**Instructions for Initial CCTS DSMB Protocol Submission**

Go to <https://redcap.uky.edu/redcap/surveys/?s=ARWCEAPHY7> to complete a service request form.

1. Select Regulatory Services

2. Scroll down to Data Safety Monitoring Board (DSMB) and select the DSMB services that you need.

3. Upload the following documents into the Service Request Form:

* + - IRB Approval
    - Study Protocol
    - Research Description (Form B)
    - Stamped Informed Consent Form
    - General Information Sheet

The CCTS DSMB Coordinator will send these documents to the CCTS DSMB for review.

If the CCTS DSMB accepts the study, the Principal Investigator (PI) will receive an acceptance letter with notice of the next available CCTS DSMB agenda. The PI must attend the CCTS DSMB meeting to address any questions or concerns.

**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.**

**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.

Final reports MUST be received no later than 1 week prior to the CCTS DSMB meeting date for review.

If no data has been collected at the time of initial study review the PI will submit a CCTS DSMB report with all sections completed noting that no participants have been enrolled.

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 using blue font. After the data have been reviewed by the CCTS DSMB please change the font to black. Thus at each DSMB review only AE’s, SAE’s Withdrawals and Protocol Violations that have not previously been seen are in blue 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 documents MUST be received no later than 1 week prior to the meeting date for review.