



St. Joseph's Health Centre (SJHC): CONSENT FORM GUIDELINES

Studies require consent when patients are asked to participate in any intervention or to provide or give permission to use any information outside that indicated for the condition for which they are being treated. Subjects recruited as controls or as part of a comparison group are, by definition, also undergoing an added and unnecessary burden and should be asked to provide informed consent prior to their participation. Access to secondary data via charts or administrative records that are analyzed and reported in group format preserving individual confidentiality with required privacy protections in place do not require informed consent when this is done for the purpose of improving service quality and clinical outcomes.

A consent form should provide, to the extent possible, all the information needed for an individual to make an informed decision. Although written information is provided, a verbal explanation should also be given during an interaction that provides the potential subject time to consider the information and to ask questions. The invitation to participate in a research study should be presented in a way that avoids coercion or undue influence.

Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject. The procedures used in obtaining informed consent should be designed to educate eligible subjects in terms that they can understand. Therefore, informed consent language (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks and benefits) must be written using language and a form of presentation that can be understood readily by people who meet study inclusion criteria.

The written presentation of information is used to document the basis for consent and for the subjects' future reference. The consent document should be revised when deficiencies are noted or when additional information should be provided to study participants (ex. change in protocol).

The following guidelines are designed to help you with the components and wording of your consent form. The **sample consent form** found on our website may be used as a template (go to www.stjoe.on.ca > Research > Research Ethics Board > Research forms). We encourage your use of this

template because the format is generally well-received by SJHC patients and it includes all the required subheadings.

Guidelines:

General

- Information in the consent form should be written in the second person (i.e. “you”), in lay language, and, to the extent possible, at no higher than a grade-8 reading level. Terms such as “randomization”, “double-blind” and “placebo”, should be explained in simple language, assuming no familiarity with a technical vocabulary.
- The title of the study should be indicated at the top of the consent form, followed by the name of the investigator(s). If there is a sponsor, add their name, address, phone or website.
- Acronyms, short forms and abbreviations should be spelled-out and/or defined.
- Larger font sizes should be used if older subjects are involved.
- The form should be placed on the SJHC institutional letterhead, the pages should be numbered (e.g. Page 1 of 5) and a version date included (e.g. SJHC consent form, version: Sept. 8, 2004).

The form should, whenever possible, have information grouped as described below. Headings in brackets correspond to the SJHC sample consent form.

Introduction (STATEMENT OF RESEARCH)

- A statement that the study involves research.
- A statement of request for the individual to participate in research, and the reasons for why the participant is being asked to participate.

Purpose (WHY IS THIS STUDY BEING DONE?)

- A description of the purpose of the research (hypothesis, objective, research question).

Number of Participants/Duration of Study (HOW MANY PEOPLE WILL TAKE PART IN THE STUDY AND FOR HOW LONG? and HOW LONG WILL I BE IN THE STUDY?)

- The approximate number of participants in the trial, and whether the study is multi-centered.
- The expected duration of the study and the length of individual commitment to the study; for example, a five-year study may follow-up individual subjects

over an 18-month time frame because the entire sample can take more than a year to enroll in the study.

Randomization (RANDOMIZATION - ASSIGNMENT TO A GROUP):

- Explain the term “randomization” in a way appropriate for the study population.
- Describe randomization groups.

Treatment/Intervention (TREATMENT)

- Describe intervention, treatment, drugs, dosage, and frequency.
- Discuss availability of treatment following study.

Procedures (WHAT IS INVOLVED IN THE STUDY? and PROCEDURES AND MEDICAL TESTS)

- A description of the nature of participation and of the research procedures (including time commitment). Only procedures being done specifically for research need be described.

Risks (WHAT ARE THE RISKS OF THE STUDY?)

- A clearly detailed description of probable or foreseeable risks or discomforts that may arise from research participation.
- A description of the steps taken to minimize, treat, or correct commonly expected risks or discomforts.
- Instructions should include names and numbers of person(s) to call to deal with and to report adverse events.
- For research involving more than minimal risk: include an approved injury statement or a statement regarding compensation.
- If additional risks are identified during the course of the research, the consent process and documentation will require revisions to inform subjects as they are re-contacted or newly contacted.

Risks to Fetus/Infant (ARE THERE REPRODUCTIVE RISKS?)

- Women of child-bearing potential should be warned if there are potential risks to the fetus. If so, they should be advised not to become pregnant or breastfeed during the study. They or their partner should be encouraged to discuss an appropriate method of family planning during the treatment period. Similar warnings may be required for male subjects.

Benefits (ARE THERE BENEFITS TO TAKING PART IN THE STUDY?)

- A description of benefits to the subjects, to others, and to scientific knowledge that may reasonably be expected from the research. Benefits should not be exaggerated. (Note: general statements such as “A benefit of this study is that Drug X may help your medical condition” should be avoided.)

Alternatives (WHAT OTHER OPTIONS ARE THERE?)

- A Description/outline of treatment options if the subject chooses not to participate.

Participant Rights (WHAT ARE MY RIGHTS AS A PARTICIPANT?)

- An assurance that participants have the option *not* to participate, and the right to withdraw at any time without affecting the quality of their care.
- A statement regarding the possibility of commercialization of research findings and the presence of any apparent or actual or potential conflict of interest on the part of researchers, their institutions or sponsors.

Confidentiality (WHAT ABOUT CONFIDENTIALITY?)

- An indication as to who will have access to information collected on the identity of participants, and a description of how confidentiality will be protected.
- A statement of possible access to record by study staff, REB, sponsor, Health Canada, Food and Drug Administration (FDA), etc.

Costs/Compensation (WILL THERE BE COMPENSATION OR COSTS?)

- Describe any costs to the subject.
- A statement outlining any intent to pay subjects for their participation, or not, including whether or not payment will be pro-rated (*specific dollar amounts of payment to participants may be listed in the consent form, but **not** in advertisements*).
- The following standard clause is recommended:

(For industry-sponsored studies: “If you become ill or physically injured as a result of participation in this study, medical treatment will be provided. The reasonable costs of such treatment beyond that provided by your insurance will be covered by the sponser, _____, for any injury or illness that is a direct result of participation in this trial. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities.”)

OR

(For non-industry-sponsored studies: “If you become ill or are physically injured as a result of participation in this study, medical treatment will be provided. In no way does signing this consent form waive you of your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities.”)

Contact Information (WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?)

- The name and contact number of the principal investigator at St. Joseph’s Health Centre.
- Include a statement indicating that participants may discuss their rights as a participant by contacting Dr. Hazel Markwell (Director, Clinical Ethics, SJHC) at 416-530-6750.

Approval Process (APPROVAL PROCESS)

- The approval process at SJHC should be mentioned.

Consent/Signatures (SIGNATURES)

- The consent statement, in which participants agree to participate, should be written in the first person (i.e. “I”).
- The statement should repeat some of the key points that the subject should understand to participate. It should also mention that participation is voluntary and that subjects will receive a copy of the signed informed consent form.
- The form should be signed and dated by the subject and by the person who has explained the study and obtained consent. The person obtaining consent should:
 - a) be knowledgeable about the study protocol in order to answer questions.
 - b) be able to obtain information from the investigators to address issues raised by the prospective participant.
 - c) whenever possible, not be in a treating relationship with the prospective - participant.
- If a subject is unable to read or if their legally acceptable representative is unable to read, an impartial witness should be present during the entire informed consent discussion; after the subject, or their representative, has orally consented to the subject’s participation in the trial, or after signing (if capable), the witness should sign and personally date the consent form.

In addition, please consider the following:

- If you anticipate that you may wish to re-contact study participants in the future for further research, please include this information in your initial consent form.
- If you believe you may wish to use data from the study for future research please provide participants with as much information as possible about the future use of this data (*i.e., the type of research, protection of participant confidentiality, etc.*).
- Any audio/video taping, or photography must be addressed both in the consent form and **in a separate audio/videotaping consent form.**
- For studies involving children, parental consent is required for those under age 16. An **assent form** should be used whenever possible for the child to indicate his/her voluntary participation.