**Implied Consent in Minimal Risk Research**

Implied consent is acceptable in certain minimal risk research. TCPS 2 defines "minimal risk" research as research “*in which the probability and magnitude of possible harms implied by participation in the research are no greater than those encountered by participants in those aspects of their everyday life that relate to the research.”*

**What is implied consent?**

With implied consent, participants indicate that they knowingly agree to participate in the study by completing a research activity (e.g., by completing a survey/questionnaire). It does not require a signed consent form (i.e., express consent), but it does require provision of information to research participants to make an informed choice.

It is most commonly used in research that involves the completion of a simple, onetime survey/questionnaire, where the act of completion and return of the survey/ questionnaire implies their consent to participate.

The following steps are needed to obtain implied consent:

1. Along with the research activity (e.g., survey/questionnaire), participants are provided with a written Recruitment Email or Implied Consent Form. All aspects of consent must be included (i.e. purpose of the research, the time involved, statement regarding risks and benefits to participants, the ability - or not - to withdraw from participation, information on confidentiality and privacy, contact information for questions about the research, and contact information for questions about rights as a research participant, etc...).
2. Participants complete the study activity and return any relevant documents to study team, implying their consent to participate in the research.

**When express consent (i.e., written or verbal) is required within the framework of an implied consent model:**

PHIPA defines implied consent as consent given based on an individual’s **action (e.g. completion of a survey)** or inaction in particular factual circumstances. For example, when an individual discloses their personal health information for the purposes of filling out a prescription, a pharmacist can reasonably infer consent to the collection of that information.

PHIPA defines express consent as consent that has been clearly and unmistakably given, either orally or in writing.

Researchers who wish to collect personal health information within a survey that more broadly focuses on general health care knowledge and opinions must obtain both implied and express consent. For example: An on-line survey that uses a variety of tools to obtain data related to knowledge, opinions and quality of life may also seek to link healthcare utilization data through a prescribed entity such as Institute for Clinical Evaluative Sciences (IC/ES) or Canadian Institute for Health Information (CIHI). While implied consent may be used for completion of the survey in general, express consent will be required for those questions related to healthcare utilization, where the collection of the respondent's health card number and other identifying information will be sought. Those questions related to the collection of personal health information (PHI) must:

1. Inform the respondent of what PHI is being requested (e.g., full name, full date of birth, OHIP number, etc...)
2. Indicate how it will be collected (i.e., will it be separated from the rest of the survey/questionnaire by being directed to a new page of the survey or will the respondent be asked to provide their email address for subsequent contact by the study team to gather the required information?)
3. Provide the opportunity to expressly consent yes or no (i.e. ‘*Yes, I consent to be contacted via email to link my survey information to provincial health administrative data for research purposes.’* or ‘*No, I do not consent to be contacted via email to link my survey information to provincial health administrative data for research purposes.’*

**My minimal risk study is going to use implied consent; what documents do I need to submit to the REB?**

If the research study is using implied consent, the following information and documents should be included with the initial application or submitted with an Amendment to the REB for review:

1. An explanation as to why implied consent is appropriate.
2. The written Implied Consent Form, which is typically the first page of the survey/questionnaire, and/or the Recruitment Email, which would include all aspects of consent, as described above.
3. The proposed survey/questionnaire.

**Instructions for the Implied Consent Form Template**

This Implied Consent Form template may only be used for minimal risk research.

Note, if your study design allows for obtaining written or verbal consent (i.e. express consent), it is unlikely that the REB will accept implied consent.

TIPS FOR WRITING THE IMPLIED CONSENT FORM

* Delete the guidance page as well as this instructional page prior to REB submission.
* Only use the header logos that are applicable to your study
* Use plain (lay) language that is easy for a non-medical person to understand:
	+ Use short sentences and sections and simple words; avoid scientific or technical explanations;
	+ Ensure that the final form is properly formatted and free of spelling or grammar errors;
	+ Aim for grade 8 reading level, ideally no more than grade 10.
* Define all acronyms and abbreviations when they first appear.

How to use this template

* An Implied Consent Form template is provided. Depending on the study design, the template language (without the headings) may be inserted into a Recruitment Email instead of creating a separate Implied Consent Form.
* *GREY highlighted text*: General instructions.
* **BLUE text:** To be deleted/modified as relevant prior to REB submission.
* **BLACK text:** OHSN-REB approved template wording and/or examples that should not be altered without justification.
* This template is intended to serve as a **GUIDE**. Depending on the details of your study, you may need to provide different information and details than those stated in the template.

**Implied Consent Form**

**Study Title:** [Insert Study Title]

**Principal Investigator:** [Insert name and contact information]

**OHSN-REB Number:** [Insert #]

INTRODUCTION

You are being asked to participate because [explain the main features of the population to which the research applies]. This study examines [describe the objectives of the study].

ARE THERE ANY CONFLICTS OF INTEREST?

*Describe any conflict of interest that exists or may appear to exist as it relates to any of the investigators, study staff or member of their immediate family. A conflict of interest exists if there is a potential benefit to the investigator(s), study staff or member of their immediate family beyond the professional benefit from academic achievement or presentation of the results. Examples include, but are not limited to, speaker’s fees, travel assistance, consultant fees, honoraria, gifts, and intellectual property rights such as patents. A declaration of conflict of interest should include the identity of the person with the conflict of interest, the type of incentive or inducement, and its source. See examples below.*

The [identify individual e.g., study doctor/researcher], [insert name], is receiving personal financial payment from [identify source of funds e.g., the study Sponsor] for [include reason for payment e.g., providing advice on the design of the study]. You may request details about this payment.

or

There are no conflicts of interest to declare related to this study.

or

The [insert recipient of funding e.g., hospital] is receiving financial payment from the [sponsor/funder name] to cover the cost of conducting this study.

WHAT WILL HAPPEN DURING THIS STUDY?

Your participation in this study will require the completion of a [survey/questionnaire]. The [survey/questionnaire] asks questions about [describe the types of questions]. This should take approximately [length of time] of your time.

The information you provide is for research purposes only. Some of the questions are personal. You can choose not to answer questions if you wish.

*If email will be used for study purposes (e.g., distribution of questionnaires, etc.), add:* Communication via e-mail is not absolutely secure. We do not recommend that you communicate sensitive personal information via e-mail.

VOLUNTARY PARTICIPATION AND WITHDRAWAL:

You do not have to be in this study if you do not want to be. You can choose to end your participation in this research (called withdrawal) at any time without having to provide a reason. *Specify any other potential areas where participants might be concerned about a potential penalty or discrimination, such as:* The decision will not affect your employment or [any healthcare services you are entitled to] at [The Ottawa Hospital or The University of Ottawa Heart Institute.].

*If data is coded/de-identified:* If you decide to leave the study, you can ask that the information that was collected about you not be used for the study. Let the research team know if you choose this.

*If data is anonymous or anonymized:* The [questionnaire/survey] is anonymous. This means that you can withdraw from participating at any time while completing the survey/questionnaire simply by closing your browser or not returning the hardcopy document; however, once the completed survey/questionnaire has been returned to the study team, it will not be possible to withdraw your information. Any information recorded before you withdraw will be used by the researchers for the purposes of the study, but no information will be collected after you withdraw your permission.

RISKS AND/OR BENEFITS
*Inform participants of all reasonably foreseeable risks, harms, discomforts or inconveniences. Include both physical and psychological/emotional risks as applicable to the research. Inform participants of potential benefits to themselves and in general that may arise. If there is no known benefit, ensure this is stated.*

Participation involves minimal risk to you. Some of the questions may however make you feel uncomfortable.

You may not receive direct benefit from participating in this study. We hope the information learned from this study will help other people with [specify] in the future.

PRIVACY/CONFIDENTIATLITY:

*For anonymous studies:* The [survey/questionnaire] is anonymous which means that your answers will not be linked to you in any way.

*For studies where data is coded/de-identified:* Records identifying you at this centre will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

*For all studies:* Authorized representatives of the following organizations may look at your original (identifiable) research [and medical] records at the site where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines.

*Include only those organizations requiring permission for direct access to participant medical records or research records containing identifying information (e.g., permission to conduct on-site monitoring/auditing).  Include a brief description of their role in the research. See suggestions below, or modify as applicable to the research:*

* [Insert sponsor name], the Sponsor of this study
* The Ottawa Health Science Network Research Ethics Board who oversees the ethical conduct of this study.
* [Ottawa Hospital Research Institute or Ottawa Heart Institute Research Corporation], to oversee the conduct of research at this location.

Information that is collected about you for the study (called study data) may also be sent to the organizations listed above. Your name, address, email, or other information that may directly identify you will not be used. The records received by these organizations may contain your [disclose identifiers e.g., participant code, pseudo-initials, sex, and partial date of birth (month and year)].

*If race/ethnicity information is collected as part of the study, identify this and provide a rationale. See suggested text or modify as applicable:*This research study is collecting information on race and ethnicity as well as other characteristics of individuals because [specify reason e.g., these characteristics may influence how people respond]. Providing information on your race or ethnic origin is [voluntary/required]. *(If required, state why, e.g.  because the main objective of the study to determine how to better involve new Canadians in future research opportunities).*

*If email will be used for study purposes (e.g., distribution of questionnaires, etc.), please add:*
Communication via e-mail is not absolutely secure. We do not recommend that you communicate sensitive personal information via e-mail.

If the results of this study are published, your identity will remain confidential. It is expected that the information collected during this study will be [include description of proposed uses of data, e.g., used in analyses and will be published/ presented to the scientific community at meetings and in journals].

Your de-identified data from this study may be used for other research purposes. If your study data is shared with other researchers, information that links your study data directly to you will not be shared.

Even though the risk of identifying you from the study data is very small, it can never be completely eliminated.

*If data will be sent outside of Canada:*
Any information sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries dealing with protection of information may not be as strict as in Canada. However, all study data, that are transferred outside of Canada will be coded (this means it will not contain your personal identifying information such as your name, address, medical health number or contact information). The information will be transferred in compliance with all relevant Canadian privacy laws. By returning your completed survey/questionnaire, you are consenting to the disclosure of your coded information to organizations located outside of Canada.

COST AND/OR PAYMENT:
*If participation could result in additional costs, include an explanation of these potential costs. Describe compensation provided to participants, or state if no compensation is provided. Suggestions are provided below.*

*If no cost or payment:* You will not be paid for being in this study, nor will there be any cost to you.

*If paid:*
If you decide to participate in this study, you will receive [$ specify amount of payment including payment interval if applicable e.g., every three months].

*If gift card:*As a token of our appreciation, you will be given a [$ specify amount of gift card] gift card to [provide category of stores or specific store name] for your participation in this study. The gift card will be sent to you by mail after completion of the [questionnaire/interview/ focus group].

RIGHTS OF PARTICIPANTS

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study.

You have the right to be informed of the results of this study once the entire study is complete. *Explain how the participant can obtain the results, for example*: If you would like to be informed of the results of this study, please contact the research team] *or* If you would like to be informed of the results of this study, please let the research team know.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

QUESTIONS:

If you have any questions about taking part in this study, you may contact [contact’s role] at [phone number].

If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study at all. Please contact The Ottawa Health Science Network Research Ethics Board, Chairperson at 613-798-5555 extension 16719.

CONSENT

By completing this [research activity – e.g., survey/questionnaire] your consent to participate is implied.