

**OIA-302 WORKSHEET: Calculation of Approval Intervals**

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The purpose of this worksheet is to provide support for Office of IRB Administration (OIA) staff members who send communications after an IRB review in which the letter needs to include approval and expiration dates. This worksheet, or equivalent, describes how to calculate these dates. This worksheet, or equivalent, is to be used. It does not need to be completed or retained.

TYPE OF REVIEW		START APPROVAL DATE	END APPROVAL DATE <sup>1</sup>
Initial Review	Convened IRB granted approval	Date of convened IRB meeting	Date of convened meeting plus the approval interval minus one day. <sup>2</sup> If no continuing review is required, an END APPROVAL DATE will not be generated.
	Convened IRB required modifications to secure approval; subsequently verified by <u>non-committee review</u>	Date the OIA verified that the required modifications had been made.	
	<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>3</sup> If no continuing review is required, an END APPROVAL DATE will not be generated.
	<u>Designated reviewer</u> required modifications to secure approval; subsequently verified by <u>non-committee review</u>	Date the OIA verified that the required modifications had been made.	
Continuing Review	Convened IRB granted approval	Date of convened IRB meeting	Date of convened meeting plus the approval interval minus one day. <sup>4</sup> If no continuing review is required, an END APPROVAL DATE will not be generated. If the continuing review is approved within the 30 days immediately preceding the <u>expiration date</u> , the END APPROVAL DATE can be maintained by adding the approval interval to the <u>expiration date</u> in accordance with guidance on the maintenance of a fixed anniversary date. <sup>5</sup>
	Convened IRB required modifications to secure approval; subsequently verified by <u>non-committee review</u>	The date the OIA verified that the required modifications had been made.	
	<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>6</sup> If no continuing review is required, an END APPROVAL DATE will not be generated. If the continuing review is approved within the 30 days immediately preceding the <u>expiration date</u> , the END APPROVAL DATE can be maintained by adding the approval interval to the <u>expiration date</u> in accordance with guidance on the maintenance of a fixed anniversary date. <sup>7</sup>
	<u>Designated reviewer</u> required modifications to secure approval; subsequently verified by <u>non-committee review</u>	Date the OIA verified that the required modifications had been made.	

<sup>1</sup> Last date that the protocol is approved. The expiration date is the day after this date, which is the first date that the protocol is no longer approved.

<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 = October 14, 2007.

<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 = October 14, 2007.

<sup>4</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 = October 14, 2007.

<sup>5</sup> [Continuing Review Guidance \(2010\) | HHS.gov](#). For example, if the current expiration date is April 15, 2007 and the study is renewed for one year by the convened IRB or a designated reviewer on March 23, 2007, the new expiration date would be April 15, 2008.

<sup>6</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 = October 14, 2007.

<sup>7</sup> [Continuing Review Guidance \(2010\) | HHS.gov](#). For example, if the current expiration date is April 15, 2007 and the study is renewed for one year by the convened IRB or a designated reviewer on March 23, 2007, the new expiration date would be April 15, 2008.

Modifications	Convened IRB granted approval to modifications to previously approved <u>research</u>	Date of convened IRB meeting	Previous END APPROVAL DATE, <sup>8</sup> unless either 1) no continuing review is required and thus no END APPROVAL DATE is required or 2) continuing review was not previously required; however, the modification now requires the study to undergo continuing review. In scenario 2, calculate END APPROVAL DATE as the date of the convened meeting plus the approval interval minus one day.
	Convened IRB required modifications to secure approval of modifications to previously approved <u>research</u> ; subsequently verified by <u>non-committee review</u>	The date the OIA verified that the required modifications had been made.	
	<u>Designated reviewer</u> granted approval to modifications to previously approved <u>research</u>	Date the <u>designated reviewer</u> granted approval	Previous END APPROVAL DATE, <sup>9</sup> unless either 1) no continuing review is required and thus no END APPROVAL DATE is required or 2) continuing review was not previously required; however, the modification now requires the study to undergo continuing review. In scenario 2, calculate END APPROVAL DATE as START APPROVAL DATE plus the approval interval minus one day.
	<u>Designated reviewer</u> required modifications to secure initial approval of modifications to previously approved <u>research</u> ; subsequently verified by <u>non-committee review</u>	Date the OIA verified that the required modifications had been made.	

<sup>8</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.

<sup>9</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.