Health Sciences North
Horizon Santé-Nord

Research Services Office
T: 705-523-7100 ext. 2409
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Study #:

Health Sciences North Research Ethics Board Informed Consent Form (ICF) Checklist	Review		
General	**Yes**	**No**	**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)	☐	☐	☐
Sponsor's Study ID, if applicable. (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)	☐	☐	☐

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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**	**No**	**N/A**
[If applicable] An introductory statement to the patient's Substitute Decision Maker. (HSN – all applicable research)	☐	☐	☐
A statement that the study is a clinical trial, a type of study that involves research (TCPS, GCP – all research)	☐	☐	☐
Information that the individual is being invited to participate. (TCPS – all research)	☐	☐	☐
A statement about why they are being invited to participate (explain the main features of the population to which the research applies). (TCPS – all research)	☐	☐	☐
[If time permits] A statement that prospective participants should take their time making a decision about whether to participate, and a statement that study staff will inform them about timelines for decision-making. (TCPS – all research)	☐	☐	☐
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.	☐	☐	☐

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(US funded trials, trials intended for submission to the FDA)			
[If applicable] A statement that participating may impact future health care options, and an assurance that this will be discussed with them. (HSN, drug, NHP, and medical device trials – all research)	☐	☐	☐
Is there a conflict of interest?	**Yes**	**No**	**N/A**
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)	☐	☐	☐
If the recipient of funding (e.g., hospital) is receiving financial payment from the Sponsor/Funder to cover the cost of conducting the study, this is indicated. (TCPS – all research)	☐	☐	☐
What is the background information for this study?	**Yes**	**No**	**N/A**
Describe, in lay language, the standard of care for the population, and how the project/agent/device being assessed is different from the standard treatment. Each participating site must ensue the standard treatment described is consistent with the standards of care at their site. (GCP – all research)	☐	☐	☐
State whether Health Canada has approved the sale/use of the product/agent/device. (Health Canada – all regulated trials)	☐	☐	☐
Why is this study being done?	**Yes**	**No**	**N/A**
A statement of the research purpose in lay language. (TCPS, GCP – all research, unless use of deception approved by the REB)	☐	☐	☐
A description of the Phase of the study- what is currently known about the treatment, and what gaps do the current study aim to address? (HSN – all research)	☐	☐	☐

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What other choices are there?	Yes	No	N/A
A description of 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)	☐	☐	☐
An assurance that they do not have to take part in the study to receive treatment or care. (GCP – all research)	☐	☐	☐
How many people will take part in this study?	**Yes**	**No**	**N/A**
Approximate number of participants involved in the trial. (HSN, GCP – all research)	☐	☐	☐
The expected duration of the entire research, and when results are expected to be known (TCPS – all research)	☐	☐	☐
What will happen during this study?	**Yes**	**No**	**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)	☐	☐	☐
What is the study intervention?	**Yes**	**No**	**N/A**
Describe intervention by study group, including a clear identification of experimental components of the study. (GCP – all research)	☐	☐	☐
What are the responsibilities of study participant?	**Yes**	**No**	**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)	☐	☐	☐

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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)	☐	☐	☐
How long will participants be in the study?	**Yes**	**No**	**N/A**
Specify the total length of research involvement, including the duration of intervention, and follow-up schedule. TCPS – all research)	☐	☐	☐
Can participants choose to leave the study?	**Yes**	**No**	**N/A**
A statement that participants can choose to end their participation in the research (called withdrawal) at any time without providing a reason. (TCPS – all research)	☐	☐	☐
A statement that participant may withdraw their permission to use information collected about them for the study, but that this would mean withdrawing from the study. (TCPS – all research)	☐	☐	☐
Can participation in this study end early?	**Yes**	**No**	**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)	☐	☐	☐
A statement that if the participant is removed from the study, the study doctor will discuss the reasons with them, and (if applicable) plans will be made for their continued care outside of the study.	☐	☐	☐

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(GCP – all research)			
What are the risks or harms of participating in this study?	**Yes**	**No**	**N/A**
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**	**No**	**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)	☐	☐	☐
How will participant information be kept confidential?	**Yes**	**No**	**N/A**
An assurance that if the participant chooses to participate in the study, the study staff will only collect the information needed for the study. (HSN – all research)	☐	☐	☐
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	☐	☐	☐

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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)	☐	☐	☐
A statement that although the likelihood that someone may identify participants from the study data is very small, it can never be completely eliminated. (HSN – all research	☐	☐	☐
A statement indicating whether or not participants' family doctors/healthcare providers will/may be informed about their participation in the study. (GCP – all research)	☐	☐	☐
What is the cost to participants?	**Yes**	**No**	**N/A**

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The anticipated expenses, if any, to the subject for participating in the trial. (GCP – drug, NHP, other clinical trials)	☐	☐	☐
Are study participants paid to be in this study?	**Yes**	**No**	**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)	☐	☐	☐
What happens if I have a research related injury?	**Yes**	**No**	**N/A**
The compensation and/or treatment available to the participant in the event of a research-related injury. (GCP - drug, NHP, other clinical trials)	☐	☐	☐
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)	☐	☐	☐
What are the rights of participants in a research study?	**Yes**	**No**	**N/A**
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)	☐	☐	☐
Statement that participants have a right to be informed of the results once the study is complete, and a description of how to obtain the results. (TCPS – all research)	☐	☐	☐
A statement that participants' rights to privacy are legally protected by federal and provincial laws. (TCPS – all research)	☐	☐	☐
A statement that by signing the form, participants do not give up any legal rights. (TCPS – all research)	☐	☐	☐
A statement that participants will be provided with a copy of the signed and dated consent form prior to participating in the study.	☐	☐	☐

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(GCP – all research)			
What if researchers discover something about a research participant?	**Yes**	**No**	**N/A**
If incidental findings are possible, describe an anticipated management plan. (TCPS – all research)	☐	☐	☐
Whom do Participants Contact for Questions?	**Yes**	**No**	**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)	☐	☐	☐
Directs participants with questions about their rights or ethical issues related to the study to contact the HSN REB via email at: reb@hsnsudbury.ca (HSN – 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**	**No**	**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)	☐	☐	☐

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If participant samples/data may be used in sub-studies, future research, or biobanking, a separate area for them to consent to this. (TCPS – all applicable research)	☐	☐	☐
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)	☐	☐	☐