**SUNNYBROOK RESEARCH ETHICS BOARD (REB)**

**Informed Consent Form Checklist**

**Instructions**

The Sunnybrook REB requests that all ICFs follow the prescribed structure and format as set out in this checklist. Other ICFs not in this format, that are compliant with the applicable regulations and guidelines as outlined in this checklist, will be accepted for review.

This ICF checklist outlines section headings with corresponding content, and whether the content is a requirement of the Sunnybrook REB, TCPS2 or GCP. **The wording in the ICF Checklist is directly from the guidelines (TCPS2 or GCP) and is not an acceptable language level for ICF submissions to the Sunnybrook REB. Please refer to the** [**Informed Consent Form Template**](http://sunnybrook.ca/research/content/?page=sri_csrc_reo_forms) **for suggested language approved by the Sunnybrook REB.**

* Sections and headings in **BLACK TEXT** should be included in an ICF.
* Sections and headings in **RED TEXT** may be omitted if they are not relevant to the specific protocol.

For queries related to the ICF Checklist, contact the [Research Ethics Office](http://sunnybrook.ca/research/content/?page=sri-csrc-reo-home).

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**Informed Consent Form Checklist**

**Definitions**

**Clinical Trial** - Any investigation involving participants that evaluates the effects of one or more health related interventions on health outcomes.

**Human biological materials** - Tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, urine, saliva, and other body fluids. The term also includes materials related to human reproduction, including embryos, fetuses, fetal tissues and human reproductive materials.

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| **REB** | **TCPS2** | **GCP** | ELEMENTS |
|  |  |  | GENERAL |
| ✓ |  |  | Sunnybrook letterhead. |
| ✓ |  |  | Full study title (as it appears on the protocol and REB application). |
|  | 3.2 b |  | The identity of the researcher/Principal Investigator (PI), Sponsor or funding sources. |
| ✓ |  |  | 24 Hour Contact Number (Required for studies that include greater than minimal risk research procedures or interventions). |
| ✓ |  |  | Consent version date on all pages; number all pages Page x of y (preferably in the footer). |
| ✓ |  |  | Written consistently in second person (“You/Your”) except signature section (first person). |
| ✓ |  |  | Suitable reading level (grade 6 to 8) in lay language. Whenever possible, avoid using technical/medical terms, and acronyms. However, when required, they should be clearly defined at first use. |
| ✓ |  |  | Thorough check of formatting to enhance readability: font size (12); font type (Arial or Times New Roman); bullets, adequate margins, spacing (no page breaks across sections), and headings. |
| ✓ |  |  | Thorough check of spelling, punctuation, grammar. |
|  |  |  | INFORMED CONSENT |
|  |  | 4.8.10m | That the subject’s participation in the research trial is voluntary. |
|  |  | 4.8.10 a | That the trial involves research. |
| ✓ |  |  | [If applicable] An introductory statement to the patient’s Substitute Decision Maker. |
|  |  |  | INTRODUCTION |
|  | 3.2 a |  | Information that the individual is being invited to participate [Sunnybrook language is “being asked to consider participating”] in a research project. |
| ✓ |  |  | For clinical trials involving an investigational agent, state that <investigational agent> has not been approved for this indication by Health Canada (*for* D*ivision 5 clinical trials*) although it has been allowed for use in this research study. |
|  |  |  | WHAT IS THE USUAL TREATMENT? |
| ✓ |  |  | For clinical trials, describe the usual treatment(s), and if applicable include an explanation that the participant may not receive the usual treatment if they participate in the research study. |
|  | 11.4d |  | **For clinical trials involving a placebo control**, describe any intervention or therapy that will be withdrawn or withheld for purposes of the research; and of the anticipated consequences of withdrawing or withholding the therapy. |

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| **REB** | **TCPS2** | **GCP** | ELEMENTS |
|  |  |  | WHY IS THIS STUDY BEING DONE? |
|  | 3.2 b |  | A statement of the research purpose in plain language. |
|  |  | 4.8.10 b | The purpose of the trial. |
|  |  |  | WHAT WILL HAPPEN DURING THIS STUDY? |
|  |  | 4.8.10 c | The trial treatment(s) and the probability for random assignment to each treatment. |
|  |  |  | HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY? |
|  |  | 4.8.10 t | Approximate number of subjects involved in the trial. |
| ✓ |  |  | The expected duration of the entire research. |
|  | 3.2 b |  | The expected duration of participation. |
|  |  | 4.8.10 s | The expected duration of the subject’s participation in the trial. |
|  |  |  | WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS? |
| ✓ |  |  | [If applicable] A description of competitive enrolment. |
|  | 3.2 b |  | A description of research procedures. |
|  |  | 4.8.10 d | The trial procedures to be followed, including all invasive procedures. |
|  | 11.5 |  | **For clinical trials**, which specific elements are required for research purposes, as well as the differences between research and the standard clinical care patients might otherwise receive. |
|  |  | 4.8.10 f | Those aspects of the trial that are experimental. |
|  | 3.2 b |  | An explanation of the responsibilities of the participant. |
|  |  | 4.8.10 e | The subject’s responsibilities. |
|  | 11.2 |  | **For phase I clinical trials**, explain the untested nature of the therapy. |
|  | 11.2 |  | For phase II clinical trials, provide details on the access to the new drug upon trial completion. |
|  | 12.2 |  | **Note: Collection of samples/tissues for future unknown research and/or banking (i.e. where the research purpose is not yet known) must have a separate informed consent form.**  Researchers who seek to collect human biological material for research shall provide to prospective participants or authorized third parties the following:   1. The type and amount of biological materials to be taken; 2. The manner in which the biological materials will be taken, and the safety and invasiveness of the procedures for acquisition; 3. The intended uses of the biological materials including any commercial use; 4. The measures employed to protect the privacy and minimize risks to participants; 5. The length of time the biological materials will be kept, how they will be preserved, location of storage (i.e. Company/Institution Name, City, Country) and process for disposal, if applicable; 6. Any anticipated linkage of biological materials with information about the participant; and 7. The researchers’ plan for handling results and findings, including clinically relevant information and incidental findings. |
|  | 13.2 |  | **Researchers conducting genetic research** shall advise prospective participants of the plan for managing information revealed through the research. |
|  | 13.7 |  | **Researchers who propose research involving the collection and banking of**  **genetic material** shall indicate how they plan to address the associated ethical issues, including confidentiality, privacy, storage, use of the data and results, possibility of commercialization of research findings and withdrawal by participants as well as future contact of participants, families, communities and groups. |

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| **REB** | **TCPS2** | **GCP** | ELEMENTS |
|  |  |  | WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY? |
|  | 3.2 c |  | A plain language description of all reasonably foreseeable risks, both to the participant and in general,that may arise from research participation. |
|  |  | 4.8.10 g | The reasonably foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, fetus, or nursing infant. |
| ✓ |  |  | The procedure or treatment may involve unforeseeable risks to the participant. |
|  |  | 4.8.10 q | The person to contact in the event of a trial-related injury. |
| ✓ |  |  | Describe the risks as follows:   * Separate the risks by study drug, procedure or intervention as appropriate. * Address incidence/frequency, severity, and long term impact/reversibility. * List frequencies/percentages in order of importance (i.e. rare but serious, very likely, likely, less likely, rare). * Include percentage frequency with each side effect. * Any serious side effects or risks such as stroke, heart attack or death should be listed in a separate paragraph and not buried in the text, or listed first if using the table format. |
| ✓ |  |  | Where there is a stated risk to an embryo, fetus or nursing infant, describe the need for birth control during and after the study as applicable. |
|  | 3.2 d |  | An assurance that prospective participants will be given, in a timely manner throughout the course of the research project, information that is relevant to their decision to continue or withdraw from participation. |
|  |  | 4.8.2  4.8.10 p | An assurance that new information will be provided to the subject or the subject’s legally acceptable representative in a timely manner whenever such information is relevant to a subject’s willingness to continue participation in a trial. |
|  |  |  | WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY? |
|  | 3.2 c |  | A plain language description of all reasonably foreseeable potential benefits, both to the participant and in general,that may arise from research participation. |
|  |  | 4.8.10 h | The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this. |
| ✓ |  |  | Reasonably expected benefits to others. |
|  |  |  | WHAT OTHER CHOICES ARE THERE? |
|  |  | 4.8.10 i | The alternative procedure(s) or course(s) of treatment that may be available to the subject, and their important potential benefits and risks. |
|  |  |  | CAN PARTICIPATION IN THIS STUDY END EARLY? |
| ✓ |  |  | [If applicable] A statement noting that << the sponsor may end the study at any time and for any reason. >> |
|  | 3.2 l |  | In clinical trials, information on stopping rules and when researchers may remove participants from trial. |
|  |  | 4.8.10 r | The foreseeable circumstances and/or reasons under which the subject’s participation in the research study may be terminated. |
|  | 3.2 d |  | An assurance that prospective participants are under no obligation to participate; are free to withdraw at any time without prejudice to pre-existing entitlements; and will be given information on the participant’s right to request the withdrawal of data or human biological materials, including any limitations on the feasibility of that withdrawal. |
|  |  | 4.8.10m | The subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled. |
|  |  |  | WHAT ARE THE COSTS OF PARTICIPATING IN THIS STUDY? |
| ✓ |  | 4.8.10 l | The anticipated expenses, if any, to the subject for participating in the trial. |

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| **REB** | **TCPS2** | **GCP** | ELEMENTS |
|  |  |  | **WHAT HAPPENS IF I HAVE A RESEARCH RELATED INJURY?** |
|  | 3.2 j |  | Information about compensation for injury. |
|  |  | 4.8.10 j | The compensation and/or treatment available to the subject in the event of a research-related injury. |
|  | 3.2 k |  | A statement to the effect that, by consenting, participants have not waived any rights to legal recourse in the event of research-related harm. |
|  |  | 4.8.4 | None of the oral and written information concerning the trial, including the written informed consent form, should contain any language that causes the subject or the subject’s legally acceptable representative to waive or appear to waive any legal rights, or that releases or appears to release the investigator, the institution, the sponsor, or their agents from liability for negligence. |
|  |  |  | **ARE STUDY PARTICIPANTS PAID TO PARTICIPATE IN THIS STUDY?** |
| ✓ |  |  | Note: The Sunnybrook REB recommends that there be consideration to reimburse study participants for participation-related expenses that are above standard of care. |
|  | 3.2 j |  | Information about any payments, including incentives for participants, reimbursement for participation-related expenses. |
|  |  | 4.8.10 k | The anticipated prorated payment, if any, to the subject for participating in the trial. |
|  |  |  | HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL? |
|  | 3.2 i |  | An indication of what information will be collected about participants and for what purposes; an indication of who will have access to information collected on the identity of participants, description of how confidentiality will be protected, a description of the anticipated uses of data (including secondary uses of data); and information indicating who may have a duty to disclose information collected, and to whom such disclosures could be made. |
|  |  | 4.8.10 n | That the sponsor(s), monitor(s), auditor(s), regulatory authorities and Sunnybrook Research Institute, Sunnybrook Health Sciences Centre and Sunnybrook REB will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations. |
|  |  | 4.8.10 o | That records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. |
|  | 3.2 f |  | The measures to be undertaken for dissemination of research results, and whether participants will be identified directly or indirectly. |
|  |  | 4.8.10 o | If the results of the trial are published, the subject’s identity will remain confidential. |
| 21 CFR Part 50 | | | For clinical trials subject to FDA’s jurisdiction, include the following exact statement “A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U. S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.” |
|  |  |  | ARE THERE ANY CONFLICTS OF INTEREST/RELATIONSHIPS? |
|  | 3.2 e |  | Information concerning the possibility of commercialization of research findings, and the presence of any real, potential or perceived conflicts of interest on the part of researchers, their institutions, or the research sponsors. |
| ✓ |  |  | Describe any relationships, financial or otherwise, that the participant’s physician, PI, or study doctor has with respect to the research study and/or its sponsors. |
|  |  |  | COMMUNICATION WITH YOUR FAMILY DOCTOR |
|  |  | 4.3.3 | It is recommended that the investigator inform the subject’s primary physician about the subject’s participation in the trial if the subject has a primary physician and if the subject agrees to the primary physician being informed. |

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| **REB** | **TCPS2** | **GCP** | ELEMENTS |
|  |  |  | WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY? |
| ✓ |  |  | Person to contact for further information about the study (minimum Investigator). |
|  | 3.2 g |  | The identity and contact information of a qualified designated representative who can explain scientific or scholarly aspects of the research to participants. |
|  | 3.2 h |  | The identity and contact information of the appropriate individual(s) outside the research team whom participants may contact regarding possible ethical issues in the research. |
|  |  | 4.8.10 q | The person(s) to contact for further information regarding the trial and the rights of trial subjects, and whom to contact in the event of trial-related injury. |
|  |  |  | DOCUMENTATION OF INFORMED CONSENT |
|  | 3.5 |  | Research shall begin only after the participants, or their authorized third parties, have provided their consent. |
|  |  | 4.8.8 | Prior to a subject’s participation in the trial, the written informed consent form should be signed and personally dated by the subject or by the subject’s legally acceptable representative, and by the person who conducted the informed consent discussion. |
|  |  | 4.8.11 | Prior to participation in the trial, the subject or the subject’s legally acceptable representative should receive a copy of the signed and dated written informed consent form and any other written information provided to the subjects. |
| ✓ |  |  | Participant/Substitute decision-maker  By signing this form, I confirm that:   * This research study has been fully explained to me and all of my questions answered to my satisfaction * I understand the requirements of participating in this research study (TCPS2 3.2) * I have been informed of the risks and benefits, if any, of participating in this research study * I have been informed of any alternatives to participating in this research study * I have been informed of the rights of research participants * I have read each page of this form * I authorize access to my personal << health >> information, << medical record >>, and research study data as explained in this form * I have agreed, or agree to allow the person I am responsible for, to participate in this research study (GCP 4.8.10 n) * I understand that my family doctor may be informed of my participation in this research study * This informed consent document may be placed in my medical records |
| ✓ |  |  | I **agree** to allow my << type of sample(s) >> to be collected for the optional study(ies) as described in this consent form.  I **do not agree** to allow my << type of sample(s) >> to be collected for the optional study(ies) as described in this consent form. |
| ✓ |  | 4.8.8 | Participant/substitute decision-maker name, signature and date |
| ✓ | 4.1 | 4.8.9 | Name, signature and date of person assisting with the consent process if applicable (only if translator/ for use if participant unable to read)\*\* |
| ✓ |  | 4.8.7; 4.8.8; 4.8.11 | Person obtaining consent  By signing this form, I confirm that:   * This study and its purpose has been explained to the participant named above * All questions asked by the participant have been answered * I will give a copy of this signed and dated document to the participant |
| ✓ |  | 4.8.8 | Name, signature and date of person obtaining consent\* |

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| **REB** | **TCPS2** | **GCP** | ELEMENTS |
|  |  |  | (Continued) DOCUMENTATION OF INFORMED CONSENT |
| ✓ |  |  | [**Required for clinical trials**]  Statement of the Investigator  I acknowledge my responsibility for the care and well-being of the above participant, to respect the rights and wishes of the participant as described in this informed consent document, and to conduct this study according to all applicable laws, regulations and guidelines relating to the ethical and legal conduct of research. |
| ✓ |  |  | [**Required for clinical trials**]  Name, signature and date of investigator |

*\*The “person obtaining consent” serves as a witness that the consent process occurred.*

*\*\*An impartial witness need only be utilized if the participant or his/her legal representative is unable to read or if there is some concern about the participant’s level of understanding.*

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| **Revision History** | |
| **Version Date** | **Summary of Changes** |
| July 6th, 2022 | General: Minor modifications  What is Usual Treatment: Updated TCPS section  What are the Responsibilities of Study Participants: Revised to reflect updates to TCPS  Are Study Participants Paid to Participate in this Study?: Sunnybrook REB guidance updated  Are There Any Conflicts of Interest/Relationships?: Sunnybrook REB guidance updated  What are the Rights of Participants in a Research Study?: Sunnybrook REB guidance added and other corrections implemented  Documentation of Informed Consent: Revised to include ICH GCP section references  Revision History: Addition of “Revision History” section |
| September 8th, 2016 | Original version |