Category: Trial Recruitment and Study Conduct (IITs) – Completed Project

Early Termination for Multicenter IUSCCC Sites With No Accruals

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1.Background

Indiana University (IU) has a well-established and robust multicenter program. Trials managed within this program are IU-led 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-led 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.

2. Goals

The goal of the policy is to identify low-performing sites and remove them from the workload. Sites that are not contributing to the overall study accrual goals are recommended for closure to allow other sites to participate in the trial. Closing participating sites also allows the team to take on additional sites and trials to better serve the Investigators in meeting their enrollment goals.

3. Solutions and Methods

a standard operating procedure (sop) was created, and all principal investigators were notified by email. This SOP is discussed during the site initiation visit (SIV) with each site ensuring clear expectations are set for all parties. Depending on risk level, shown below, sites are given a timeline to accrue their first subject. If a site has not accrued in the allotted time, a warning letter will be issued with a deadline to accrue a subject. If the deadline is missed, sites are subject to termination. Sites have up to one month to appeal the warning letter, which is reviewed by the IU investigator, multicenter manager, and multicenter project manager. If an appeal is awarded, the site will be allowed to remain open and will be re-evaluated depending on the risk level.

High-Risk Trials: Sites must accrue within one year of site activation (open to enrollment); if no subjects are accrued after nine months of activation, a warning letter will be issued to the site PI

Moderate and Low-Risk Trials: Sites must accrue within six months of site activation; if no subjects are accrued after three months of activation, a warning letter will be issued to the site PI

4. Outcomes

Since rolling out this policy, one site has received a warning letter and was subsequently terminated which allowed the multicenter team to take on an additional site that is now accruing therefore contributing to trial endpoints, outcomes, and goals.

5.Lessons Learned and Future Directions

We will continue to utilize this SOP. As always, we remain open to suggestions and improvements as we

all continue to work towards a cure. We hope this process will continue to encourage site participation while also allowing effective workloads that contribute to research goals.