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

Communication – Investigators and Research Staff

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CATEGORY	Research Ethics Board	**Reviewed/Effective Date:**	February 7, 2018
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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:

The purpose of this Standard Operating Procedure (SOP) is to describe the Women's College Hospital (WCH) Research Ethics Board (REB) communications with the principal investigator (PI) and his/her research staff.

In the interest of enhancing human research participant protection, it is important for the WCH REB to foster collaboration and open communication between and among the WCH REB, investigators, and research staff. This applies not only to communication related to a specific research study, but also communication related to ethical issues as well as WCH REB processes, policies, and procedures.

All investigators participating in WCH REB approved research shall be informed, in writing, of all determinations made by the WCH REB for the protocol.

2.0 DEFINITION(S):

See Glossary of Terms

3.0 RESPONSIBILITY:

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

The REB Chair or designee is responsible for overseeing all communications with investigators conducted on behalf of the REB and for the content of all review and approval letters issued on behalf of the REB.

The REO staff is responsible for drafting correspondence on behalf of the REB following a convened meeting or delegated review procedure. The REO staff is responsible for distributing the REB correspondence to appropriate parties and for day-to-day operational communication with the investigator and investigator staff.

4.0 PROCEDURES:

4.1. Notification of REB Decisions

4.1.1. The Research Ethics Office (REO) will notify the participating investigators in writing of the WCH REB's decision as soon as possible following the review of new studies, modifications to currently approved studies, or applications for continuing review.

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Research Ethics Board Standard Operating Procedures

Communication – Investigators and Research Staff

4.1.2. Notification of the WCH REB decisions regarding amendments and continuing reviews will be prioritized over new studies.

4.1.3. If the study is not approved or re-approved for continuing review, the WCH REB Chair or delegate will notify the investigator of the WCH REB's decision by telephone followed by written notice.

4.1.4. Using the Review Letter Template, the WCH Research Ethics Coordinator drafts a letter summarizing the WCH REB's decision and the reasons for not approving (when appropriate).

4.1.5. The WCH REB Chair or delegate reviews the drafted WCH REB review letter. Any proposed modifications should be documented electronically. Once the letter is finalized, the WCH REB Chair or delegate signs the letter.

4.1.6. The WCH Research Ethics Coordinator sends the WCH REB review letter to the Principal Investigator and copies any relevant research staff (e.g. research assistant, research coordinator, research manager, etc.).

4.1.7. Upon receipt of the PI response to the WCH REB review letter, the Research Ethics Coordinator will follow-up with the PI and/or his/her research staff to request any additional clarifications as required/requested by the WCH REB Chair or reviewers.

4.1.8. Once all of the WCH REB conditions are satisfied, the REO will notify the PI in writing of the final approval and the period of approval. The PI will be asked to use the unique WCH REB number assigned in any subsequent correspondence with the WCH REB for matters related to that particular study.

4.1.9. The WCH REB Chair or delegate reviews and signs the approval letter.

4.1.10. The WCH Research Ethics Coordinator sends the WCH REB approval letter to the PI and copies any relevant research staff (e.g. research assistant, research coordinator, research manager, etc.).

4.2 Other Communication with the Investigator or Research Staff

4.2.1 The REO staff will respond to queries in a timely and professional manner to encourage communication with the investigator and research staff;

4.2.2 REO communication procedures will be reviewed and modified on a continual basis for quality improvement purposes.

5.0 REFERENCES:

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2), Articles 6.18, 6.19;
2. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103, 46.109, 46.115;

WOMEN'S COLLEGE RESEARCH INSTITUTE
Health care for women | REVOLUTIONIZED

Research Ethics Board Standard Operating Procedures

Communication – Investigators and Research Staff

3. US Food and Drug Administration (FDA) CFR Title 21 Part 56.115
4. Sunnybrook Health Sciences Centre Research Ethics Board Standard Operating Procedure– *Communication: Investigators and Research Staff (*REB-SOP-VI-01.003)