April 1, 2015

Dear Colleagues,

The purpose of this communication is to inform you of changes in CTEP’s Protocol Status Update (PSU) form and in the capture of protocol status changes via CTSU’s RSS. These changes are effective April 2, 2015, although CTEP PIO will continue to accept the previous version of the PSU until April 15, 2015. If your protocol is using RSS, please begin making the changes below in RSS on April 2. These changes have been made to assist CTEP in determining factors that lead to premature study closure and to more closely align with ClinicalTrials.gov statuses and data elements.

Changes that affect both RSS and PSU:

* To better capture the reasons why a study may be terminated early, the PSU contains reasons for early closure. While there may be many reasons that a study may be closed prematurely, please select the largest contributing factor. When possible, consider reviewing the reason with your statistician for guidance on the largest factor.
* The addition of a new terminal status of FDAAA/IRB Completed. This new status after *Complete* has been added for trials where there is long term follow up required as a primary objective. PIO will still not require a protocol amendment for trials past complete. This new status was also added to allow mapping to the ClinicalTrials.gov status of Completed.

Changes that affect the PSU only:

* The requirement for a publication citation to complete a trial has been removed, as this information that is captured via other sources.
* To better synchronize with FDAAA requirements, PIO will no longer accept an actual or anticipated primary completion date (APCD) prior to the *Closed to accrual and treatment* date.

Changes that affect RSS only:

* APCDs are now available for input via RSS. Please continue to submit the first APCD with your protocol submission worksheet (PSW), but updates to the APCD must be performed within RSS, including the switch from anticipated to actual PCD
* RSS can now accept status changes through FDAAA/IRB complete.
* RSS will collect status reasons for closed to accrual and both temporary statuses.
* RSS will enforce the status workflow from pre-activation to FDAAA/IRB complete.
* Future date requests will continue to be supported.

If you have any questions regarding these changes or the form, please contact CTEP PIO at pio@ctep.nci.nih.gov. For questions regarding RSS managed studies, please contact CTSUcontact@westat.com. The updated PSU may be found at this link: <http://ctep.cancer.gov/protocolDevelopment/docs/Protocol_Status_Update_Form.docx>