Women's College Hospital Research Ethics Board
Application and Consent Form Checklist

Determinants of Community Health (DOCH)

APPLICATION FORM CHECKLIST

(*Application forms will NOT be accepted if the following items are incomplete. Please attach a copy of this checklist with the application)*

☐ **The Principal Investigator must be on staff at WCH and must be willing to take responsibility for the conduct of the study. This should be your supervisor at WCH.**

☐ **Copy of the Collaborative Institutional Training Initiative (CITI) Training https://www.citiprogram.org/**

☐ **Complete TAHSN application form with necessary signatures (*TAHSN form must be completed in your WCH supervisor's name*)**

☐ **Determinants of Community Health (DOCH) student must be listed as a Co-Investigator**

☐ **Signature of Principal Investigator (supervisor at WCH) and Co-Investigator (DOCH Student)**

☐ **Division/Department Head Approval Signature (Check with your supervisor for the appropriate leader to provide approval)**

☐ **DOCH Students must provide a secure email address (e.g. University of Toronto or WCH) under the contact section for Co-Investigators or Study Coordinators on the application form. External non-secure e-mail addresses will not be accepted (e.g. hotmail, yahoo, etc.). IMPORTANT: This email address is for YOU, not for the PI/your supervisor. The REB will get in touch with you directly, CCing the PI.**

☐ **Study Protocol** (with version date)

☐ **Include Supplementary Material (e.g. questionnaires, scales, interview scripts, focus group discussion themes, etc.) (If applicable)**

☐ **Advertisements (e.g. posters, scripts) (if applicable)**

☐ **Information letters (if applicable)**

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☐ **Informed Consent Form**

☐ **Two collated packages of the complete application form. One original and one copy (e.g. application form, consent form, questionnaires, telephone scripts etc.)**
Remember to keep a copy of your ethics submission CONSENT FORM CHECKLIST
(Refer to the REB's Sample Consent Form on the website as a guide)

☐ **WCH Letterhead**

☐ **Font 12 (larger if all elderly or visually impaired)**

☐ **Page Numbers (1 of 2)**

☐ **Version Date (spelling out the month e.g. December 1, 2007)**

☐ **Language**
- readable, define all medical terms and acronyms at first use
- grade 6 – 8 reading level
- Written in the second person

☐ **Full Title**
- exactly as on the protocol

☐ **Identify Principal Investigator and DOCH Student by name, and contact number for PI**

☐ **Introduction and Statement of Research**

☐ **Background**

☐ **Purpose**

☐ **Procedures**
- number of subjects, duration of participation
- description of procedure (e.g. explanation of physical assessment)
- clearly define what is experimental and what is standard of care (if applicable)

☐ **Risks**
- provide adequate disclosure and meaningful frequency information
- assurance that new information will be provided to the participant

☐ **Benefits**
- avoid potentially coercive statements

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☐ **Indicate Alternatives to Participation** (if applicable)

☐ **Confidentiality**
- be sure to **ask permission** for access to health records (if applicable)

☐ **Participation / Freedom to Withdraw**
- statement that participation is voluntary
- statement that patients are free to withdraw at anytime without affecting medical care

☐ **Compensation**
- WCH standard language is strongly preferred (injury or illness) (If interventional)
- information about any costs, re-imbursement, payment (and pro-rating)
- potential commercialization of research findings/conflict of interest

☐ **Questions**
- Full contact information for the Principal Investigator (for questions about the study) and the Chair of the Research Ethics Board (for questions about rights of research participants.
- Do not include home number of student. WCH contact number is mandatory.

☐ **Consent**
- Statement that subjects will receive a signed copy of the consent form.

☐ **Signatures**
- Subject and person obtaining consent

Please Note:

It is the policy of the REB that the Continuing Renewal Form and currently approved consent form be submitted one month before the expiry date of the study. REB approval for DOCH studies will expire 12 months from the initial REB approval date.

According to Tri-Council Policy Statement "The REB shall be promptly notified when the project concludes". The annual renewal and termination form can be found on the Research Ethics Board Website listed below. If the PI chooses to continue the study, it may be renewed if justified.

When submitting revisions to the REB (e.g. revised consent forms) please include a copy with tracked changes and a clean copy

Remember to change the version date on all revised documents

Please quote the REB# and WCH PI on all correspondence (e.g. emails and surface mail)

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REB approval letters will be mailed directly to the WCH PI. Please check with your supervisor for a copy of the approval letter.

References:

- Research Ethics link at: **http://www.womensresearch.ca/research-services/**
- International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. (1997). *Good Clinical Practice: Consolidated Guideline.* Minister of Health, Therapeutic Products Directorate, Health Canada.
- Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, 2010 (TCPS2) *Tri-Council Policy Statement – Ethical Conduct for Research Involving Humans.*

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