



Early Termination for Multicenter IUSCCC Sites with No Accruals

Amber Bauchle; Mario Contreras; Kathy Miller, Tim Lautenschlaeger

Indiana University Melvin and Bren Simon Comprehensive Cancer Center

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.



Month x, 2023

RE: Protocol number and title

Dear Dr. XXX,

We would like to thank you for your participation in CTO-IUSCCC-0000. Per IU Simon Comprehensive Center's policy, all sites will be monitored for accrual. For high/moderate/low risk trials, sites must accrue within 6 months of site activation. Institution X was OPEN TO ACCRUAL on MM/DD/YYYY. As no accruals have taken place, your site is subject to termination. Please note, your site will have one month to accrue a subject or close out procedures may begin.

You may appeal to the IU Sponsor-Investigator and provide justification to remain active as a site. The appeal will be discussed with the Sponsor-Investigator, CTO Multicenter Team Manager, and Multicenter Project Manager until a decision is reached. You will be notified by email on the appeal decision. If the appeal is denied and your site has not accrued, closeout procedures will begin.

Please do not hesitate to contact us with any questions or concerns.

Best Regards,

Dr. XXXXXX

Cc: IU PI

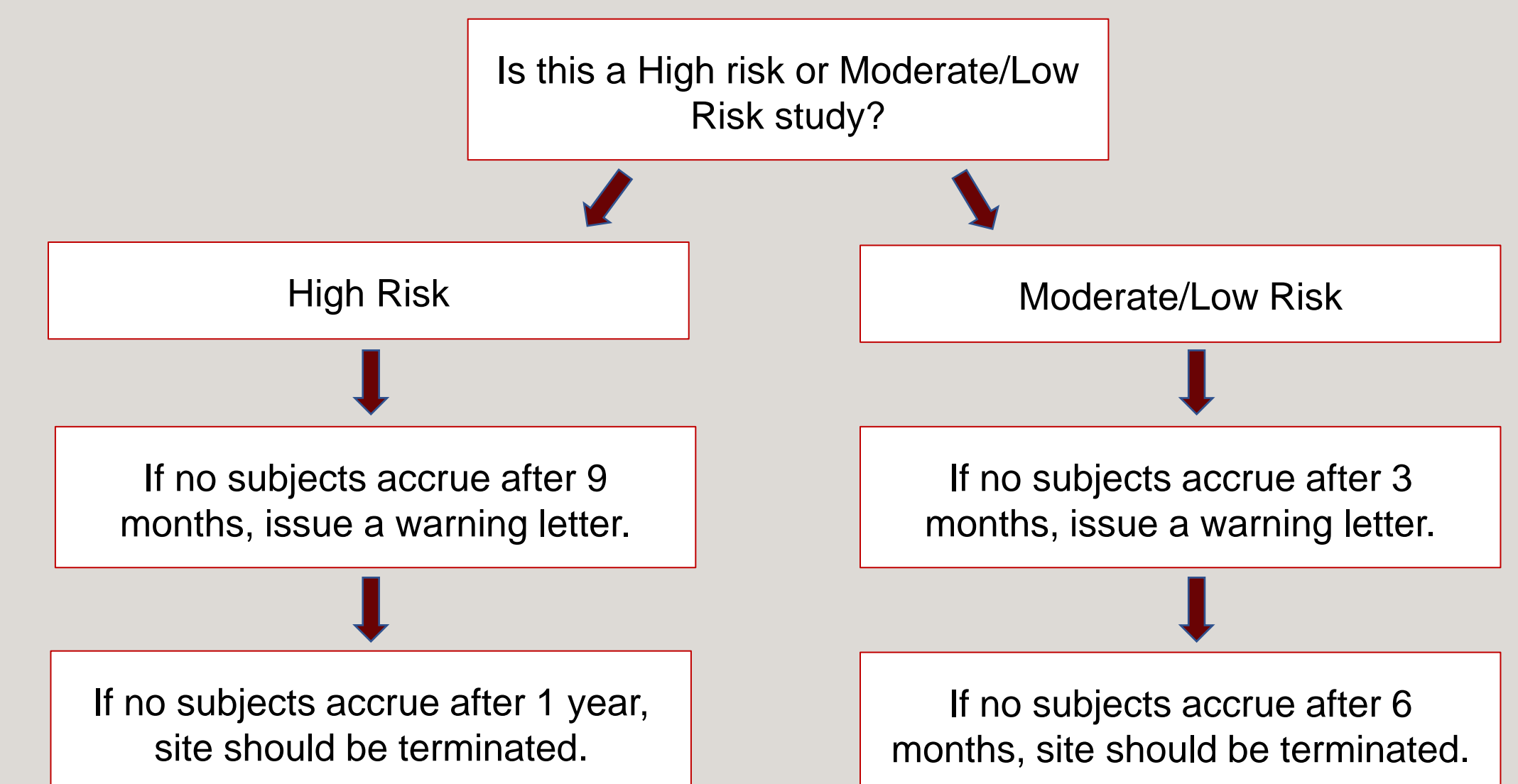
Site PI

Site SC



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.