Memorial Sloan Kettering Cancer Center

Championing Project Management and Leadership when Identifying a Gap in Clinical Research

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BACKGROUND

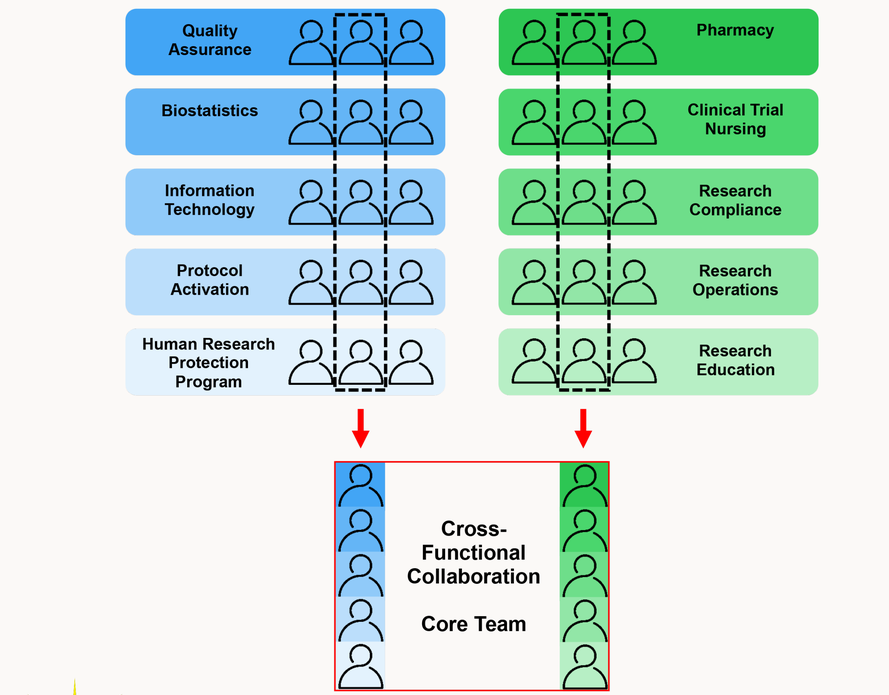
The randomization, blinding, and unblinding processes in clinical trials are essential cornerstones in clinical trial methodology, ensuring unbiased participant allocation to treatment groups and the eventual disclosure of study results. Standard Operating Procedures (SOPs) are indispensable tools for maintaining consistency and quality in such processes. However, the absence of a defined SOP for randomization, blinding, and unblinding poses significant risks to participant's welfare, trial integrity and regulatory compliance. This case study delves into how Memorial Sloan Kettering Cancer Center's (MSK's) Clinical Research Quality Assurance (CRQA) team identified the absence of a randomization, blinding, and unblinding guidelines, and proactively addressed this gap.

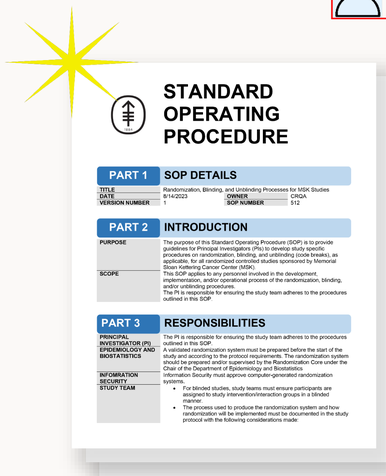
GOALS

The principal aim of this project was to provide guidance, tools, and templates to all study personnel involved in the development and implementation of the randomization, blinding, and unblinding process, to ensure consistency, regulatory adherence, and protect the health and welfare of participants. Moreover, the project sought to exemplify effective project management and leadership in navigating cross-functional collaboration and overcoming inherent challenges in SOP development.

METHODS

Due to the complexity and interdisciplinary nature of the randomization, blinding, and unblinding policy, the CRQA team assumed responsibility in recognition of the extensive overlap between various departments involved in the policy's implementation. With input required from multiple teams, the traditional method of determining ownership through departmental meetings would have been time-consuming and potentially inefficient. The CRQA team initiated the project by conducting an exhaustive assessment of existing processes and documentation concerning randomization, blinding, and unblinding processes. Through stakeholder engagement and cross-functional collaboration with pertinent departments such as Biostatistics, Protocol Activation, Human Research Protection Program, Pharmacy, Clinical Trial Nursing, Research Compliance, Research Operations, etc., the team pinpointed essential requirements and best practices for randomization, blinding, and unblinding processes. Leveraging project management methods and regular communication channels, the CRQA team drafted the SOP, facilitated meeting sessions, solicited feedback, and iteratively refined the document.




STANDARD OPERATING PROCEDURE

PART 1 SOP DETAILS

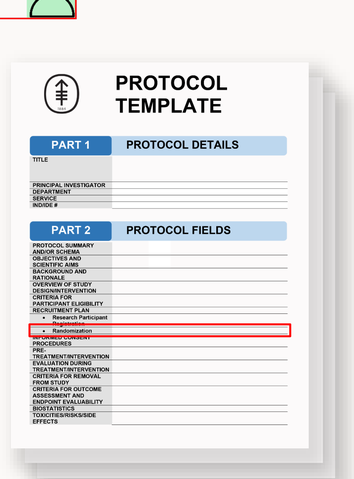
TITLE	Randomization, Blinding, and Unblinding Processes for MSK Studies		
DATE	6/14/2023	OWNER	CRQA
VERSION NUMBER	1	SOP NUMBER	512

PART 2 INTRODUCTION

PURPOSE	The purpose of this Standard Operating Procedure (SOP) is to provide guidelines for Principal Investigators (PIs) to develop study specific procedures on randomization, blinding, and unblinding (code breaks), as applicable, for all non-commercial clinical studies sponsored by Memorial Sloan Kettering Cancer Center (MSK).
SCOPE	This SOP applies to any personnel involved in the development, implementation, and/or operational process of the randomization, blinding, and/or unblinding procedures. The PI is responsible for ensuring the study team adheres to the procedures outlined in this SOP.

PART 3 RESPONSIBILITIES

PRINCIPAL INVESTIGATOR (PI)	The PI is responsible for ensuring the study team adheres to the procedures outlined in this SOP.
EPIDEMIOLOGY AND BIOSTATISTICS	A validated randomization system must be prepared before the start of the study and according to the protocol requirements. The randomization system should be prepared and/or supervised by the Randomization Core under the Chair of the Department of Epidemiology and Biostatistics.
INFORMATION SECURITY	Information Security must approve computer-generated randomization systems.
STUDY TEAM	• For blinded studies, study teams must ensure participants are assigned to study intervention/intervention groups in a blinded manner. • The process used to produce the randomization system and how randomization will be implemented must be documented in the study protocol with the following considerations made:


PROTOCOL TEMPLATE

PART 1 PROTOCOL DETAILS

TITLE	
PRINCIPAL INVESTIGATOR	
DEPARTMENT	
SERVICE	
IND/IDE #	

PART 2 PROTOCOL FIELDS

PROTOCOL SUMMARY	
AND/OR SCHEMA	
OBJECTIVES AND	
SCIENTIFIC AIMS	
BACKGROUND AND	
RATIONALE	
OVERVIEW OF STUDY	
DESIGN/INTERVENTION	
CRITERIA FOR	
PARTICIPANT ELIGIBILITY	
RECRUITMENT PLAN	
• Research Participant	
• Registration	
• Randomization	
INFORMED CONSENT	
PROCEDURES	
PRE-TREATMENT/INTERVENTION	
EVALUATION DURING	
TREATMENT/INTERVENTION	
CRITERIA FOR REMOVAL FROM STUDY	
CRITERIA FOR OUTCOME ASSESSMENT AND	
RESPONSE EVALUABILITY	
BIOSTATISTICS	
TOXICITIES/RISKS/SIDE EFFECTS	

RESULTS

The collaborative endeavors of the CRQA team culminated in the expedited and successful development and implementation of a comprehensive SOP for randomization, blinding, and unblinding processes. Moreover, the institutional protocol template was updated to incorporate instructions and placeholders to describe the randomization, as required by the new clinical research SOP. By assuming the leadership role and effectively managing the project, the CRQA team ensured that all stakeholders were engaged, and their expertise was harnessed throughout the process. The new SOP not only rectified the identified gap but also elevated overall quality assurance practices within the organization. Furthermore, the project served as a testament to the significance of proactive problem-solving, effective communication, and strong leadership in propelling continuous improvement initiatives in a clinical research program.

CONCLUSION

This case study underscores the pivotal role of project management and leadership in addressing critical gaps in protocol management processes within clinical trial operations. By spearheading cross-functional collaboration and steering the development of vital SOPs, quality assurance teams can uphold the highest standards of quality, integrity, and compliance in clinical research programs. Through proactive identification and resolution of deficiencies, organizations can fortify their processes, ensuring the reliability and validity of trial outcomes while adhering to regulatory standards. As exemplified in this case, effective project management and leadership are indispensable in driving transformative changes.