WOMEN'S COLLEGE RESEARCH INSTITUTE
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Research Ethics Board Standard Operating Policies and Procedures

Informed Consent Elements

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ISSUED BY:	Research Ethics Office		
APPROVED BY	Vice President, Research		

The WCH REO webpage version of this document is considered the most current.

Please ensure that you have reviewed all linked documents and other reference material within this SOP

1.0 POLICY STATEMENT:

This Standard Operating Procedure (SOP) describes the necessary elements for disclosure of information to make an informed decision to participate in a research study as set forth in:

1. The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2)
2. Health Canada, Food and Drugs Regulations (Division 5) including the ICH Guidance E6: Good Clinical Practice: Consolidated Guideline (ICH GCP)
3. US Department of Health and Human Services, Code of Federal Regulations (45 CFR 46)
4. US Food and Drug Administration, Code of Federal Regulations (21 CFR 50)

Free and informed consent lies at the heart of ethical research involving human research participants. The Women's College Hospital (WCH) Research Ethics Board (REB) must review all consent documents and procedures, including recruitment methods. Investigators must obtain informed consent from the potential research participant for from his/her legally acceptable representative prior to conducting any study-related procedures, unless a waiver of informed consent has been granted by the REB.

The REB must approve the Informed Consent Form (ICF) and/or other means to document informed consent before a researcher conducts any study procedures involving participants.

2.0 DEFINITION(S):

See Glossary of Terms

3.0 RESPONSIBILITY:

This SOP applies to the REB Chair, Vice-Chair, REB Members, Research Ethics Office (REO) staff and Investigators.

The Investigator is responsible for providing the REB with a detailed description of the consent documents, the consent process and recruitment methods.

The Investigator, the sponosor and Research Ethics Board (REB) are jointly responsible for ensuring that all necessary information is included so prospective participants can make an informed decision about choosing to participate and ongoing participation in a research study.

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The Investigator is responsible for ensuring and documenting that the ICF and/or other approved means is provided to prospective participants so they may make a free and informed decision according to current applicable regulations.

The REB is responsible for determining whether informed consent expemptions or waivers are appropriate.

4.0 PROCEDURES:

4.1. General Informed Consent Form Document Requirements for All Studies

a. Use language in the ICF that is as nontechnical, as practical and understandable to the participant or the participant's substitute decision maker (SDM) as ranked in the Health Care Consent Act – and the impartial witness where applicable;

b. Use a signature page that has a statement indicating that the participant discussed the information contained in the ICF with the researcher, had all questions answered, and agrees to participate in the study. The page must allow the participant (or SDM) to print his/her name, sign and date beneath this statement;

c. Use a signature page that has a statement beneath the participant's signature that the researcher discussed the ICF with the participant or the legally acceptable representative and answered all questions. The page must allow the researcher to print his/her name, sign and date beneath this statement;

d. If the participant or SDM is unable to read, use a signature page that also has a statement that the participant understands the information in the ICF and agrees to participate in the study. The page must allow the person assisting with the consent process (either an impartial witness or a translator) to print his/her name, sign, and date beneath this statement;

e. Unless otherwise approved by the REB, use the Women's College Hospital logo on both the first page of the ICF. Include the consent version date and page numbers in the footer of all pages of the consent.

4.2. Specific Informed Consent Form Documentation Requirements

For consent to be informed, prospective participants shall be given adequate time and opportunity to process the information provided, pose any questions they may have, and discuss and consider whether they will participate.

The REB will ensure that the proposed time, opportunity, and ICF provide the necessary elements and conditions for free and informed consent. Below is a list of commonly required ICF elements.

Although not all listed elements will be required for all research studies, the REB may ask the researcher to explain why omitted elements are not included for a particular project.

a. A statement indicating that the individual is **being invited** to participate in a research project;

b. A statement of the research purpose, the identity of the researcher, the identity of the funder or sponsor, the expected duration and nature of participation, the number of participants involved

at Women's College Hospital and all sites, a description of research procedures and an explanation of the responsibilities of the participant;

c. All reasonably foreseeable risks and potential benefits, both to the participants and in general, that may arise from research participation;

d. Potential benefits should be stated using moderate language, i.e. "may" rather than "will".

e. An assurance that prospective participants:

   i. are under no obligation to participate; are free to withdraw at any time without prejudice to pre-existing entitlements;

   ii. 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;

   iii. will be given information on their rights to request the withdrawal of data or human biological materials, including any limitations on the feasibility of withdrawals;

f. 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 the researchers, their institutions or the research sponsors;

g. Measures to be undertaken for the dissemination of research results and whether participants will be identified directly or indirectly;

h. The identity and contact information of a qualified designated representative who can explain scientific aspects of the research to participants;

i. The identity and contact information of the appropriate individual outside of the research team whom participants may contact regarding possible ethical concerns that arise as a result of participation in the research;

j. An indication of what information will be collected about participants and for what purpose; an indication of who will have access to information collected about the identity of participants, a description of how confidentiality will be protected, a description of the anticipated uses of data as well as data management and storage; and information indicating who may have a duty to disclose and in what context;

k. Information about payments, including incentives for participants, reimbursement for participants, reimbursement for participation-related expenses and compensation for injury;

l. A statement to the effect that, by consenting, participants have not waived any rights to legal recourse in the event of research-related harm.

1.1 Specific Documentation Requirements for Clinical Trials

A clinical trial is any investigation involving participants that evaluates the effects of one or more health-related interventions on health outcomes. The WCH Principal Investigator must register a clinical trial in

a public trials registry if the study prospectively assigns participants to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome.

A regulated clinical trial is an investigation in respect of a drug for use in humans that is intended to discover or verify the clinical, pharmacological or pharmacodynamic effects of the drug, identify any adverse events in respect of the drug, study the absorption, distribution, metabolism and excretion of the drug, or ascertain the safety or efficacy of the drug.

The ICF for a clinical trial must include the elements required for all studies (Section 3.2 above) and, in addition, the following elements:

a. The trial treatment(s) and the probability for random assignments to each treatment;

b. A description of those procedures that are investigational and those that are standard of care;

c. Information on stopping rules and when the researchers may remove participants from the trial;

d. Details on access to the new drug upon trial completion;

e. The alternative procedure(s) or course(s) of treatment that may be available to the participant, and their important potential benefits and risks;

f. For research involving more than minimal risk, an explanation as to whether compensation and/or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

g. That monitors, auditors, the WCH REB, and the regulatory authorities (where relevant) will be granted direct access to the participant's health records for verification of clinical trial procedures and/or data, without violating the confidentiality of the participant, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the participant or the participant's SDM is authorizing such access;

h. A statement indicating where applicable clinical trials will be registered and publicly accessible on the Web. For *applicable* clinical (drug) trials subject to FDA regulations, the following statement must be included on the ICF.: A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."

4.3. Specific Documentation Requirements for Research Studies Involving the Collection of Human Biological Material

The ICF for a research study that seeks consent from prospective participants to collect human biological materials must include the elements required for all studies (Section 3.2 above) and, in addition, the following elements (see Articles 12.2, 13.2 and 13.3 of the TCPS):

a. The type and amount of biological materials to be taken;

b. The manner in which the biological material will be taken, and the safety and invasiveness of the procedures for acquisition;

c. The intended uses of the biological materials including any commercial use;

d. The measures employed to protect the privacy and minimize risks to participants;

e. 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 processes for security, access and disposal, if applicable;

f. Any anticipated linkage of biological materials with information about the participants;

g. The researcher's plan for handling results and findings, including clinically actionable information and incidental findings.

h. For research involving genetic testing, researchers must develop a plan for managing information that may be revealed through research, which shall be provided to both the REB and to the prospective participants as part of the informed consent process;

i. Plans for management of genetic information revealed through testing should consider factors such as clinical relevance potential risks and benefits for participants, and families;

j. When the management plan involves notification of results to individuals, researchers should provide opportunities to both make informed choices about whether they wish to receive information about self and to express preferences re notification of biological relatives, or others with whom the participant may have a family, community or group relationship;

k. The plan for management of genetic information generated through research must also include measures for safeguarding information through its entire life cycle, including dissemination of research findings and measures in place to prevent re-identification of de-identified information;

l. Researchers must inform the REB and the prospective participants of any data-sharing requirements with funders of genetic research, and should have a plan for ensuring the protection of personal information in all aspects of data management, including publication and dissemination;

m. If the research involves banking of genetic material, this needs to be clearly indicated in the research proposal and in the consent form for prospective participants, including information addressing confidentiality, privacy, storage, use of data and results, the possibility of commercialization of findings and withdrawal by participants as well as future contact.

n. Researchers who intend to bank genetic material also must inform the REB and the prospective participants, through the consent form, about the potential for secondary use of material.

4.4. Revisions to the Informed Consent Form

The ICF must be amended whenever important new information becomes available that may be relevant to the participant's consent and willingness to continue to participate. Any revisions made to

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the approved ICF must be submitted to the REB for review and approval prior to use. Refer to REB-SOP-IV-04.001, *Amendments, Notifications, Changes in Study Personnel, Ongoing Communication Submissions Review Procedures* for amendment request submissions to the WCH REB.

5.0 REFERENCES:

1. Holland Bloorview Research Ethics Board Standard Operating Procedure - *Informed Consent Elements* (REB-701);
2. Guidance Document for Clinical Trial Sponsors: Clinical Trial Applications (Health Canada File: 13-108409-403)
3. Health Care Consent Act, 1996 (http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_96h02_e.htm
4. International Committee of Medical Journal Editors (http://www.icmje.org/publishing_10register.html)
5. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2), Articles 3.3, 11.2, 3.2, 13.2, 13.7
6. The International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice (GCP), Section 4.8, 4.8.2, 4.8.10
7. U.S. Food and Drug Administration (FDA) 21 CFR 50.25
8. US Department of Health Services (HHS) 45 Code of Federal Regulations (CFR) 46.116, 46.117
9. Women's College Hospital Research Ethics Board Standard Operating Procedure - *Amendments, Notifications, Changes in Study Personnel and Ongoing Communication Submissions Review Procedures* (SOP-IV-04.001)