HBRA-CSIG-2019-001-AUD
September 2019

MINISTRY OF HEALTH
SINGAPORE

Human Biomedical Research Act

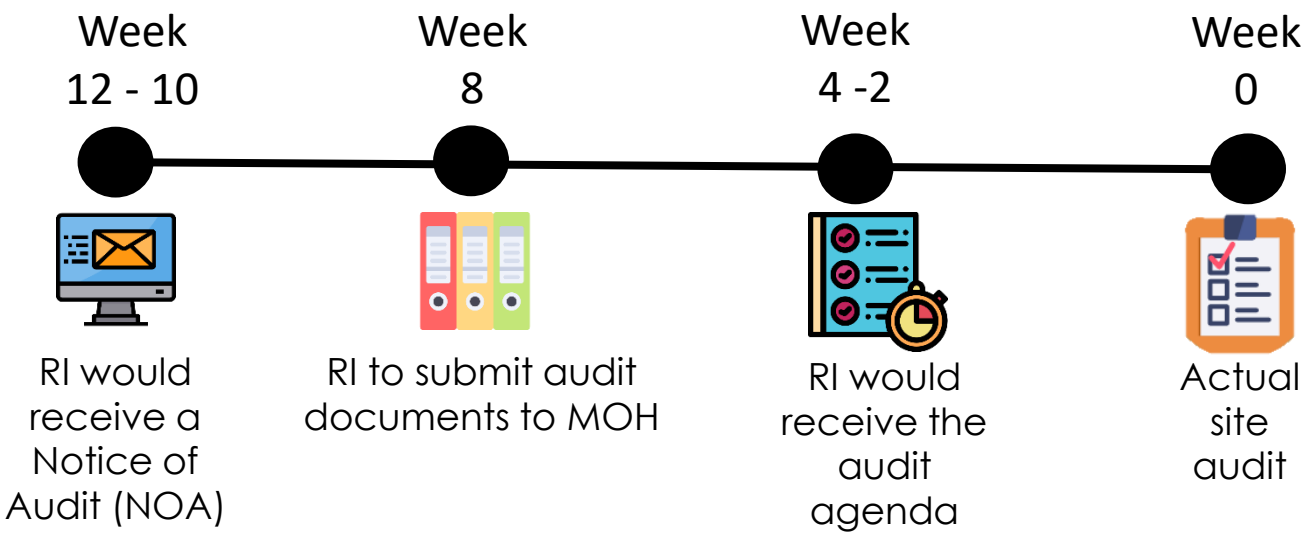
HBR Regulatory Audit

- **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 <u>before</u> 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 <u>on-site</u>

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

ii) Review of consent documents

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

iii) Review of protocol-related documents (PD)

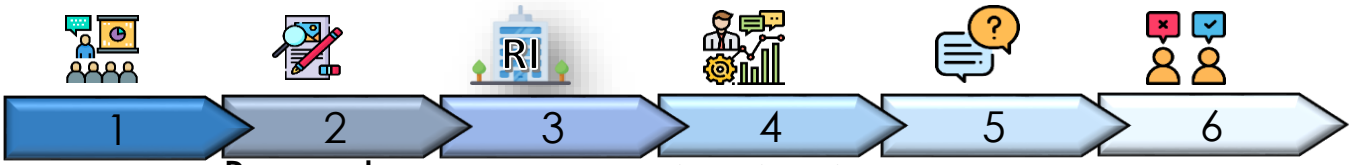
RIs are strongly encouraged to prepare <u>1 PD folder for each HBR/rHBR protocol</u> (e.g. IRB appointment letters and declaration documents, meeting minutes etc.).

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.

KFA 1	KFA 2	KFA 3	KFA 4	KFA 5
HBR Governance	Data Governance	Safety & SOC Monitoring	RI-IRB Operations	Appropriate Consent
SFA 1 Duties of RI	**SFA 1** Data confidentiality & protection against loss, unauthorised disclosure/use	**SFA 1** Management of serious adverse events (SAEs)	**SFA 1** IRB admin records	**SFA 1** Process of obtaining appropriate consent
SFA 2 Duties of Researcher	**SFA 2** Re-identification of anonymised data	**SFA 2** Management of suspected offences or contraventions (SOCs)	**SFA 2** IRB study records	**SFA 2** Consent elements
SFA 3 Conduct of rHBR	**SFA 3** Restriction on disclosure of information	**SFA 3** Management of reportable adverse outcomes (RAOs)	**SFA 3** IRB functions and duties	**SFA 3** Withdrawal and waiver of consent

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



1 Opening Meeting
- Sharing by audit team
- Sharing by RI

2 Documentary review (On-site)
- RAO log
- SAE/SOC log
- IRB documents
- Consent forms
- Staff training records

3 Site visits & interview
- Animal facilities
- Assisted reproduction (AR) centres
- Document storage facilities
- Interviews

4 Discussion with research office and IRB rep
- RI system & governance
- Conduct of HBR & rHBR

5 MOH internal discussion
- Observations & SOCs

6 Closing Meeting
- Sharing of observations & SOCs
- Sharing of good practices

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 Action and Preventive Action

Questions?

Contact us at hbr_enquiries@moh.gov.sg

Brought to you by:
MOH Biomedical Research Regulation Branch
Regulatory Compliance & Enforcement Division