HRP-302 | 10/23/2024

**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]](#footnote-1)

**INITIAL REVIEW APPROVAL INTERVALS**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type of Review** | **Date Approved** | **2018 Common Rule Approval Date** | **Expiration Date[[2]](#footnote-2)** | **Expedited Anniversary Date** |
| Convened IRB granted approval | Date of convened IRB meeting | 2018 Common Rule – same as date approved  \*N/A Pre-2018 | Date of the convened meeting plus the approval interval minus one day[[3]](#footnote-3) | N/A |
| Convened IRB required modifications to secure approval; subsequently verified by Non-Committee Review | Date of convened IRB meeting | 2018 Common Rule – same as date approved  \*N/A Pre-2018 | Date of the convened meeting plus the approval interval minus one day | N/A |
| Designated Reviewer granted approval | Date the Designated Reviewer granted approval | 2018 Common Rule – same as date approved  \*N/A Pre-2018 | APPROVAL DATE plus the approval interval minus one day.  \*Set 3-year approval interval for 2018 Common Rule expedited and exempt research with no CR requirement. | N/A  \*For 2018 Common Rule expedited studies with status updates only – same as expiration date |

**CONTINUING REVIEW APPROVAL INTERVALS** (when last day of approval interval is 30 days or less away from day of review)[[4]](#footnote-4)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type of Review** | **Date Approved** | **2018 Common Rule Approval Date** | **Expiration Date** | **Expedited Anniversary Date** |
| Convened IRB granted approval | Previous END APPROVAL DATE plus one day | 2018 Common Rule – date of initial approval from main study workspace  \*N/A Pre-2018 | Previous END APPROVAL DATE plus current approval interval[[5]](#footnote-5) | N/A |
| Convened IRB required modifications to secure approval; subsequently verified by Non-Committee Review | Previous END APPROVAL DATE plus one day | 2018 Common Rule – date of initial approval from main study workspace  \*N/A Pre-2018 | Previous END APPROVAL DATE plus current approval interval | N/A |
| Designated Reviewer granted approval | Previous END APPROVAL DATE plus one day | 2018 Common Rule – date of initial approval from main study workspace  \*N/A Pre-2018 | Previous END APPROVAL DATE plus current approval interval  \*N/A for exempt research | N/A  \*For 2018 Common Rule expedited studies with status updates only – same as expiration date, if applicable |

**CONTINUING REVIEW APPROVAL INTERVALS** (when last day of approval interval is greater than 30 days from day of review)[[6]](#footnote-6)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type of Review** | **Date Approved** | **2018 Common Rule Approval Date** | **Expiration Date** | **Expedited Anniversary Date** |
| Convened IRB granted approval | Date of convened IRB meeting | 2018 Common Rule – date of initial approval from main study workspace  \*N/A Pre-2018 | Date of the convened meeting plus the approval interval minus one day[[7]](#footnote-7) | N/A |
| Convened IRB required modifications to secure approval; subsequently verified by Non-Committee Review | Date of convened IRB meeting | 2018 Common Rule – date of initial approval from main study workspace  \*N/A Pre-2018 | Date of the convened meeting plus the approval interval minus one day | N/A |
| Designated Reviewer granted approval | Date the Designated Reviewer granted approval | 2018 Common Rule – date of initial approval from main study workspace  \*N/A Pre-2018 | APPROVAL DATE plus the approval interval minus one day  \*N/A for exempt research | N/A  \*For 2018 Common Rule expedited studies with status updates only – same as expiration date, if applicable |

**MODIFICATIONS**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type of Review** | **Date Approved** | **2018 Common Rule Approval Date** | **Expiration Date** | **Expedited Anniversary Date** |
| Convened IRB granted approval | Date of convened IRB meeting | 2018 Common Rule – same as previously set date from main study workspace  \*N/A Pre-2018 | Previous END APPROVAL DATE[[8]](#footnote-8) | N/A |
| Convened IRB required modifications to secure approval; subsequently verified by Non-Committee Review | Date of convened IRB meeting | 2018 Common Rule – same as previously set date from main study workspace  \*N/A Pre-2018 | Previous END APPROVAL DATE | N/A |
| Designated Reviewer granted approval | Date the Designated Reviewer granted approval | 2018 Common Rule – same as previously set date from main study workspace  \*N/A Pre-2018 | Expedited studies: 2018 Common Rule + status updates - APPROVAL DATE plus the approval interval  Expedited studies: CR required / Pre-2018 Common Rule - Previous END APPROVAL DATE  Exempt studies: Previous END APPROVAL DATE | N/A  \*For 2018 Common Rule expedited studies with status updates only – same as expiration date |

1. This document satisfies AAHRPP elements II.2.E-II.2.E.2 [↑](#footnote-ref-1)
2. Approval interval may not exceed one calendar year. [↑](#footnote-ref-2)
3. 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. [↑](#footnote-ref-3)
4. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-continuing-review-2010/index.html [↑](#footnote-ref-4)
5. 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. [↑](#footnote-ref-5)
6. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-continuing-review-2010/index.html [↑](#footnote-ref-6)
7. 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. [↑](#footnote-ref-7)
8. 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. [↑](#footnote-ref-8)