**Instructions for Interim Review of CCTS DSMB Study**

The CCTS DSMB Meetings are held **3 times a year. If the PI is not available to attend the CCTS DSMB meeting they must ensure that a sub-investigator is present to answer questions or the study will not be reviewed.**

For each interim review the CCTS DSMB coordinator will send the Principal Investigator (PI) a Data Request Letter 1 month prior to the scheduled CCTS DSMB meeting.

**Preparation for the CCTS DSMB Meeting**

Submit the report to include the following documents in the order listed below to the CCTS DSMB Coordinator 3 weeks prior to the CCTS DSMB meeting:

* Title Page (including study name, IRB number, principal investigator name and study review date)
* Table of Contents Page
* One page Abstract briefly describing the study
* Study Overview
* Adverse Event Log
* Protocol Violation (Deviation/Exception) Log
* Withdrawal Log
* A summary of all adverse events, serious adverse events, withdrawals and protocol violations including the circumstances, when they occurred and where the participant was in the study at the time of the occurrence.

All of the logs and the summary of adverse events, serious adverse events, withdrawals and protocol violations will be a cumulative list throughout the study. Please highlight the new events since the last review in blue font. All previously reviewed data should be in black font.

The CCTS DSMB coordinator will review the documents for completeness and accuracy. If the CCTS DSMB Coordinator notices any items that need to be addressed the PI will be notified to correct these items and resubmit the documents to the CCTS DSMB. Final reports MUST be received no later than 1 week prior to the meeting date for review.