

**Date:** January 10, 2014

**To:** Investigators with In Review and Open Protocols

**From:** Shanda Finnigan, MPH, RN, CCRC, Associate Branch Chief, CTOIB, CTEP, DCTD, NCI

**Subject:** Required Amendment/Revision due to the Retirement of AdEERS and Transition to CTEP-AERS

The Adverse Event Expedited Reporting System (AdEERS) will be retired in May of 2014. The CTEP Adverse Event Reporting System (CTEP-AERS) is live and open for use in place of AdEERS for all protocols. Information regarding CTEP-AERS and instructions for training is available on the CTEP website: <http://ctep.cancer.gov/protocolDevelopment/electronic_applications/adverse_events.htm>

All In Review and Open protocols (those that are not Complete or Administratively Complete) must amend/revise all “AdEERS” references throughout the protocol to “CTEP-AERS.” If AdEERS is written out within the protocol, “Adverse Event Expedited Reporting System,” replace it with “CTEP Adverse Event Reporting System.”

These amendments/revisions will be treated as editorial amendments by CTEP and can be included with any other changes made to the protocol.

The due date for these amendments/revisions is May 1, 2014. Amendments do not need to be made prior to the use of CTEP-AERS.

If your protocol does not reference AdEERS, please ignore this request.

Summary of Change (SOC) information

Please add the following change information on the SOC for your revision/amendment:

References to the “Adverse Event Expedited Reporting System (AdEERS)” have been changed to “CTEP Adverse Event Reporting System (CTEP-AERS)” throughout the protocol.

The SOC must be submitted as the first page of the protocol but there is no requirement for a hyperlink to these changes.