Policy regarding Expiration of Approved IRB protocols.  
Affective April 1, 2016

Regulations under 45 CFR 46 and 21 CFR 56 require that the IRB conduct substantive and meaningful continuing review of research not less than once per year. Thus, for research requiring review by the convened IRB, the IRB approval period may extend no more than 365 days after the convened meeting at which the research was last approved. For research within categories appropriate for expedited review, the IRB approval period may extend no more than 365 days after the expedited review at which the research was last approved.

The regulations permit no grace period and no exceptions to this one year requirement. Once an IRB approved protocol has expired, no further study intervention, including subject recruitment, enrollment, intervention and data analysis may occur. Research that continues after the approval period expires is research conducted without IRB approval.

Investigators will receive an email notification 60 days and again within the first week of the month the protocol is expiring informing them that the protocol is up for renewal. A final email notification will be sent on the day the protocol expires, informing the investigators that the protocol has expired and all study interventions must cease.

OHRP guidance suggests that study intervention for subjects already enrolled can continue past the expiration date if the IRB determines that it is in the best interests of subjects already enrolled to continue participating in the research (for example, when the research interventions hold out the prospect of direct benefit to the subjects or when withholding those interventions poses increased risk to the subjects). While this determination may initially be made by the investigator, WCMC requires that the investigator must seek confirmation that the IRB agrees with this determination as soon as possible.

Request to continue study interventions on already enrolled subjects should be submitted to the IRB via email at irb@med.cornell.edu prior to scheduled intervention. The Chair of the appropriate IRB (the IRB that has or will review the continuing review) will review the request. If the Chair agrees that it is in the best interests of the subjects to continue with the study intervention, either because there would be increased risk to the subject if the intervention were to be discontinued, or there is potential for direct benefit with continued intervention, then the request for continued study intervention will be granted for a period no longer than 30 days. If the Chair concludes that there is no direct to the subject with continued study intervention, or that there will not be an increased risk to the subjects if the intervention were to be discontinued, then the request will not be approved.

Human research protocols that have been expired for over 60 days, for which no continuing review application has been submitted will be closed for lack of response. In order to resume human subject research (including data analysis) once the protocol has been closed by the IRB office, a new protocol will need to be submitted and will have to undergo the CSEC/IRB review process de novo.

If a continuing review application has been reviewed by the IRB, and has received either modifications required or deferred determination, or there is a continuing review in progress, notification will be sent through the comments section in eIRB that investigators have 30 days from receipt of this notification to submit the response or the continuing review. If the response or the continuing review is not received within 30 days of receipt of the notification, the study will be closed and a new protocol will need to be submitted for review and approval.