SOP Title:	Ongoing Review Activities		
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Approved By:	Dr. Elizabeth Stephenson		

1.0 PURPOSE

This standard operating procedure (SOP) describes the procedures for the ongoing review activities that occur after the initial Research Ethics Board (REB) approval of a research project and prior to the formally scheduled continuing review of the research project.

2.0 POLICY STATEMENT

In addition to the formally scheduled continuing review, the REB must receive and review all new information and changes (amendments, notifications, ongoing communications) generated throughout the course of the research.

The SickKids REB has adopted a proportionate approach to ethics assessment based on the general principle that the more invasive or harmful the proposed and ongoing research, the greater the care in assessing the research. Proportionate review reserves the most intensive scrutiny, and correspondingly more protection, for the most ethically challenging research.

3.0 DEFINITIONS

See Glossary of Terms

4.0 RESPONSIBILITY

All REB members, REO Personnel and Researchers are responsible for ensuring that the requirements of this SOP are met.

5.0 PROCEDURES

5.1 Submission and Review

5.1.1 Prior to implementation of any changes to SickKids REB approved research, investigators must notify the REB of any new information and changes to the approved protocol and associated study documents using the Amendment application form in the eREB and receive approval of that application.

5.1.2 Any changes in research staff (e.g. addition of co-investigators, change in research assistants, new investigator covering the principal investigator (PI) temporarily for a leave, etc.) must be documented to the REB using the Staff Change application form in the eREB.

5.1.3 The REB Chair or designee reviews the new information to determine the appropriate level of REB review required (i.e., Full Board or delegated review);

5.1.4 For amendments requiring Full Board review, the responsible REO Personnel assigns the amendment to the next available Full Board meeting. For amendments that meet the criteria for delegated review, the responsible REO Personnel will forward the amendment to the designated reviewer;

5.1.5 The Chair or delegate has the authority to direct any delegated review request to the full board for review;

5.1.6 The following types of amendments for previously approved studies may be referred to the Full Board for review:

- Addition of genetic testing, new genetic tests, or tissue banking where genetic testing may, or will be performed;
- Addition of an open label extension phase following a randomized trial;
- Emergency amendments that arise because of participant safety concerns that are submitted after implementation, and:
- Significant changes to a protocol that may affect participant safety and may include (but are not limited to) a:
    - Change in drug dosing/duration of exposure
    - Decrease in monitoring
    - Change in recruitment technique that may affect confidentiality or the perception of Coercion
    - Change in experimental procedure or study population
- Any amendment that requires approval from Health Canada
    - Amendments to the protocol that affect the selection, monitoring, or dismissal of a clinical trial participant
    - Amendments to the protocol that affect the evaluation of the clinical efficacy of the drug
    - Amendments to the protocol that alter the risk to the health of a clinical trial participant
    - Amendments to the protocol that affect the safety evaluation of the drug
    - Amendments to the protocol that extend the duration of the clinical trial
    - Amendments to the chemistry and manufacturing information that may affect the safety or quality of the drug

5.1.7 For studies that are funded or supported by the US Federal government or that are subject to the regulations of the US Food and Drug administration, only minor changes that do not affect risk level in previously approved research may be reviewed by the REB under delegated review procedures.

5.1.8 When the amendment includes a change to the consent form, the Researcher must indicate their plan for the provision of the new information to current and/or past research participants;

5.1.9 The Researcher must indicate the type of review being requested (i.e., Full Board, delegated review). Supporting correspondence documentation and/or background information may be appended to the amendment submission;

5.1.10 The REB Chair or designee also may use delegated review procedures for review of amendments when the conditions are met;

5.1.11 The REB must find that the criteria for approval are still met in order to approve the amendment, notification, ongoing communication;

5.1.12 Modifications to the approved research may not be initiated without prior REB review and approval except where necessary to eliminate apparent immediate hazards to human participants. If changes are to eliminate immediate hazards, the researcher must notify the REB immediately.

5.2 Documentation and Communication

5.2.1 REB review activities will be documented, and retained per REO operational procedures;

5.2.2 Research Ethics Board notice of approval or changes required to obtain continuing approval will be distributed to the Researcher in a timely manner.

6.0 REFERENCES

See References