



HRP-302 | 2/2/2024

## 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.<sup>1</sup>

### 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 <sup>2</sup>
Convened IRB required modifications to secure approval; subsequently verified by <u>Non-Committee Review</u>	Date of convened IRB meeting	Date of convened IRB meeting	Date of the convened meeting plus the approval interval minus one day <sup>ii</sup>
<u>Designated Reviewer</u> granted approval	Date the <u>Designated Reviewer</u> granted approval	Date the <u>Designated Reviewer</u> granted approval	APPROVAL DATE plus the approval interval minus one day. None for exempt research.
<u>Designated Reviewer</u> required modifications to secure approval; subsequently verified by <u>Non-Committee Review</u>	Date the <u>Designated Reviewer</u> required modifications to secure approval	Date the <u>Designated Reviewer</u> required modifications to secure approval	APPROVAL DATE plus the approval interval minus one day. None for exempt research.

<sup>1</sup> This document satisfies AAHRPP elements II.2.E-II.2.E.2

<sup>2</sup> 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.

## 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 <sup>3</sup>
Convened IRB required modifications to secure approval; subsequently verified by <u>Non-Committee Review</u>	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 <sup>iv</sup>
<u>Designated Reviewer</u> granted approval	Date the <u>Designated Reviewer</u> granted approval	Date the <u>Designated Reviewer</u> granted approval	APPROVAL DATE plus the approval interval minus one day
<u>Designated Reviewer</u> required modifications to secure approval; subsequently verified by <u>Non-Committee Review</u>	Date the <u>Designated Reviewer</u> 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
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<sup>3</sup> 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.

Convened IRB granted approval	Date of convened IRB meeting	Date of convened IRB meeting	Previous END APPROVAL DATE <sup>4</sup> , except no end date for exempt research.
Convened IRB required modifications to secure approval; subsequently verified by <u>Non-Committee Review</u>	Date of convened IRB meeting	Date the IRB Office verified that the required modifications had been made	Previous END APPROVAL DATE <sup>v</sup> , except no end date for exempt research.
<u>Designated Reviewer</u> granted approval	Date the <u>Designated Reviewer</u> granted approval	Date the <u>Designated Reviewer</u> granted approval	Previous END APPROVAL DATE <sup>v</sup> , except no end date for exempt research.
<u>Designated Reviewer</u> required modifications to secure approval; subsequently verified by <u>Non-Committee Review</u>	Date the <u>Designated Reviewer</u> required modifications to secure approval	Date the IRB Office verified that the required modifications had been made	Previous END APPROVAL DATE <sup>v</sup> , except no end date for exempt research.

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<sup>4</sup> 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.