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

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BACKGROUND

- Memorial Sloan Kettering Cancer Center (MSK) has a robust clinical research portfolio that is vital to MSK's mission.
- Before opening for patient enrollment, each protocol must undergo a series of committee reviews based on the participating investigators and resources needed to conduct the protocol.
- Approximately 300 new prospective protocols go through the review and activation process each year.
- Historically, individual clinical departments were responsible for managing their own protocol review committee (N=18) and additional groups were responsible for managing MSK's institutional committees (N=7).
- Protocols were reviewed in an asynchronous manner, one committee at a time.
- The previous structure inherently created vague and inconsistent review requirements, incomplete submissions, lack of transparency, unclear scope, inaccurate data entry and repetitive reviews from various committees. All these factors contributed to delays in the protocol review process.
- MSK leadership charged Clinical Research Administration with optimizing protocol review and activation to decrease Time to IRB Approval (TTIA).
- Two new centralized sub-units, the **Protocol Review Core (PRC)** and Protocol Activation Core (PAC) were created.
- PRC is charged with managing 25 departmental and institutional review committees, including MSK's PRMS, and increasing efficiencies within the review process while maintaining the quality of protocol reviews.

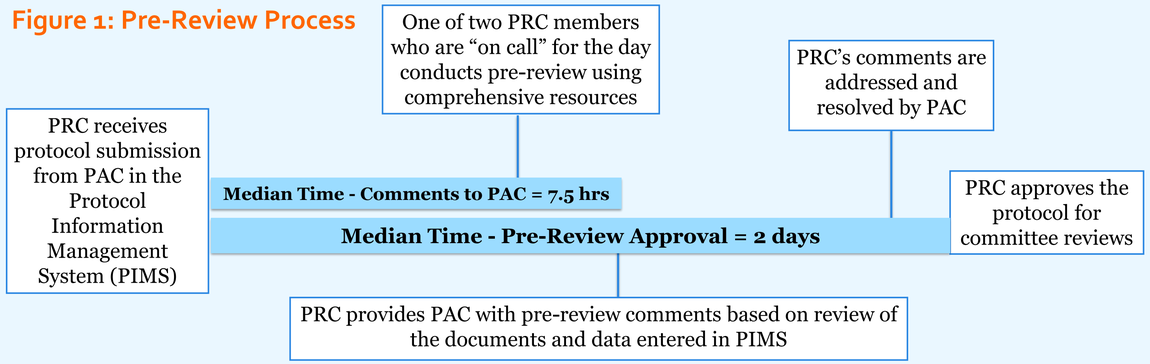
GOALS

- **In support of the institution initiative to decrease TTIA, our goal was to develop and implement a new comprehensive pre-review process that increases efficiency, reduces bottlenecks, and ensures protocols are ready for committee reviews.**
- In conjunction with this overarching goal, we identified the following sub-goals:
  - Define review requirements (i.e., required documents, required committee reviews)
  - Improve quality of regulatory protocol data in the Protocol Information Management System (PIMS)
  - Ensure complete submissions for committee reviews
  - Focus committee scope & streamline review flows
  - Increase transparency and communication
  - Conduct pre-reviews within 24 hours of receipt

CHANGES INTRODUCED

The Protocol Review Core developed and implemented a **comprehensive, standardized pre-review process:**

Figure 1: Pre-Review Process

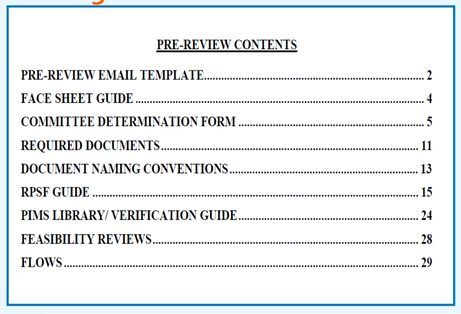


RESOURCES

PRC developed multiple resources to ensure consistency and transparency to enable a standardized pre-review process.

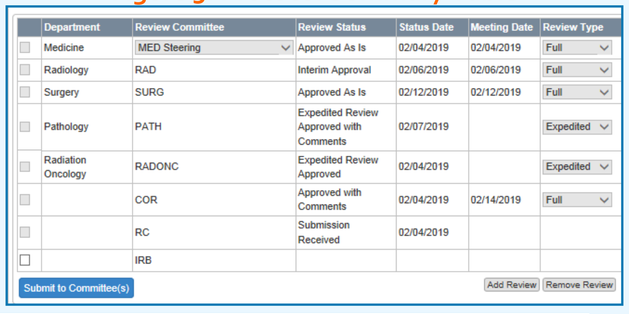
- **Committee Determination Form**, which is a smart form with guided questions to ensure protocols are reviewed by all appropriate departmental and institutional committees
- **Best Practices** Guidance
- **PIMS Library** that defines data fields in our institutional database
- **Pre-Review Guide**, which extensively details standardized requirements for pre-review, such as required documents and naming conventions (Figure 2)
- **New PIMS Functionality**, including snapshots of required reviews/statuses available (Figure 3)
- **Efficient Review Flows** that help maximize the number of concurrent reviews and minimize TTIA (Figure 4)

Figure 2: Pre-Review Guide



PRE-REVIEW CONTENTS

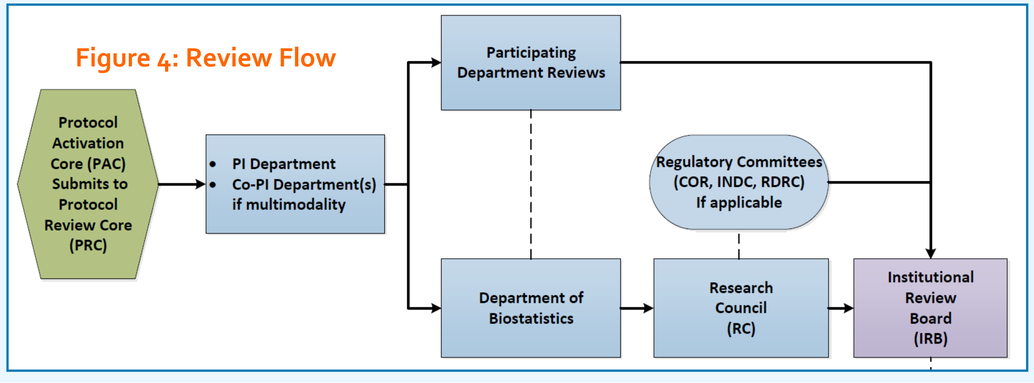
Figure 3: Protocol Summary Table



Department	Review Committee	Review Status	Status Date	Meeting Date	Review Type
Medicine	MED Steering	Approved As Is	02/04/2019	02/04/2019	Full
Radiology	RAD	Interim Approval	02/06/2019	02/06/2019	Full
Surgery	SURG	Approved As Is	02/12/2019	02/12/2019	Full
Pathology	PATH	Expedited Review Approved with Comments	02/07/2019		Expedited
Radiation Oncology	RADONC	Expedited Review Approved	02/04/2019		Expedited
	COR	Approved with Comments	02/04/2019	02/14/2019	Full
	RC	Submission Received	02/04/2019		
	IRB				

Submit to Committee(s) | Add Review | Remove Review

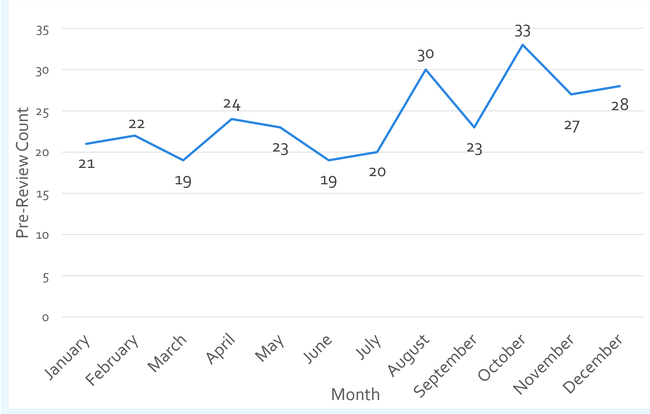
Figure 4: Review Flow



IMPACT

- PRC conducted **289** pre-reviews in 2018 (Figure 5).
- **Eighty percent** of pre-review comments were sent to PAC within 24 hours of receipt, with a median time of **7.5 hours.** Median time to pre-review approval was **2 days** (Figure 1).
- Rapid turnaround results in prompt placement of protocols on committee meeting agendas.
- Revised workflows and resources developed by PRC expedites turnaround time, ensures consistent and high quality PIMS data, facilitates confirmation of review type (full or expedited) and allows for concurrent reviews.
- Improved compliance with institutional and regulatory requirements. One of the most notable examples has been the **52% increase** in Committee on Radiation (COR) submissions from 2017 to 2018, which demonstrates PRC's effectiveness in determining required committee reviews.

Figure 5: 2018 Pre-Reviews (by month)



DISCUSSION

- PRC's new pre-review process has 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.
- Collaboration between centralized groups (PRC and PAC) as well as shared resources have been instrumental in our successful first year.
- Continual improvements and adaptability are essential with the ever-changing landscape of clinical research.
- Improved quality of PIMS data ensures institutional leadership is utilizing accurate data in their reporting and decision making.
- In the future, we hope to utilize our experience to increase the percentage of pre-reviews completed within 24 hours, further decrease time to approval at review committees, increase quality of protocol submissions, and inform future collaborations within the clinical research community.
- We will continually assess the needs of our stakeholders (PAC, PI, committee members) as well as the value added in our processes and incorporate changes to improve our workflows.