

SOP Title:	Determination of Study Approval and Expiry Dates		
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Approved By:	Dr. Elizabeth Stephenson		

1.0 PURPOSE

This standard operating procedure (SOP) describes the how the study approval date, the study expiry date, and subsequently the study approval period are determined.

2.0 POLICY STATEMENT

The approval date and approval period of a study, whether during initial or continuing review, are determined by the REB. The assignment of the expiration date is based upon the type of review and the determination of approval period.

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 Assignment of Study Approval Dates

- 5.1.1 When a research study (or continuing review application) is approved without modifications required at a convened meeting, the date of the convened meeting is the date of REB approval.
- 5.1.2 When the research study (or continuing review application) is approved pending modifications at a convened meeting, the date of REB approval is the date that the requested changes are verified and approved by the Chair, or their designee.
- 5.1.3 When a research study (or continuing review application) is reviewed and approved through a delegated review process, the date that approval is given by the Chair, or their designee is the date of REB approval.

5.2 Length of Approval Period

- 5.2.1 The REB shall review research studies appropriate to the degree of risk, but not less than once a year;

- 5.2.2 The REB may require review more often than annually when there is a high degree of risk to participants relative to the population;
- 5.2.3 The REB may consider review of research more often than annually when any of the following are true:
- Proposed procedures have not been used in humans;
 - The stage of the research is such that many of the risks are unknown;
 - More than minimal risk exists to vulnerable populations with no prospect of direct benefit;
 - There have been previously confirmed instances of serious or continuing non-compliance with the researcher;
 - The REB believes that more frequent review is required.

5.3 Assignment of Study Expiration Dates

5.3.1 The approval period expires at 11:59 p.m. on the date of expiry.

5.3.2 Initial Applications:

- For research reviewed and approved without modifications at a convened board meeting, the expiration date will be on the same calendar day one year from the approval date of the full board decision letter. For example, if the committee meeting date is 10/17/2010, then the date of REB expiration is 10/17/2011 for a one year approval, or 4/17/2011 for a six month approval.
- For research reviewed and approved pending modifications at a convened board meeting, the expiration date will be one calendar year from the date that the Chair, or their designee verifies the requested changes and grants final approval. For example, if the committee approves a research study pending modifications on 10/17/2010 and the responses are verified by the Chair, or their designee on 11/20/2010, then the date of REB approval is 11/20/2010 and the expiration is 11/20/2011 for a one year approval, or 5/20/2011 for a six month approval.
- For research reviewed using the delegated review process, the expiration date will be on the same calendar day one year from the date that the Chair, or their designee verifies any requested changes and grants final approval. For example, if the Chair, or their designee grants approval on 10/17/2010, then the date of REB expiration is 10/17/2011 for one year approval, or 4/17/2011 for a six month approval.

5.3.3 Continuing Review Submissions

5.3.3.1 Review of a change in a protocol (i.e. modification or amendment) does not alter the expiry date by which continuing review (renewal) must occur because continuing review is review of the full protocol, not simply a change to it.

5.3.3.2 Renewal Applications:

- For research studies where the renewal is reviewed and approved at a convened meeting or by the Chair, or their designee before the current date of expiry (i.e., an approved study), the new expiration date will be on the same calendar day one year from the previous expiry date. For example, if a study expired on 10/17/2011 and the

renewal was reviewed and approved on 10/17/2011, the new expiry date is 10/17/2012.

- For research studies where the renewal is reviewed and approved at a convened meeting or by the Chair, or their designee after the current date of expiry (i.e., an expired study), the new expiration date will be on the same calendar day one year from the previous expiry date. For example, if a study expired on 10/17/2011 and the renewal was reviewed and approved on 10/20/2011, the new expiry date is 10/17/2012. The lapse in approval due to the expiration of the study and the dates of the lapsed approval are documented in the REB study file. The investigator will be asked to provide the REB with an action plan to prevent any future lapses in approval.

6.0 REFERENCES

See References