

Developing a Standardized Library of Informed Consent Language to Ensure Consistency and Quality across Clinical Trials at a Large Academic Medical Center

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1. Background

As the volume of clinical trials at our institution continues to increase, and in view of recent changes to the Common Rule, it has become necessary to develop institutional guidelines for consent writers to ensure consistency, clarity, and quality of informed consent forms across all clinical trials. In January 2018, MSK launched a centralized Protocol Activation Core (PAC) composed of 6 Protocol Activation Managers (PAMs) and 1 Editor. Over the last 15 months, this team (now 10 PAMs and 2 Editors) has written consent forms for all newly-opened clinical trials. Creating this new unit has increased the quality of our consent documents, but it has left primary disease management teams (DMTs) with insufficient resources and training to write or edit consent forms if, for example, a new trial arm is added or a protocol amendment is mandated by the research sponsor. The PAC Editors have created a consent style guide for PAMs and DMTs, and the PAC team is developing a library of IRB-approved frequently used terms and standard descriptions to ensure clarity and consistency as new consent forms are written and older consents are updated and revised.

2. Goals

- Develop PAC Consent Library Excel tool to share with primary DMTs and study teams
- Pilot the PAC Consent Library with 3-5 high-volume DMTs to train the team members and elicit feedback
- Negotiate sponsor-specific language and develop master consent templates and libraries with industry partners
- Roll out PAC Consent Library to all DMTs and track metrics on (a) number of times amendments are returned from the IRB to DMTs for issues with consent language, and (b) time required for PAMs and DMT administrators to write or amend consents

3. Solutions and Methods

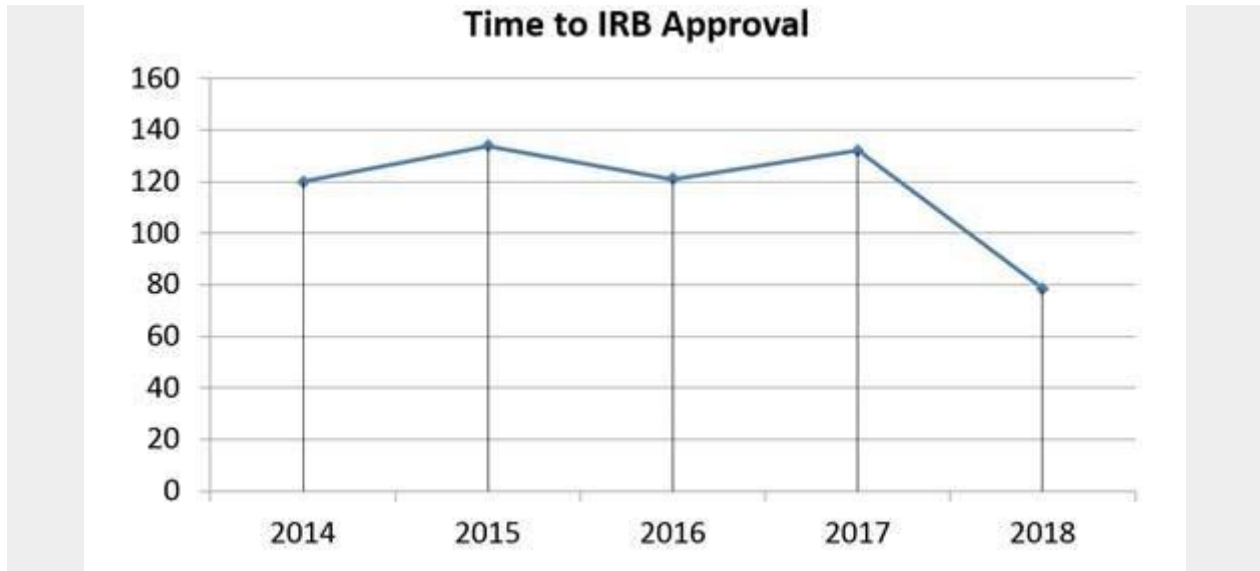
We have developed a multi-tab Microsoft Excel tool that is organized according to sections of the consent form (e.g., tests and procedures, risks, costs). The PAC Library includes only language that has been approved by MSK's IRB since the PAC unit was launched in 2018. The consent Library is shared among PAC consent writers and primary DMTs, and updated as needed based on feedback from these groups, and from the IRB and principal investigators (PIs).

4. Outcomes and Future Directions

- Consent writing has been standardized across the institution, according to disease and type of trial
- Time required to develop and revise consents has decreased

Category: Training & Quality Assurance – Work in Progress

- IRB members and PIs have become familiar with standardized descriptions and language, which has increased the efficiency of consent review (Median time for protocol/consent review by the IRB has decreased, with time-to-IRB approval decreasing from 135 days in 2017 to 80 days in 2018; see Figure.)



The most exciting prospect for the PAC Library is the development of a “smart” eConsent authoring tool that uses keywords to pull language from the Library and insert it into the appropriate section(s) of a consent document as it’s being written. As PI interest in MSK’s eConsent platform increases, writing and editing consents in the same platform will create a more streamlined and consistent approach to developing informed consent forms.