regarding the study?
- Is the **contact information** of that individual provided?
- Has the **Director, Research Ethics** been cited should participants wish to raise concerns?

Overall

- Does the information on the consent form **match the protocol**? Are there any inconsistencies (e.g., participant age, time commitment, compensation amount)?
- Is there a clear distinction between **clinical care / research** procedures

Signature Page

- Are the appropriate signatures requested, in an acceptable format (signature, date)? That is, is there a signature **statement** indicating that **information has been provided**?
- Are all permissions ***required*** for *participation* and for data to be *useable* all included in a single signature? (e.g., audio/video taping, use of quotes)
- Are additional optional permissions (those that are **not required** for participation or for usability of the data) requested separately, and clearly indicated? (e.g., participating in future studies, use of quotes, re-contact for future studies; transport data outside Canada)?
- Is contact information or other **personal information** beyond the participants' signature requested? If so, is the **purpose** for this clearly indicated or inferable? Is it appropriate to ask?