Accepted! Refining Minimal Submission Requirements for Protocol Review and Activation

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Background
- Memorial Sloan Kettering (MSK) receives 450 protocol submissions for activation each year. Providing the minimal critical information up front is a key component for successful trial activation.
- MSK’s Minimal Submission Requirements (MSR) were developed by leadership to ensure activation readiness and includes a comprehensive list of items that, if missing, will delay trial activation.
- The Protocol Review Core (PRC) is a sub-unit within the Protocol Activation, Review & Human Research Protection Program (HRPP) Office, responsible for providing the resources and education necessary for the Principal Investigator (PI) and study teams to submit protocols that meet MSK’s MSR. (Figure 1)

Goals
- Streamline the MSR’s to improve transparency and understanding
- Improve education for clinical research staff
- Standardize process for completing MSR reviews

Solutions and Methods
- Collaborated with stakeholders to modify the MSRs (2020-Present) (Figure 3)
- Launched bi-monthly MSR trainings for study teams (January 2022)
- Expanded centralized team who review MSR from 3 to 6 and standardized processes (April 2022)

Outcomes
- 140 Research staff trained from 44 study teams and 14 departments over 18 training sessions
- 16 Updates made to the MSR guidelines since November 2020
- 1 Median days from last submission to acceptance (2021-2023) across 1,417 total submissions
- 47% Prospective studies accepted as is in 2023 (17% increase from 2021); 43% returned once and 10% returned more than once
- 38% MSK-sponsored studies accepted as is in 2023, compared to 21% in 2021

Lessons Learned
- A centralized team who specializes in the review of new protocol submissions is critical in managing ambiguous and complex submissions across numerous departments (Figure 1).
- Collaboration with stakeholders was key in refining the requirements.
- Goal of improving submission completeness is ongoing. Magnitude of varying study teams presents a training challenge.

Future Directions
- Utilize Tableau dashboard to conduct targeted trainings.
- Enhance staff education:
  - Obtain feedback from staff
  - Consider MSR office hours
  - Develop additional resources
- Continue collaboration with stakeholders and regularly assess requirements.
- Expand ability to leverage technology to ensure complete submissions.