Category: Finance/CCSG/PRMS – Completed Project

What's in a Pre-Review? Establishing a Streamlined Method for Ensuring Quality Submissions to Protocol Review Committees

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1. Background

The robust clinical research portfolio at Memorial Sloan Kettering Cancer Center (MSK) is vital to MSK's mission and provides novel treatment options to patients. Prior to opening for enrollment, protocols must undergo a series of committee reviews. Historically, separate groups were responsible for review committees. Protocols were reviewed by one committee at a time, which created vague and inconsistent review requirements, incomplete submissions, lack of transparency, unclear scope, inaccurate data entry and repetitive reviews which contributed to delays in the protocol review process.

In 2018, when MSK centralized protocol review and activation, one primary area of focus was to decrease time to Institutional Review Board (IRB) approval (TTIA). Two centralized cores, the Protocol Review Core (PRC) and Protocol Activation Core (PAC), were created with a mission of streamlining the review process. PRC is charged with managing 25 departmental/institutional review committees and increasing efficiencies within the review process while maintaining the quality of protocol reviews. PAC navigates protocols through the review process and serves as the liaison between investigators, research operations, and other departments.

2. Goals

One of PRC's major goals was to develop a new comprehensive pre-review process to increase efficiency, reduce bottlenecks and ensure protocols are ready for committee reviews.

Our sub-goals were to:

- Define review requirements
- Improve data quality
- Ensure complete submissions
- Focus committee scope/streamline review flows
- Increase transparency/communication
- Conduct pre-review within 24 hours

3. Solutions and Methods

PRC developed the following resources to aid implementation of the new standardized pre-review workflow shown in Figure 1:

- Pre-Review Guide (standardized requirements)
- Committee Determination Form (identifies required reviews)
- New functionality in MSK's homegrown Protocol Information Management System (PIMS)
- PIMS Library (defines data fields)
- Efficient review flows

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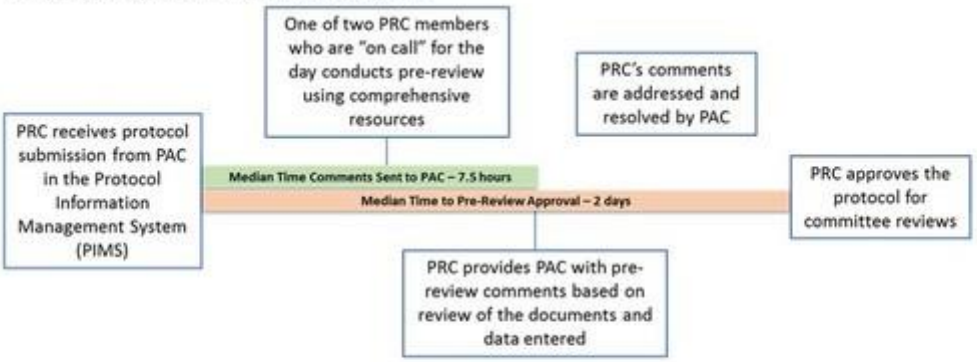
Figure 1: The Protocol Review Core developed and implemented **a structured, standardized pre-review process** to meet the above goals.



4. Outcomes and Future Directions

PRC conducted 289 pre-reviews in 2018. Eighty percent of pre-review comments were sent to PAC within 24 hours of receipt, with a median time of 7.5 hours. The median time to pre-review approval (time between receipt and resolution of issues) was 2 days. This rapid turnaround decreased the time between protocol submission and committee reviews. PRC's new workflow and resources ensured consistent and high quality PIMS data, allowed for concurrent reviews, and improved compliance with institutional/regulatory requirements. Notably, PRC saw a 52% increase in Committee on Radiation submissions, demonstrating success in determining appropriate committee reviews.

Discussion:
PRC's new process contributed to reducing MSK's median TTIA from 135 days in 2017 to 80 days in 2018 by streamlining workflows throughout the review process and across committees. Clear communication, adaptability, and continual improvement of shared resources were key to managing the launch of the new workflow successfully. Additionally, the improved quality of PIMS data ensures that institutional leadership utilizes accurate data in reporting and decision making.

Future goals:

- Utilize our experience to increase the percentage of pre-reviews completed within 24 hours, further decrease time to approval at committees, increase quality of submissions, and inform future collaborations within the clinical research community.

- Apply the knowledge/experience gained from developing/implementing the pre-review process to standardize other aspects of committee management.