Streamlining Regulatory Reporting to MOH according to HBRA Requirements

Singapore Healthcare Management 2018

SingHealth

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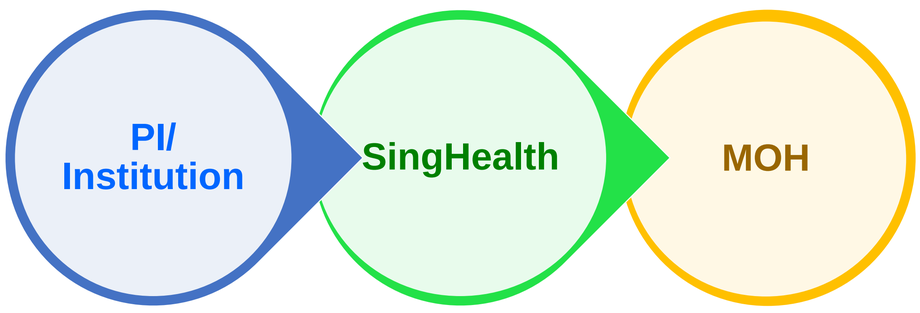
INTRODUCTION

- The Human Biomedical Research Framework of **Human Biomedical Research Act (HBRA)** was activated on 1 Nov 2017.
- SingHealth had notified MOH of its operation as an Research Institution (RI). One of the key duties of an RI is to provide supervision, review and proactively monitor the safety and ethical conduct of the research. Timely reporting of Serious Adverse Events (SAEs) and Contraventions to MOH are required.
- To ensure full compliance to HBRA and proper conduct of human biomedical research within SingHealth, the **SingHealth Office of Research Integrity and Compliance (ORIC)** is responsible for streamlining the reporting process to MOH.
- A central tracking system and workflow have been created to identify and follow up on events requiring reporting to MOH.

METHODOLOGY

Notification Process of HBR SAEs & Contraventions

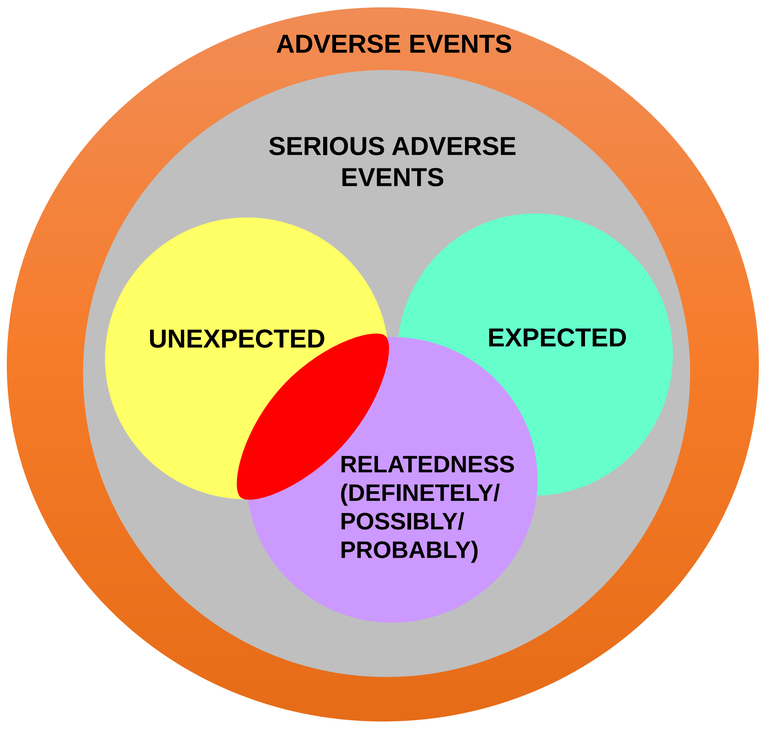


Principal Investigators (PI) are required to report SAEs and Protocol Deviations/Non-Compliances to the CIRB through iSHaRe.

SingHealth RESEARCH iSHaRe

ORIC would extract details of the SAEs and Protocol Deviations/Non-Compliances from iSHaRe to track any reportable events.

HBR Serious Adverse Events



ORIC will report local and overseas Unexpected and Possible/Probably/Definitely Related SAEs to MOH.

ORIC will submit all relevant information to MOH within 7 days (SAE resulting in Death or is Life-threatening) or 15 days (Non-life threatening SAE)

HBR Contraventions

SingHealth will adopt the definitions of HSA "Serious Breach" for MOH reporting of contraventions.

Serious Breach:
A breach which is likely to affect to a significant degree:

(a)The safety, or physical or mental integrity, of any subject, or
(b)The scientific value of the study

ORIC will track all non-compliances reported and submit a contravention report to MOH if it meets the Serious Breach Criteria.

ORIC will submit all relevant information to MOH within 7 days

RESULTS

- An efficient central tracking system and workflow process have been developed to monitor the safety and compliance of research.
- This reduces the workload of researchers and eliminate duplication of reporting at institution level.

CONCLUSION

The central tracking system and workflow, enable SingHealth to

- Assess the reportable events to MOH efficiently
- Comply with MOH regulatory requirements