SOP Title:	Continuing Review – Study Renewal		
SOP #:	IV.07.001	Original Issue Date:	February 23, 2015
Category:	REB Review of Research	Reviewed/Effective Date:	October 1, 2019
Issued by:	Research Ethics Office (REO)	Revision Date:	October 1, 2019
Approved By:	Dr. Elizabeth Stephenson		

1.0 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.

2.0 POLICY STATEMENT

REBs must establish procedures for conducting the continuing review of approved research involving human participants at intervals appropriate to the degree of risk, but not less than once a year. Periodic review of research activities is necessary to determine whether approval should be continued or withdrawn.

3.0 DEFINITIONS

See Glossary of Terms

4.0 RESPONSIBILITY

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

5.0 PROCEDURES

5.1 Criteria for determining which projects require review more than annually

5.1.1 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;

5.1.2 The REB will require continuing review progress reports on an annual basis unless they designate otherwise. The REB considers the following when determining which projects require review more often than annually and in determining the appropriate interval for progress reporting:

- The nature of any risks posed by the research project;

- The degree of uncertainty regarding the risks involved;
- The vulnerability of the participant population;
- The experience of the investigators in conducting research;
- There have been previously confirmed instances of serious or continuing non-compliance with the researcher;
- The projected rate of enrollment; and
- Whether the research project involves novel interventions.

5.2 Continuing Review by the Full Board

5.2.1 Continuing review applications are due by the application deadline for the applicable Full Board meeting (i.e., the expiry date must be on or before the Full Board meeting date), regardless of the type of review they may undergo;

5.2.2 To assist the Researchers in submitting on time, a courtesy reminder(s) prior to the expiry date may be generated;

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

5.2.4 The REB may request verification from sources other than the investigator that no material changes have occurred since 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;

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

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

5.2.7 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 additional determinations regarding the conduct of the research, as applicable.

5.2.8 Renewal of studies funded by the US Federal Government or regulated by the US Food and Drug Administration must be reviewed by the fully convened 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.

5.3 Continuing Review by Delegated Review Procedures

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

5.3.2 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 in 5.2.8 are met;

5.3.3 The responsible REO 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;

5.3.4 The responsible REO Personnel will forward the application to the REB Chair or designee;

5.3.5 The REB Chair or designee 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;

5.3.6 Upon reviewing an application that was sent for delegated review, if the REB Chair or designee determines that the risks are now greater than minimal, they will refer the application for review by the Full Board.

5.4 REB Determinations

5.4.1 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 form 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,
- Any complaints from research participants have been followed-up appropriately;

5.4.2 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.

5.5 Continuing Review Applications not Received by the Expiry Date

5.5.1 There is no grace period extending the conduct of the research beyond the expiration date of REB approval.

5.5.2 Extensions beyond the expiration date will not be granted. If continuing review reports/renewals are not submitted as scheduled, the study approval will be considered expired.

5.5.3 In the event of an expiry 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;

5.5.4 The REB will evaluate the Researcher's reasons for the lapse and identify the steps taken to prevent future expirations;

5.5.5 If the REB approval expires 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 expiry in approval will be documented.

5.5.6 The REB Manager in consultation with the 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 Researcher or their Department 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.

6.0 REFERENCES

See References