



<b>SOP Title</b>	<b>Continuing Review</b>
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### Approvals

<b>Name and Title of Signatories</b>	<b>Signature</b>	<b>Date mm/dd/yyyy</b>
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### 1. PURPOSE

This Standard Operating Procedure (SOP) describes the procedures for the continuing review of research that has been approved by the HSREB and is overseen by the Health Sciences Research Ethics Board (HSREB) and the criteria for continued HSREB review.

### 2. GENERAL POLICY STATEMENT

Research involving human participants is subject to continuing review from the date of the initial REB approval throughout the life of the study. The Research Ethics Board must establish procedures for conducting the continuing review of approved research studies, at intervals appropriate to the degree of risk, but not less than once a year. For multiyear research studies, a Continuing Ethics Review (CER) Form must be submitted on an annual basis. For studies lasting less than one year, an End of Study Report Form must be submitted. Periodic review of research activities is necessary to determine whether approval should be continued or withdrawn.

### 3. RESPONSIBILITY

This SOP is applicable to the Office of Human Research Ethics (OHRE), HSREB Chair, Vice-Chair(s) and HSREB members.

The HSREB Chair, Vice-Chair(s) and assigned HSREB members are responsible for conducting an in-depth review of all progress reports for their assigned research projects. For research studies requiring review at a convened HSREB meeting, appropriate documentation for the review will be available to all HSREB members

### 4. DEFINITIONS

See Glossary of Terms

### 5. SPECIFIC POLICIES AND PROCEDURES.

#### 5.1. Continuing Review by the Full Board

5.1.1. Investigators are required to submit an application for continuing review using the CER Form at a frequency determined by the HSREB at the time of initial approval but not less than once per year;

5.1.2. The OHRE must review the CER form, at a minimum, once per year until all data have been collected, contact with study participants or patient charts has concluded and an End of Study Report has been acknowledged by the OHRE;

5.1.3. The OHRE 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 study,
- The degree of uncertainty regarding the risks involved,
- The vulnerability of the participant population,
- The experience of the Investigators in conducting research,
- The REBs previous history with the investigators,
- The projected rate of enrollment; and estimated study closure date,
- Whether the research study involves novel interventions;

5.1.4. It is the Investigator's responsibility to submit the CER form on time. To assist the Investigators, the OHRE staff will send a courtesy reminder at different time points prior to the expiry date. Should an Investigator fail to submit the CER form despite the reminder/follow-up notifications, a notice that REB approval has expired will be issued and the study will be suspended. If the CER form is still not submitted within 2 weeks of the study expiry date the REB may close the file and Investigators will be required to submit a new study. If the CER form is submitted after the expiry date but before file closure this will result in a lapse in REB approval. The OHRE may also elect to pursue investigations for serious or continuing non-compliance.

5.1.5. Once the CER form is submitted, the Ethics Officer (EO) reviews the application for completeness and may request any clarifications, or missing documents or information, if applicable.

5.1.6. 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;

5.1.7. The EO will assign the application to the agenda of the next applicable HSREB meeting;

5.1.8. The HSREB will discuss the research study and make a decision regarding the continued approval of the research as well as any additional determinations regarding the conduct of the research study, if applicable.

## **5.2. Continuing Review by Delegated Review**

5.2.1. Research that was previously reviewed by delegated review procedures may be reviewed at the time of continuing review using delegated review procedures. However, if the HSREB Chair, or designee, determines that the risks are now more than minimal, the HSREB Chair, or designee, will refer the study for Full Board review at a convened HSREB meeting. The HSREB will discuss the research at a convened 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;

- 5.2.2. Research that was previously reviewed by the Full Board may also be reviewed at the time of continuing review using delegated review procedures when there are minimal risk changes;
- 5.2.3. The EO reviews the continuing review application for completeness, including verification of the currently approved Letter(s) of Information, and may request any clarifications, or missing documents or information, if applicable;
- 5.2.4. The EO distributes the renewal progress reports to the HSREB Chair, or designee, for review;
- 5.2.5. The HSREB Chair, or designee, will make a decision regarding the continued approval of the research study.

### **5.3. HSREB Determinations**

5.3.1. For continuation of approval to be issued, the HSREB must determine that:

- There have been no material changes to the study protocol or Letter(s) of Information/Consent that have not been previously submitted and approved,
- There is no conflict of interest or new information that has emerged that might adversely affect the safety or well-being of study participants,
- Risks to research participants are minimized and reasonable in relation to the anticipated benefits,
- Letter(s) of Information continue to be compliant with applicable guidelines, regulations and policies;

5.3.2. The HSREB may also make additional determinations, including:

- Requiring changes to the Letter(s) of Information,
- Requiring changes for the continuing review interval (based on risks),
- Imposing special precautions (e.g., frequency of monitoring, the requirement, for interim reports or duration of approval period),
- Lifting or relaxing special precautions,
- Requiring modifications to the research,
- Suspending or terminating REB approval;

### **5.4. Continuing Ethics Review not Received by the Expiry of the Continuing Ethics Review Period**

- 5.4.1. If the CER form for continuing review is not submitted by the expiry date, a warning or suspension notice will be issued to the Investigator. When suspended, the Investigator must suspend all study related activities as specified by the REB. The responsible REB Office Personnel will follow-up with the Investigator to ensure that the application for continuing review is submitted as soon as possible;
- 5.4.2. In the event of a lapse in approval, it is the Investigators responsibility to promptly notify the OHRE if there is safety related needs that require study participants to continue to receive study related treatments/procedures. The HSREB Chair or designee will review the request as quickly as possible and discuss the proposed continued activities with the Investigator;
- 5.4.3. The Investigator must document the reasons for the lapse and identify the steps taken to prevent future lapses. These activities will be documented and filed;

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

## 6. References

- 6.1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2010 (TCPS2); Article 2.8 and 6.12;
- 6.2. The International Conference on Harmonization Good Clinical Practices, Sections 3, 4.4, 4.5, 4.10, 4.11, 4.12;
- 6.3. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.109, 46.111, 46.113, 46.115;
- 6.4. OHRP Guidance on Continuing Review;
- 6.5. US Food and Drug Administration (FDA) CFR Title 21 Part 56.102, 56.108, 56.109, 56.110, 56.111, 56.115;
- 6.6. FDA Information Sheets: FAQ Section IV.

## 7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
406.001	Original	01/20/2014
406.002	Erika Basile's position updated Minor administrative corrections for clarity	05/22/2014
406.003	Minor administrative changes for clarification	06/09/2014
406.004	Minor administrative changes for clarification	07/29/2014
406.005	Changes to 5.4.1 and 5.4.2	10/24/2014
406.006	Revisions to section 5 for clarification	11/13/2014
406.007	Minor administrative corrections for clarity	05/10/2016