HRP-302 | 3/29/2024

WORKSHEET: Approval Intervals

The purpose of this worksheet is to provide support for IRB staff members who send communications after an IRB review where the letter needs to include approval and Expiration Dates. This worksheet describes how to make these calculations.[[1]](#endnote-2)

INITIAL REVIEW APPROVAL INTERVALS

|  |  |  |  |
| --- | --- | --- | --- |
| **Type of Review** | **Approval Date** | **Effective Date** | **End Approval Date** |
| Convened IRB granted approval | Date of convened IRB meeting | Date of convened IRB meeting | Date of the convened meeting plus the approval interval minus one day[[2]](#endnote-3) |
| Convened IRB required modifications to secure approval; subsequently verified by Non-Committee Review | Date of convened IRB meeting | Date the IRB Office verified that the required modifications had been made | Date of the convened meeting plus the approval interval minus one dayii |
| Designated Reviewer granted approval | Date the Designated Reviewer granted approval | Date the Designated Reviewer granted approval | APPROVAL DATE plus the approval interval minus one day or two years for exempt research.[[3]](#endnote-4) |
| Designated Reviewer required modifications to secure approval; subsequently verified by Non-Committee Review | Date the Designated Reviewer required modifications to secure approval | Date the IRB Office verified that the required modifications had been made | APPROVAL DATE plus the approval interval minus one day or two years for exempt research.iii |

CONTINUING REVIEW APPROVAL INTERVALS

|  |  |  |  |
| --- | --- | --- | --- |
| **Type of Review** | **Approval Date** | **Effective Date** | **End Approval Date** |
| Convened IRB granted approval | Date of convened IRB meeting | Date of convened IRB meeting | Date of the convened meeting plus the approval interval minus one day.[[4]](#endnote-5) |
| Convened IRB required modifications to secure approval; subsequently verified by Non-Committee Review | Date of convened IRB meeting | Date the IRB Office verified that the required modifications had been made | Date of the convened meeting plus the approval interval minus one day.iv |
| Designated Reviewer granted approval | Date the Designated Reviewer granted approval | Date the Designated Reviewer granted approval | APPROVAL DATE plus the approval interval minus one day |
| Designated Reviewer required modifications to secure approval; subsequently verified by Non-Committee Review | Date the Designated Reviewer required modifications to secure approval | Date the IRB Office verified that the required modifications had been made | APPROVAL DATE plus the approval interval minus one day |

MODIFICATIONS

|  |  |  |  |
| --- | --- | --- | --- |
| **Type of Review** | **Approval Date** | **Effective Date** | **End Approval Date** |
| Convened IRB granted approval | Date of convened IRB meeting | Date of convened IRB meeting | Previous END APPROVAL DATE[[5]](#endnote-6) |
| Convened IRB required modifications to secure approval; subsequently verified by Non-Committee Review | Date of convened IRB meeting | Date the IRB Office verified that the required modifications had been made | Previous END APPROVAL DATE v |
| Designated Reviewer granted approval | Date the Designated Reviewer granted approval | Date the Designated Reviewer granted approval | Previous END APPROVAL DATE v |
| Designated Reviewer required modifications to secure approval; subsequently verified by Non-Committee Review | Date the Designated Reviewer required modifications to secure approval | Date the IRB Office verified that the required modifications had been made | Previous END APPROVAL DATE v |

1. This document satisfies AAHRPP elements II.2.E-II.2.E.2 [↑](#endnote-ref-2)
2. For example, if the convened IRB approved research on April 15, 2007 for one year, the end date of the approval interval is April 15, 2007 + one year – one day = April 14, 2008. If the convened IRB approved research on April 15, 2007 for six months, the end date of the approval interval is April 15, 2007 + six months – one day = November 14, 2007. [↑](#endnote-ref-3)
3. Two-year effective date will be implemented July 1, 2023. Exempt research conducted under a Limited IRB review are excluded from the two-year closure requirement and, instead, annual notifications are sent. See Investigator Manual (HRP-103), “What are my obligations after receiving an Exempt determination?” [↑](#endnote-ref-4)
4. For example, if the convened IRB approved research on April 15, 2007 for one year, the end date of the approval interval is April 15, 2007 + one year – one day = April 14, 2008. If the convened IRB approved research on April 15, 2007 for six months, the end date of the approval interval is April 15, 2007 + six months – one day = November 14, 2007. [↑](#endnote-ref-5)
5. For example, if the last date of the approval interval was April 14, 2008, and the convened IRB approved a modification on November 16, 2007, the end date of the approval interval remains April 14, 2008. [↑](#endnote-ref-6)