

PEDIATRIC RESEARCH OFFICE – STANDARD OPERATING PROCEDURE

NON-ENROLLING STUDIES

- 1) Study that has not enrolled in 6+ months is identified/flagged*
- 2) PRO leadership will meet with PI and lead study coordinator to assess non-enrollment on study
- 3) During meeting determine if it is feasible to continue enrollment?
 - a. If no, then take to CHRI leadership for possible closure based on findings within 30 days
 - b. If yes, then we can discuss ways to increase enrollment
 - i. Add new staff (study coordinators, APRN, or Sub-Is) to assist with recruitment
 - ii. Advertisement (Social Media, Flyers)
 - iii. Opt-In list (CHMC and/or UNMC)
- 4) If continuing to enroll, PI will be notified of 90 day window to boost enrollment
- 5) After 90 day “probationary” period, PRO Leadership will reassess enrollment numbers. If set enrollment goals were not met, PRO Leadership will notify PI of study closure in writing within 10 business days.

*Exceptions to this SOP are studies that may be seasonal (i.e. RSV, influenza, enterovirus), orphan drug studies that were approved during intake process, and COG trials.



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