

# GUIDELINES FOR OBTAINING CONSENT AND ASSENT

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## 1. Purpose

The purpose of this guideline is to provide researchers with information on consent and assent as it pertains to research involving human participants. Consent templates and appendices are also provided below to help researchers prepare their consent and assent documents.

## 2. Background

Individuals conducting research involving human participants must ensure that their participants provide voluntary, informed, and ongoing consent. In some cases, where consent from participants is not applicable (see Section 4 below) researchers must obtain assent from their participants. For more information on the importance of obtaining consent and assent, see [Chapter 3 of The Tri-Council Policy Statement \(TCPS 2\)](#).

## 3. The Three Important Components of Consent

According to the TCPS 2, consent must (i) be given voluntarily, (ii) it must be informed, and (iii) it shall be ongoing.

### I. Voluntariness

Researchers have a responsibility to ensure that participants who decide to participate in their projects do so voluntarily. Part of this responsibility entails that researchers are aware of situations where undue influence, coercion, or incentives might undermine the voluntariness of participants' consent. Special care should be taken in situations where researchers and participants stand in already existing asymmetrical relationships. For example, employers and employees, teachers and students, correctional officers and prisoners, physicians/nurses/counsellors and patients, and researchers, family and friends are examples of asymmetrical relationships that may place an undue influence on participants to participate in research projects.

Researchers who stand in asymmetrical relationships must demonstrate to the Research Ethics Board (REB) that there is no undue influence on potential participants to participate in their projects. In all cases, the consent form should clearly indicate that participants' participation in the study is completely voluntary and that decisions regarding whether or not to participate in a project will have no effect on participants' relationships with any member of the research team.

## II. Informed Consent

Consent must be informed. This entails that research participants have a clear understanding of the following information:

- i. The type of research being performed;
- ii. The name(s) of the investigator(s) conducting the study;
- iii. The potential risks and benefits of the project;
- iv. What their participation involves;
- v. Any potential, real, or perceived conflicts of interest;
- vi. Any applicable funding sources;
- vii. Any incentives, reimbursements, costs, or compensation relevant to the study;
- viii. How confidentiality or anonymity will be maintained;
- ix. How participants may withdraw from the study; and
- x. Who will have access to the data, and how the data will be managed and destroyed.

Research participants should also be given an opportunity to ask any questions they might have regarding any of the above information.

It is the duty of the researcher to convey all of the above information to participants in an accessible manner. To this end, consent forms should (i) be written at a grade 6-8 reading level, (ii) be addressed to the participant (i.e., in second person by using “you-statements”), (iii) contain no technical terms or long sentences, and (iv) contain no extraneous information. Also, in cases where potential participants do not speak or understand the language that the study is being primarily conducted in, researchers must provide adequate translations and appropriate interpreters.

## III. Ongoing Consent

Researchers should obtain consent from their participants prior to their participation in research-related activities (i.e., before collecting any data from participants, or accessing data). In some cases, however, this requirement may be waived. In these types of cases, the onus is on the researcher to demonstrate to the REB why consent is not being obtained prior to participants participating in research-related activities.

Researchers have a responsibility to respect the autonomy of their participants throughout all stages of the research. This entails that researchers not only obtain initial consent from their participants, but also that participants provide ongoing consent – or at least tacit consent – throughout the duration of their participation. Where possible, researchers should incorporate various mechanisms into their research design to allow for participants to change their minds regarding their participation and withdraw from the study.

## 4. Assent

In some cases, potential participants may be unable to consent to participating in a research study. In cases such as this, potential participants must nonetheless agree or assent to participate in the project. Assent forms are typically used when a participant lacks the full capacity to understand the nature of the research and thus cannot provide consent. (Recall that consent, according to the TCPS 2, must be voluntary, informed, and ongoing, and if participants cannot understand the nature of the research, they cannot meet the informed component of consent.) Assent is typically sought by researchers conducting research involving children, whose ability to understand – and not simply their age – makes them incapable of consenting to participate in a project.

Some factors that determine whether child assent is adequate, or whether consent of a third party is required, include: (i) the nature of the research, (ii) the research setting, (iii) the level of risk, and (iv) any legislation or legal requirements. Even if a legitimate third party (e.g., legal guardians for young children) gives their consent, participants lacking the capacity to consent must also assent to participate in the project.

For more information on determining whether consent or assent is appropriate, see [Chapter 3 of The Tri-Council Policy Statement](#).

## 5. Instructions for Completing the Consent Form

The following templates have been designed to help you construct and organize your consent documents. Some sections are optional and may not apply to your research; these sections should be deleted if they do not apply. Instructions are identified by **blue text** in square brackets. Please remove these instructions once you have completed the section. The template also contains suggested wording in black text. You can modify this wording if you desire. Please ensure that your consent/assent form is carefully edited and includes page numbers on all pages.

References are provided throughout the templates to the relevant articles in the Tri-Council Policy Statement. These are in **green text** and in square brackets (e.g., “[TCPS 2 Article 3.2(a)]”). See [www.pre.ethics.gc.ca](http://www.pre.ethics.gc.ca) for a specific discussion of each article. Please remove these references before submitting your consent/assent form.

Please remove all **blue** and **green** instructional text before submitting it for REB approval.

**N.B.** One of the most common reasons for delay of REB approval is an inadequate consent agreement.

## 6. Consent Form Template and Confirmation of Agreement Form

Please remove all **blue** and **green** text, the header, and the footer before submitting your consent document. Please revise the page numbers accordingly. Black text is suggested wording.

[Insert university letterhead or logo here, as well as all partner logos. Ensure that they appear at the correct resolution and ratio.]

### **Toronto Metropolitan University Consent Agreement**

You are being invited to participate in a research study. Please read this consent form so that you understand what your participation will involve. Before you consent to participate, please ask any questions to be sure you understand what your participation will involve. [TCPS 2 Article 3.2(a)]

TITLE OF THE STUDY [If the study involves using different consent forms for different populations, identify the population group as the subtitle of the study.]

INVESTIGATORS This research study is being conducted by [insert names of all investigators - faculty, students, and other. Students must include the name of their supervisor], from [insert department affiliation] at Toronto Metropolitan University.

This study is funded by [insert all sponsoring agencies/organizations or delete if not applicable].

[As per, Article 3.2(e) of the TCPS 2, if there is a possibility of **commercialization of the research findings**, and the presence of any real or perceived **conflicts of interest** on the part of the researchers, institutions or sponsors, this shall be clearly stated.]

If you have any questions or concerns about the research, please feel free to contact [insert contact persons' names, addresses, TMU email address, and TMU phone number. Please do not include personal cell phone or home numbers].

PURPOSE OF THE STUDY [TCPS 2 Article 3.2(b)] [Please state **what** the study is designed to assess, explore, or establish in lay terms, avoiding technical terms or jargon. Language used should be at a **grade 6-8 comprehension level**. State the **number of participants** being recruited for this study and the **eligibility and ineligibility** criteria used to identify prospective participants. If the research is being conducted by a **graduate student in partial completion of**

**a degree requirement**, please indicate that the results will contribute to, for example, a major research paper, doctoral dissertation, etc.]

WHAT YOU WILL BE ASKED TO DO [OR] WHAT PARTICIPATION MEANS If you volunteer to participate in this study, you will be asked to do the following things:

[Describe the **procedures chronologically** using simple language, short sentences, and either short paragraphs or bullet points. Use subheadings to help organize this section and increase readability. Medical and scientific terms should be defined and explained. Indicate the **location** where the research will be conducted and the **expected duration** of the participant's involvement. Please be specific regarding the amount of time participation will require. For example, if participants will be expected to attend a TMU clinic for six visits, inform them of this, as well as the amount of time each visit will require. If participants will be asked to complete a questionnaire or interview, describe the types of questions that they will be asked to answer, and how long the questionnaire or interview is likely to take. We strongly recommend that you include one or two sample questions. Provide clear information about any demographic data that will be collected. Include a statement of whether or not research findings will be available to participants and how/where they will be made available to participants.]

POTENTIAL BENEFITS [TCPS 2 Article 3.2(c)] [Describe potential benefits participants may expect to receive from the research, and state the potential benefits, if any, to science or society expected from the research. Please ensure you do not overstate the benefits (e.g., despite conducting a study with a very small sample size, and with no broad dissemination plans, you suggest that the research will change public policy). If you cannot guarantee benefits to the participant, please include the following statement:]

I cannot guarantee, however, that you will receive any benefits from participating in this study.

WHAT ARE THE POTENTIAL RISKS TO YOU AS A PARTICIPANT [Do NOT state that there are no potential risks or harms involved in your study. If potential risks are very low, you may simply state that and then detail the possible risks. Provide a brief description of any risks or discomforts the participant might encounter as a result of participation. A description of provisions you have made to address these risks or discomforts is required. For example, because of the personal nature of the questions asked, a participant may reflect on unpleasant memories while responding to a questionnaire or interview. Subjects should be informed of the potential for discomfort and told that if they begin to feel uncomfortable, they may skip answering a question or stop participation, either temporarily or permanently. See **Appendix B** below for the additional cautions to be provided to inform participants in clinical trials.]

[If there are rare but possibly catastrophic effects that the participant may experience, these should be stated. Additionally, if there are significant physical or psychological risks to

participants that might cause the researcher to terminate the study, please describe them.] [TCPS 2 Article 3.2(c)]

CONFIDENTIALITY [Describe the extent, if any, to which confidentiality of records identifying participants will be maintained and the measures adopted to maintain that confidentiality. State whether pseudonyms will be assigned and if/how participants can indicate their preference of whether or not their real name will be used in published material. If the latter is an option, please include a check box on the signatory page for participants to opt in or out.]

[Provide information on length of retention, the security of identified data, and whether data will be shared with participants, and if so, how. If information will be released to any other party for any reason, state the agency/person to which the information will be furnished, the nature of the information, and the purpose of the disclosure. If there is the potential that participants will disclose information that you would be required to report to legal authorities, this must be clearly stated (e.g., a duty to report child abuse, professional duties to report, etc.).]

[If participants are to be audio- or video-recorded, describe the participant's right to review/edit the recordings or transcripts. Describe how the recording will be stored, who will have access to the raw and transcribed recordings, if the recordings will be used for educational purposes, and when they will be destroyed. If participants are to be audio- or video-recorded, the Confirmation of Agreement form should include a check box or extra signature line so that participants can clearly express their wish to be audio- or video-recorded.]

INCENTIVES FOR PARTICIPATION [Incentives are described in Article 3.2 of the TCPS 2. Incentives are monetary or other benefits that encourage participation. If an incentive is offered to participants, describe what is being offered. If there are pro-rated amounts based on different phases or tasks of the research, this must be clearly stated. **Do not offer an hourly rate for the incentive.** If payment is in the form of a lottery or draw, state the probability of winning and how winners will be notified. If the participant chooses to stop participation (described below under Voluntary Participation and Withdrawal), the full lump sum or pro-rated amount must be given to the participant whether or not they complete the research. If an incentive is not offered, state that the participant will not be paid to participate in this study.] [TCPS 2 Article 3.2(j)]

COSTS OF PARTICIPATION [If there are costs associated with participation (e.g., tests, office visits, parking, childcare, etc.), specify, in detail, the extent of these costs. If the costs are high to the participant, you are encouraged to offer reimbursement. If you are providing reimbursement of these costs, please note reimbursements in this section. Reimbursements are not incentives; reimbursements are for costs directly related to participation. This does not necessarily include a reimbursement for someone's time.] [TCPS 2 Article 3.2(j)]



**COMPENSATION FOR INJURY** [As per Article 3.2(k) of the TCPS 2, by consenting to research, participants have not waived any rights to legal recourse in the event of research-related harm. If your research involves greater than minimal risk, please outline the compensation for injury. See Appendix B for injury covered and not covered by the study. **If this does not apply to your research, simply remove this section, or include the following sentence:**]

By agreeing to participate in this research, you are not giving up or waiving any legal right in the event that you are harmed during the research.

**VOLUNTARY PARTICIPATION AND WITHDRAWAL** [Participants must be informed that their participation is entirely voluntary. They must be told that they do not have to answer every question or complete all aspects of the research. If your research involves an online survey or task, there should be an option for complete withdrawal whereby the data entered by the participant up to that point is NOT included in the analysis. If this is not possible, it must be clearly stated in the consent form. Can a participant's data be removed from the study after the fact? If so, please provide a cut-off date for data to not be used. Participants must be told they can stop participating at any time and that if they choose to stop, they will still receive the full incentive (if pro-rated based on phases, participants are entitled to that pro-rated amount) and reimbursements. Participants must be told that withdrawal from the study will not influence future relations with the researchers, Toronto Metropolitan University and any other institutions/partners. A sample text follows. Please note the text may not be applicable to all types of research (e.g., studies not involving questions).] [TCPS 2 Article 3.2(d)]

Participation in this study is completely voluntary. You can choose whether to be in this study or not. If any question makes you uncomfortable, you can skip that question. You may stop participating at any time and you will still be given the incentives and reimbursements described above. If you choose to stop participating, you may also choose to not have your data included in the study. Your choice of whether or not to participate will not influence your future relations with Toronto Metropolitan University [and/or other institutions/partners of the research] or the investigators [please include names] involved in the research.

[If appropriate, describe the anticipated circumstances under which the participant's involvement may be terminated by the investigator without regard to the participant's consent.]

**QUESTIONS ABOUT THE STUDY** If you have any questions about the research now, please ask. If you have questions later about the research, you may contact:

[Insert contact name of primary investigator and/or other investigators, title, address, TMU phone number, and TMU email address. Do not provide personal/home numbers or addresses. Students should include their research supervisors as contacts.]

This study has been reviewed by the Toronto Metropolitan University Research Ethics Board. If you have questions regarding your rights as a participant in this study, please contact:

Research Ethics Board  
c/o Office of the Vice President, Research and Innovation  
Toronto Metropolitan University  
350 Victoria Street  
Toronto, ON M5B 2K3  
416-979-5042  
[rebchair@torontomu.ca](mailto:rebchair@torontomu.ca)

[INSERT TITLE OF PROJECT]

CONFIRMATION OF AGREEMENT

[As per Article 3.12 of the TCPS 2, consent needs to be documented either in a signed consent form or in documentation by the researcher of another appropriate means of consent. Signed consent is also mandatory in some cases (e.g., Health Canada regulations and Civil Code of Quebec).]

[As per Article 3.2 (k), research participants must be informed that by signing the consent form participants are not waiving any legal rights in the event of research-related harm.]

Your signature below indicates that you have read the information in this agreement and have had a chance to ask any questions you have about the study. Your signature also indicates that you agree to participate in the study and have been told that you can change your mind and withdraw your consent to participate at any time. You have been given a copy of this agreement. You have been told that by signing this consent agreement you are not giving up any of your legal rights.

\_\_\_\_\_  
Name of Participant (please print)

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Date

[If participants are being audio- or video- recorded, there should be a separate consent statement about this and an additional signature line or check box inserted here.]

I agree to be [audio-/video-recorded] for the purposes of this study. I understand how these recordings will be stored and destroyed.

\_\_\_\_\_

\_\_\_\_\_  
Signature of Participant\_\_\_\_\_  
Date

[If participants will have their blood (or saliva or other biological material) drawn or used, there should be a separate consent statement about this, and an additional signature line or check box inserted here.]

I understand that this research involves the collection and analysis of my [insert all relevant human biological materials here] and its collection, use, and destruction have been explained to me.

\_\_\_\_\_  
Signature of Participant\_\_\_\_\_  
Date

[NOTE: If this consent agreement is being developed to obtain parental or third-party permission, the signature line should be labeled “Parent/guardian of Participant - Third Party or Legal Representative.” In addition, include a line that would be used by the parent/guardian to indicate the name of the child for whom they are giving permission. **Remove this signature line if not applicable to your study.**]

\_\_\_\_\_  
Signature of Participant or Parent/Guardian\_\_\_\_\_  
Date\_\_\_\_\_  
Name of Child (print) if applicable

## 7. Consent Template for Online Survey

[SAMPLE CONSENT DOCUMENT FOR ONLINE SURVEY]

[Please remove all blue and green text, the header, and the footer before submitting your consent document. Please revise the page numbers accordingly. Black text is suggested wording.]

**TORONTO METROPOLITAN UNIVERSITY <INSERT LOGO IF POSSIBLE>  
Consent to Participate in Research**

[TITLE OF THE STUDY]

### **INTRODUCTION AND PURPOSE**

My name is \_\_\_\_\_. I am a [graduate student/ faculty member] at Toronto Metropolitan University [if lead investigator is a student, introduce faculty supervisor here, e.g., “working with my faculty supervisor, Professor \_\_\_\_\_,”] in the School/Department of \_\_\_\_\_. I would like to invite you to take part in my research study, which concerns [in plain language briefly explain study purpose].

### **WHAT YOU ARE BEING ASKED TO DO**

You are being asked to voluntarily complete this online survey. It involves questions about [themes, types of questions] and should take about [time] to complete. In order for all of your answers to be collected, you must go to the end of the survey and click the ‘submit survey’ button. This will demonstrate your full consent to participate.

### **POTENTIAL BENEFITS**

There is no direct benefit to you for taking part in this study [or state direct benefits if they exist]. My hope is that the research will [describe benefits to society/scientific knowledge as applicable].

### **WHAT ARE THE POTENTIAL RISKS TO YOU**

[Describe any potential risks/discomforts from study participation and what will be done to minimize and/or address these risks. If your survey is asking questions that could make someone uncomfortable (e.g., thoughts about mental health, experiences with violence, etc.) please ensure you offer a list of free online and/or (geographically specific supports like an online support group, etc.) to mitigate the risk. In addition, you should allow participants to skip a question if they feel uncomfortable. IT IS IMPORTANT TO SET UP YOUR SURVEY TO ALLOW PARTICIPANTS TO SKIP QUESTIONS OR SELECT A ‘CHOOSE NOT TO ANSWER’ OPTION. In addition, research needs to be informed and voluntary with an option to stop participation. A

participant could start a survey and realize halfway through that they no longer want their data collected. An online survey needs to account for this voluntary withdrawal. An example of such wording is:] Some of the survey questions may make you uncomfortable or upset, or you may simply wish not to answer some questions. You are free to decline to answer any questions you do not wish to answer, or to stop participating at any time by closing your browser. If you close your browser before getting to the end of the survey, and do not confirm your consent to participate at the end of the survey by clicking the 'submit survey' button, your information collected up to that point will not be used.

[Option for surveys that might cause someone to become upset.] A list of online, free support groups is listed here in case you feel you need support during or after the survey is completed. You could also contact the researcher/s if you would like us to find supports for you. Please note that if you do this your identity will be disclosed to the researcher. Please print this page or write down the contact information in case you want to access this information once you complete the survey.

#### **YOUR IDENTITY WILL BE [ANONYMOUS OR CONFIDENTIAL]**

[Most online surveys are anonymous, meaning you will not be able to determine who actually participated because you will not be collecting data in the survey that could potentially identify an individual, such as tracking Internet Protocol (IP) addresses. If you are asking for participants' names in order to provide some type of incentive (e.g., a lottery ticket, payments to participants via PayPal, or mailing gift cards), this would technically not be an anonymous survey unless you collect the names via a separate submission process not linked to the original survey responses. Sample wording for an anonymous survey is provided. Please change the wording if your survey is not anonymous.]

The survey is anonymous and as such I will not be collecting information that will easily identify you, such as your name or other unique identifiers. Although your Internet Protocol (IP) address can be tracked through the survey platform, I, or any member of the research team, will not be collecting this information. Your IP address may be observed only to ensure that one individual is not completing the survey multiple times. [If you are tracking IP addresses for other reasons, such as determining geographical responses, please make this clear in the consent process.]

#### **HOW YOUR INFORMATION WILL BE PROTECTED AND STORED**

This survey uses [insert name of survey platform, i.e., SurveyMonkey™, Qualtrics™, Skype™, etc.], which is an American (USA) company. [Or for FluidSurveys use the following sentence:] This survey uses FluidSurveys and the servers are located in Canada; however, personal information may be disclosed to FluidSurveys' affiliates located in the USA. [If you are using a different Canadian platform, please stipulate the issues related to protection and storage of data.]

Consequently, US authorities under the provisions of the USA Freedom Act (formerly known as the Patriot Act) may access the survey data. If you would rather participate through an email or paper-based survey, please contact the researchers. Please note, email or paper-based surveys may allow your identity to be known to the researcher/s, but if you select this option your information will be kept confidential.

To further protect your information, data stored by the researcher will be password protected and/or encrypted. [If data will be shared between research sites or transported/transmitted, please outline how the data will be securely transmitted. TMU researchers are encouraged to use TMU's Google Drive to share electronic data amongst researchers.] Only the researcher/s named in this study will have access to the data collected. Any future publications will include collective information (i.e., aggregate data). Your individual responses (i.e., raw data) will not be shared with anyone outside of the research team.

When the research is completed, the researcher/s will keep the data for up to [XX] months/years after the study is over. [If different, give accurate information about retention and use of study data in future, e.g., "I will destroy this data at the end of the study."]

#### **INCENTIVE FOR PARTICIPATION**

[Include information on all incentives being offered. Please note that for anonymous online surveys, if an incentive is offered (i.e., payment of an honorarium via PayPal or other method, the risk of someone completing multiple surveys and using an alias to get multiple payments is a possibility. Incentives for anonymous survey participation should be well thought out.]

You will receive a \$20 gift card for your participation in the survey. [Provide instructions on how the incentive will be forwarded to the participant.]

[OR, if there will be no payment/compensation:] You will not be paid for taking part in this study.

#### **YOUR RIGHTS AS A RESEARCH PARTICIPANT**

Participation in research is completely voluntary and you can withdraw your consent at any point *up to* clicking the 'submit survey' button at the end of the survey. However, because the survey is anonymous, once you click the 'submit survey' button at the end of the survey, we will not be able to determine which survey answers belong to you, and so we cannot withdraw your information from our study once you click on the 'submit survey' button.

Please note that by clicking the 'submit survey' button at the end of the study you are providing your consent for participation. By consenting to participate you are not waiving any of your legal rights as a research participant.

## QUESTIONS

If you have any questions about this research, please feel free to contact the researcher/s.  
[List names of all researchers, including supervisors for graduate research, including phone numbers (not a personal phone number) and email address (use a TMU email address).]

If you have any questions about your rights or treatment as a research participant in this study, please contact the Toronto Metropolitan University Research Ethics Board at [rebchair@torontomu.ca](mailto:rebchair@torontomu.ca) (416) 979-5042.

Please print a copy of this page for your future reference.

**START SURVEY** <start survey button>

[SURVEY QUESTIONS]

[At the end of the survey include a SUBMIT button or check box stating:]  
By clicking SUBMIT I am consenting to participate in this study.

## 8. Appendix A: Assent Agreement Template

### Assent Agreement (Template)

**Note to Investigators:** If children without the capacity to consent on their own will be included in the study, an assent agreement is necessary. A written assent agreement is used to inform the child of the study using age-appropriate language so he/she can determine whether or not to participate in the research. If the child is not yet able to read, alternative procedures may be used to present the information verbally to the child in order to obtain verbal assent.

Assent must usually be accompanied by parental consent but may be obtained without parental consent depending upon the nature of the study [minimal risk only, non-medical, non-therapeutic] and the age level of the child [older adolescents]. Any research involving therapeutic or medical or invasive testing or clinical trials with children as research subjects should not be undertaken without the informed written consent of the parent(s) or guardian(s).

The structure of an assent agreement includes:

1. A heading;
2. A title;
3. A description of the purpose, procedures, and other information contained in the related parental consent form, but in simpler language;
4. A description of what the child will be asked to do and how long he/she will be involved;

5. A description of how children might indicate that they no longer want to participate;  
and
6. Age-appropriate level of language that can be understood by the targeted age group.

## 9. Appendix B: Additional Information on Obtaining Consent for Clinical Trials

### Information Regarding Clinical Trials

**[Note to Investigators:** The following is additional information to include if your study involves more than minimal risk (primarily for clinical trials).]

[There must be a statement as to whether any medical treatments are available if injury occurs, and if so, what treatment is available and where further information can be obtained.]

#### **Sample Statement (if injury is not covered by the study [primarily for clinical trials])**

It is unlikely that participation in this research will result in harm to participants. If any complications arise, we will assist you in obtaining appropriate attention. If you need treatment or hospitalization as a result of being in this study, you are responsible for payment of the cost for that care. If you have insurance, you may bill your insurance company. You will have to pay any costs not covered by your insurance. Toronto Metropolitan University will not pay for any care, lost wages, or provide other financial compensation.

#### **Sample Statement (if injury is covered by the study)**

It is unlikely that participation in this research will result in harm to participants. If you need any treatment or hospitalization as a result of being in this study, all reasonable and customary medical expenses, above what your insurance will cover, will be paid by [note signing authority], as long as you have notified the investigator immediately of the injury, you have followed all of the directions of the study investigator, you have followed medical advice regarding the injury, and you have not deliberately caused the injury.

In addition, as per Article 3.2 of the TCPS 2, in clinical trials, information on stopping rules and when researchers may remove participants from trial must be included in the consent form.

## 10. Appendix C: Additional Information on Projects Administering Health Care



Below is additional information to be included in Consent/Assent Forms for Studies Involving Personal Health Information (as required by the Personal Health Information Protection Act, which came into force on November 1, 2004, and pursuant to the Ontario Personal Health Information Protection Act, 2004).

Under the Personal Health Information Protection Act, 2004, the following information must be provided to the Research Ethics Board when requesting approval of research studies involving the collection, use and disclosure of personal health information.

The Act defines personal health information as follows (s.4):

“Personal Health Information” means identifying information about an individual in oral or recorded form that:

- a) Relates to the physical or mental health of the individual including information that consists of the health history of the individual’s family;
- b) Relates to the providing of health care to the individual, including the identification of a person as a provider of health care to the individual;
- c) Is a plan of service within the meaning of the *Long-Term Care Act, 1994* for the individual;
- d) Relates to payments or eligibility for health care with respect to the individual;
- e) Relates to the donation by the individual of any body part or bodily substance, or is derived from the testing or examination of any such body part or bodily substance;
- f) Is the individual’s health number; or
- g) Identifies an individual’s substitute decision-maker.

**Identifying Information** means information that identifies an individual, or for which it is reasonably foreseeable in the circumstances that it could be utilized, either alone or with other information, to identify an individual.

For projects that involve administering health care to human participants, researchers must disclose the following information to research participants:

- i. Describe all persons who will be involved in the research, including his or her roles in relation to the research, and his or her related qualifications. Please provide information regarding who will have access to the personal health information (as described above), and why this person’s access to personal health information is necessary.
- ii. Describe the anticipated public or scientific benefit of this study.
- iii. Describe all personal health information required to be collected and from which potential sources.
- iv. Provide a blank copy of all data collection sheets or Case Report Forms to be used during the research study.

- v. Justify why the research cannot reasonably be accomplished without using personal health information.
- vi. Describe how the personal health information will be used in the research.
- vii. If the personal health information is to be linked to other information: (a) provide details of all linkages to be made; (b) explain how the linkages will be made; (c) describe the information to which it will be linked; and (d) explain why these linkages are required.
- viii. When the researcher proposes to obtain personal health information without obtaining consent from the person, justify why consent is not being sought.
- ix. Describe how long personal health information will be retained in an identifiable form and why.
- x. Describe the reasonably foreseeable harms and benefits that may arise from the use of personal health information, and how the researcher intends to address those harms.
- xi. Describe how and when the personal health information will be disposed of or returned to the health information custodian.
- xii. Has the researcher applied for the approval of another Research Ethics Board and, if so, please provide the response to, or status of, the application.
- xiii. Describe whether the researcher's interest in the disclosure of the personal health information or the performance of the research would likely result in an actual or perceived conflicts of interest with other duties of the researcher.