|  |
| --- |
| 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) Exempt and non-FDA regulated minimal risk research undergoing expedited review do not expire. |
| TYPE OF REVIEW | APPROVAL DATE | EFFECTIVE DATE | END APPROVAL DATE[[2]](#endnote-1) |
| Initial Review | 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[[3]](#endnote-2) |
| 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 |
| 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. None for exempt research. |
| 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 |
| Continuing <30 d | Convened IRB granted approval | Previous END APPROVAL DATE plus one day. | Previous END APPROVAL DATE plus one day | Previous END APPROVAL DATE plus current approval interval[[4]](#endnote-3) |
| Convened IRB required modifications to secure approval; subsequently verified by Non-Committee Review |
| Designated Reviewer granted approval |
| Designated Reviewer required modifications to secure approval; subsequently verified by Non-Committee Review |
| Continuing >30 d | 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[[5]](#endnote-4) |
| 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 |
| 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 |
| Modifications | Convened IRB granted approval to modifications to previously approved research. | Date of convened IRB meeting | Date of convened IRB meeting | Previous END APPROVAL DATE[[6]](#endnote-5), except no end date for exempt research. |
| Convened IRB required modifications to secure approval of modifications to previously approved research; subsequently verified by Non-Committee Review | Date of convened IRB meeting | Date the IRB Office verified that the required modifications had been made |
| Designated Reviewer granted approval to modifications to previously approved research | Date the Designated Reviewer granted approval | Date the Designated Reviewer granted approval |
| Designated Reviewer required modifications to secure initial approval of modifications to previously approved research; 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 |

1. This document satisfies AAHRPP elements II.2.E-II.2.E.2 [↑](#footnote-ref-1)
2. Last date that the protocol is approved. The Expiration Date is the date after this date, which is the first date that the protocol is no longer approved. [↑](#endnote-ref-1)
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. [↑](#endnote-ref-2)
4. For example, if the last date of the approval interval was April 14, 2008, and the convened IRB approved research on March 16, 2008 for one year, the end date of the next approval interval is April 14, 2008 + one year = April 14, 2009. if the last date of the approval interval was April 14, 2008, and the convened IRB approved research on March 16, 2008 for six months, the end date of the approval interval is April 14, 2008 + six months = November 14, 2008. [↑](#endnote-ref-3)
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. [↑](#endnote-ref-4)
6. 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-5)