

Revising an Institutional PRMC Charter to Achieve NCI Standards: Impacts, Efficiencies, and Potential for Further Improvement

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1. Background

The University of Cincinnati Cancer Center (UCCC) re-examined its processes to ensure that we are improving our research and patient care, in preparation to seek NCI designation. In 2018, UCCC's Protocol Review and Monitoring Committee (PRMC) in conjunction with the Clinical Trials Office staff reviewed and extensively revised the existing PRMC Charter to bring the processes and practices of the UCCC PRMC in line with those of other NCI Designated Cancer Centers.

2. Goals

It was anticipated that many of the procedural changes would also promote greater efficiency within our PRMS, especially with respect to member review time per protocol and number of MD PRMS member reviewers required at each meeting.

3. Solutions and Methods

The following specific updates were made to the UCCC PRMC Charter: 1. Creating an expedited administrative review process, 2. Allowing for deferral to a single PRMS of a multi-center trial, 3. ensuring accrual review expressly defines and takes rare cancers into account, 4. Adding Data Table 4 study type definitions, 5. Defining member roles and responsibilities and 6. Clarifying the PRMC's authority to open and terminate protocols.

4. Outcomes

Turn-around-time is defined as the numbers of days between submission date and approval date. Average (mean) number of days for turnaround time for previous charter was 18.45 days (SD = 8.69) whereas current charter averaged 15.42 days (SD = 12.66) (Table 1, Figs. 1 & 2). This yields a 16% decrease or ~3 days. While this is not a statistically significant difference ($W = 926.5$, $p = 0.665$) it's real added value to our physician reviewers allowing them to devote more time to patients and research. Number of protocols discussed at each meeting was defined as ratio of total studies each month to how many studies underwent full PRMC review at meeting (see Figure 3). Average ratio between all studies to the full review for current charter is 1.90 whereas previous charter is 1.69. These are similar results as the total number of studies under review has increased under the new charter by 106%.

Figure 4 illustrates average number of reviewers/meeting has increased in new charter, explained by increase in number of protocols coming to PRMC. But Figure 5 shows more specifically that 33 of the 112 reviews under the current charter were achieved administratively, requiring no MD review. Previously, 0% of studies were administratively reviewed; 32% are now reviewed administratively. The administrative review type averages TAT of 4.42 days. This facilitates a decrease in TAT for fast track (11.22 days vs. 9.90 days). While the difference between full review type is minimal, the new changes allow more studies to be reviewed at full review.

5. Lessons Learned

Our data demonstrates, implementing the NCI’s PRMS requirements resulted in a PRMC that was more efficient in terms of reviewer time and volume of studies reviewed. As we continue to obtain additional data, we anticipate increasing efficiencies to support our physicians and increased overall volume of new protocols. Driving this continued effort to better our PRMC charter is our center’s goal to expand options for cancer patients and continue to pursue NCI designation.

Table 1.

	Previous Charter	Current Charter
N	22	112
Mean	18.45	15.41
SE	1.85	1.19

