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

Continuing Review (Annual Renewal) Procedures

SOP NO:	REB-SOP-IV-05.003	**Revision Date:**	February 13, 2017
CATEGORY	Research Ethics Board	**Reviewed/Effective Date:**	February 13, 2017
SUB-CATEGORY	Section IV: Review of Research	**Original Issue Date:**	December 21, 2012
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:

The purpose of this Standard Operating Procedure (SOP) is to describe the annual renewal procedures of research overseen by the Women's College Hospital (WCH) Research Ethics Board (REB) and the criteria for continuation of WCH REB approval.

Research is subject to continuing WCH REB review from the date of the initial WCH REB approval throughout the life of the project. The approval of any study will remain valid for a 12-month period unless otherwise stipulated by the WCH REB at the time of initial approval. The level of research ethics review may be adjusted over the life of the project based on the level of risk. **The investigator must seek renewed approval for a further 12 months prior to the expiration of the current approval.** At the very least, a continuing review should consist of a completed annual status report with sufficient details to enable the WCH REB to make an informed decision about the continued ethical acceptability of the research.

The investigator cannot continue with the study after the initial approval period without applying for a renewal of WCH REB approval. Failure by the investigator to ensure timely submission of progress reports for continuing review is a serious matter that may lead to suspension or termination of the research or expiration of WCH REB approval.

If any new information is received through continuing review that might affect the rights and welfare of research participants, the WCH REB may require that the research be modified, suspended, or terminated. The WCH REB will also consider if this new information should be communicated to research participants.

2.0 DEFINITION(S):

See Glossary of Terms

3.0 RESPONSIBILTY:

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

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The REB Chair and assigned reviewers (if applicable) are responsible for conducting proportionate reviews of the progress report(s) for their assigned research studies. For research requiring continuing review at a convened REB meeting, appropriate documentation for the review will be available to the REB members.

4.0 PROCEDURES:

4.1 Continuing Review by the Convened WCH REB

4.1.1 Investigators are required to submit research progress reports using the designated WCH REB form at a frequency determined by the WCH REB at the time of initial approval or the previous Continuing Review. At a minimum, the WCH REB requires a progress report once per year until all data have been collected and contact with study participants or patient charts has concluded.

4.1.2 The deadline for investigators to submit the annual renewal applications to the Research Ethics Office (REO) is on the 1st of the month of which the study expires (e.g. if the study expires on April 25th, then the deadline for submission for that study will be April 1st). For studies that are U.S. federally funded, the research must be reviewed within no more than 30 days prior to the end of the approval period in order to retain the renewal date;

4.1.3 It is the investigator's responsibility to submit progress reports on time. To assist investigators with this responsibility, REO staff will send an initial email notice reminding investigators to submit their progress report 6 weeks prior to the end of the approval period, and will follow-up once with a reminder at 4 weeks and 2 weeks prior to the end of the approval period. If no response is received by 1-2 weeks before the end of the approval period, an additional email or phone reminder will be provided. After these 4-5 reminders, no further reminders will be provided.

4.1.4 When a clinical trial is subject to oversight by a DSMB, the DSMB report or statement will be made available to the WCH REB during the continuing review process.

4.1.5 The WCH Research Ethics Coordinator reviews the continuing review submission and may request any clarifications, or missing documents or information.

4.1.6 Continuing Reviews will be scheduled for the WCH REB meeting that occurs immediately prior to the end of the approval period, to preserve the expiry date each year. The WCH Research Ethics Coordinator adds the research study to the WCH REB meeting agenda and assigns it to the WCH REB Chair. The WCH REB Chair may assign review of the study to the original primary and secondary reviewers as well.

4.1.7 The research annual renewal application may be discussed at a convened WCH REB meeting whereby the WCH REB makes its decision regarding the approvability of the research and additional determinations regarding the conduct of the study.

4.1.8 Extensions of approval beyond the end of the approval period are not granted. Exception to this is at the discretion of the WCH REB Chair.

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4.2 Continuing Review by Delegated Review Procedures

4.2.1 Investigators are required to submit research progress reports using the designated WCH REB form at a frequency determined by the WCH REB at the time of initial approval or the previous Continuing Review. At a minimum, the WCH REB requires a progress report once per year until all data have been collected and contact with study participants or patient charts has concluded.

4.2.2 Research that was previously reviewed by a delegated review procedure is reviewed at the time of continuing review using delegated review procedures. However, if the WCH REB Chair or delegate determines that the risks are now more than minimal, the WCH REB Chair will refer the study for full board review at a convened WCH REB meeting.

4.2.3 Research that was previously reviewed by the convened WCH REB may be reviewed at the time of continuing review using delegated review procedures when there are minimal-risk changes, no changes to the previously approved research, and all of the participants enrolled in the study are in follow-up.

4.2.4 The REO staff distributes the renewal forms/progress reports to the WCH REB Chair or delegate for review.

4.2.5 The WCH REB Chair or delegate makes a decision regarding the approvability of the research and additional determinations regarding the conduct of the study.

4.3 WCH REB Determinations

4.3.1 To grant continuation of approval, the WCH REB must determine that:

- there have been no material changes to the study protocol or consent form that have not been previously submitted and approved;
- there is no conflict of interest or new information that has emerged that might adversely affect the safety or well-being of study participants;
- informed consent forms continue to be compliant with applicable guidelines, regulations, and policies.

4.3.2 The WCH REB may also make additional determinations, including:

- requiring changes to the informed consent form(s);
- requiring changes for continuing review interval (based on risks);
- imposing special precautions (e.g. frequency of monitoring, the requirement for interim reports, or duration of approval period);
- lifting or relaxing special precautions;
- requiring modifications to the research;

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- suspending or terminating WCH REB approval.

4.4 Documentation and Communication

4.4.1 Continuing WCH REB review activities will be documented, filed, and retained as per REO operational procedures.

4.4.2 WCH REB notice of continuing approval or changes required to obtain continuing approval will be distributed to investigators in a timely manner.

4.4.3 If the progress report is not received by the annual renewal deadline, the WCH Research Ethics Coordinator will send an email notification to the investigator and study contact person. This email will inform the investigator that he/she has failed to submit the annual renewal form by the annual renewal deadline. This email will also serve as a warning to the investigator, that if they fail to submit this annual renewal form before the end of the approval period, the WCH REB study file will be suspended, at which point they must cease all study activities. As well, WCH Finance will be notified to suspend the corresponding cost centre until WCH REB approval is reinstated.

4.4.4 If the study is not reviewed and approved by the WCH REB by the end of the approval period, the WCH REB Chair will be notified and will determine appropriate action. This may include suspension of study activities and enrollment. Participants already enrolled in the study should receive appropriate medical care to ensure their safety and well-being. The WCH REB Chair will decide whether prospective research data collection (except safety data) will be allowed and whether procedures that are being performed only for the purposes of the study should be undertaken until WCH REB approval is reinstated.

4.4.5 The investigator is responsible for promptly notifying the WCH REB if there is a need to continue study-related medical treatment of current study participants for their safety and well-being.

4.4.6 These activities will be documented and filed in the REO study file.

5.0 REFERENCES:

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2), Article 2.8 and 6.12;
2. The International Conference on Harmonization (ICH) Good Clinical Practices(GCP), Sections 3, 4.4, 4.5, 4.10, 4.11, 4.12;
3. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45, Parts 46.109, 46.111, 46.113, 46.115;
4. OHRP Guidance on Continuing Review
5. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Tile 21, Parts 56.108, 56.109, 56.110, 56.111, 56. 115;

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6. FDA Information Sheets: FAQ Section IV;
7. ISO 14155 Clinical investigation of medical devices for human subjects – Good Clinical Practice;
8. Sunnybrook Health Sciences Centre Research Ethics Board Standard Operating Procedure– *Continuing Review (REB Renewal)* (REB-SOP-IV-05.003)