

# Human Biomedical Research Act

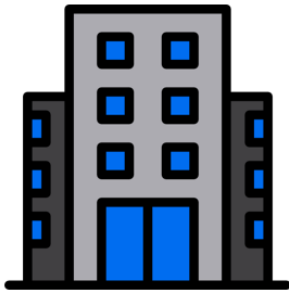
## TB Regulatory Audit

- ❖ The Ministry of Health (MOH) is committed to protect the safety and welfare of tissue donors, ensuring that their health and well-being are not compromised, and their privacy and autonomy respected.
- ❖ In an effort to ensure that all tissue banking activities conducted in Singapore for research purposes fulfil the legal requirements under the Human Biomedical Research Act, Tissue Banks (TBs) will be audited by MOH from 2020 onwards.

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### Who would be audited?

#### Tissue Bank

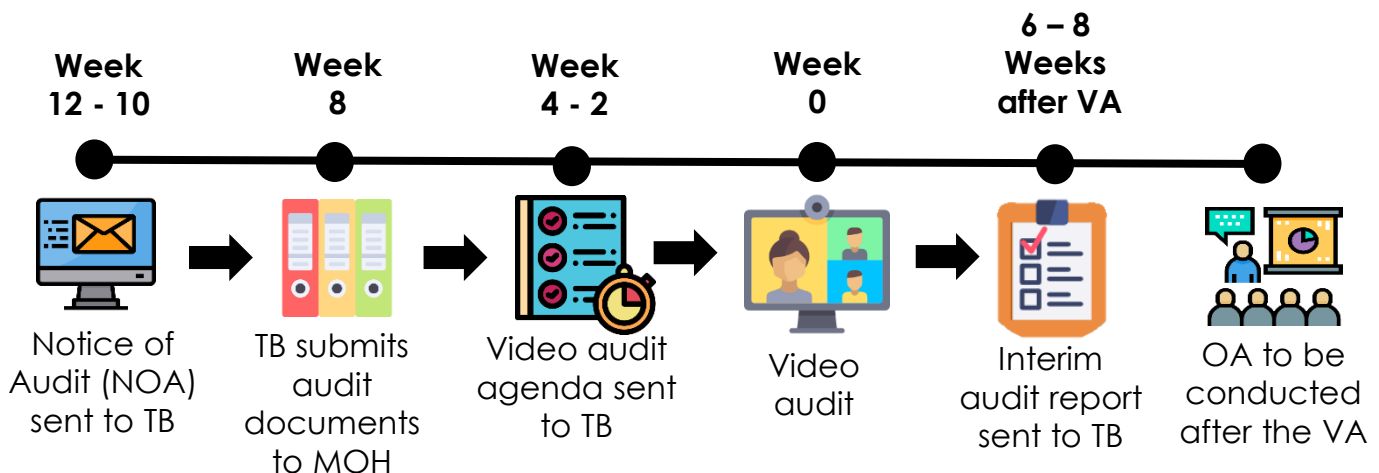


All TBs that have notified MOH of their operation.

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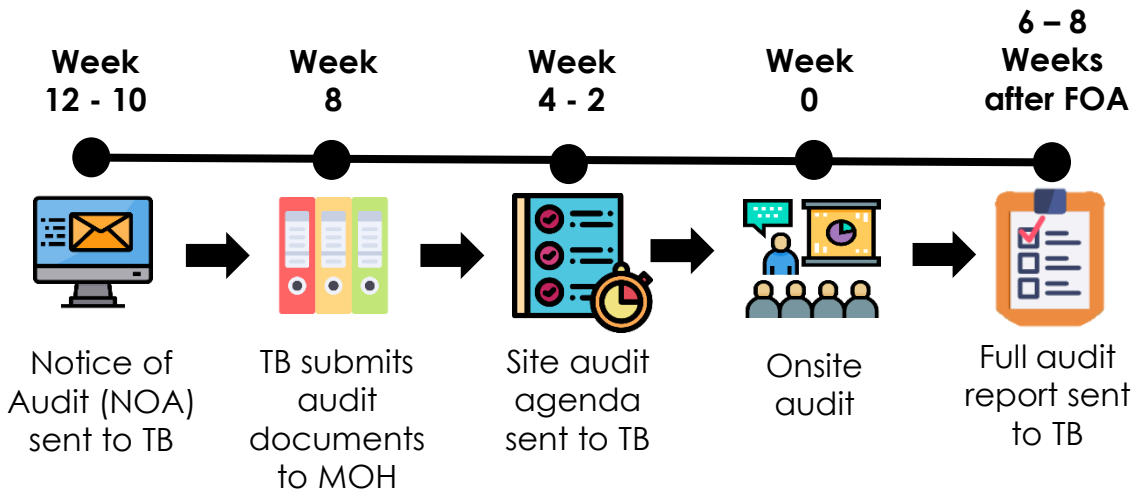
### What is the timeline for the TB audit?

#### Mode 1 : Offsite Video Audit (VA) + Onsite Audit (OA)



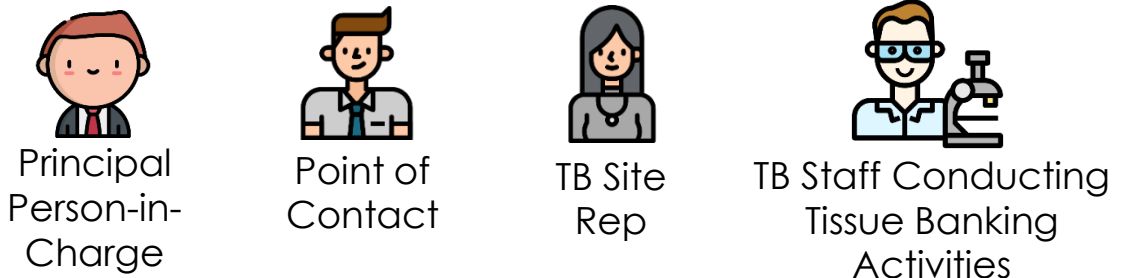


## Mode 2 : Full Onsite Audit (FOA)



Note: TB will be informed of the mode of TB audit in the NOA.

### 3 Who might be involved during the audit ?



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

### 4 How do I prepare for the TB audit?

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

- i) Organisation Chart & TB Reporting Structure (Icon: Organizational chart)
- ii) Audit Dossier (one for each TB site) (Icon: Audit dossier)
- iii) SOPs and Workflows (Icon: SOPs and workflows)
- iv) Key Statistics (Icon: Key statistics chart)
- v) Consent Form Template (Icon: Consent form template)



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

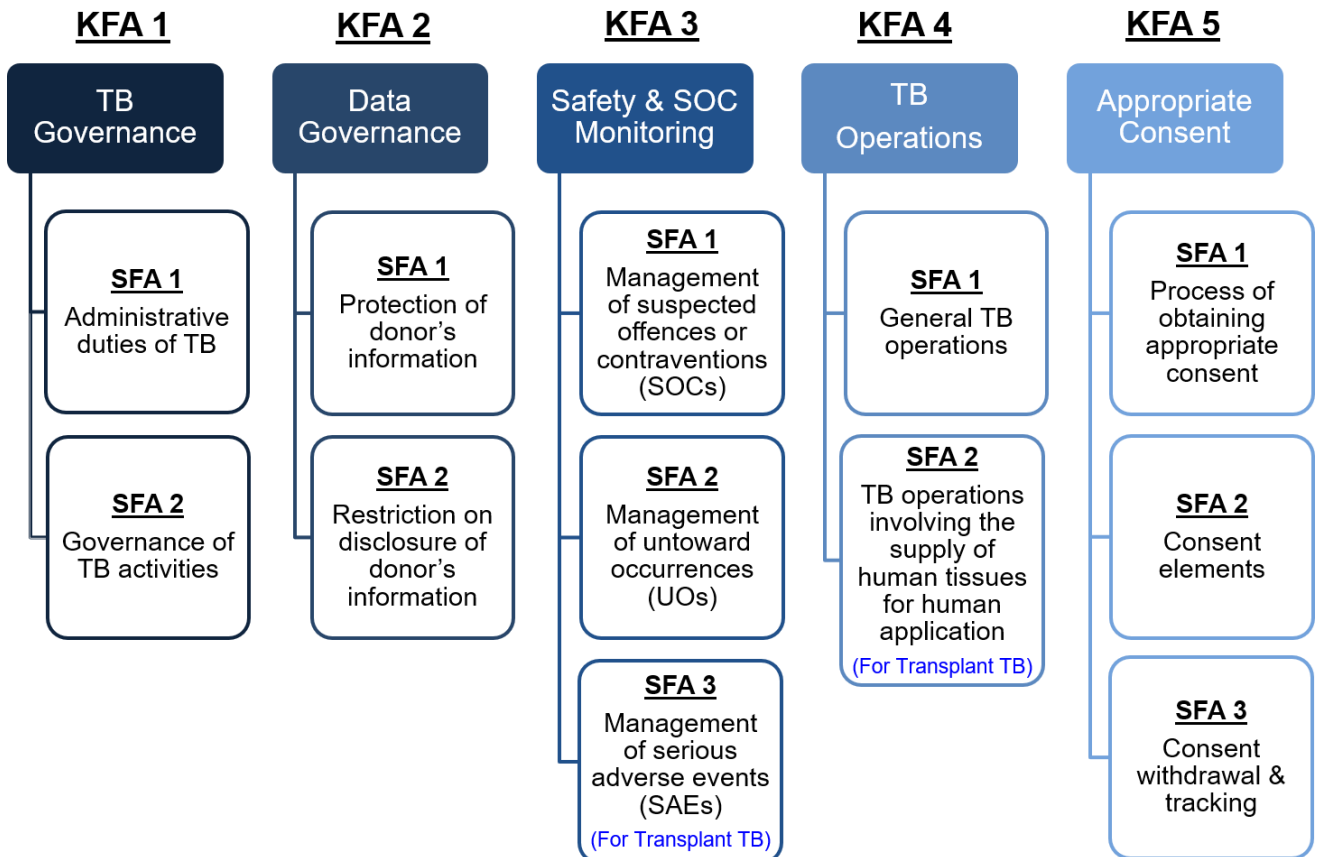
It is strongly encouraged for every TB site to have 1 folder for each of the following documentations:

- i. Monitoring of serious adverse event (SAE), untoward occurrence (UO) and suspected offence or contravention (SOC).
- ii. Consent forms signed by the tissue donors.
- iii. TB's operationalization of its SOPs / workflows and other documentations (e.g. documentation that the recipient of the tissue sample is informed of donor's consent conditions).

### 5


## How would the audit be conducted?

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







ii. Audit processes

 **Opening (VA / OA)**

- Sharing by MOH audit team.
- Sharing by TB.
- Demo of IT systems.

 **Interviews (VA / OA)**


- POCs.
- TB staffs conducting tissue banking activities.

 **Documentary review (OA)**

- SAE, SOC & UO log.
- Consent documents.
- TB operations documents.
- Staff training records.

 **Site visits (OA)**

- Main & satellite sites.
- Document storage facilities.
- Human tissue storage facilities.

 **Closing (VA / OA)**

- Sharing of observations & SOCs.
- Sharing of good practices.

VA – Offsite Video Audit; OA – Onsite Audit

## 6 What happens after the audit?



i) Audit findings (observations & SOCs) will be emailed to the TB.



ii) TBs to reply with CAPA (Corrective & Preventive Action Plan) for SOCs within **15 working days** from receipt of the email from MOH.



iii) Implementation of CAPA will be subject to checks and inspection by MOH.



### 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