

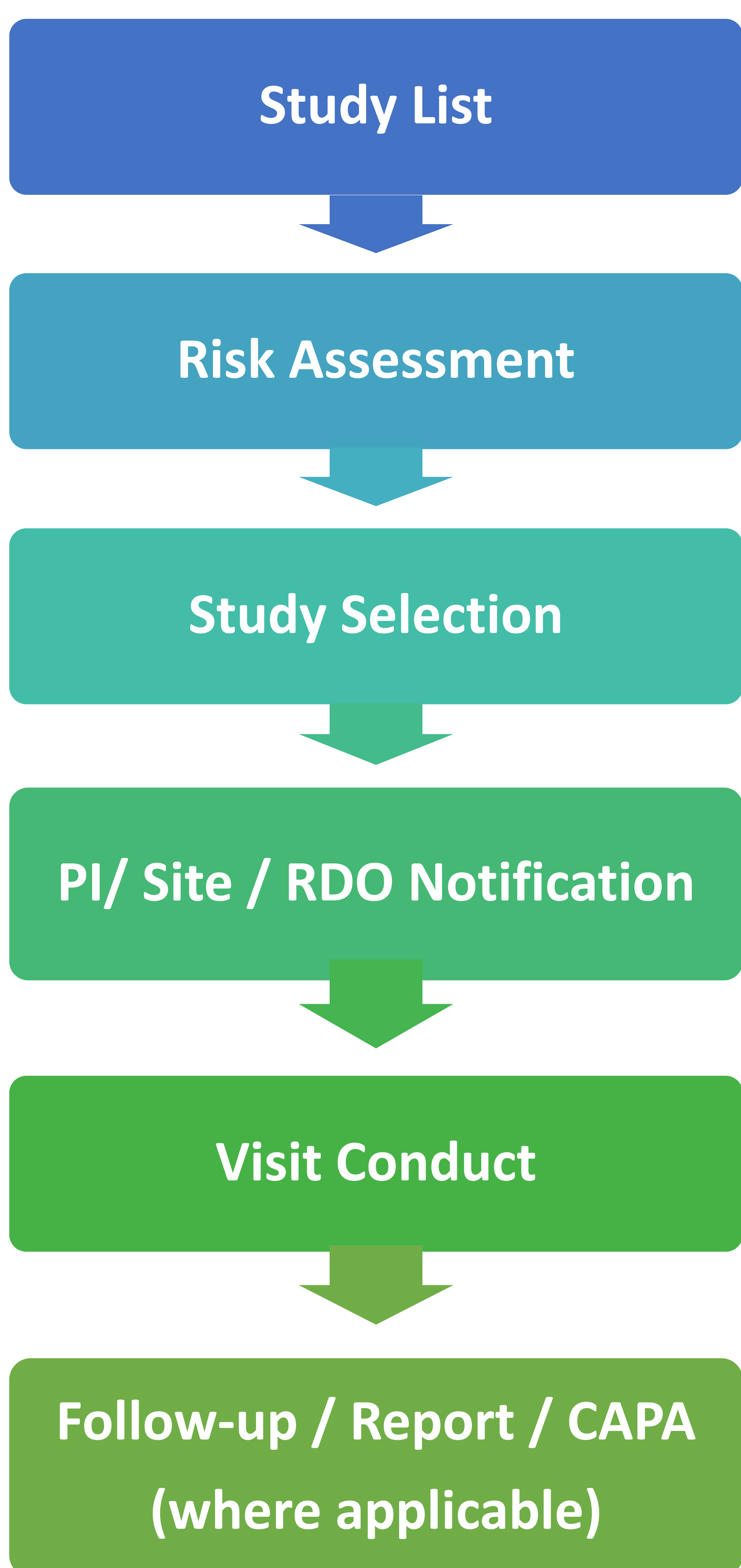


INTRODUCTION

Adequate oversight of research is required to ensure regulations, standards and guidelines are adhered. A risk-based monitoring framework is developed to address the different types of research across various SingHealth institutions.

METHODOLOGY

- A monitoring framework is developed to identify, select and monitor research regulated by Human Biomedical Research Act (HBRA) and/or Health Sciences Authority (HSA).
- Studies are stratified into High, Medium and Low risk categories.
- Monitoring strategies for each category will be defined in a monitoring plan.
- Significant findings, actions and recommendations will be provided in a monitoring report.



	RISK CATEGORY		
	High	Medium	Low
TYPES OF CLINICAL RESEARCH	HBRA-Regulated Human Biomedical Research (HBR) HSA-Regulated Clinical Trial (CTC, CTA)	HBRA-Regulated Human Biomedical Research (HBR) HSA-Regulated Clinical Trial (CTN)	Exempted
EXAMPLES OF STUDIES	<ul style="list-style-type: none"> ▪ Device (Unregistered, Registered Class C and D) ▪ Surgical / Radiotherapy ▪ Vulnerable Population ▪ Phase 1 / First-In-Man 	<ul style="list-style-type: none"> ▪ Biomarker Study ▪ Genomics Study ▪ Psychiatric / Cognitive Study ▪ Diagnostic Imaging 	<ul style="list-style-type: none"> ▪ Medical Record Review ▪ Prospective / Retrospective Surveillance ▪ Health Economics and Outcomes Research
IRB REVIEW	Full Board	Expedited (based on specific sets of criteria)	Exempted
POPULATION	<ul style="list-style-type: none"> ▪ Vulnerable Patients ▪ Healthy Volunteers 	<ul style="list-style-type: none"> ▪ Vulnerable Patients ▪ Healthy Volunteers ▪ Targeted Patients 	<ul style="list-style-type: none"> ▪ General Population ▪ Healthy Volunteers ▪ Targeted Patients

RESULT

- By defining a risk-based monitoring framework, an effective oversight of research within SingHealth is established.
- Monitoring process ensures data quality, integrity and patient safety.
- Monitoring resources are optimized.

CONCLUSION

Risks of research are appropriately managed with an effective monitoring framework within SingHealth, resulting in scientific quality while adhering to applicable regulatory guidelines.