fraserhealth	**RESEARCH ETHICS BOARD** **STANDARD OPERATING PROCEDURES**	
	SOP Number	405
	Continuing Review	
	Date of Issue **Date of Revision**	2005 12 28 2018 03 30 2022 07 13

Purpose: This standard operating procedure (SOP) describes the procedures for the continuing review of research that is overseen by the Research Ethics Board (REB), and the criteria for continued REB approval.

Reference: 2019 10 08 CAREB SOP 404.003

Responsibility: All REB members and REB Office Personnel are responsible for ensuring that that requirements of this SOP are met.

The REB Chair or designee and the assigned REB reviewer are responsible for conducting an in-depth review of all submitted materials for their assigned research projects.

All other REB members are responsible for reviewing the submitted materials for each research application in enough depth to be prepared to discuss the research meaningfully at a Full Board meeting.

Procedure

The REB conducts continuing review of approved research involving human participants at intervals appropriate to the degree of risk to which participants are exposed, but not less than once a year. The REB makes the determination concerning the duration of the approval period and the interval by which continuing review must occur at the time of initial review and approval.

1.0 Continuing Review by the Full Board

1.1 The Researcher is required to submit an application for continuing review (i.e., renewal) of research at a frequency to be determined by the REB and which will be defined at the time of the initial approval of the research, or as otherwise revised;

1.2 At a minimum, the REB requires that an application for continuing review be submitted once per year until all of the data has been collected, all contact with research participants has concluded and the closure of the research has been acknowledged by the REB;

1.3 The REB may determine that the research requires continuing review more frequently than once per year by considering the following:

- The nature of any risks posed by the research,
- The degree of uncertainty regarding the risks involved,
- The vulnerability of the participant population,
- Whether the research involves novel interventions,
- The REB believes that more frequent review is required;

1.4 Continuing review applications are due by the deadline for the applicable REB meeting (i.e., the expiry date must be on or after the REB meeting date and prior to the date of the subsequent REB meeting, regardless of the type of review they may undergo;

1.5 To assist the Researchers in submitting on a time, a courtesy reminder prior to the expiry date is generated at least one month prior to the expiry date;

1.6 The responsible REB Office Personnel reviews the application for completeness, and requests any clarifications, missing documents or other information from the Researcher, as applicable;

1.7 The REB may request verification from sources other than the Researcher that no material changes have occurred since the previous REB review. For example:

- Based on the results of a previous audit or inspection (internal or external),
- Suspected non-compliance,
- Studies involving vulnerable populations,
- Studies involving a potentially high risk to participants,
- Suspected or reported protocol deviations,
- Participant or Research Staff complaints,
- Any other situation that the REB deems appropriate;

1.8 The responsible REB Office Personnel will assign the application to the agenda of the next REB meeting if the research meets the criteria for Full Board review;

1.9 A summary report of the continuing review applications assigned to the REB meeting may be attached to the REB meeting agenda;

1.10 For research that meets the criteria for Full Board review, the REB will discuss the research at a Full Board meeting and will make a decision regarding the continued approval of the research, as well as any other determinations regarding the conduct of the research, as applicable;

1.11 Continuing review of studies funded by the U.S. Federal Government or regulated by the U.S. Food and Drug Administration must be reviewed by the Full Board unless they clearly meet the following criteria:

- The research is (i) permanently closed to the enrollment of new participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow up of participants, OR
- Where no participants have been enrolled and no additional risks have been identified, OR
- Where the remaining research activities are limited to data analysis;

Continuing review of studies funded by the U.S. Federal Government or regulated by the U.S. Food and Drug Administration that meet the above criteria may be reviewed via delegated review by the REB Chair.

1.12 The REB Chair or designee can put a request forward for continuing review by the Full Board at any time;

1.13 Annual renewals will be reviewed by the Full Board if required by the study Sponsor, Funding Agency, or Regulatory Agency;

2.0 Continuing Review by Delegated Review Procedures

2.1 When the research received initial approval via delegated review it may undergo delegated review at the time of continuing review;

2.2 Research that was previously reviewed by the Full Board may also be reviewed at the time of continuing review using delegated review procedures if the conditions are met;

2.3 The responsible REB Office Personnel reviews the continuing review application for completeness, including verification of the currently approved informed consent form(s), and requests any clarifications, missing documents or other information as applicable;

2.4 The responsible REB Office Personnel will forward the application to the appropriate REB reviewer;

2.5 The reviewer may request additional information or clarification, as necessary, and will make a decision regarding the continued approval of the research and the continued conduct of the research;

2.6 Upon reviewing an application that was sent for delegated review, if the reviewer determines that the risks are now greater than minimal, the reviewer will refer the application for review by the Full Board.

3.0 REB Determinations

3.1 To grant a continuation of the approval of the research the REB must determine that:

- There have been no material changes to the research or to the informed consent that have not been previously submitted and approved,
- There is no new conflict of interest or new information that has emerged that might adversely affect the safety or the well-being of research participants,
- Risks to research participants are minimized and reasonable in relation to the anticipated benefits,
- Selection of research participants is equitable,
- Informed consent processes continue to be appropriate and documented,
- Adequate provisions are in place for monitoring and data protection to ensure the safety and privacy of participants and confidentiality and integrity of the data,
- Where applicable, the reports of Data Safety Monitoring Boards and Sponsor-generated Safety Reports are favourable for continuation of the study,
- There is no new information which might affect the willingness of the study participants to participate,
- Any complaints from research participants have been followed-up appropriately;

3.2 The REB may also make additional determinations, including:
- Request changes to the informed consent form(s),
- Request changes for the continuing review interval (based on risks),
- Impose special precautions (e.g., frequency of monitoring, the requirement for interim reports or duration of approval period),
- Require modifications to the research,
- Suspend or terminate REB approval.

4.0 Required Information and Documentation

4.1 The following information and documentation is required to be included with continuing review submissions:
- An assessment of whether the annual renewal qualifies for delegated review based upon the delegated review criteria for the applicable REB,
- Whether or not the study involves enrollment of human participants,
- Whether or not the study is currently open to enrollment, or will be open in the future for enrollment. If so, the consent and/or assent form(s) must be current,
- The number of participants enrolled at institutions covered by the REB approval certificate,
- The enrollment goal,
- The number of participants who discontinued their participation; and a summary of the reasons for the withdrawals if known,
- A summary of the progress of the study including any summary reports,
- A summary of the impact of all unanticipated problems, including serious or unexpected adverse events either observed throughout the study period or submitted to the Principal Investigator by the Sponsor for other sites in multi-centre trials,

- Whether there are any outstanding actions that the REB has requested the Investigator to take with regard to an unanticipated problem, SAE or safety letter, and if so, an explanation why these actions are outstanding,
- A summary of recent findings and new information, including changes in the Investigator's situation or qualifications,
- Based on the information provided, an opinion on whether any changes should be made to the protocol or the consent form,
- A summary of any monitoring that took place, including any reports from any third party observations of the research carried out under U.S. Federal Regulations,
- Any changes in conflict of interest since the last approval,
- A summary of any complaints about the research from participants or others since the last REB review,
- if the study has expired, a written explanation for the late renewal and confirmation by the Researcher that NO study related actions took place during the time over which there was no valid ethics approval,
- Additional comments and information or documents, including reports from DSMBs or DMCs that are available.

5.0 Continuing Review Applications not Received by the Expiry Date

5.1 If an application for continuing review is not submitted with all required information by the expiry date, a warning or suspension notice will be issued to the Researcher. When suspended, the Researcher must suspend all research activities as specified by the REB. The responsible REB Office Personnel will follow-up with the Researcher to ensure that the application for continuing review is submitted as soon as possible;

5.2 In the event of a lapse in approval, the Researcher is responsible for notifying the REB if there is a need to continue research-related medical treatment of current research participants for their safety and well-being. The Researcher should provide as much detail as possible about the proposed continued activities. The REB Chair or designee will review the request as quickly as possible and discuss the proposed continued activities with the Researcher;

5.3 The Researcher must document the reasons for the lapse and identify steps taken to prevent future lapses;

5.4 If the REB approval lapses and the Researcher wants to continue with the research, the REB will complete the review of the research as soon as possible and the Researcher may resume the suspended activities once approval of the research has been issued. The lapse in approval will be documented;

5.5 The responsible REB Office Personnel in consultation with the REB Chair is fully authorized to do one or more of the following as deemed appropriate:
- Hold the review or approval of current or future submissions by the Principal Investigator until the status of the expired study has been addressed,
- Notify the funding agency, industry sponsor or the appropriate regulatory authority of the expiry of the ethics approval for the study,

- Notify financial accounts personnel to advise them that the study is no longer approved and that no further funds from the account should be released,
- Terminate the study.

6.0 U.S. Federally Funded Research

6.1 Studies that are funded or supported by the U.S federal government are considered open and subject to annual review requirements until a research project no longer involves human participants, as defined by the Office of Human Research Protections (OHRP). OHRP considers a research project to no longer involve human participants when investigators have finished obtaining data through interaction or intervention with participants or obtaining identifiable private information about the participants which includes the using, studying, or analyzing identifiable private information (including identifiable tissue).