MSK's Protocol Review Core:
A specialized approach to protocol review committee management

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BACKGROUND

Prior to 2018, Memorial Sloan Kettering Cancer Center's (MSK) pre- and post-activation protocol review system was fragmented. Each departmental and institutional regulatory group had independent staff and unique leadership and processes to manage their review committees. Committees were siloed with little communication between groups, causing unclear review scope and inefficiencies for new reviews, amendment reviews and monitoring of protocols. This was further complicated by MSK's large research portfolio with 800+ active prospective protocols and 1200+ retrospective and biospecimen clinical research studies at any given year; most recently 552 total protocols entered the review & activation process in 2019. Beginning in October 2017, the Protocol Review Core (PRC) was formed within the Protocol Activation and Human Research Protection Program (HRPP) Unit to work alongside the Protocol Activation Core (PAC) and the HRPP in improving protocol monitoring, review and activation at the Center.

GOALS

To improve the overall institutional protocol review process, PRC's major goals were to:
- Create a specialized team to manage complex review processes throughout the protocol lifecycle
- Standardize pre- and post-activation reviews while simultaneously customizing best practices based on individual committee needs
- Leverage technology using our homegrown Protocol Information Management System (PIMS) and external resources to increase transparency and efficiencies
- Provide collaborative approach to protocol review and activation in order to provide high-level customer service to enhance varied collaborators' experiences
- Decrease Time to Activation (TTA) and Time to IRB Approval (TTIA), defined as the number of days from the first review to when a protocol is open for patient enrollment and IRB approval, respectively

CHANGES IMPLEMENTED
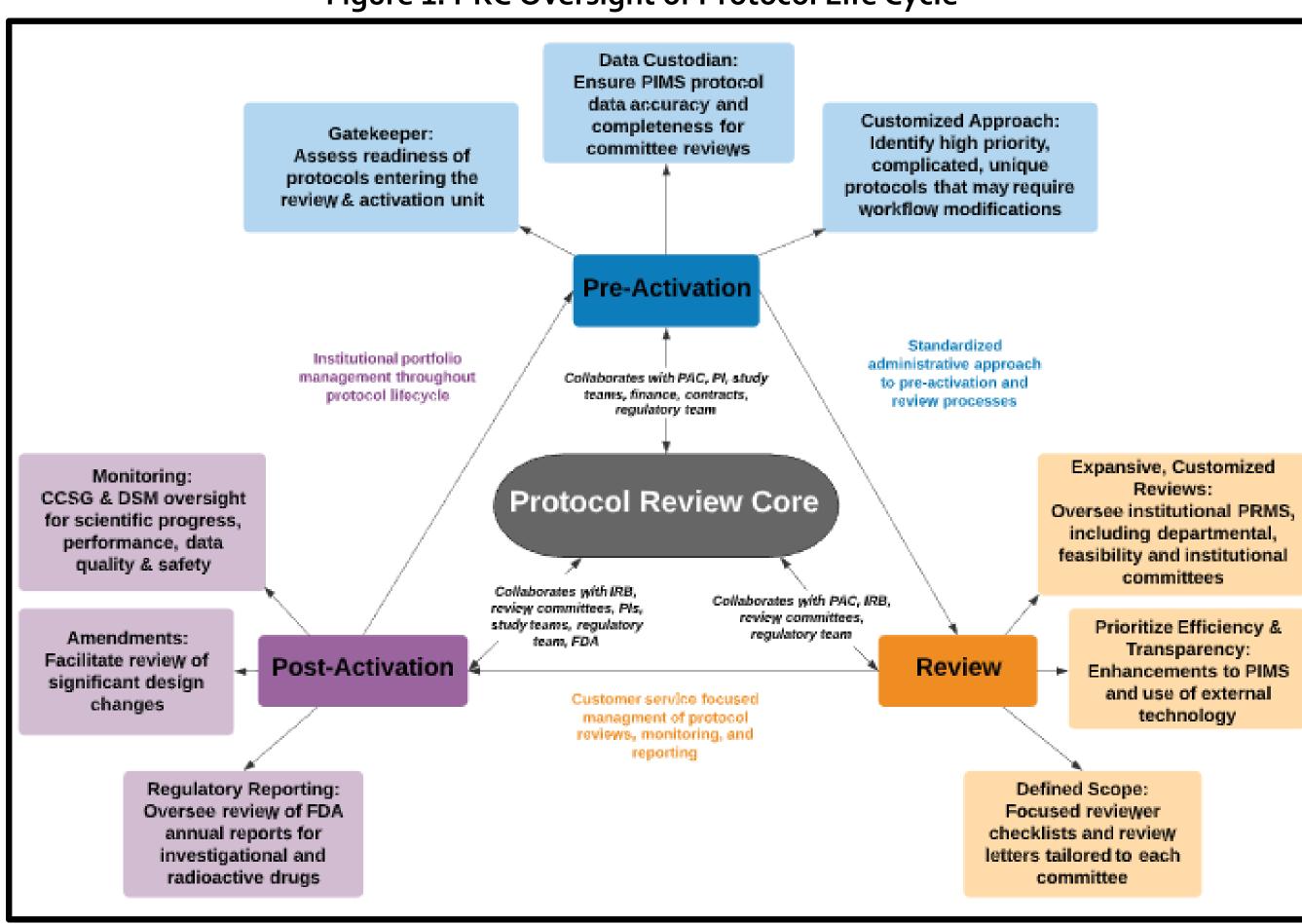
Figure 1: PRC Oversight of Protocol Life Cycle

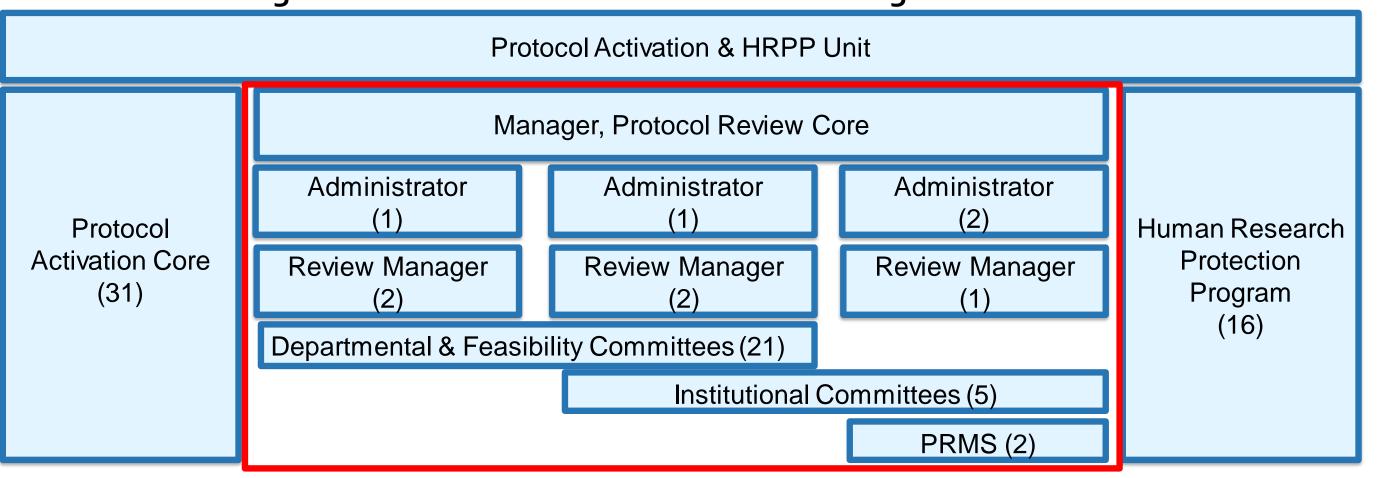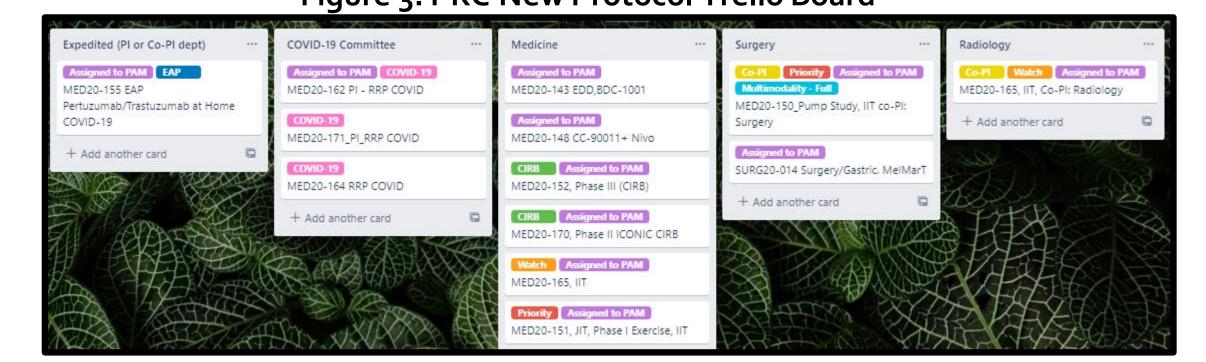Figure 2: Protocol Activation & HRPP Unit Organization Chart
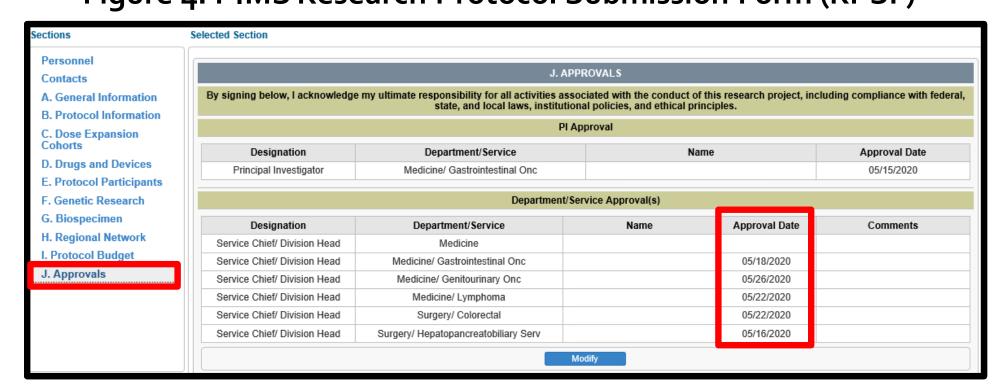

Figure 3: PRC New Protocol Trello Board

IMPACT

PRC's integration into MSK's protocol review process has resulted in a standardized approach to protocol reviews while simultaneously increasing efficiencies and enhancing user experience. This centralized structure has resulted in:

- Streamlined oversight of protocol life cycle (Figure 1)
- Collaborative culture and workflows within our unit: PRC, PAC, HRPP (Figure 2)
- PRC actively managing the review of protocols from initial submission to study closure, including 19 departmental, 2 feasibility, 5 institutional and 2 PRMS committees (Figure 2)
- Leveraging technology to define/triage high priority, complicated, and/or unique protocols to facilitate protocol review & activation (Figure 3) and to obtain electronic approvals from service chiefs (Figure 4) prior to entering the review & activation unit
- Decrease in institution's median TTA, TTIA, and Departmental Time to Approval (DTTA) for all protocol types from 2017 to 2019
  - TTA: 177 to 137
  - TTIA: 132 to 86
  - DTTA: Industry: 32 to 17, IIT: 64 to 49, NCI: 37 to 22

Figure 4: PIMS Research Protocol Submission Form (RPSF)

DISCUSSION

Lessons Learned:
- PRC is an essential component of optimizing the protocol review process at MSK.
- Customizing our approach has enhanced our engagement of previously siloed, independently managed groups.
- Formalized best practices support PRC's mission in quality and efficient protocol reviews.

Future Directions:
- Broaden scope of feasibility committees to capture additional groups (e.g. information technology, infection control)
- Data visualization technology
- Standard Operating Procedures to share with external groups