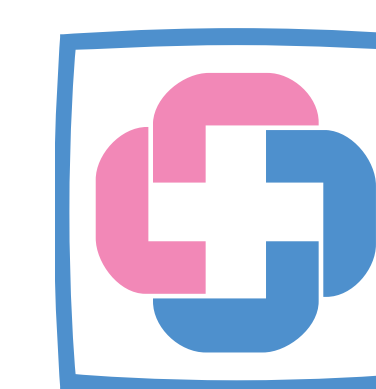




**Singapore Healthcare  
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# Research Quality Audit Framework in KK Women's and Children's Hospital

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Children's Hospital**  
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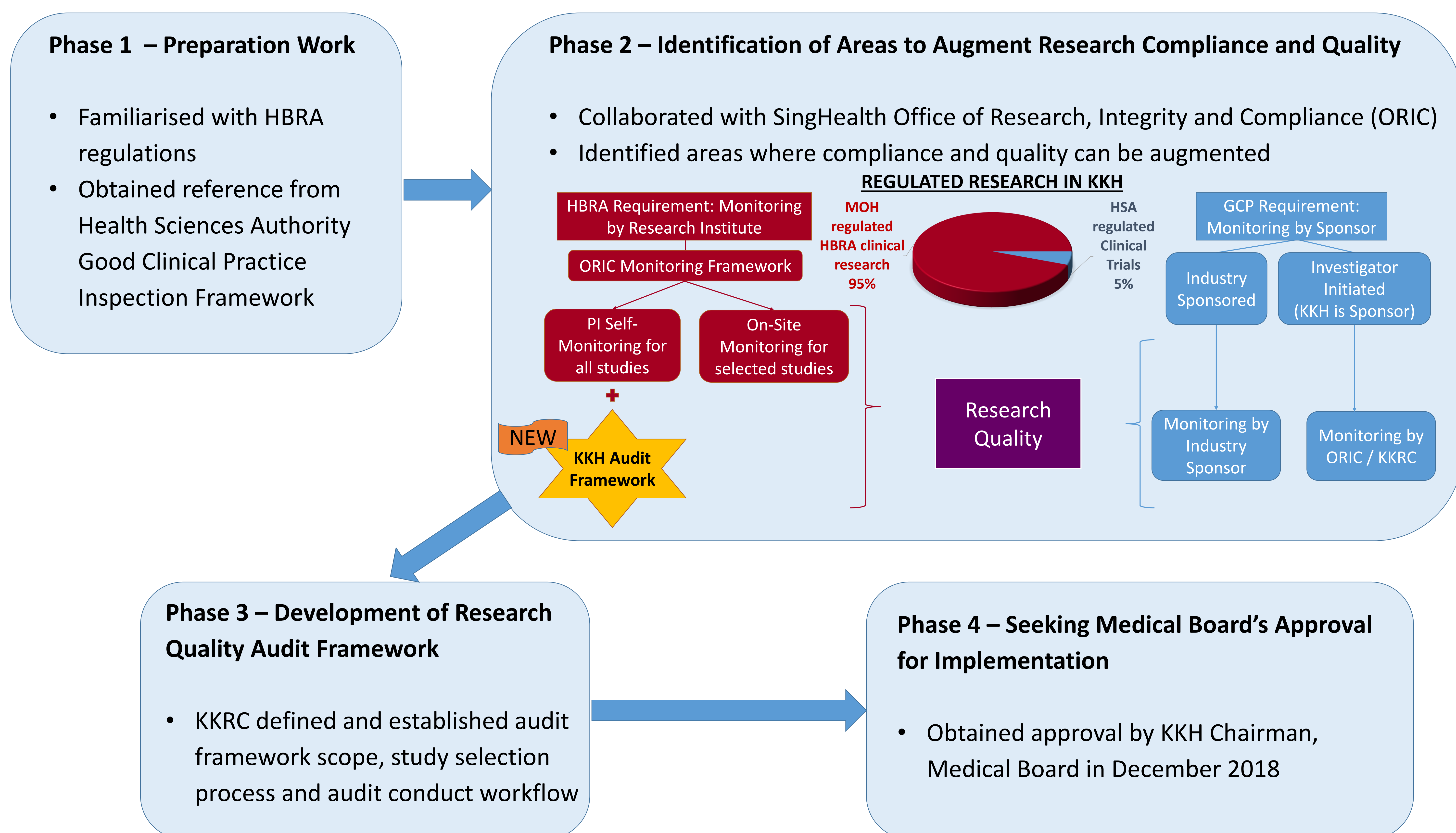
## INTRODUCTION

The Human Biomedical Research Act (HBRA) came into force on 1 November 2017. As clinical research regulated by the new HBRA regulations makes up approximately 95% of all regulated research in KK Women's and Children's Hospital (KKH), KK Research Centre (KKRC) seeks to reduce the risks of research non-compliance through research internal audits.

## OBJECTIVES

The audit framework aims to increase oversight of clinical research in KKH through a broad-based study selection using a simple dynamic algorithm based on risk evaluation. We hope that the framework will ensure regulatory compliance and lead to an overall enhancement of research quality at KKH.

## METHODOLOGY



## RESULTS

- The KKH Research Quality Audit Framework was launched in January 2019 and a hospital policy has been developed.
- Research studies for audit were selected based on a risk-based approach:

Level 1 Institutional Risk	Based on level of research activities in each division within KKH (At least 1 study from each division will be selected annually to maintain oversight)
Level 2 Study Protocol Risk	Based on MOH Audit Risk Assessment (Risk scoring of research protocols including minor, pregnant women, target recruitment number, length of research study, complexity of research protocols, number of research sites, etc.)

- Audit visits have been conducted for 8 HBRA regulated research till May 2019 and it is on an ongoing basis.
- Areas for improvement identified during the audits were communicated with the research study teams through audit reports and also sharing with the research community (e.g. Clinical Research Coordinator Network).

## CONCLUSION

Risks of research regulatory non-compliances have been reduced through the corrective and preventive actions from the findings of the internal audits as well as communication with the KKH research community.