MINISTRY OF HEALTH
SINGAPORE

# 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.**

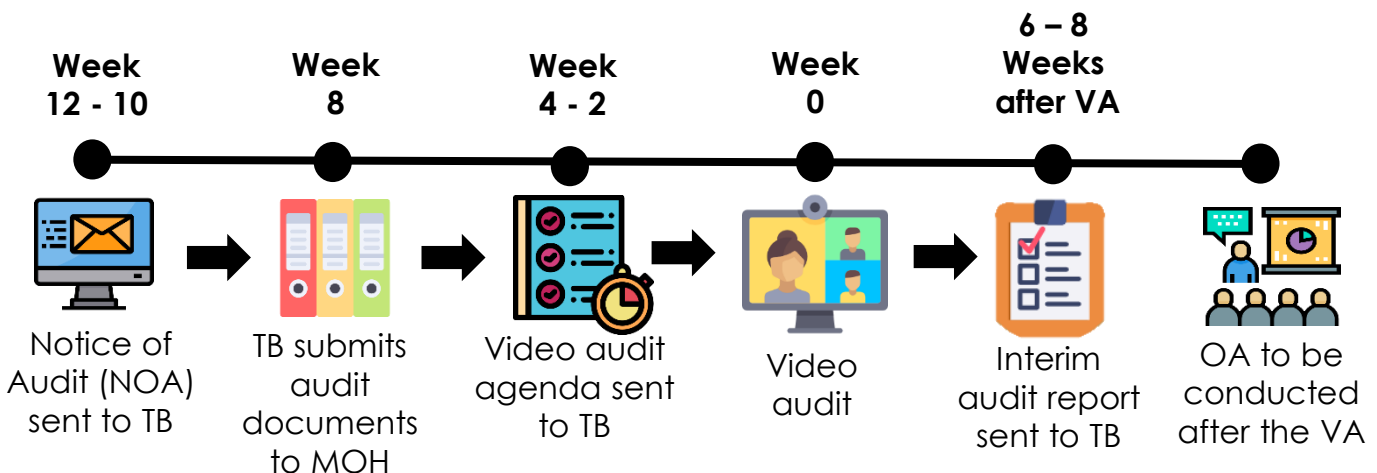**1** | ## Who would be audited?

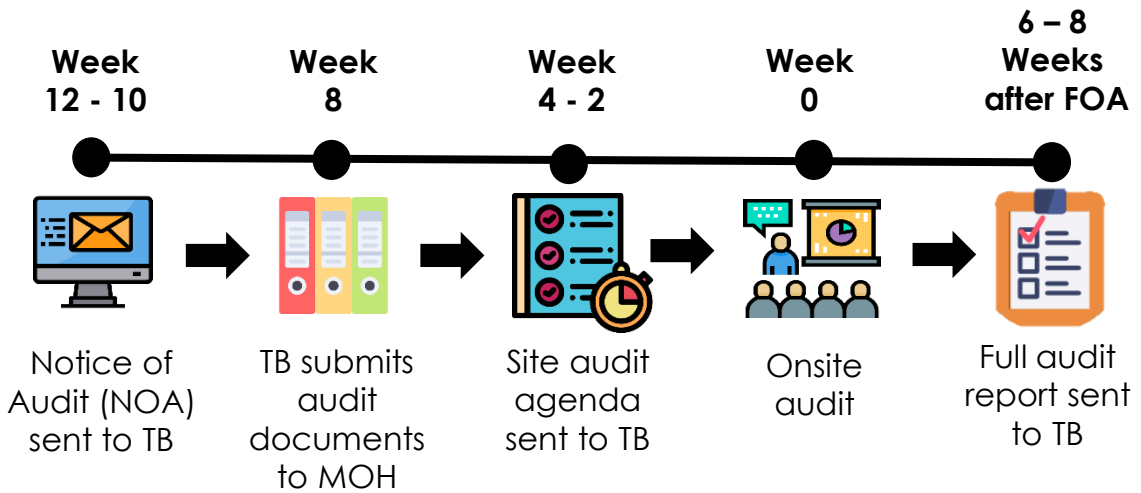### Tissue Bank
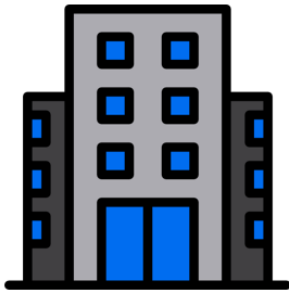
All TBs that have notified MOH of their operation.

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

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

Week 12 - 10	Week 8	Week 4 - 2	Week 0	6 – 8 Weeks after VA	
Notice of Audit (NOA) sent to TB	TB submits audit documents to MOH	Video audit agenda sent to TB	Video audit	Interim audit report sent to TB	OA to be conducted after the VA

Mode 2 : Full Onsite Audit (FOA)

Week 12 - 10	Week 8	Week 4 - 2	Week 0	6 – 8 Weeks after FOA
Notice of Audit (NOA) sent to TB	TB submits audit documents to MOH	Site audit agenda sent to TB	Onsite audit	Full audit report sent to TB

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

3. Who might be involved during the audit ?

Principal Person-in-Charge	Point of Contact	TB Site Rep	TB Staff Conducting Tissue Banking Activities
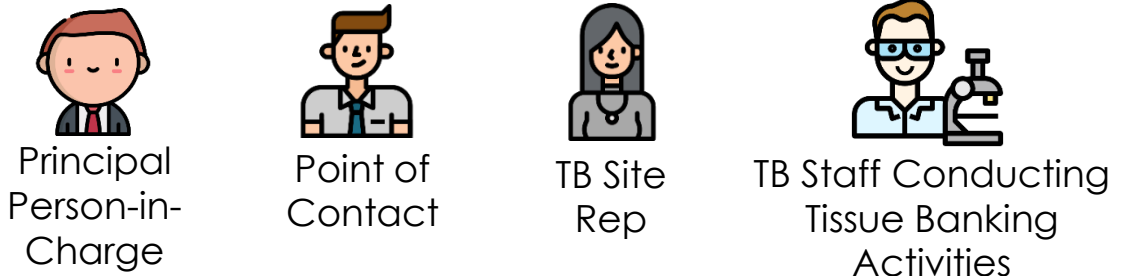
Note: Please refer to the audit agenda for more information.

4. How do I prepare for the TB audit?

a) Documents to be submitted before audit

i) Organisation Chart & TB Reporting Structure

ii) Audit Dossier (one for each TB site)

iii) SOPs and Workflows
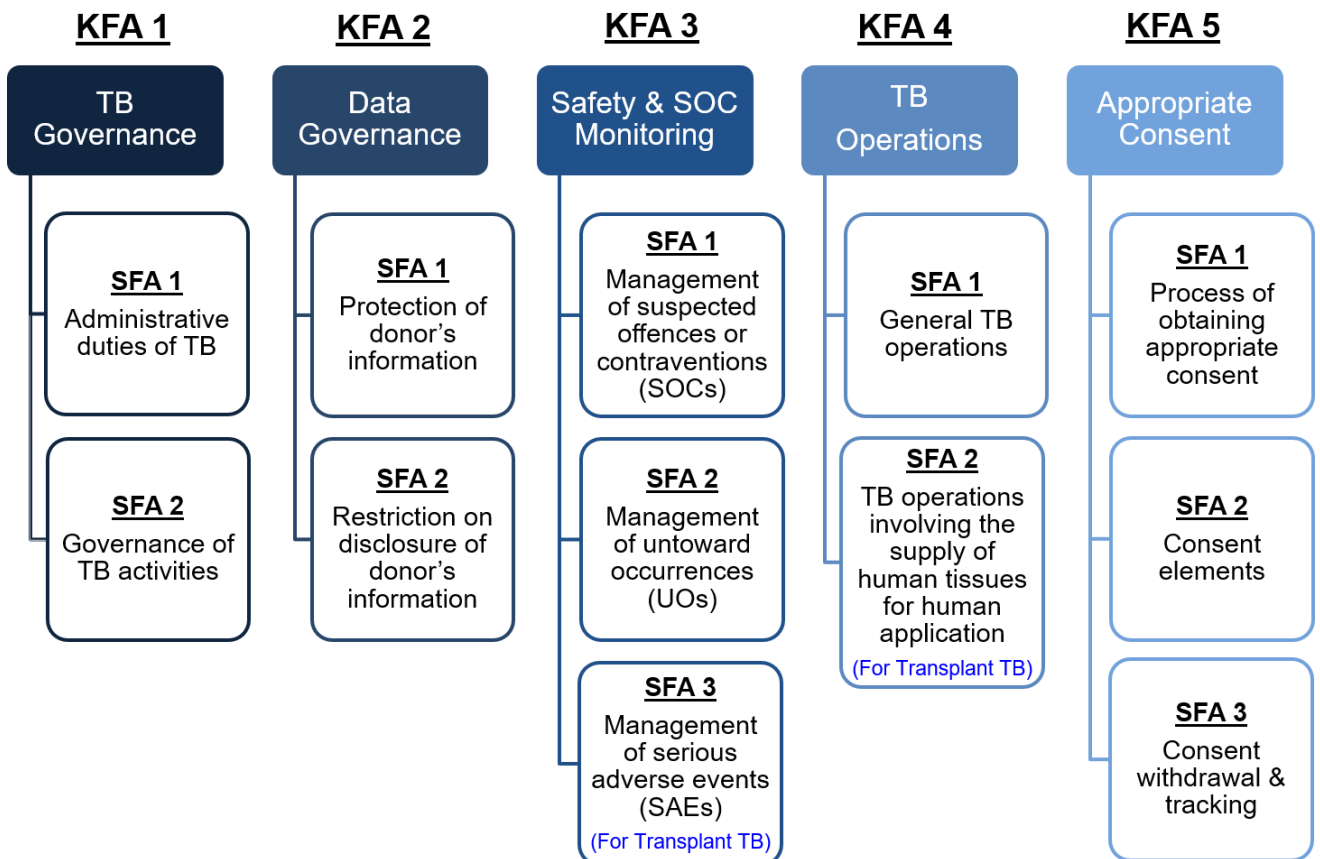
iv) Key Statistics

v) Consent Form Template

b) Documents/items to be reviewed <u>on-site</u>

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 <u>K</u>ey <u>F</u>ocal <u>A</u>reas(KFA) with specific sub-focal areas(SFA) for each KFA.

KFA 1	KFA 2	KFA 3	KFA 4	KFA 5
TB Governance	**Data Governance**	**Safety & SOC Monitoring**	**TB Operations**	**Appropriate Consent**
SFA 1 Administrative duties of TB	**SFA 1** Protection of donor's information	**SFA 1** Management of suspected offences or contraventions (SOCs)	**SFA 1** General TB operations	**SFA 1** Process of obtaining appropriate consent
SFA 2 Governance of TB activities	**SFA 2** Restriction on disclosure of donor's information	**SFA 2** Management of untoward occurrences (UOs)	**SFA 2** TB operations involving the supply of human tissues for human application *(For Transplant TB)*	**SFA 2** Consent elements
		SFA 3 Management of serious adverse events (SAEs) *(For Transplant TB)*		**SFA 3** Consent withdrawal & tracking

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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 Action and Preventive Action) 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

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