MEMORANDUM

To: NCI CIRB Stakeholders

From: John D. Horigan
CIRB Director of Board Operations
NCI CIRB Operations Office

Date: July 15, 2016

Subject: New FAQ: Timing of CIRB Continuing Review & Amendment Review

The CIRB bases its continuing review on the most current CIRB-approved version of the protocol and consent form. Because the CIRB’s review and approval of amendments takes place prior to activation of the amendment by the coordinating group, the CIRB’s continuing review may be based on a version of the protocol and consent form that is not yet activated by the coordinating group.

When the CIRB’s continuing review is based on a newly approved amendment that has not yet been activated, the CIRB’s continuing review determination letter will reference a protocol version date that has not yet been posted.

The hypothetical timeline below illustrates the typical series of events:

In this hypothetical example, the Continuing Review determination based on the May 20, 2015 version of the protocol (Amendment 1) was posted July 16, 2015, but the amendment itself was not posted until August 1, 2015.

The CIRB Operations Office has developed a new FAQ #51 included below for your reference:
Q#51: **Why is the CIRB’s continuing review approval letter based on a protocol version that isn’t posted?**

A#51: The CIRB conducts continuing review using the most current CIRB-approved protocol and consent form. Sometimes, a continuing review occurs after a protocol amendment has been approved by the CIRB, but before the newly approved protocol amendment has been activated by the Coordinating Group and posted to the CTSU website. When this happens, the CIRB’s approval letter for continuing review includes the following template statement, in order to clarify the timing issue:

> Please note, the continuing review of this study was based on the most current CIRB-approved version of this study which is Protocol Version Date MM/DD/YY. This version has not yet been activated by the Coordinating Group, so it is not yet posted on the CTSU website.

If you have any questions regarding the changes, email the CIRB Helpdesk at ncicirbcontact@emmes.com or call 1-888-657-3711.