

# Human Biomedical Research Act

## HBR Regulatory Audit

- ❖ The Ministry of Health (MOH) is committed to protect the safety and welfare of research subjects, ensuring that their health and well-being are not compromised, and their privacy and autonomy respected.
- ❖ In an effort to ensure that all Human Biomedical Research (HBR) conducted in Singapore fulfil the legal requirements under the Human Biomedical Research Act, Research Institutions (RIs) will be audited by MOH from January 2019 onwards.

1

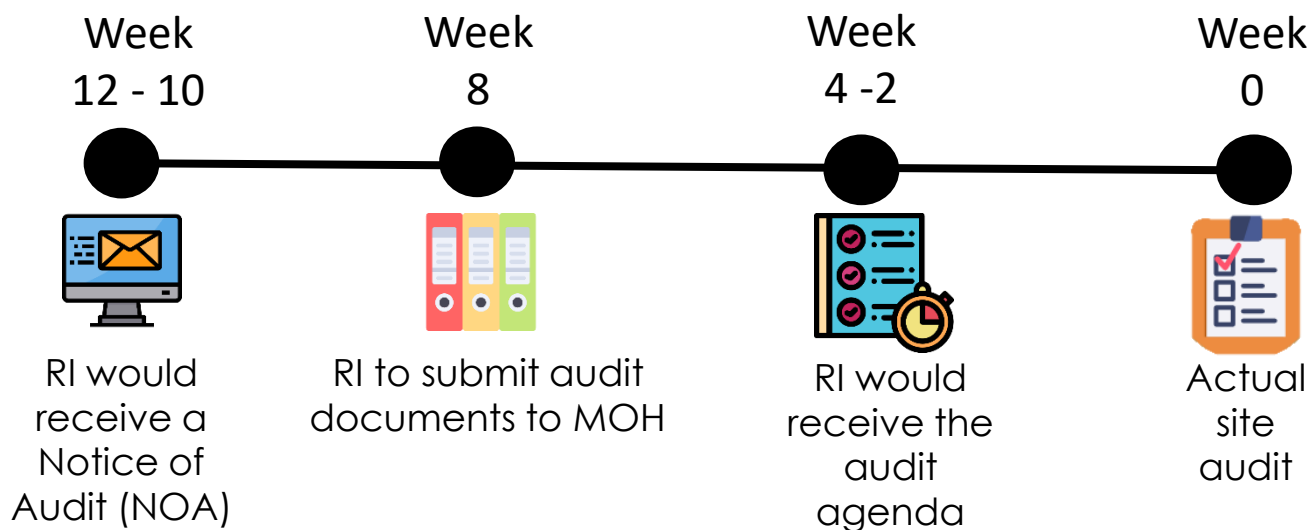
### Who would be audited?



All RIs that have notified MOH of their operation.

2

### What is the timeline for the HBR audit?





3

## Who might be involved during the site audit?



Principal Person-in-Charge



Point of Contact



IRB Rep



Research Office Rep



PI / Co-I



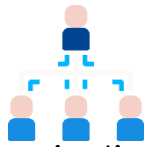
Research Coordinator

Note: Please refer to the audit agenda for more information.

4

## How do I prepare for the HBR audit ?

### a) Documents to be submitted before site audit



i) Organisation chart & HBR reporting structure



ii) HBR study protocols document & dossier (including restricted HBR)



iii) SOPs and workflows



iv) Key statistics



v) IRB documents

### b) Documents/items to be prepared on-site



i) Opening meeting : briefing & demo of HBR IT systems

#### ii) Review of consent documents



RIs are strongly encouraged to prepare 1 consent folder for each HBR/rHBR protocol. This folder should contain all the consent forms signed by the recruited research subjects.

#### iii) Review of protocol-related documents (PD)



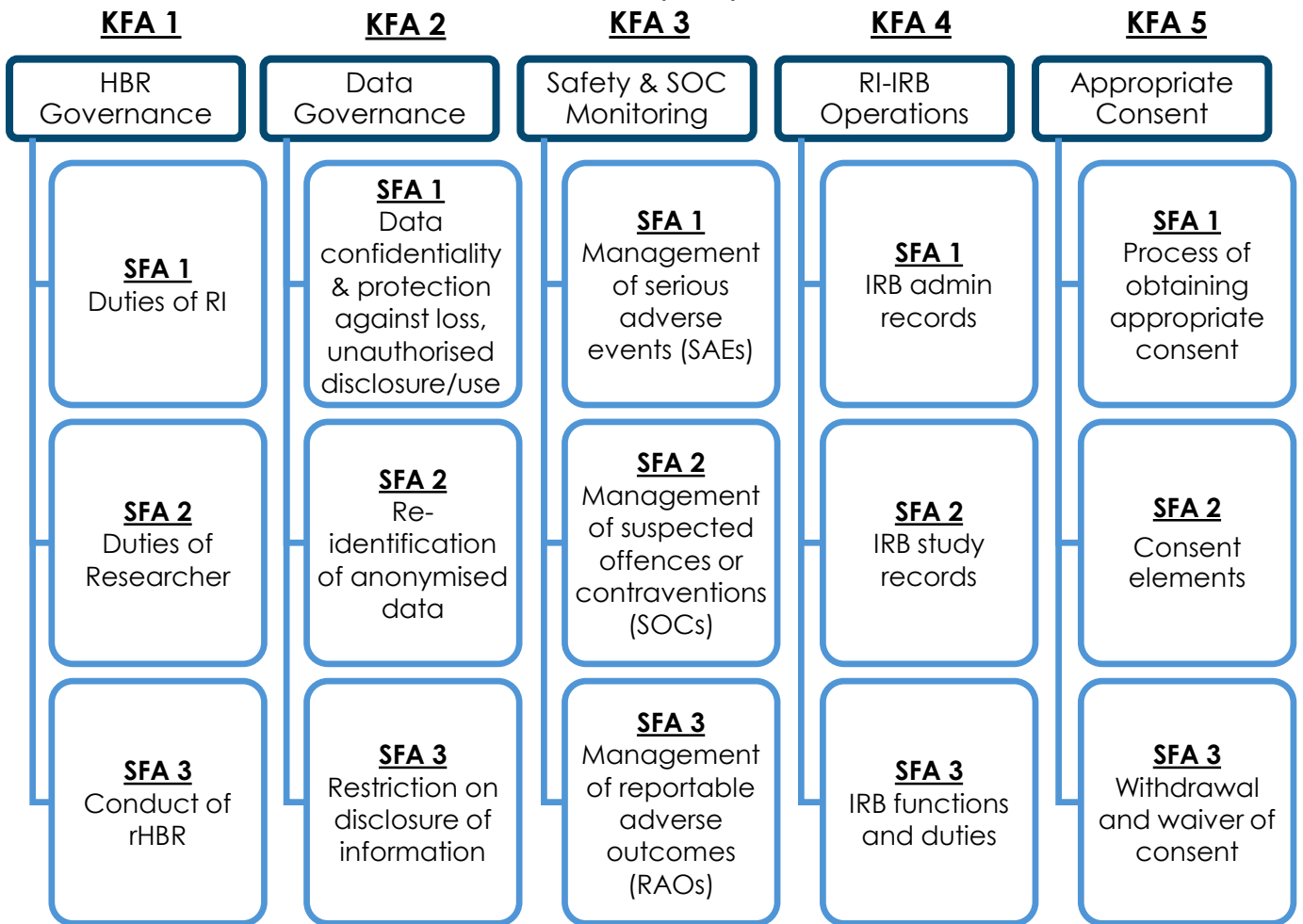
RIs are strongly encouraged to prepare 1 PD folder for each HBR/rHBR protocol (e.g. IRB appointment letters and declaration documents, meeting minutes etc.).



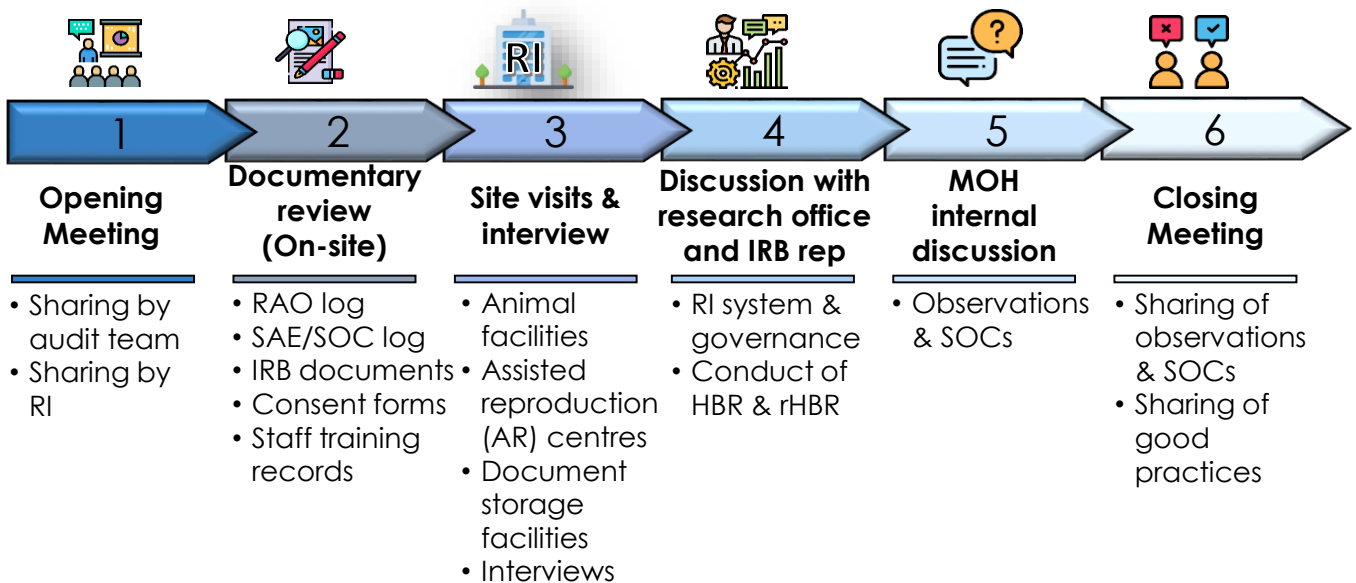
5

# How would the audit be conducted?

The HBR audit would focus primarily on 5 Key Focal Areas(KFA) with specific sub-focal areas(SFA) for each KFA.



The HBR audit would usually be conducted over a span of 2 – 3 days.





6

## What happens after the on-site audit?



i) Audit findings (observations & SOCs) communicated through email to RI.



ii) RIs to reply with CAPA\* for SOCs within **15 working days** from receipt of audit findings.



iii) Implementation of CAPA for observations and SOCs detected from audit may be subject to checks and inspection by MOH as required.

\* CAPA: Corrective & Preventive Action Plan



### Questions?

Contact us at [hbr\\_enquiries@moh.gov.sg](mailto:hbr_enquiries@moh.gov.sg)

Brought to you by:

MOH Biomedical Research Regulation Branch  
Regulatory Compliance & Enforcement Division