**Instructions for Study Inactivation and Study Closure**

**Instructions for Study Inactivation**

A Principal Investigator (PI) may request inactivation of their study with the CCTS DSMB when the study meets all of the following criteria:

* Study is closed to enrollment
* Any corresponding follow-up activities are complete
* 30 days or more have passed since completion of follow-up activities

A formal request for inactivation should be sent to the CCTS DSMB coordinator. The request will be scheduled for the next CCTS DSMB meeting. The Principal Investigator or their sub-investigator must attend the meeting to address any questions or concerns. If the CCTS DSMB approves the study for inactivation the PI will receive a formal notice.

**Once a study has been inactivated it is the responsibility of the PI to notify the CCTS DSMB of any change in status that may warrant re-activation. During inactivation the PI must continue to submit continuation reviews and IRB approvals to the CCTS DSMB.**

**Instructions for Study Closure**

A study must remain open with the CCTS DSMB until the study is closed with the IRB.

A formal written request for closure should be sent to the CCTS DSMB coordinator. The request will be scheduled for the next CCTS DSMB meeting. The Principal Investigator or their sub-investigator must attend the meeting to address any questions or concerns. If the CCTS DSMB approves the study for closure the PI will receive a formal notice of closure.