Health Sciences North
Horizon Santé-Nord

Research Services Office
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reb@hsnsudbury.ca

Health Sciences North Research Ethics Board
Informed Consent Form (ICF) Checklist

General	Yes	N/A
Appropriate logo on the first page displaying affiliations (i.e., letterhead). (HSN – all research)	☐	☐
Full study title (as it appears on the protocol and REB application). (HSN – all research)	☐	☐
Identifies the Principal Investigator (PI). (TCPS – all research)	☐	☐
Identifies the name(s) of the sponsor or granting agencies. (TCPS – all research)	☐	☐
If the study involves more than minimal risk – 24 hour emergency contact number listed. (HSN – all research)	☐	☐
Version # and date on all pages; number on all pages *Page x of y.* (HSN – all research)	☐	☐
Written consistently in second person (“You/Your”) except signature section (first person). (HSN – all research)	☐	☐
Written in a font size appropriate to the target population. (HSN – all research)	☐	☐
Suitable reading level (grade 6 to 8) in lay language. When acronyms are used, they are clearly defined at first use. (HSN – all research)	☐	☐
None of the wording is coercive or would unduly influence a person to participate or to continue to participate in the trial. (TCPS – all research)	☐	☐
The consent form does not contain any language that causes the participant or the participant's legally acceptable representative to waive or to 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. (GCP – drug, NHP, other clinical trials)	☐	☐
The consent form includes information on the measures taken to meet confidentiality obligations and explain any reasonably foreseeable disclosure requirements (TCPS – all research)	☐	☐
Introduction	**Yes**	**N/A**
A statement that the study involves research (TCPS, GCP – all research)	☐	☐
Information that the individual is being invited to participate. (TCPS – all research)	☐	☐
[If applicable] An introductory statement to the patient’s Substitute Decision Maker. (HSN – all applicable research)	☐	☐

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An assurance that participation is voluntary, prospective participants are under no obligation to participate; that participants can refuse to participate and are free to withdraw at any time without penalty or 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. (TCPS, GCP – all research)	☐	☐
For FDA and US Department of Health & Human Services (HHS) studies, a description of the consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation. (US funded trials, trials intended for submission to the FDA)	☐	☐
Why is this study being done?	**Yes**	**N/A**
A statement of the research purpose in lay language. (TCPS, GCP – all research, unless use of deception approved by the REB)	☐	☐
What will happen during this study?	**Yes**	**N/A**
The trial treatment(s) and the probability for random assignment to each treatment (if applicable). (HSN – all applicable research, unless use of deception approved by the REB Required for all GCP – drug, NHP)	☐	☐
Ensure consistency with the protocol (e.g., number of visits, inclusion/exclusion, study procedures, expected risks, etc.). (HSN – all research, unless use of deception approved by the REB)	☐	☐
How many people will take part in this study?	**Yes**	**N/A**
Approximate number of participants involved in the trial. (HSN, GCP – all research)	☐	☐
The expected duration of the entire research. (TCPS – all research)	☐	☐
The expected duration and nature of participation for the participant. (TCPS, GCP – all research)	☐	☐
What are the responsibilities of study participants?	**Yes**	**N/A**
A description of the research procedures, including all invasive procedures and those aspects of the study that are experimental. (TCPS, GCP – all research)	☐	☐
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. (TCPS – all clinical trials)	☐	☐
An explanation of the responsibilities of the participant. (TCPS, GCP – all research)	☐	☐
For phase II & III clinical trials, provide details on the access to the new drug upon trial completion. (TCPS – all phase II & III clinical trials)	☐	☐
What are the risks or harms of participating in this study?	**Yes**	**N/A**

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Description of all reasonably foreseeable risks or inconveniences, both to the participant and in general that may arise from research participation. (TCPS, GCP – all research)	☐	☐
[If applicable] any foreseeable risks to an embryo, fetus, or nursing infant. *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.* (GCP – drug, NHP, other clinical trials)	☐	☐
For FDA and HHS studies, a statement that the treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) which are currently unforeseeable. (US funded trials, trials intended for submission to the FDA)	☐	☐
What are the benefits of participating in this study?	**Yes**	**N/A**
Description of all reasonably foreseeable potential benefits, both to the participant and in general that may arise from research participation. (TCPS – all research) A statement that there is no intended clinical benefit to the participant, if applicable. (GCP – drug, NHP, other clinical trials)	☐	☐
What other choices are there?	**Yes**	**N/A**
The alternative procedure(s) or course(s) of treatment that may be available to the participant, and their important potential benefits and risks. (GCP – drug, NHP, other clinical trials)	☐	☐
A statement that the participant or the participant's legally acceptable representative will be informed, in a timely manner, if new information becomes available that may affect their willingness to continue or withdraw from participation. (TCPS, GCP – all research)	☐	☐
Can participation in this study end early?	**Yes**	**N/A**
The foreseeable circumstances and/or reasons under which the participant's participation in the research study may be terminated. (TCPS, GCP – clinical trials)	☐	☐
For FDA and HHS studies, any anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent. (US funded trials, trials intended for submission to the FDA)	☐	☐
What are the costs of participating in this study?	**Yes**	**N/A**
The anticipated expenses, if any, to the subject for participating in the trial. (GCP – drug, NHP, other clinical trials)	☐	☐
What happens if I have a research related injury?	**Yes**	**N/A**
The compensation and/or treatment available to the participant in the event of a research-related injury. (TCPS, GCP – all research)	☐	☐
A statement to the effect that, by consenting, participants have not waived any rights to legal recourse in the event of research-related harm. (TCPS – all research)	☐	☐

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Are study participants paid to participate in this study?	Yes	N/A
Information about any payments, including incentives for participants, reimbursement for participation-related expenses. (TCPS – all research) The payment schedule is prorated and not wholly contingent on completion of the trial. (GCP – drug, NHP, other clinical trials)	☐	☐
How will my information be kept confidential?	**Yes**	**N/A**
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. (TCPS – all research)	☐	☐
Confirmation that records identifying the participant will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. (GCP – drug, NHP, other clinical trials)	☐	☐
The measures to be undertaken for dissemination of research results, and whether participants will be identified directly or indirectly. (TCPS – all research) **For clinical trials**, a statement that if the results are published, the participant's identity will remain confidential. (GCP – drug, NHP, other clinical trials)	☐	☐
For clinical trials if accessing medical records, that the sponsor / funding agency monitor(s), auditor(s), REB, HSN/RI staff and the regulatory authority(ies) 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 and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access. (HSN – all applicable research GCP – similar wording to above is a requirement) **For FDA studies**, a statement that the Food and Drug Administration may inspect the records. (FDA - trials intended for submission to the FDA)	☐	☐
For FDA studies, the following statement must be included: "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." (FDA - trials intended for submission to the FDA)	☐	☐
Does(do) the investigator(s) have any conflicts of interest?	**Yes**	**N/A**

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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. (TCPS – all research)	☐	☐
If PI or study doctor will receive a fee for enrolling them in the research study, this is indicated. (HSN – all research)	☐	☐
Contact Information	**Yes**	**N/A**
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 and the rights of trial participants. (TCPS, GCP – all research)	☐	☐
The person(s) to contact for further information regarding the trial and whom to contact in the event of trial-related injury. (GCP – drug, NHP, other clinical trials)	☐	☐
The identity and contact information of a qualified designated representative who can explain scientific or scholarly aspects of the research to participants e.g. coordinator, investigator, co-investigator. (TCPS – all research)	☐	☐
Signature Page	**Yes**	**N/A**
Participant/substitute decision-maker name, signature and date. (TCPS – all research, unless exception approved GCP – drug, NHP, other clinical trials)	☐	☐
Name, signature and date of the person who conducted the informed consent discussion. (HSN – all research unless exception approved GCP – drug, NHP, other clinical trials)	☐	☐
If applicable, name, signature and date of person assisting with the consent process if applicable (only if translator / for use if participant unable to read). (GCP – drug, NHP, other clinical trials)	☐	☐
For clinical trials, a request that the investigator inform the participant's primary physician about the participation in the trial if the participant has a primary physician and agrees to the primary physician being informed. A prompt for a yes / no response. (GCP – drug, NHP, other clinical trials)	☐	☐