**Instructions for use:**
Use of this checklist is optional. Some items in this checklist may not apply to every study.

The wording in this checklist is based on the wording in the various regulations/guidelines/policies, and is **not suitable** for inclusion in the Informed Consent Form (ICF). Please refer to the applicable WOHS REB Consent Form Template for appropriate wording and suggested text. **Please do not provide a copy of this checklist to the REB for review.**

**Normative References:**

This checklist is informed from the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2); Tri-Council Policy Statement (TCPS2); US Code of Federal Regulations (US CFR) 21 CFR 50 and 45 CFR 46; and Canadian General Standards Board (CGSB) “Research ethics oversight of biomedical clinical trials”. The requirements of the Food and Drugs Act and applicable Regulations have been considered and incorporated into the “GCP” column. Items from each of these standards have been grouped together when appropriate.

**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.

| **Element Number** |  **Application** | **of Element** |  | **Description of Element** |
| --- | --- | --- | --- | --- |
|  | **TCPS2** | **GCP** | REB Required |  |
| **General and**  | **Formatting** |  |  |  |
|  |  |  | √ | Institutional letterhead/logo on the first page and signature pages |
|  |  |  | √ | Title of the consent form e.g., “Participant Informed Consent Form” |
|  | X |  |  | Full Study title (as it appears on the study protocol and REB application). Plus, study acronym name, if applicable |
|  |  |  | √ | The footer in each page must include a version date, include page x of y |
|  |  |  | √ | Written consistently in second person (“you/Your”) except signature page (first person) |
|  |  |  | √ | Written in simple non-technical language; suitable reading level (Grade 6 to 8). All acronyms and abbreviations must 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, clarity |
|  | 3.2 b |  |  | Identity of the Researcher/Principal Investigator/Study Doctor, Sponsor and/or funding sources |
| 1. 2
 |  |  | √ | 24 Hour Contact Number (Required for studies that include greater than minimal risk research procedures or interventions) |
| **Introduction** |  |  |  |  |
| 1. 4
 | X | X |  | A statement that the participant is being invited to participate in research |
|  |  | 4.8.10m |  | That the subject’s participation in the research trial is voluntary. |
|  |  | 4.8.10 a |  | That the trial involves research. |
| 1. 4
 |  |  | √ | [If applicable] An introductory statement to the patient’s Substitute Decision Maker. |
|  |  |  | √ | **For clinical trials involving an investigational agent**, state that <investigational agent> has not been approved for this indication by Health Canada (for Division 5 clinical trials) although it has been allowed for use in this research study. |
| **Is there a conflict of interest?** |
| 1. 49
 | X |  |  | Information concerning the presence of any real, potential or perceived conflicts of interest on the part of the researchers, their institutions or the research sponsors |
| 1. 50
 |  |  |  | A statement concerning any personal benefits that may accrue to the researcher, if applicable and deemed necessary by the REB |
| **Why Is this**  | **study being** | **done and** | **what is** | **standard of care?** |
| 1. 5
 | X | X |  | A statement of the research purpose in plain language |
|  |  |  |  | **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. |
|  | 11.2c |  |  | **For clinical trials involving a placebo control,** describe any therapy that will be withdrawn or withheld for purposes of the research; and of the anticipated consequences of withdrawing or withholding the therapy. |
| **What other**  | **choices are**  | **there?** |  |  |
| 1. 6
 |  | 4.8.10 i |  | A description of available alternative procedures or courses of treatment that are available outside of the research project |
| 1. 7
 |  | 4.8.10 i |  | The important potential benefits and risks of alternative procedures or courses of treatment that are available |
| **How many**  | **people will** | **take part** | **in this** | **study?** |
| 1. 8
 |  | X |  | The approximate number of research participants  |
| **What will ha** | **ppen during** | **this study** | **?** |  |
| 1. 9
 |  | 4.8.10 c |  | The probability of randomization to each intervention |
| **What is the study intervention?; What else do I need to know about the study intervention?; What are the study procedures?** |
| 1. 10
 | 3.2 b | 4.8.10 d4.8.10 f |  | A description of the research intervention and procedures to be used, including clear indication of those aspects that are experimental |
|  | 11.6 |  |  | **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. |
| 1. 12
 | X |  |  | Participants are informed of any therapy that will be withdrawn or withheld for the purposes of the research, and the anticipated consequences of withholding or withdrawing therapy |
| **Mandatory sample collection** |
| 1. 13
 | 12.2 |  |  | The type and amount of biological materials to be taken |
| 1. 14
 | 12.2 |  |  | The manner in which the biological materials will be taken, and the safety and invasiveness of the procedures for acquisition |
| 1. 15
 | 12.2 |  |  | The intended uses of the biological materials, including any commercial use |
| 1. 16
 | 12.2 |  |  | The measures employed to protect the privacy and minimize risks to participants |
| 1. 17
 | 12.2 |  |  | The length of time the biological materials will be kept, how they will be preserved, location of storage (e.g., in Canada, outside Canada), and process for disposal if applicable |
| 1. 18
 | 12.2 |  |  | Any anticipated linkage of biological materials with information about the participant |
| 1. 19
 | 12.2 |  |  | 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. |
|  | 11.1 |  |  | **For phase II clinical trials,** provide details on the access to the new drug upon trial completion. |
| **What are the responsibilities of study participants?** |
| 1. 21
 | 3.2 b | 4.8.10 e |  | An explanation of the responsibilities of the participant |
| **How long will participants be in the study?** |
| 1. 2
 | 3.2 b |  |  | The expected duration of participation |
| **Can participants choose to leave the study?** |
| 1. 3
 |  |  |  | The process involved for participation withdrawal |
| 1. 4
 |  |  |  | The effects of a participant choosing to withdraw |
| 1. 25
 | 3.2 d |  |  | Information on the participant’s 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. |
| **Can participation in this study end early?** |
| 1. 26
 | 3.2 l |  |  | **In clinical trials,** Information on stopping rules and when researchers may remove participants from the clinical trial without the participant’s consent |
| 1. 27
 |  |  | √ | A statement identifying those with the authority to modify the research subjects participation (such as the Researcher, Sponsor, REB or regulatory authority(ies)) |
|  |  | 4.8.10 r |  | The foreseeable circumstances and/or reasons under which the subject’s participation in the research study may be terminated. |
| **What are the risks and harms of participating in this study?** |
| 1. 28
 | 3.2c |  |  | A plain language description of all reasonably foreseeable risks or inconveniences, to participants, and in general, that may arise from research participation |
| 1. 29
 |  |  | √ | A statement that the particular treatment or procedure may involve risks to the participant which are currently unforeseeable |
|  |  |  |  | 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. |
|  **What are the** | **reproductive** | **Risks?** |  |  |
| 1. 30
 |  | 4.8.10 g |  | A plain language description of all reasonably foreseeable risks to an embryo or fetus or nursing infants, if the participant is or could become pregnant |
| 1. 31
 |  |  |  | A statement that the particular treatment or procedure may involve risks to an embryo or fetus (if the participant is or could become pregnant) that are currently unknown |
| **Are there benefits of participating in this study?** |
| 1. 32
 | 3.2c | X |  | A plain language description of potential benefits, both to participants and in general, that may arise from participation |
| 1. 33
 |  | 4.8.10 h |  | If there is no known clinical benefit to the participant, the participant shall be informed  |
| **How will participant information be kept confidential?****\*Provisions required by the Personal Health Information Protection Act (PHIPA) must also be considered and included when applicable.** |
| 1. 34
 | 3.2 i |  |  | An indication of what information will be collected about participants and for what purpose |
| 1. 35
 | 3.2 i |  |  | An indication of who will have access to information collected about the identify of participants, including specification that the monitor(s), auditor(s), the REB and the regulatory authority(ies) will be granted direct access to the participant’s original medical records for verification of clinical trial procedures and data |
| 1. 36
 | X | 4.8.10 o |  | A description of how confidentiality will be protected and, to the extent permitted by the applicable laws and regulations, records identifying the participant will not be made publicly available. |
| 1. 7
 | X |  |  | A description of the anticipated uses of data |
| 1. 38
 | 3.2 i |  |  | Information indicating who may have a duty to disclose information collected, and to whom such disclosures could be made |
| 1. 9
 |  |  |  | Any limits to the confidentiality of the research records |
| 1. 0
 | 3.2 f |  |  | The measures undertaken for dissemination of research results |
| 1. 41
 |  | 4.8.10 o |  | If the results of the trial are published, the participant’s identity will remain confidential |
| **Will information about this study be available online?** |
| 1. 42
 | 21 | CFR Part | 50 | The following statement shall be provided to each clinical trial to each clinical trial participant: "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." The registration number must be provided in the consent form prior to institutional approval\*Mandatory for inclusion, verbatim, in US FDA regulated clinical trials |
|  **What is the** | **cost to parti** | **cipants?** |  |  |
| 1. 3
 |  | 4.8.10 l |  | Any anticipated expenses associated with participation in the clinical trial |
| **Are participants paid to be in this study?** |
| 1. 44
 | 3.2 j |  |  | A description of the compensation, if any, that will be provided to the participant in the event that he/she is injured during the research |
| 1. 45
 | 3.2 j |  |  | Information about any payments, including incentives for participants and reimbursement for participation related expenses |
| 1. 46
 | 3.2 e |  |  | Information on the possibility of commercialization of research findings |
| 1. 47
 |  | 4.8.10 j |  | A description of the type of response that will be undertaken if injury occurs to a participant during the research (e.g., that treatment will be made available and covered by[X]), or that no such response is planned |
| 1. 48
 | 3.2 k |  |  | A statement that the participant has not waived any legal rights/rights to legal recourse in the event of research-related harm |
| **What are the rights of participants in a research study?** |
| 1. 48
 | 3.2d |  |  | An assurance that 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 |
|  |  | 4.8.24.8.10 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. |
| **Communication with Family Doctors** |
|  |  | 4.3.3 |  | **For clinical trials,** 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. |
| **Whom do participants contact for questions?** |
| 1. 51
 | X | X |  | The identity and contact information for a qualified individual who can explain the scientific or scholarly aspects of the clinical trial (e.g., for further information about the clinical trial) |
| 1. 52
 | X | X |  | The identity and contact information for an appropriate individual outside the research team whom participants may contact regarding possible ethical issues in the research (e.g., for questions about participant rights) |
| 1. 53
 |  | X |  | The person to contact in the event of research-related injuries |
| **Documentation of Informed Consent** |
| 1. 54
 | 3.5 |  |  | Research shall begin only after the participants, or their authorized third parties, have provided their consent. |
|  |  |  | √ | By signing this consent form I agree that:• This study has been explained to me and any questions I had have been answered.I know that I may leave the study at any time. I agree to take part in this study. • I know that my participation is voluntary and that I may leave the study at any time.• I understand the requirements of participating in this research study• 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• [if applicable] I understand that my family doctor may be informed of my participation in this research study• [if applicable] I understand that participation in this research study will be documented in my medical records. |
|  |  |  | √ | [ ]  I **agree** to be informed of any incidental findings learned as a result of my {type of sample} being tested[ ]  I **do not agree** to be informed of any incidental findings learned as a result of my {type of sample} being tested |
|  |  |  |  | [ ]  I **agree** to notify my family doctor about my participation in this research study[ ]  I **do not agree** to notify my family doctor about my participation in this research study |
|  |  | 4.8.8 |  | Signature and date of signature of the participant (or their substitute decision-maker/legally authorized representative, if applicable) |
| 1. 5
 |  | 4.8.8 |  | Signature and date of the person obtaining consent |
|  | 4.1 | 4.8.9 |  | Signature and date of person assisting in the consent discussion (if participant or their substitute decision-maker/legally authorized representative, as applicable, is unable to read or if translator is used) |