



**WORKSHEET: Approval Intervals**

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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.<sup>1</sup>

TYPE OF REVIEW		START APPROVAL DATE	END APPROVAL DATE <sup>i</sup>
Initial Review	Convened IRB granted approval	Date of convened IRB meeting	Date of the convened meeting plus the approval interval minus one day <sup>ii</sup>
	Convened IRB required modifications to secure approval; subsequently verified by <u>Non-Committee Review</u>	Date the IRB office verified that the required modifications had been made.	
	<u>Designated Reviewer</u> granted approval	Date the <u>Designated Reviewer</u> granted approval	For research that requires continuing review use the START APPROVAL DATE plus the approval interval minus one day. For research that is eligible for expedited review where continuing review is not required an ADMINISTRATIVE CHECK-IN date will be applied. The ADMINISTRATIVE CHECK-IN date will be 12 months from the START APPROVAL DATE minus one day. For exempt research use a three-year approval interval.
	<u>Designated Reviewer</u> required modifications to secure approval; subsequently verified by <u>Non-Committee Review</u>	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 <sup>iii</sup> .
	Convened IRB required modifications to secure approval; subsequently verified by <u>Non-Committee Review</u>	The date the IRB office verified that the required modifications had been made.	If continuing review is no longer required, an ADMINISTRATIVE CHECK-IN date will be applied. Calculate as above.
	<u>Designated Reviewer</u> granted approval	Date the <u>Designated Reviewer</u> granted approval	START APPROVAL DATE plus the approval interval minus one day <sup>iv</sup> .
	<u>Designated Reviewer</u> required modifications to secure approval; subsequently verified by <u>Non-Committee Review</u>	Date the IRB office verified that the required modifications had been made.	If continuing review is no longer required, an ADMINISTRATIVE CHECK-IN date will be applied. Calculate as above.
Modifications	Convened IRB granted approval to modifications to previously approved research.	Date of convened IRB meeting	Previous END APPROVAL DATE <sup>v</sup> unless either 1) no continuing review is required and thus the previous ADMINISTRATIVE CHECK-IN date is applied; 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 <u>Non-Committee Review</u>	The date the IRB office verified that the required modifications had been made.	
	<u>Designated Reviewer</u> granted approval to modifications to previously approved research	Date the <u>Designated Reviewer</u> granted approval	
	<u>Designated Reviewer</u> required modifications to secure initial approval of modifications to previously approved research; subsequently verified by <u>Non-Committee Review</u>	Date the IRB office verified that the required modifications had been made.	

<sup>i</sup> 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.

<sup>1</sup> AAHRPP II.2.C, II.2.E, II.2.F



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- <sup>ii</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.
- <sup>iii</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.
- <sup>iv</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.
- <sup>v</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.