

# **GUIDELINES FOR WRITING A RESEARCH CONSENT FORM**

**St. Michael's Hospital Research Ethics Board**

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## 1. Introduction

This document replaces the 1997 “Guidelines for Writing a Research Consent Form” and provides guidelines for consistency in the development and review of research consent forms.

Please read these guidelines carefully before submitting your application to the Research Ethics Board (REB) Office. It is highly recommended that research staff ‘pre-test’ the consent form on co-workers to ensure that the consent form is clear, complete and understandable.

Incomplete or improper consent form(s) will result in the research application being referred back to the applicant before review by the REB. Consent forms that comply with the following structure and format will facilitate the review of your protocol.

## 2. The Consent Process

Research involving human participants at St. Michael’s Hospital requires the direct, voluntary, informed and written consent of the research participant, or from a substitute decision maker if the research participant is not capable of giving consent to the research.<sup>1</sup> It is the responsibility of the investigator or his/her designate to ensure that consent is obtained from the research participant prior to the commencement of any study procedures.

The consent process is on-going and continues throughout the participant’s involvement in the study. The consent form documents are only one step of the consent process. It will be necessary to document in the study file other events in the consent process, for example, when an incapable participant becomes capable of providing direct consent.

## 3. Research Consent Forms

The REB requests that all research consent forms follow the prescribed structure and format as set out in this document to facilitate REB review. Consent forms for all studies must fulfill the requirements of the Tri-Council Policy Statement<sup>2</sup>, and consent forms for investigational drug studies must also fulfill the ICH Good Clinical Practice guidelines.<sup>3</sup> However, compliance with the ICH Good Clinical Practice guidelines is encouraged for all studies where the principles may be relevant.

### 3.1. Approved Version of Consent Form

Only consent forms that have been approved by the REB may be presented to, and/or discussed with potential participants. All subsequent amendments to the consent form must be approved by the REB prior to use.

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<sup>1</sup> Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Canadian Institutes of Health Research, Natural Sciences and Engineering Council of Canada, and Social Sciences and Humanities Research Council of Canada, August 1998 (Tri-Council Policy) section 2, articles 2.1 to 2.11. Available on the web at <http://www.nserc.ca/programs/ethics/english/policy.htm#contents>

<sup>2</sup> Ibid

<sup>3</sup> ICH Harmonized Tripartite Guideline, Good Clinical Practice: Consolidated Guideline (E6), Therapeutic Products Directorate, Health Canada, 1997, see website [http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/goodclin\\_e.html](http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/goodclin_e.html) (ICH GCP)

Each time the consent form is revised, a new version date should appear on all the pages (for example, in the footer<sup>4</sup> of the document) to ensure the correct, approved document is given to potential participants. Each page of the consent form must also include the short study title. In this way, if the pages become separated, they can still be easily identified. This also permits the Research Ethics Monitor and regulatory authorities to quickly identify the latest version of the REB-approved consent form.

### **3.2. Printed on Letterhead**

The first page of all research consent forms must be on current St. Michael's Hospital letterhead. Information printed on letterhead must not "bleed onto" or overprint the letterhead printing or logo. After the first page, the rest of the document may be printed on plain white paper.

The St. Michael's Hospital logo cannot be manipulated (lengthened, shortened, etc.) without prior approval from Public Relations.

### **3.3. Page Numbering**

All pages must be numbered, in the form "Page x of y", preferably located in the footer. Ensure that the footer information does not bleed into (overprint) the letterhead information.<sup>5</sup>

### **3.4. Font Size**

The text must be legible for participants. It is recommended that a font size of 11 points (or larger) be used. If the research participant population may have difficulty reading the document (i.e. ophthalmic restrictions) consideration should be given to using a larger font size, using visual aids in the document or during the consent process, etc.

### **3.5. Title of the Consent Form**

The title of the consent form should clearly indicate that it is a consent form or information document for a research study, for example: **Consent to Participate in a Research Study**. This should be followed by the full and correct title of the study protocol, as it appears on the protocol. If the title is long or complicated for a lay person, a simplified version of the title should be added. This shortened title may also be used in the footer for each page of the consent form.

### **3.6. Level of Language and Summaries**

All research consent forms must be written in simple and clear language that is easily understood by a non-medical person. This may be achieved by writing shorter sentences with one major idea per sentence. It is recommended that consent forms

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<sup>4</sup> Footers are located in the margin of the bottom of each page, and are accessible in Microsoft Word, go to:  
View dropdown menu → Header and Footer.

<sup>5</sup> To create a different set-up for the first page of the consent form (which is the letterhead page), using Microsoft Word, go to:

View dropdown menu → Header and Footer → Page Set-up → Different First Page

be written at a grade 7 education level.<sup>6</sup> Less complex language or other communication aids may be needed depending on the proposed participant population.

Responsibility for the clarity and readability of the consent form rests with the study team. **It is not the responsibility of the REB to provide an editorial service.**

Consent forms are to be written in second person (for example, “You are invited to participate...”) with the signature page in first person (for example, “I consent to participate...”).

Use either the term “participant” or “subject” consistently throughout the consent form, including on the signature page.

All acronyms and abbreviations, such as CHD, COPD, etc. must be defined prior to first use. For example: “chronic heart disease (CHD).” The name “St. Michael’s Hospital” should always appear in full.

For complex research studies with long and detailed consent forms, it may be helpful to include a brief, one page summary letter which describes the proposed study in simple, easy to understand language. If the participant is interested in participating, and would like additional information, he or she is invited to read more in the actual consent form. This document also requires REB review and approval.

If the study includes many clinic visits, procedures or interventions, it is recommended that a schedule of visits (for example, in chart form) be appended to, or included in, the consent form. This will assist the participant to better understand the types of procedures and amount of time required of them.

### **3.7. Headings in the Consent Form**

It is strongly recommended that the following headings be used to ensure that all relevant information is clearly conveyed to potential research participants. Headings may be omitted if they are not relevant, for example, the heading “Risks to Reproduction” may be omitted if the study is a qualitative study with a questionnaire.

The topics in the consent form should also follow the order suggested by the headings in this document. Sections 4 – 27 below suggest the headings, as well as the order of the headings that should be used in the consent form. It is strongly recommended that the description of potential harms precede the discussion of potential benefits. This will ensure that the potential harms are discussed as soon as possible after the purpose and description of the research study.

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<sup>6</sup> To assist in determining readability of the consent form using Microsoft Word, go to:

Tools → Spelling & Grammar → Options → Show Readability Statistics.

When Word finishes checking spelling and grammar, information about the reading grade level will be displayed. For practical suggestions regarding the readability of consent forms see, Paasche-Orlow et al. Readability standards for informed consent forms as compared with actual readability. N Engl J Med 2003;348:721-6.

## 4. Introduction

It is recommended that an introductory paragraph include or paraphrase the following:

”Before agreeing to take part in this research study, it is important that you read the information in this research consent form. It includes details we think you need to know in order to decide if you wish to take part in the study. If you have any questions, ask a study doctor or study staff. You should not sign this form until you are sure you understand the information. All research is voluntary. You may also wish to discuss the study with your family doctor, a family member or close friend. If you decide to take part in the study, it is important that you are completely truthful about your health history and any medications you are taking. This will help prevent unnecessary harm to you.”

### 4.1.1 Investigator(s)

Principal Investigators, Qualified Investigators<sup>7</sup> or researchers (hereinafter referred to as “investigators”) should refer to themselves either as ‘study doctor’, or ‘study physician’, to ensure there is no confusion with the treating or primary care doctors.

If the primary investigator is also the treating doctor for the research participant, this should also be clearly stated.

The first name listed should be the name of the principal investigator from St. Michael’s Hospital followed by any other investigators at St. Michael’s Hospital. For multi-centre research, it may or may not be relevant to include information regarding the primary investigators from other sites.

If the research is a student project, include explicit acknowledgment of the student’s status, the name of the supervisor, and the supervisor’s affiliation with St. Michael’s Hospital.

Furthermore, if the primary investigator (or the student’s supervisor) is not a member of the St. Michael’s Hospital staff, the name and telephone number of a responsible St. Michael’s Hospital person must be included. This information should appear directly below the title of the study.

Other information to include:

- The name(s), degree(s), department affiliation(s) and telephone numbers of all St. Michael’s Hospital investigators;
- Time of availability of the investigators at St. Michael’s Hospital should be clearly indicated (for example, Monday to Friday 9:00 a.m. - 5:00 p.m.);

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<sup>7</sup> The term preferred by Health Canada for the investigator responsible for a clinical study.

- If the nature of the research requires that someone from the study team be available for questions on a 24 hour basis, provide the contact information; and
- Include the names and contact numbers for research coordinators at St. Michael's Hospital, if relevant.

#### **4.2. Declaring a Conflict of Interest**

Conflicts emerge from relationships with defined roles which create expectations of behaviour, duties or obligations, and these expectations run up against competing interests or obligations.<sup>8</sup>

It is the responsibility of every investigator to identify actual, potential or perceived conflicts of interest or competing interests with respect to, but not limited to, each of the following: the named investigators, any recruiting doctor (who is not listed as an investigator), research participants and their families, students and other trainees, and the Hospital/Research Institute/University. The most difficult to identify is a perceived conflict of interest, since it is the perception of the research participants or the public, and not of the investigator, which must be considered or anticipated.

Benefits to an investigator which may create a conflict of interest need not be only monetary, but could include prestige, promotion and other non-monetary influences. For example, a conflict of interest may arise when an investigator is the inventor of a new device, or owns shares in the company that manufactures the device or drug that is being tested. As a result, the investigator may have competing duties and obligations to both the company and the research participants. Also the investigator may be influenced by the attainment of prestige, promotion or recognition in the scientific community.

The consent form should identify all actual, potential or perceived conflicts of interest for the investigator, and/or research staff. The Research Ethics Board will assist investigators in identifying and managing conflicts of interest.

As a general rule, if the Investigator or their staff will be additionally compensated for their work in the study or will receive a personal benefit from conducting this study, this must be disclosed in the consent form. In addition, if the Investigator has a significant financial interest in the outcome of the study or research program (including shares in the sponsoring company or research organization) a statement explaining the interest must be added.<sup>9</sup>

The declaration in the consent form should include the following details:

1. Identification of the persons with competing interest(s);
2. The type of incentive, inducement or benefit; and

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<sup>8</sup> Meyers C. Managed care and ethical conflicts: anything new? J. Med. Ethics, Oct 1999; 25: 382 – 387 and the issue on Conflict of Interest in Monash Bioethics Review. October 2004 23(4). Ordering available on the world wide web on June 22, 2005 <http://www.arts.monash.edu.au/bioethics/mbr.html>

<sup>9</sup> Investigators must also be familiar with and abide by the University of Toronto, Policy on Conflict of Interest Academic Staff, June 22, 1994. Available on the web at [http://www.utoronto.ca/govcncl/pap/policies/conacad.html#\\_Toc468887714](http://www.utoronto.ca/govcncl/pap/policies/conacad.html#_Toc468887714)



### 3. The source of such benefit.

#### Examples:

“Dr. X, declares that he (may) will gain financially by being involved in this study because he will be paid by (sponsor) for his time and effort during the study. This may create a competing interest or conflict of interest for the study doctor.”

“As a result of her participation in this study, Dr. X has received (or may receive) one or more of the following other benefits (from sponsor(s) that have activities related to the present study): speaker's fees, travel assistance, industry-initiated research grants, investigator-initiated research grants, consultant fees, honoraria, gifts, intellectual property rights such as patents, etc. This may create a competing interest or conflict of interest for the study doctor.”

“The spouse of Dr. X owns shares in the company that is sponsoring the study and may benefit financially if the outcome of the study shows that the product helps patients. This may create a competing interest or conflict of interest for the study doctor.”

### **4.3. Study Sponsors**

The name of the company(ies) and/or granting agency(ies) sponsoring the research must be provided. When a clinical research organization organizes a study, the participating partners or companies should also be included under this heading. When a sponsoring company contracts the work to another company, such subcontractors should also be listed.

In addition, if the study is financed through a granting agency, but is receiving support from another company or agency (for example, the drug is supplied by the manufacturer), this should also be stated. Potential participants are entitled to know all the companies or agencies which are involved in the study.

Funds coming from unrestricted donations must also be acknowledged.

## **5. Purpose of the Research**

This section should answer the question: “Why am I being invited to participate?” and “What is the purpose of the study?” Include a brief summary of the type of to participation by the participant and the amount of time requested of the participant. (Detailed information will be provided under Description of the Research.) If there is a placebo or non-treatment arm, this should be clearly set out early in the Consent Form.

The following information may be included:

1. Information that the individual is being invited to consider taking part in a research study, in a manner appropriate for the prospective participants' cultural settings.<sup>10</sup>
2. The consent form should clearly state why their involvement is sought.
3. Indicate why the participant is invited; for example, they have been invited because he or she is suffering from a specific disease.
4. Provide a brief description of the purpose of the study.
5. Explain what hypothesis is being tested and what the study is intended to demonstrate in lay language.
6. Provide information on relevant background information or prior studies undertaken, or the literature reviewed and the justification for the study.
7. Describe the design of the study, and include a description of the phase of a drug development study<sup>11</sup>, if relevant.
8. It may be appropriate to mention specific inclusion/exclusion criteria in this section if the recruiter would not know if a participant is eligible or if there could be consequences to a non-eligible participant (either here or under Description of Research), e.g. illegal/recreational drug use not allowed, HIV testing, parental notification for adolescent survey of sexual experience.

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<sup>10</sup> Tri-Council Policy article 2.4(a).

<sup>11</sup> One example of descriptions for drug development study phases is found in the Health Canada document "Guidance for Clinical Trial Sponsors: Clinical Trial Applications", under section 2 'Definitions' and found at the following website address: [http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/ctd\\_cta\\_guidance\\_e.html#app1](http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/ctd_cta_guidance_e.html#app1) (accessed Dec. 20, 2004)

Phase I - Initial safety studies on a new drug, including the first administration of the drug into humans, usually conducted in healthy volunteers. These trials may be conducted in patients when administration of the drug to healthy volunteers is not ethical.

Phase I trials are designed mainly to determine the pharmacological actions of the drug and the side effects associated with increasing doses. Pharmacokinetic as well as drug-drug interaction studies are usually considered as Phase I trials regardless of when they are conducted during drug development as these are generally conducted in healthy volunteers. Phase I trials also include trials in which new drugs are used as research tools to explore biological phenomena or disease processes.

Phase II - Clinical trials to evaluate the efficacy of the drug in patients with medical conditions to be treated, diagnosed or prevented and to determine the side effects and risks associated with drug. If a new indication for a marketed drug is to be investigated, then those clinical trials may generally be considered Phase II trials.

Phase III - Controlled or uncontrolled trials conducted after preliminary evidence suggesting efficacy of the drug has been demonstrated. These are intended to gather the additional information about efficacy and safety that is needed for further risk/benefit assessment of the drug. In this phase, clinical trials are also conducted in special patient populations (for example, renal failure patients), or under special conditions dictated by the nature of the drug and disease.

Phase IV - All studies performed after the drug has been approved by the regulator for the market, and related to the approved indication. These studies are often important for optimizing the drug's use. They may be of any type but must have valid scientific objectives. Commonly conducted studies include safety studies and studies designed to support use under the approved indication such as mortality and morbidity studies, or epidemiological studies.

## 6. Description of the Research

This section should answer the following questions in detail: “How will the study be conducted?” and “How will the participants be involved?” Some or all of the following information may be relevant:

1. Begin with a description of the proposed research as it will be experienced by the research participants.
2. Indicate the total time commitment involved for participation in the study  
Example 1:  
“You will be asked to attend 3 clinic visits over a period of 6 months, and each clinic visit is expected to take about 4 hours of your time.”  
  
Example 2:  
“The study involves 8 questionnaires which will take approximately 3 hours in total. These can be done on different days if you prefer.”
3. Distinguish clearly between those interventions, drugs, delivery techniques, devices, etc. that are part of the standard therapy and those that are research-related, if relevant. If a placebo arm is involved, or a placebo is being used, explicit mention of this must be made.
4. Indicate frequency and duration of specific testing or procedures, as well as the route of drug administration, if applicable (i.e., I.V., oral, continuous infusion, etc.).
5. If the study will use an experimental drug, device or procedure, clearly state that it is experimental or investigational. Explain if drugs are being used for unapproved indications. Indicate that it has not been approved by Health Canada for use outside of the research study.
6. State whether any therapy that the participant was receiving prior to enrolment in the study will or may be altered or discontinued as a result of participation in the study.
7. If a questionnaire is proposed to be used, it may be appropriate to summarize the types of questions to be asked. Sensitive questions which are likely to irritate or upset participants, for example, questions about annual income, sexuality, abuse, etc., should be summarized in the consent form so that participants are not surprised after consenting to participate. Inform the participant that they are not required to answer all the questions if they do not wish to.
8. Identify which procedures are or are not part of standard care for the participant’s condition.

9. Whether or not standard care is being withheld or withdrawn.
10. Whether the participant will be assigned randomly or by pre-selection to a particular arm of the study.
11. Explain such aspects of the research design as randomization or sequential assignment, including the probability of assignment.
12. If masking or blinding is used, include a description of what this means, and details of when and how a code may be broken.
13. If the participants are required to undergo specific testing to determine eligibility for participating in the research, this must be explained (for example, HIV testing, illegal/recreational drug use, MRI). Rarely, this may require a separate consent form for the eligibility-determining portion of the study.
14. If additional visits to hospital or prolongation of hospital stay are anticipated or necessary, this must be explained.
15. If the participant's health record will be reviewed, whether or not information will be obtained from it, this must be explained.
16. If blood will be drawn, indicate total volume (i.e. millilitre and/or teaspoon equivalents). Also indicate whether blood will be stored or destroyed. Clearly state for what purpose the blood is collected, and whether or not genetic testing will be done. A similar description should be given if other samples, such as tissue, sputum, cerebral spinal fluid, etc are to be taken. If genetic testing is intended and optional in the study, a separate consent form is strongly recommended.
17. Provide a brief description of the procedures to be performed to monitor the participant's progress during the study.
18. Indicate whether the participant may opt out of any aspect of the study, and if so how this would be documented.
19. Indicate if future treatment options will be affected by participation in the study (for example, autologous bone marrow transfer may preclude certain treatment options in the future).
20. If the study involves taking photographs, videotaping or sound recordings, this must be explained.
21. Indicate whether the service/drug/intervention/device will or will not be available to the participant once the research is complete, assuming it is found to be beneficial.

22. Explain the role and responsibilities of participating in the study; for example, keep a diary, keep drugs out of reach of children, advise study staff of any health concerns during the study, advise if taking new medications or herbal remedies, etc.
23. Clearly state if there will be indefinite follow-up of the health of the participant, and how that information will be obtained.
24. State the total number of participants to be enrolled in the whole study, and the number of sites where the research is being conducted.
25. State the number of participants expected to be recruited from St. Michael's Hospital.<sup>12</sup>

### **6.1. Placebo**

If a placebo is to be used, explain:

1. That a placebo is an inactive substance, with no medication in it, and it looks the same as the real medication.
2. The potential harm of receiving the placebo and any measures taken to reduce such harms.
3. The reasons why a placebo-controlled study is warranted.
4. What the chances are of receiving a placebo as compared to receiving active medication; and
5. Treatments that are currently used in the disorder, including a discussion of their effectiveness.

### **6.2. Sham Procedures**

If a sham surgery or sham procedure is to be used, explain:

1. What is involved in the surgery or procedure;
2. The harms or risks of having the sham surgery or procedure;
3. Whether or not there are cumulative risks to having the sham surgery or procedure repeated;
4. The chances of having the sham surgery or procedure;
5. What measures will be taken to reduce harms and risks to participants; and
6. The reasons why a sham surgery or procedure is warranted.

### **6.3. Deception**

If deception is necessary and justified for the study, and fully informed consent will not be obtained in advance of the intervention (for example, if participants are not told in advance that they will be observed), patients must be subsequently advised of what has taken place. At this point, fully informed consent of the participant must be sought. A brief description of the consent process to be followed at the end of the study should be included.

For example:

“At the final visit of the study, we will discuss your participation.”

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<sup>12</sup> ICH GCP article 4.8.10(t)

#### **6.4. Future Use of Research Data or Samples**

Also refer to the section of this document entitled “Protecting Your Health Information.”

If tissue/blood banking is required, the consent must clearly state the specific, defined reasons the banking is required, and the defined, finite duration for which the samples will be stored.

It is strongly recommended that a separate consent form be used for future uses of data or samples, unless it is a mandatory part of the main study.

1. If future use of the research data beyond the current study is anticipated, this should be explained (for example, subsequent use of videos, DNA banking, and creation of a permanent cell line).
2. The purpose of future research on this data should be explained to ensure that specific consent from the participant is obtained.
3. Set out options for the participant regarding the possible uses of samples, ensuring that the consent you request is as specific as possible. Consent which is not sufficiently specific is not considered to be valid consent. Thus, the goal is to ensure that consent obtained for studies in the future on collected samples will satisfy the research ethics board reviewing the future study.
4. Explain when or if the research data/samples are to be destroyed or if they will be sold.
5. Explain if REB approval will be sought for future research on the data (justification will be required if REB approval will not be sought).
6. For genetic/DNA research which is optional, a separate consent form is strongly suggested. See “Genetic Studies”, last section of this document.

### **7. Potential Harms (Injury, Discomforts or Inconvenience)**

The REB must weigh the foreseeable harms and inconveniences of the study against the anticipated benefit for the individual research participant and for society. A study should only be initiated and continued if the anticipated benefits justify the harms.<sup>13</sup>

The consent form must include a description of known and reasonably expected harms or inconveniences to the participant.<sup>14</sup> Potential harms may include physical, psychological, emotional, psychosocial and social harms, risks, side-effects, discomforts, inconveniences or injuries. They also include potential effects of a breach of the privacy and confidentiality of the participant’s health information. Potential harms are defined in terms of the magnitude of harm, the expected duration and the probability of its occurrence. Harms should be put in the context of everyday events (for example, the harm of exposure to chest x-rays may be compared to the harm of exposure to ambient radiation from flying).

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<sup>13</sup> ICH GCP article 2.2

<sup>14</sup> ICH GCP article 4.8.10(g)

Rarely, there will be no known harms to the participants. If relevant, this may be stated in the following way:

“There are no known harms associated with participation in this study. “

If there are known potential harms to the participants, such harms must be clearly stated, preferably in order of severity or importance. The information set out in this section should include:

1. Current knowledge with respect to the probability of the occurrence of the harm(s) (for example, a rash occurs in 30% of the people taking this drug).
2. Clinical importance of the harm(s); i.e. indicate severity and expected duration of the side effects.

Example 1:

“There may be a small amount of bleeding when blood is taken from a vein and there may be slight discomfort and bruising or redness that will usually disappear in a few days.”

Example 2:

“This medication may lead to cardiac arrhythmias (irregular heart beats) which may lead to increased risk of heart attacks.”

3. Any relevant knowledge regarding the probability of reversibility (for example, liver problems, as indicated by elevated liver function tests, will return to normal when the drug is stopped).
4. Any relevant knowledge regarding harms from placebos, if applicable, should be described.
5. If side effects of experimental treatment are compared to side effects from placebo use, the comparison must be explained so participants will be able to understand the summarized information.
6. If there are any drug interactions that the participant should be aware of, these should be explained. A list of contraindicated drugs may be attached.
7. If there is a possibility of difficulties arising during a procedure or intervention, explain who will be present to monitor for these difficulties and how the difficulty will be addressed.
8. If relevant, explain how the participant can gain access to counselling if distress or other harms arise during a procedure, intervention, interview, etc. If adverse reactions during interviewing are possible, consider whether trained counsellors should be available immediately after the interview. This may be advisable for studies where deception is involved.

9. If personal and confidential information is obtained as a result of the study (for example, DNA analysis) which may cause harm to the participant if it is released to non-health care practitioners (for example, insurers, employers, etc.) then the extent of the risk and the potential impact of the risk should be clearly outlined.
10. Remind participants of the importance of informing study personnel about medications taken and following the instructions of study personnel, for example, “It is important that you are completely truthful with your study doctor with respect to your health history and any medications you may be taking, and that you follow the instructions of your study doctor in order to prevent any unnecessary harms to you should you decide to participate in this study.”

If there are steps that will be taken to reduce or minimize the potential harms, explain what extra investigations, monitoring, etc. will be undertaken.

## **8. Reproductive Risks**

St. Michael's Hospital REB encourages the inclusion of women in research whenever possible. Sufficient ethical justification must be provided if women's participation is to be limited.

When study drugs or interventions are toxic to fetuses or affect reproduction, the following information should be included:

1. The risks to offspring be stated as explicitly as possible (including whether they are known or unknown) including the likelihood and description of anomalies of formation or physical defects, and teratogenicity of the study drug.
2. Specific risks related to women of child-bearing potential must be described. The study must clearly explain any risks that her participation may cause to herself, to an unborn child she may be carrying, and newborns at the time of the study, and risks which may arise for her should she wish to become pregnant in the future.
3. Whether female participants of child-bearing potential cannot be pregnant during the study. This statement should be justified where appropriate.
4. The effect of the study on men and their fertility or spermatogenesis and whether female partners of male participants cannot become pregnant during the study.
5. Whether or not women who are able to have children, but are not likely to become pregnant (consider nuns, lesbians, celibate women, etc.) may participate and under what conditions. Requiring such women to begin family planning strategies in order to participate in the study may be unreasonable.



6. Whether or not women who are in menopause or have vasectomized partners may participate and under what conditions.
7. Whether the potential participant should take this information to her doctor in order to discuss any specific methods of family planning.
8. Explain what may happen if a participant becomes pregnant during a study and whether or not they may continue in the study.
9. Women, or female partners of male participants, should be advised, when relevant, to tell the investigator immediately if she thinks she has become pregnant during the study.
10. If women participants, or female partners of male participants, will be requested to allow the investigators to continue following the health of the mother and the child, and for how long.
11. If female participants or female partners of male participants cannot be pregnant or donate eggs and if male participants should not donate sperm for a period of time after the study is over.
12. Whether breastfeeding is recommended during the study and if not, for how long.

If the female participant or the male participant's female partner cannot be pregnant before, during, or after study participation, this should be clearly stated in the consent form. The strength of the recommendation should reflect the amount of knowledge on the severity of adverse effects of the study drug, procedures, testing, etc. on the development of the fetus. If the study drug affects certain family planning methods, making them less effective, this information should be included in the consent form.

Example 1:

"Pregnancy and this study are not compatible. Due to the risk or potential risk to the fetus, women who are pregnant, or planning to become pregnant are therefore excluded from this study. Women of childbearing potential are advised to discuss appropriate family planning with their doctor if they are interested in enrolling in this study. Unless you have had a hysterectomy, a tubal ligation, are post-menopausal, or not at risk of pregnancy, you are advised to practice an appropriate method of family planning."

Example 2:

"It is not known whether XXX may cause side effects to pregnant women, to an unborn child (an embryo or a fetus), or to children of breastfeeding women. Because of these unknown risks, if you are pregnant or trying to become pregnant you

cannot enter the study. If you are breastfeeding a child, you cannot enter the study.

If you can have children, you are required to have a negative pregnancy test result before enrolling in the study. You are a woman who can have children if:

- you have not completed menopause;
- you have not had a hysterectomy;
- you have not had surgery to become sterile (i.e., a tubal ligation);
- your sexual partner has not had surgery to become sterile (i.e., a vasectomy).

If you are sexually active and can have children, you must not become pregnant during the time you are participating in the study, and for a period of x months after the study.

If you miss a menstrual period or think you might be pregnant during the study, you must tell the study doctor immediately.

If you become pregnant during the study or within X days from your last dose of the study drug, the study doctor will ask to follow the outcome of your pregnancy and the condition of your newborn.

Men who are participating in this study also need to understand the danger of taking the study drug whose effects on a fetus are unknown. Female partners of male participants cannot be pregnant during the time their male partner is participating in the study, and for X days after the last dose of the study drug.

Please speak to a doctor to discuss which family planning method is best suited for you.”

## 9. Potential Benefits

The consent form should include a summary of the potential benefits that the participant may reasonably be expected to experience as a result of participating in the study. For example:<sup>15</sup>

1. If there is no intended clinical benefit to the participant or it is anticipated that the participants will not benefit from participation in this study, this should be clearly stated.

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<sup>15</sup> ICH GCP article 4.8.10(h)

2. If the research participants themselves, other patients with a similar condition or society may benefit from the participant's involvement in this study, this should be stated and the potential benefits described.
3. Potential benefits to the participant should not be overstated; it may create an inducement to participation. Participants may already be predisposed to expect a benefit, and need to understand that benefits cannot be guaranteed.
4. The following statements should be drafted to reflect the specific study.

Example 1:

"...will help us to better understand the effects of drug x on disease y."

Example 2:

"You may receive no direct benefits from being in this study. However, results from this study may further medical or scientific knowledge."

## 10. Alternatives to Participation

This section is usually included for interventional drug or device studies, and may not apply to qualitative studies such as surveys, focus groups, etc. The alternative procedure(s) or course(s) of treatment that may be available to the participant, including any potential harms and/or benefits must be outlined.<sup>16</sup> For example:

1. If there is a treatment alternative(s), the alternative(s) should be identified and described. Disclose any standard treatment that would be withheld if the person consents to participate.
2. If there is no treatment alternative (i.e. no available therapy), or the alternative to participation in the study is non-treatment, then this should be explained.
3. A general statement of prognosis using conventional therapy should be included in cases where the prognosis is poor (i.e. some oncology studies, pulmonary arterial hypertension studies, etc.).
4. It must be clear when participants have choices, what they may be, and with whom this may be further discussed.
5. Include a discussion of the likely consequences of deciding not to participate in the study, particularly in research related to treatment. This also applies when invasive methodologies are involved, or where there is a potential for physical or psychological harm.<sup>17</sup>
6. Include a clear statement that participants are under no obligation to participate. This is especially important when the participant is a healthy volunteer.

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<sup>16</sup> ICH GCP article 4.8.10(i)

<sup>17</sup> Tri-Council Policy article 2.4(c)

## 11. Protecting Your Health Information

It is important for the prospective research participant to know that their health information obtained in the course of the study will be treated confidentially and that their identity will remain confidential if the results of the study are published.<sup>18</sup>

It is also important for the prospective research participant to know who will have access to the research data/samples, and how the data/samples will be stored.<sup>19</sup> This requires a clear explanation of whether the information that is being collected will be kept confidential but will remain identifiable or whether it will be unidentifiable (anonymized). Information/samples are considered to be unidentifiable and anonymous only when all identifying information has been removed such that no links exist to determine to whom the information/sample belonged. Information/samples are considered to be still identifiable even if all identifying information has been removed but a link exists to the identifying information and therefore it is still possible to determine to whom the information/sample belonged.

In this section, the following should be included:

1. Indicate to the participant what the investigator plans to do with their information, (for example, publish results, review of health records, transfer of information to sponsor, etc.). Indicate also the purpose(s) for which their information is being collected, used or disclosed.
2. Describe the steps that will be taken to maintain confidentiality:
  - 2.1. Who will have access to the information and how (for example, whether or not there is a separate log linking name to participant study ID number).
  - 2.2. That any information collected will only be disclosed with the participant's permission or as required by law.
  - 2.3. If information is transferred electronically, how security will be ensured.
3. Describe how the results of the study will be published; that is, whether research data will be presented at conferences, seminars or other public forums. Even if this is not known at the start of the study, information should be included on how confidentiality will be maintained in any publication or presentation.
4. It should be stated that no information that discloses the participant's identity may be released or published without consent of the participant.
5. If the consent form is to be included in the participant's medical chart, this should be made clear. The REB prefers that the consent form be stored in the research study file only. If it is important that the medical chart contain information about the participant's involvement in the study, for example for the participant's safety, then consider a separate information sheet to be inserted into the participant's medical chart. (Further discussion with the participant may

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<sup>18</sup> ICH GCP article 4.8.10(o)

<sup>19</sup> ICH GCP article 4.8.10(n)

- be needed to ensure that they understand the difference between information stored in the medical chart or in the research study file.)
6. It should be carefully explained that no assurance of confidentiality--whether for research or for care and treatment--can be absolute. In rare circumstances, there are exceptions, such as when disclosures are required by law--to report suspected child abuse or communicable diseases, for example.

For example:

“Experience in similar studies indicates that the greatest risk in this study to you is the unintentional release of information from your health records. The study doctor will protect your records and keep confidential all the information in your study file, including your name, address and telephone number. The chance that this information will accidentally be given to someone else is small.”

7. Where the research study may result in a participant providing information pertaining to his or her involvement in potentially illegal activities (i.e., an investigator is interviewing persons who have participated in illegal drug use or assisted suicide), and there is a possibility that the research records may be of interest to the courts, coroner, police or other authorities, careful consideration must be given to the clarity and the amount of assurance to be given to the participants. In such cases, the investigator is encouraged to discuss with the REB these issues in advance of beginning the study.
8. Carefully outline who else may have access to this information (for example, Regulatory Authorities, Sponsor, Research Ethics Board, Institution) for review or monitoring purposes.
9. Indicate also that participants may be contacted by a representative of the Research Ethics Board to ask questions about the participant's experience with the recruitment and consent process or regarding their experience in the study, with a view to assuring and improving the quality of those processes.
10. If genetic information from tissue, plasma or blood is collected as part of the study (and is not optional as part of a sub-study) discussion of the harms and benefits as outlined in the later section “Genetic Studies” should be included.

## **12. Study Results**

It is strongly recommended that participants be advised of study results or study findings.

1. State whether and how the participant may be informed of the results when the research study is completed.

2. Summarize what types of publication are considered for the dissemination of study results to the scientific community, if known.
3. Participants have a right to know if there are restrictions to publication which may result in the study results being suppressed, disposed of, or not published. This should be explained, as it may affect the participant's decision to participate in the study.

### **13. Communication with Primary Care or Treating Doctor**

In some studies the study team may wish to communicate with or obtain information from a primary care or treating doctor and this must be clearly stated and the document submitted for REB review and approval.

For studies involving drugs, devices or surgical interventions, it is recommended that the primary care or treating doctor be advised of the participant's enrollment in the study. This depends on whether the participant has a primary care or treating doctor, and whether the participant agrees to the primary care or treating doctor being informed.<sup>20</sup>

If, in the opinion of the investigator, it is **mandatory** for the safety of the participant that their primary care or treating doctor be notified of their participation in this study, then consider making this an exclusion criterion. The participant must still be asked to provide their specific authorization to do so. Consider adding spaces for initials or a signature of the participant on the signature page to indicate the participant's agreement to this requirement (it is not advisable to rely only on a checkmark to indicate permission since it is hard to tell who completed the checkbox).

If, in the opinion of the investigator, it is **not mandatory** but highly recommended that the participant's primary care or treating doctor be notified, then this should be clearly stated in the consent form. Consider adding spaces for initials or signature of the participant on the signature page to indicate whether or not the participant agrees to notify their primary care or treating doctor, or whether the participant has no primary care or treating doctor.

If, however, information will be requested from the primary care or treating doctor, the investigator must consider how the authorization of the participant will be documented in the research study file, and how this authorization will be communicated to the treating doctor. Doctors require documentation, in writing, when they receive requests for information about one of their patients. The following authorization form is a separate document which can be sent to the primary care or treating doctor. Please note that it is preferable not to send the study consent form since it becomes a part of the doctor's clinical record, and becomes available to anyone who requests a copy of the chart. It is strongly recommended that the authorization form be signed in triplicate by the participant, with one copy stored in the research study file, one copy given to the participant and one copy sent to the treating doctor.

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<sup>20</sup> ICH GCP article 4.3.3

For example:

“To Dr. **(treating or primary care doctor)**

RE: Name of Participant/Patient and date of birth

This is to authorize you to give to Dr. **(Investigator)** and the study team the following information and data which they request regarding my physical condition and treatment, for use in the research study entitled \_\_\_\_\_. The information requested is: **(provide specific information being requested)**”

This is followed by the printed name of the participant, signature of the participant and the date.

## **14. Potential Costs of Participation and Reimbursement to the Participant**

When applicable, the following information should be included:

1. List any additional costs to the participant that may result from participation in the study, for example, transportation costs, meal expenses, etc.
2. Participants should be offered money for reasonable out-of-pocket expenses (for example, meals, and transportation costs).
3. When applicable, reimbursement must be clearly disclosed, and available equally to all participants.
4. If there is a payment for participation to reimburse for time away from work, traveling expenses, and inconvenience, the payment should be prorated for each stage of the study. Clearly state that payment for each completed stage will be made whether or not the participant completes the entire study.

## **15. Compensation for Injury**

Two separate and distinct situations can be described:

1. Immediate help for participants to obtain medical care necessary to “mitigate” any injury that is a direct result of participating in the study. This section should clearly identify who will cover necessary reasonable out-of-pocket expenses to ensure that immediate medical care is provided. For example, necessary and reasonable out-of-pocket expenses may include drugs and physiotherapy (which are not covered by OHIP).
2. Liability insurance which covers a claim by the participant (for example, for negligence). The categories claimed may include general damages (e.g. pain and suffering), loss of income, out of pocket expenses (e.g. related costs for

medical care, care services, home services, etc.) and past and future loss of income-earning opportunity.

It is strongly recommended that one of the following paragraphs be included (variations from the following must be justified):

Example 1:

"If you suffer a physical injury from (the medical device(s) or procedure(s) or taking the study medication(s) or participation) in this study, medical care will be provided to you in the same manner as you would ordinarily obtain any other medical treatment. In no way does signing this form waive your legal rights nor release the study doctor(s), sponsors or involved institutions from their legal and professional responsibilities."

Example 2:

"In no way does signing this form waive your legal rights nor release the study doctor(s), [Company X], the study sponsor or St. Michael's Hospital from their legal and professional responsibilities. In the case of research-related side effects or injury, medical care will be provided by your study doctor, or you will be referred for appropriate medical care. Although no funds have been set aside by the study sponsor to compensate you in the event of injury or illness related to the study treatment or procedures, the study doctor, St. Michael's Hospital, [Company X] and the study sponsor each have insurance that would respond to liability arising from negligence. You can make a claim for compensation for damages if any injury happens as a direct result of taking part in this study."

## **16. Participation and Withdrawal**

The consent form should clearly state that participation in research is voluntary. It is also recommended that the participant be assured that there will be no effects on the care received by the participant and their family if the participant decides not to participate or later withdraws from the study.

The following paragraph should be included:

"Participation in any research study is voluntary. If you choose not to participate, you and your family will continue to have access to customary care at St. Michael's Hospital. If you decide to participate in this study you can change your mind without giving a reason, and you may withdraw from the study at any time without any effect on the care you and your family will receive at St. Michael's Hospital."

1. The consent form should further explain whether safety assessments are recommended if the participant withdraws or terminates his or her participation



- in the study early, and whether follow-up will still be requested despite withdrawal or termination.
2. If there are parts of the research study in which a research participant could choose not to participate, this should be clearly explained (for example, if there is a genetic substudy).
  3. It is important to advise the participant whether or not withdrawal from the study includes withdrawal of any of their data compiled up to that point.
  4. If withdrawal from the intervention is permitted, but the participant will be asked to **continue participating in follow-up data collection**, this should be explained.
  5. In rare instances where it will not be possible for the participant to withdraw during a study (for example, there is an implanted device, only one intervention, or one surgical procedure, etc.) and the participant is therefore only able to withdraw from follow-up activities, the limits on the right to withdraw should be explained.
  6. In studies when distress to the participant may result, a general statement should be included advising whether the participant can suspend or end their participation in the study if distress occurs. This statement should further indicate that the participant need not provide a reason for withdrawing or terminating his or her participation in the study.
  7. If a questionnaire is involved, especially one which is complex or asks intimate questions, it must be clear in the consent form and at the beginning of the questionnaire that questions may be skipped by the participant and the participant may still participate in the study. If, however, the decision to skip a question affects the ability of the investigator to include the participant in the study, or to include the participant's data in the study, this must be clearly explained.
  8. Indicate that the study doctors have the right to stop participation in the study for various reasons, including:
    - 8.1. It is not in the participant's best interest to continue.
    - 8.2. Participant does not follow study directions.
    - 8.3. The sponsor ends the study.
  9. Also indicate what steps will be taken to contact participants who have been lost to follow-up (for example, if Equifax tracing, a private detective, or other methods will be used to locate the participant) and how many efforts will be made to attempt to locate the participant, and why this is necessary. Consider adding initial boxes on the signature page to offer a choice to participants whether or not they agree to be traced.

## 17. New Findings or Information

If any new findings become available that may affect the participant's participation in the study, this must be disclosed to the participant in a timely manner.

For example:

"We may learn new things during the study that you may need to know. We can also learn about things that might make you want to stop participating in the study. If so, you will be notified about any new information in a timely manner. You may also be asked to sign a new consent form discussing these new findings if you decide to continue in the research study."

## 18. Research Ethics Board Contact

The following must be included:

"If you have any questions regarding your rights as a research participant, you may contact **(name of the Chair)**, Chair, Research Ethics Board at 416-864-6060 ext. 2557 during business hours."

The following statements may also be added. Variations must be justified.

"The study protocol and consent form have been reviewed by a committee called the Research Ethics Board at St. Michael's Hospital. The Research Ethics Board is a group of scientists, medical staff, individuals from other backgrounds (including law and ethics) as well as members from the community. The committee is established by the hospital to review studies for their scientific and ethical merit. The Board pays special attention to the potential harms and benefits involved in participation to the research participant, as well as the potential benefit to society.

This committee is also required to do periodic review of ongoing research studies. As part of this review, someone may contact you from the Research Ethics Board to discuss your experience in the research study."

It should not be stated to the participant that a Research Ethics Board has "approved the study," since this may appear to offer a guarantee of safety. A statement that the REB has reviewed the study is permissible since review means that the REB considers the risks to fall within a scale of risks which a reasonable participant may be invited to accept, and that the risk-to-benefit ratio of the study appears favourable. The Research Ethic Board's opinion should not be employed to influence the potential participant.<sup>21</sup>

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<sup>21</sup> The University of Toronto, Guidelines on the Use of Human Subjects. 1975. See under Part 2(a)(i) entitled "Information for Consent" under "Issues to be Considered" of the document. See website <http://www.library.utoronto.ca/rir/tblconhu.html>

## 19. Study Contacts

This section is optional if contacts for investigators and/or study co-ordinators, or other study personnel, have been clearly indicated elsewhere in the consent form.

1. Provide information about whom to contact if the participant requires further information, or has problems concerning the research study. Include hours of availability and if appropriate, a 24 hour contact number.
2. Indicate the identity of the qualified designated representative at St. Michael's Hospital who can explain scientific or scholarly aspects of the research.<sup>22</sup> This will likely be the investigator.
3. Provide emergency contact information for the study doctor in case of symptom related concerns that the participants may have.

Example:

"In case of emergency, please go to the nearest emergency department and let them know that you are in a study, and the principal investigators name. If you are worried about some adverse effect that you are experiencing and want to talk to the study doctor, you can call them, 24 hours, at **(telephone number)**."

## 20. Signature Page

Ideally, the signature page should be a separate page, with the full title of the study on top, as well as the name and contact number of the investigator (in case the last page becomes separated from the rest of the consent form).

All of the signatures should be contained on the same page. If it is not possible to have all the signatures on the same page, then the participant's signature should be on the same page as the full title of the study (but then ensure each additional signature page also contains the participant's printed name). Do not reduce the size of the font of these pages.

The following paragraph is an example of the type of information that could be included on the signature page:

"The research study has been explained to me, and my questions have been answered to my satisfaction. I have been informed of the alternatives to participation in this study. I have the right not to participate and the right to withdraw without affecting the quality of medical care at St. Michael's Hospital for me and for other members of my family. As well, the potential harms and benefits (if any) of participating in this research study have been explained to me.

I have been told that I have not waived my legal rights nor released the investigators, sponsors, or involved institutions

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<sup>22</sup> Tri-Council Policy article 2.4, Table 1

from their legal and professional responsibilities. I know that I may ask now, or in the future, any questions I have about the study. I have been told that records relating to me and my care will be kept confidential and that no information will be disclosed without my permission unless required by law. I have been given sufficient time to read the above information.

I consent to participate. I have been told I will be given a signed copy of this consent form.”

1. The participant or the participant’s Substitute Decision Maker (if the participant is not capable of giving consent) must sign and personally date their own signature.<sup>23</sup>
2. If the participant is not capable to give consent for participating in research, the participant should be given the opportunity to assent (or not to object) to participating in the research study, if applicable. This should be documented either on an assent form or in the study notes regarding the consent discussion.
3. If the participant may become capable at a later time or date, this should be documented on the consent form.
4. If a Substitute Decision Maker (SDM) is consenting on behalf of the participant, the SDM must also indicate their relationship to the participant, as well as their contact information.
5. In addition, the person who conducted the consent discussion must sign and personally date the consent form on the signature page.<sup>24</sup>
6. If the time of the consent is relevant and important for the study, add a line for recording the time of the signature of the participant.
7. Prior to participation, the participant (or the SDM) should receive a copy of the signed and dated written consent form, and any other written information provided to the participants. If it is not possible to provide a signed consent form to the participant prior to the commencement of the study, provide the participant with an unsigned copy of the consent form (and any other study information) and provide a copy of the signed consent form as soon as practicable.<sup>25</sup>

## 21. Assent Form

For children, or individuals deemed incapable of providing consent, consent must be granted by a capable substitute decision maker (SDM) and assent must be obtained from the participant (if at all possible) and documented in the study notes or in an

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<sup>23</sup> ICH GCP article 4.8.8

<sup>24</sup> ICH GCP article 4.8.8

<sup>25</sup> ICH GCP article 4.8.11

assent form.<sup>26</sup> The wording in the assent form should be very simple. Sentences should use the active form at all times, and embedded phrases should be avoided. Larger font is recommended.

## **21.1. Assent Form**

21.1.1. Title of Study

21.1.2. Investigator(s)

21.1.3. Why are we doing this study?

21.1.4. What will happen during the study?

21.1.5. Are there good things and bad things about the study?

21.1.6. Who will know about what I did in the study?

Please include the statement:

“If we feel your health may be in danger, we may have to report your results to your doctor.”

21.1.7. Can I decide if I want to be in the study?

The following statement is suggested:

“Nobody will be angry or upset if you do not want to be in the study” “We are discussing the study with your substitute decision maker and you should talk to them about it too”

## **21.2. Assent**

The following section must be included at the end of the assent form instead of the consent paragraph:

"I was present when \_\_\_\_\_ read this form (or \_\_\_\_\_ read the form to the participant) and when this information was discussed. I confirm that the participant gave his or her verbal assent to take part in this study.

\_\_\_\_\_  
Name of person who obtained assent

\_\_\_\_\_  
Position of person who obtained assent

\_\_\_\_\_  
Signature of person who obtained assent

\_\_\_\_\_  
Date"

<sup>26</sup> The assent form has been adapted from the work of the Hospital for Sick Children, Toronto.

## **22. Witness to the Consent Process or Witness to the Signature Only**

The study team must consider and anticipate barriers to communication with potential research participants. The REB staff are available to discuss methods of dealing with barriers to communication.

1. There are no requirements for an impartial witness to the consent process or to the signature of the consent form by the participant if the participant reads and understands English (or the language in which the consent form is written).<sup>27</sup>
2. However, if a witness is available, either as witness for the whole consent process, or for the signature of the participant, it is helpful to document this. Thus, if no witness is present, the signature line for the witness may be left blank.
3. If the participant, or the Substitute Decision Maker, is unable to read the consent form, an impartial witness must be present during the entire consent discussion.<sup>28</sup> An interpreter is required when the participant cannot understand the language of the consent form (See section below “Interpreter’s Declaration and Signature”).
4. Upon signing the consent form, the witness must indicate the role that the witness played:
  - 4.1. If the person is a witness to the consent discussion, the witness attests that the information in the consent form, and any other written information was accurately explained, and apparently understood by the participant or the participant’s SDM, and that the consent was freely given by the participant or the participant’s SDM.<sup>29</sup>
  - 4.2. If the person is a witness to the signature of the participant only, then the witness attests that he or she has witnessed the participant (or the SDM) signing the consent form, and the consent was freely given by the participant (or the SDM), but that he or she was not present for the whole consent discussion.
5. It is also important to document if there is a relationship between the witness and the participant. For example, the witness may be a spouse or relative of the participant, or the witness may be a study-coordinator (not involved in the study) or nurse in the hospital.

## **23. Person Who Conducts the Consent Discussion**

The person who conducts the consent discussion is responsible for explaining the topics set out in the consent form, and is the person who should sign the consent form to so indicate. On occasion, there may be more than one person substantially involved in the

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<sup>27</sup> There are no requirements in the hospital by-laws, or in the ICH GCP, for a signature by a witness if the participant understands and reads English.

<sup>28</sup> ICH GCP article 4.8.9

<sup>29</sup> ICH GCP article 4.8.9

explanation of the study to the participant. The position or title of each study personnel in the consent discussion should be noted on the consent form.

## 24. Signature of the Investigator

If the investigator was not the Person Conducting the Consent Discussion, then there is no requirement for the investigator to sign the consent form. The investigator may sign the consent form to provide the participant with assurance that the investigator is involved with every aspect of the study, including the consent process (if there is no concern regarding the perceived potential coercion of the participant by doing so). However, steps should be taken to ensure that the investigator's signature does not indicate that he or she was present during the consent discussion, if this is not the case. Thus, the investigator's signature may be located under a statement, for example:

"Study Doctor's Signature

I \_\_\_\_\_ (**printed name of study doctor**) am the study doctor responsible for the conduct of this study at St. Michael's Hospital, and I have delegated the explanation of this study to this participant to \_\_\_\_\_ (**name of person conducting the consent discussion**).

\_\_\_\_\_  
Signature of Investigator

\_\_\_\_\_  
Date"

If the Investigator is routinely involved in the consent process, together with another person, then a sentence may be added to the above paragraph to the following effect:

"I have also had a discussion with the participant regarding the study, and I am of the opinion that the participant understands the nature of the study."

## 25. Interpreter's Declaration and Signature

When the potential participant and/or the participant's Substitute Decision Maker do not speak or understand English, an interpreter may be required to assist with the discussion phase of the consent process, as well as for activities during the study. An interpreter will be required to assist with the discussion of the study even if a certified translation from the English consent form is available.

It is recommended that the interpreter not be a family member of the participant and not involved in the research study when the study is a high risk study.

If an interpreter is required during the consent discussion, then this should be documented in the study file, and the interpreter must also sign the consent form. An additional page may be attached to the consent form for the interpreter's declaration, for example:

“I have been requested to interpret the consent discussion for the potential research participant (**Name of potential participant**).

I am competent in the English language and in the language of choice of the potential participant (**Language**).

I am not involved in the research study.

I agree to keep confidential all personal information of the potential participant.

I have interpreted the consent discussion. The potential participant has advised me in his/her own language that he/she has been informed about the research study, the nature and extent of his/her participation, including the risks involved. The potential participant freely gives his/her consent to participate in this study.

\_\_\_\_\_  
Signature of Interpreter

\_\_\_\_\_  
Printed Name of Interpreter

\_\_\_\_\_  
Relationship or Position of Interpreter

\_\_\_\_\_  
Contact Information of Interpreter

\_\_\_\_\_  
Date”

## 26. Genetic Studies

If entry into a genetic study is optional and separate from a main study, a separate consent form should be prepared. If participants have the option to choose certain study activities, consider adding boxes for ticking “Yes” or “No” and initialling by the participant.

If, however, the genetic study is a mandatory part of the main study, then the information about the genetic study should be included in the main study consent form.

Include the following information:<sup>30</sup>

1. Purpose of the research, potential risks and benefits:

<sup>30</sup> Tri-Council Policy articles 8.1 to 8.7 and articles 10.1 to 10.3.



- 1.1. What is required for this portion of the study? For example, need to provide **X** mL/tbsp (quantity) of blood in addition to main study.
  - 1.2. What testing will be done on the sample(s).
  - 1.3. A brief, general description of gene studies and DNA, in common language.
  - 1.4. The risks of taking blood and the risk of loss of confidentiality, for example, if information is inadvertently given to someone outside the study, insurance companies, employers etc.
  - 1.5. Whether genetic counselling is appropriate and whether it will be available.
  - 1.6. Whether individuals or families will be tracked? Will this impact the privacy of an individual other than the participant (for example, a sibling, child, or parent)? Will requests be made to provide family histories or identify family members?
  - 1.7. Describe the benefits of this research to the individual, to society, etc.
2. Regarding the storage and use of the sample:
- 2.1. How long will the sample be stored? For long term storage of samples, will efforts be made to recontact the participant or the participant's family to confirm consent to continue using the sample?
  - 2.2. What uses will be made of the sample?
  - 2.3. If samples are to be used for future studies, consent must be obtained, at the time of the future study, to use the sample again.
  - 2.4. Will the sample be sold at any time?
  - 2.5. What health information will be provided or linked to the sample?
  - 2.6. How long will the sample be stored in a linked or anonymous fashion, and will that change at a future date?
  - 2.7. Will a commercial product be developed from the sample?
  - 2.8. Will the participant profit from such a product?
3. Confidentiality of the research results, including methods used to ensure confidentiality:
- 3.1. Whether genetic information will be released to participant, family, or third parties. Upon the death of the participant, whether genetic information is accessible by family or third parties.
  - 3.2. Whether this information will become part of personal medical record, or whether there will be any mention of genetic testing in the personal medical record which could lead to further inquiries about the results of genetic testing.
  - 3.3. Is the database anonymous, identifiable or linked? Include an explanation of what this means.
  - 3.4. If information is required by law, who may request the information?

For example, the following wording may be used regarding confidentiality:

"The greatest risk in this study to you is the unintentional release of information from your health records. The study doctor will protect your records and keep private all the information in your study file, including your name, address and

telephone number. The chance that this information will be accidentally given to someone else is small.

If the genetic information from your tissue samples, plasma or blood samples were released to you, your family, or other persons like employers or insurers (referred to as “third parties”), it is possible that it could be used to prevent you from obtaining employment or insurance. In order to minimize any such risks, and since the results of these studies are not expected to benefit you directly or to alter your course of treatment, the sponsor has taken special precautions to keep your genetic information confidential so that it cannot be obtained by third parties. Results of the genetic testing are for research purposes only, and will not be made available to you, members of your family, your treating doctor, or other third parties, except as required by law. The results of the genetic testing will not become part of your personal medical record.”

4. Voluntary Participation and Withdrawal:

- 4.1. Participation or withdrawal will not affect the medical care of the participant or the participant’s family.
- 4.2. What occurs if participant withdraws: what data and/or samples, if any, will be removed and/or destroyed?
- 4.3. Who is responsible for the sample and how will the sample be destroyed.
- 4.4. Once the participant dies, can the family ask for the sample to be withdrawn, can third parties request this?

5. Future Research:

If new research is proposed to be done in the future on these samples (outside the scope of the study), it is assumed that a tissue/blood databank is being created. Special considerations apply for databanks, and the investigator should communicate with the REB regarding the protocol and consent form. The consent form should include the following:

- 5.1. Whether or not consent will be requested from the participant.
- 5.2. Whether Research Ethics Board approval will be sought for these future studies.
- 5.3. Whether approval will also be required of the organization holding the samples.