Case Comprehensive Cancer Center Protocol Review and Monitoring Committee Accrual Monitoring Policy Revised: June 2017

As part of its internal oversight responsibility for the scientific aspects of the cancer clinical trials in the Case Comprehensive Cancer Center (Case CCC) institutions, the Protocol Review and Monitoring Committee (PRMC) has the authority to terminate protocols that do not demonstrate scientific progress. One of the criteria by which scientific progress is assessed is rate of accrual. It is recognized that a variety of factors impact accrual, including overall target population, study design (e.g. Phase I trials), unanticipated temporary closure for amendments, patients on study, etc. In general, however, studies that accrue less than 50% of the expected accrual (end)c

. In general, adult interventional studies are expected to demonstrate appropriate levels of accrual as described below. The procedures described will be followed for each type of interventional clinical trial.

1. **Sponsored studies** (industry, cooperative group, institutional outside of the Case CCC) that have not accrued at least 1 patient in the previous 6 months.
   Memo will be sent to a designated clinical site CTU representative.
   Clinical Trials Unit (CTU) representative is responsible for acquiring the response from both the CTU and Principal Investigator (PI).
   Completed memo is sent back to PRMC within 2 weeks.
   PRMC will review the responses at the next PRMC meeting. Based on the responses, the PRMC will either recommend closure or continuation to further accrual. Studies that are suspended for longer than one year will be added to the review list for determination of closure.

2. **Investigator initiated studies** that have not accrued 50% of the expected 6-month accrual (# based on target and duration of study).