

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 a very small number of patients each year are unlikely to successfully answer the scientific questions posed.

Accrual to interventional clinical trials will be assessed every 6 months from study activation at a full board PRMC meeting. 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).
 - Memo will be sent to a designated clinical site CTU representative.
 - CTU representative is responsible for acquiring the response from both the CTU and PI. These responses will follow discussion between PI and CTU.
 - 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.
3. **Joint studies:**
 - Sponsored Studies: Accrual will be monitored at each site separately. Memos will be sent to the CTU representative as above. If the CTU of the non-accruing site decides to close the study, there should be communication with the other site co-PI as to how to proceed.
 - Investigator-Initiated Studies: studies will be monitored from the earliest open date. The lead site will complete the memo. Any closure decisions should be discussed between both PIs before sending form back to the PRMC. PRMC closure decisions will be communicated to PIs at both sites.
4. **Rare disease studies:**
 - Adult studies will be monitored yearly from activation; assessment will be based on factors specific to the type of disease and potential study population.

- Pediatric studies will be monitored for progress every 2 years from activation.
5. Studies that are recommended for **continuation**:
- This decision will be documented and sent to the CTU representative and PI.
6. Studies that are recommended for **closure**:
- Closure memo will be sent by the PRMC to the PI and 'cc' the CTU representatives and to the Case CCC Clinical Research Leadership Committee (Associate Director for Clinical Research, Deputy Associate Director for Clinical Research/Director of Clinical Trials, and Clinical Research Office Medical Director).
 - PI has 1 week to appeal the decision by letter to the Case CCC Clinical Research Leadership Committee via the PRMC manager. The Case CCC Clinical Research Leadership Committee will respond to the appeal in writing of their decision regarding protocol closure. This decision will be final. If no appeal is received the PRMC will notify the CTU to proceed with closure.