Early Termination for Multicenter IUSCCC Sites with No Accruals
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Background
Indiana University (IU) has a well-established and robust Multicenter program. Trials managed within this program are IU-lead Investigator-Initiated Trials with outside participating sites. The goal of the team is to expand research and provide oversight while maintaining a competitive workload that allows the team to effectively manage a large number of protocols and sites; essentially, we are IU’s own Clinical Research Organization (CRO). As we all can attest, study start-up and overall trial management take a significant amount of time and resources for all parties. The multicenter team has several policies, procedures, and templates in place to streamline trials and make it possible for IU Investigators, and sites to participate in IU Lead multicenter trials. Low-performing sites are evaluated continuously and those not contributing to overall trial data will receive a warning letter and be considered for early termination.

Goals
• Establish an SOP that clearly defines accrual expectations and consequences for sites who do not accrue within specified timeframe.
• Identify low-performing sites and remove them from workload.
• Close low-performing sites to allow team to take on additional sites and trials to better serve the Investigators in meeting their enrollment goals.

Methods
• An SOP was created, and all PIs were notified.
• This SOP is discussed during the SIV with each site therefore clear expectations are set for all parties. Depending on risk level, sites are given a certain number of months to accrue a subject.
• If a site has not accrued in the allotted time, a warning letter will be issued with a deadline to recruit a subject.
• If the deadline has past, sites are subject to termination. An appeal process is also discussed in the SOP.

Results and Future Directions
• Since implementation, one site has been terminated allowing high-performing sites to onboard.
• We plan to continue adhering to this SOP while remaining open to suggestions and improvements as we remain working towards a cure.