As the volume of clinical studies 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 studies. This situation has presented an opportunity to develop new consent templates, consent writing guidelines, and other resources to ensure quality and consistency as new consent forms are written and older consent forms are updated and revised.

METHODS

• In January 2018, MSK launched a centralized Protocol Activation Core (PAC) composed of 6 Protocol Activation Managers (PAMs), 3 Managers, and 1 Editor
• Over the last 15 months, this team has grown to 13 staff members who are involved with activating trials, which includes writing and editing consent forms for all newly-opened clinical studies
• As a result, the team has gained experience with the nuances of different studies and their effect on consent elements and structure
• This experience has lead to the revision and development of new consent writing tools that will be shared with the Center

GOALS

• Continue to develop and expand PAC Consent Library Excel tool to share with primary disease management teams (DMTs) for consent amendments
• Pilot the tool with 3-5 high-volume DMTs to train the team members and elicit feedback
• Present findings to IRB members
• Roll out PAC Consent Library to all DMTs and track efficiency metrics for DMTs, PAMs, and IRB members
  o Time required to write (PAM), review (IRB), amend (DMT/PAM) consents
  o Number of amendments returned or not approved for consent-related reasons

NEW – PAC Consent Library

• Redesigned MSK templates for treatment and verbal consents; developed templates for other consent situations (e.g., pre-screening, treatment post-progression, and specialized templates for industry partners)
• Based on NCI Model, incorporating Common Rule changes, and institutional requirements

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

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BACKGROUND

OUTCOMES

• As we have continued to expand the use of these tools, we have seen a marked decrease in time to IRB approval: 135 days in 2017 to 78.5 days in 2018

METHODS

• Language examples organized by section of consent form
• Detailed examples provided for various types of studies (e.g., Phase 1 First-in-Human, Phase 2/3 in Previously Untreated Patients, Diagnostic Imaging)
• Approved conflict of interest text, Research-related injury language (by sponsor), and required genetic testing text

FUTURE DIRECTIONS

• Continue to develop and negotiate master consent templates for industry partners
• Post consent resources for DMTs outside of PAC to access as needed for amendments
• Train DMTs to use the consent resources
• Establish a structured feedback system for the IRB to review and update these resources
• Develop “smart” eConsent authoring tool that uses keywords to collect approved text from the PAC Consent Library. Other features of this tool will include:
  o Locked sections of required language
  o Audit trail for consent edits
  o More accurate version control