IWK Research Ethics
Standard Operating Procedures

Document # **RE 4.406**	Title: **Continuing Review (REB Renewal) Process**	Effective Date: **November 19, 2024**
Pages**: 3**	Responsibility of: **Research Ethics Board**	Date Approved: **November 19, 2024**

POLICY STATEMENT

The REB will periodically review currently approved research taking place within its jurisdiction at intervals appropriate to the degree of risk to which participants are exposed, but not less often than once per year. The Chair will decide if this review should be delegated or require consideration by the full Board. In the event that an Investigator fails to provide the information necessary to such review, REB approval will be withdrawn for that project.

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

DEFINITIONS

See Glossary of Terms

RESPONSIBILITY

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

PROCEDURES

Annual/Continuing Review by the Convened REB

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

- Investigators should submit an *IWK Annual Renewal Request* Event in the ROMEO Researcher Portal 4 to 6 weeks before the study approval period ends
- It is the investigator's responsibility to submit progress reports on time. To assist

investigators in submitting annual renewal material on time, REO staff will send a reminder to the investigator 4-6 weeks before the renewal is due

- When a clinical trial is subject to oversight by a Data Safety and Monitoring Board (DSMB), or by a Sponsor's Monitor, all DSMB and Monitors' all previously unreported reports must be submitted to the Board at the time of the renewal submission to the REO.
- For studies that are multi-site, all previously unreported external adverse events (SAEs and SUSARs) must be submitted to the Board at the time of the renewal submission to the REO.
- All previously unreported minor protocol deviations must be submitted to the Board at the time of the renewal submission to the REO.
- The REO staff will make a preliminary inspection of the renewal form and other study material and may request clarification, additional documents or information before the renewal request will be presented to the Board
- Annual Renewals will be added to the agenda for the REB meeting that occurs immediately prior to the end of the approval period, to preserve the expiry date for the following year. The REB Chair will decide if this annual renewal application will be dealt with by the full Board or by delegated review
- Delegated review will usually be chosen
    - When the initial project review was also delegated
    - When the Chair deems that, although the initial review was by the full Board, there have been no significant changes in risk or other consideration since first approval

Documentation and Communication

- REO Staff will ensure that all records and associated materials relevant to annual renewal are made available to the Board or Members concerned
- A record of each annual renewal will be kept in the Project File and retained in accordance with current REO procedures (see REB SOP 3.303)
- If a requested *IWK Annual Renewal Request* Event or progress report has not been received by the end of the current approval period, the REB Chair will determine the appropriate action to take. This may include:
    - Suspension of study activities and enrolment
    - Steps to ensure participants already enrolled in the study receive appropriate medical care to ensure their continuing safety and well-being
    - Permission to continue prospective research data collection and procedures pending reinstatement of REB approval

Note: US regulations will be applied as applicable.

REFERENCES

1. Tri-Council Policy Statement: Ethical conduct for Research Involving Humans, 2018: (short name: TCPS 2), Chapter 1 Section C; Chapter 2 Section B;

2. The International Conference on Harmonization Good Clinical Practices, 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 Part 46.109, 46.111, 46.113, 46.115;
4. OHRP Guidance on Continuing Review;
5. US Food and Drug Administration (FDA) CFR Title 21 Part 56.108, 56.109, 56.110, 56.111, 56.115;

Forms/Records:

Form #	Form/Record Name
SOP 406	Continuing Review (REB Renewal) Process

Revision History:

Revision	Date	Description of changes
0.0	April 1, 2017	Initial Release
1.0	September 9, 2022	Additions to comply with TCPS2-2018
1.1	February 1, 2023	Updated logo
1.2	November 06, 2024	Clarification on safety reporting added
1.3	November 19, 2024	Updated wording, added note regarding compliance with US regulations where applicable