

Issuing Department: Human Subjects Protection Program
Policy Number: 2011-009.10
Policy Title: Institutional Review Board – More Frequent Review

Purpose

The purpose of this policy is to set forth circumstances under which the IRB may require continuing review more frequent than annually.

Definitions

See policy 2011-007.0 for definitions of:

Noncompliance, Serious | Noncompliance, Continuing | IRB Approval

Policy

The IRB may require that continuing review occur more often than annually in the following circumstances:

- The research involves the use of procedures that have not been studied in humans.
- The research is expected to result in a high frequency of morbidity or mortality.
- The investigator has a history of serious or continuing non-compliance that the IRB believes necessitates closer monitoring.
- Any other situation in which the IRB believes that more frequent continuing review is warranted.
- If none of the above applies and the research is undergoing initial review by the convened IRB, the review interval noted on Appendix A will apply unless specifically stated otherwise at a meeting. If the IRB approves research with conditions, the date of approval is the date the conditions were determined to be met. A similar review interval will be implemented for any additional IRB panels established. For studies requiring continuing review by the convened board the IRB will maintain the anniversary date by which continuing review must occur providing the PI requests continuing review at the designated meeting.
- If none of the above applies and the research is undergoing continuing review by the convened IRB after the research approval has lapsed, if approval is re-instated, the study will be approved through the original valid through date. For example, if a study valid through June 10, 2011 did not undergo continuing review on May 16, 2011, but rather obtained continuing review and approval on June 20, 2011, there would be a lapse in approval from June 11th through June 19th during which all research related activity must stop (unless otherwise approved by the IRB due to it being in the best interest of subjects). Once review and approval by the IRB was granted, the study would be assigned an approval period of June 20, 2011 – June 10, 2012 with continuing review required at the meeting convened in May 2012, the 11th month of the cycle.
- A request for continuation requiring review by the convened board that is submitted early will be placed on the agenda of the next regularly scheduled IRB meeting. If reviewed early, the approval period by which subsequent continuing review must occur will be adjusted accordingly such that it occurs within one year of the convened meeting date. For example, a study that was scheduled to be reviewed at the September 26, 2011 meeting is submitted early and the PI requests review at the August 22, 2011 meeting. The PI addresses contingencies and final approval is granted on August 30, 2011. The approval period will be from August 30, 2011 – August 14, 2012, with continuing review occurring at the July 2012 meeting.

- Requests for initial or continuing review for expedited studies will be processed as received. Anniversary dates are not maintained for expedited reviews. If continuing expedited review is required, the review interval may be shorter than 365 days when there are administrative issues (e.g., completion of training) that remain outstanding after the reviewer has completed the final review. For example, if the Chair reviews the contents of a submission on April 1st and has no concerns with the study, but training for one investigator is not completed until April 15th; the date of final IRB approval will be April 15th but the study, which requires continuing review, will only be valid through March 31st of the following year.
- If a study is reviewed by another panel as opposed to the panel to which it was originally assigned, e.g., to prevent a lapse in approval that is not due to the investigator's failure to request continuation but due to loss of quorum at a previous IRB meeting, the original review cycle will be retained, i.e., it will be based off of the assigned panels review cycle.

Each year the IRB staff will publish submission deadlines for studies requiring review by the convened board.

Procedure

Full Board:

The primary reviewers of a study will suggest the review interval for a study at a convened IRB meeting as prompted by the IRB reviewer sheet.

The majority vote of those members present will determine the review cycles.

Designated IRB staff will document the review cycle in the IRB minutes and in the electronic IRB system.

Designated IRB staff will use the information in the system to generate the correspondence to the investigator (e.g., the standard approval letter) that reflects the approval interval.

Expedited:

The expedited reviewer will complete and date the reviewer form. When the reviewer has no concerns with the content of the submission, and if there are no administrative issues to be addressed, this date will reflect the date of final IRB approval and the IRB staff will enter it into the IRB system with a review cycle of 365 days from this date, unless otherwise stipulated by the reviewer.

If there are administrative issues (i.e., issues not affecting content) that must be addressed, such administrative issues do not require additional review by the assigned reviewer. Designated IRB staff will track when the issues are addressed and use that date as the date of final IRB approval. The review cycle however will be based on the date that the reviewer completed the review of the content; i.e. the review cycle may be shorter than 365 days.

Designated IRB staff will use the information in the system to generate the correspondence to the investigator (e.g., the standard approval letter) that reflects the approval interval.

Related Policies

2011-007.0 – Definitions Applied to Policies
2011-009.4 – Institutional Review Board – Convened meeting Operations
2011-009.3 – Institutional Review Board – Expedited Reviews
2011-009.5 – Institutional Review Board – Review by Convened Board

Basis

45 CFR 46
21 CFR 56

Document Attributes:

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Reviewed and Approved By:

Richard H. Simon

07/20/2023

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Date

Director, Human Subjects Protection Program

Appendix A
IRB Initial Approval Intervals Based on Final Approval Date

Panel 1			Panel 2		
Initial Final Approval Date Range	Valid Through Date	Continuing Review Meeting Date	Initial Final Approval Date Range	Valid Through Date	Continuing Review Meeting Date
Jan 26 – Feb 25	25 th Jan	1 st Mon. Jan.	Jan 11 – Feb 10	10 th Jan	3 rd Mon. Dec.
Feb 26 – Mar 25	25 th Feb	1 st Mon. Feb.	Feb 11 – Mar 10	10 th Feb	3 rd Mon. Jan.
Mar 26 – Apr 25	25 th Mar	1 st Mon. Mar.	Mar 11 – Apr 10	10 th Mar	3 rd Mon. Feb.
Apr 26 – May 25	25 th Apr	1 st Mon. Apr.	Apr 11 – May 10	10 th Apr	3 rd Mon. Mar.
May 26 – Jun 25	25 th May	1 st Mon. May	May 11 – Jun 10	10 th May	3 rd Mon. Apr.
Jun 26 – Jul 25	25 th Jun	1 st Mon. Jun.	Jun 11 – Jul 10	10 th Jun	3 rd Mon. May.
Jul 26 – Aug 25	25 th Jul	1 st Mon. Jul.	Jul 11 – Aug 10	10 th Jul	3 rd Mon. Jun.
Aug 26 – Sep 25	25 th Aug	1 st Mon. Aug.	Aug 11 – Sep 10	10 th Aug	3 rd Mon. Jul.
Sep 26 – Oct 25	25 th Sep	1 st Mon. Sep.	Sep 11 – Oct 10	10 th Sep	3 rd Mon. Aug.
Oct 26 – Nov 25	25 th Oct	1 st Mon. Oct.	Oct 11 – Nov 10	10 th Oct	3 rd Mon. Sep.
Nov 26 – Dec 25	25 th Nov	1 st Mon. Nov.	Nov 11 – Dec 10	10 th Nov	3 rd Mon. Oct.
Dec 26 – Jan 25	26 th Dec	1 st Mon. Dec.	Dec 11 – Jan 10	10 th Dec	3 rd Mon. Nov.

Initial Full Board Approval will always be granted by Chair / administrative review & approval of contingencies may be assigned for continuing review and/or review of modifications

Emergency Panel – First continuing review will be based on schedule above depending on which Chair convened the meeting