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| 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. | | | |
| TYPE OF REVIEW | | START APPROVAL DATE | END APPROVAL DATE[[1]](#endnote-1) |
| Initial Review | Convened IRB granted approval | Date of convened IRB meeting | Date of the convened meeting plus the approval interval minus one day[[2]](#endnote-2). |
| Convened IRB required modifications to secure approval; subsequently verified by Non-Committee Review | Date the IRB office verified that the required modifications had been made. | START APPROVAL DATE plus the approval interval minus one day. If no continuing review is required, an END APPROVAL DATE will not be generated. |
| Designated Reviewer granted approval | Date the Designated Reviewer granted approval |
| Designated Reviewer required modifications to secure approval; subsequently verified by Non-Committee Review | Date the IRB office verified that the required modifications had been made. |
| Continuing Review | Convened IRB granted approval | Date of convened IRB meeting | Date of the convened meeting plus the approval interval minus one day[[3]](#endnote-3) If no continuing review is required, an END APPROVAL DATE will not be generated. |
| Convened IRB required modifications to secure approval; subsequently verified by Non-Committee Review | The date the IRB office verified that the required modifications had been made. | START APPROVAL DATE plus the approval interval minus one day. If no continuing review is required, an END APPROVAL DATE will not be generated. |
| Designated Reviewer granted approval | Date the Designated Reviewer granted approval |
| Designated Reviewer required modifications to secure approval; subsequently verified by Non-Committee Review | 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 | Previous END APPROVAL DATE[[4]](#endnote-4), unless either 1) no continuing review is required and thus an END APPROVAL DATE is not required or 2) continuing review was not previously required; however, the modification now requires the study receive continuing review. In the case of scenario 2, calculate END APPROVAL DATE as START APPROVAL DATE plus the approval interval minus one day. |
| Convened IRB required modifications to secure approval of modifications to previously approved research; subsequently verified by Non-Committee Review | The 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 | Previous END APPROVAL DATE[[5]](#endnote-5), unless no continuing review is required and thus an END APPROVAL DATE is not required. |
| Designated Reviewer required modifications to secure initial approval of modifications to previously approved research; subsequently verified by Non-Committee Review | Date the IRB office verified that the required modifications had been made. |

1. 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)
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-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. [↑](#endnote-ref-3)
4. 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-4)
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-5)