



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. Exempt and non-FDA regulated minimal risk research undergoing expedited review do not expire.

TYPE OF REVIEW		APPROVAL DATE	EFFECTIVE DATE	END APPROVAL DATE ⁱ
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 ⁱⁱ
	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.	
	<u>Designated Reviewer</u> granted approval	Date the <u>Designated Reviewer</u> granted approval	Date the <u>Designated Reviewer</u> granted approval	None .
	<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.	
Continuing ≤30 d	Convened IRB granted approval	Previous END APPROVAL DATE plus one day.	Previous END APPROVAL DATE plus one day.	If not subject to FDA and not eligible for expedited review, previous END APPROVAL DATE plus current approval interval
	Convened IRB required modifications to secure approval; subsequently verified by <u>Non-Committee Review</u>			
	<u>Designated Reviewer</u> granted approval			
	<u>Designated Reviewer</u> required modifications to secure approval; subsequently verified by <u>Non-Committee Review</u>			
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 ⁱⁱⁱ
	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.	
	<u>Designated Reviewer</u> granted approval	Date the <u>Designated Reviewer</u> granted approval	Date the <u>Designated Reviewer</u> granted approval	None, unless FDA regulated. If FDA regulated, last 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.	
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 ^{iv} , except no end date for exempt research.
	Convened IRB required modifications to secure approval of modifications to previously approved research; 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.	
	<u>Designated Reviewer</u> granted approval to modifications to previously approved research	Date the <u>Designated Reviewer</u> granted approval	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 <u>Designated Reviewer</u> required modifications to secure approval	Date the IRB Office verified that the required modifications had been made.	



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ⁱ 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.

ⁱⁱ 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.

ⁱⁱⁱ 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.

^{iv} 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.