The purpose of this worksheet is to provide support for IRB Office 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. This worksheet may be used for guidance.

TYPE OF REVIEW		START APPROVAL DATE	END APPROVAL DATE[i]
Initial Review	Convened IRB granted approval	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 Non-Committee Review		
	Designated Reviewer granted approval	Date the Designated Reviewer granted approval	START APPROVAL DATE plus the approval interval minus one day. None for exempt research.
	Designated Reviewer required modifications to secure approval; subsequently verified by Non-Committee Review		
Continuing Review | Status Report	Convened IRB granted approval	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 Non-Committee Review		
	Designated Reviewer granted approval for studies approved under the limited exceptions in the Revised Common Rule; subsequently verified by Non-Committee Review	Date the Designated Reviewer granted approval	START APPROVAL DATE plus the approval interval of 24 months minus one day. [v]
	Designated Reviewer granted approval for long-term follow-up and/or data analysis for those under the pre-2018 regulations; subsequently verified by Non-Committee Review	Date the Designated Reviewer granted approval	START APPROVAL DATE plus the approval interval of 36 months minus one day.[vi]
	Designated Reviewer granted approval for long-term follow-up and/or data analysis for those under the pre-2018 regulations and those studies approved under limited exceptions in the Revised Common Rule; subsequently verified by Non-Committee Review	Date the Designated Reviewer granted approval	START APPROVAL DATE plus the approval interval of 36 months minus one day. [vii]
	Designated Reviewer granted approval	Date the Designated Reviewer granted approval	START APPROVAL DATE plus the approval interval minus one day. [viii]
	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[iv], except no end date for exempt research.
	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	
	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.	

[i] Last date that the protocol is approved. The Lapsed 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, 2014 for one year, the end date of the approval interval is April 15, 2014 + one year – one day = April 14, 2015. If the convened IRB approved research on April 15, 2014 for six months, the end date of the approval interval is April 15, 20147 + six months – one day = November 14, 2014.

[iii] For example, if the convened IRB approved research on April 15, 2014 for one year, the end date of the approval interval is April 15, 2014 + one year – one day = April 14, 2015. If the convened IRB approved research on April 15, 2014 for six months, the end date of the approval interval is April 15, 2014 + six months – one day = November 14, 2014.

[iv] For example, if the last date of the approval interval was April 14, 2015, and the convened IRB approved a modification on November 16, 2014, the end date of the approval interval remains April 14, 2015.

[v] For Studies that are minimal risk, non-FDA, there will be a 24-month expiration date unless otherwise documented.

[vi] For Studies that are minimal risk, non-FDA, there will be a 36-month expiration date unless otherwise documented.

[vii] For Studies that are minimal risk, non-FDA, there will be a 36-month expiration date unless otherwise documented.

[viii] For Studies that are minimal risk, non-FDA, there will be no expiration date due to 2018 ruling from OHRP unless otherwise documented.