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# Best Practices for Establishing a Biobank in Singapore Research Institution

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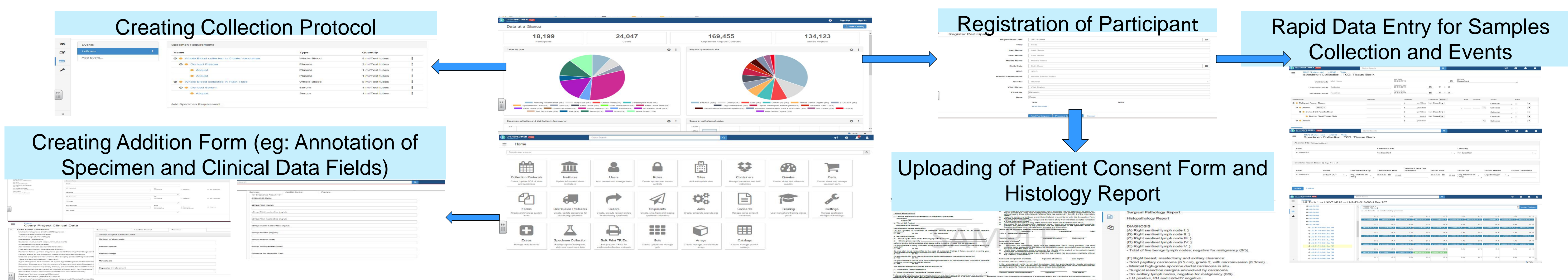
## Aims

In Singapore, all research using human biological materials are regulated under the Human Tissue Framework of the Human Biomedical Research Act (HBRA). Any individual or organization that are involved in removal, collection, storage, supply, import, export activities of human tissues for future research will be required to comply with the HTF for tissue banking activities.

As the institutional or investigator-driven collection of biospecimens are precious, an appropriate set up of biobank is an initiative response to the needs of researchers in terms of quality, access and transparency.

## Methodology

Being the custodian of the biospecimens, a biobank will need to be adequately equipped with management of data associated with the biospecimens, linkage to biospecimens, policies and procedures for appropriate banking management.

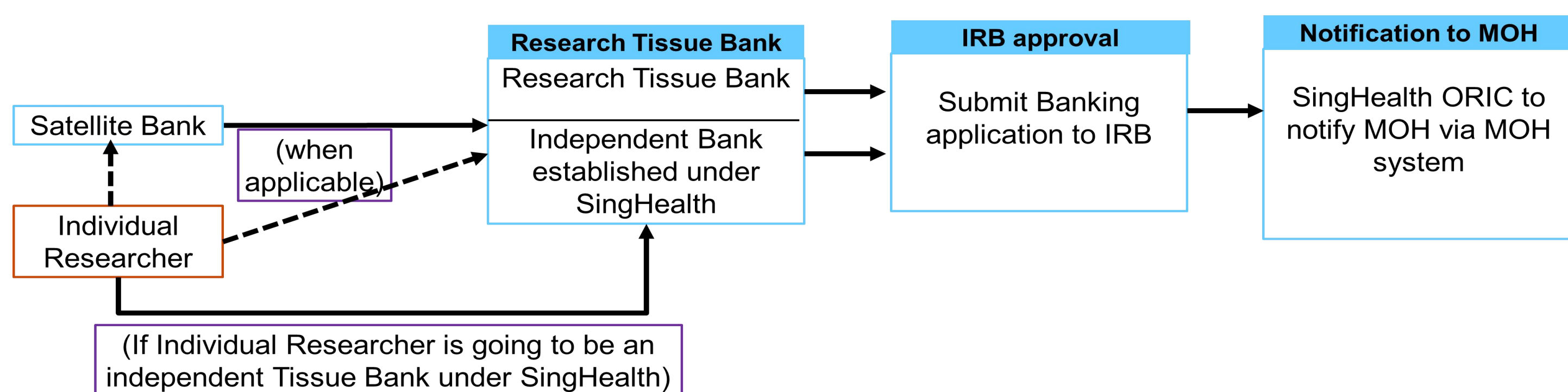


This composition of banking facility, resource, policies and procedures necessitates a harmonization of workflows within institution and a changing mindset of researchers willingness to share and collaborate.

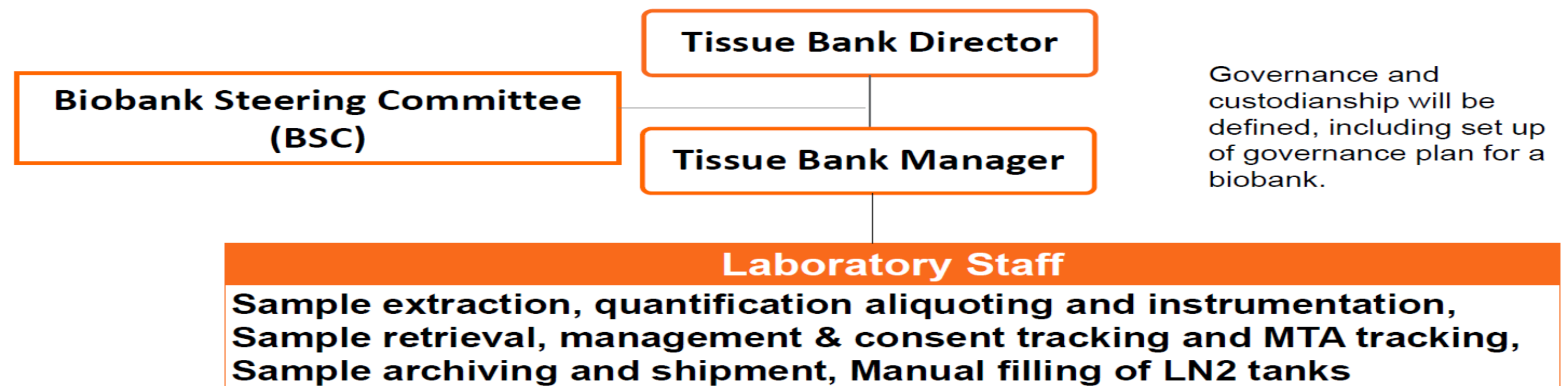
In order to establish a biobank for the custodianship of high quality biospecimens and data compliance with HBRA, best practices will be adopted from established biobanks and international biobanking guidelines, including the ISBER best practices.

The best practices for setting up a biobank will be: (i) registration of Biobank; (ii) biobank governance; (iii) Biobank workflow; and (iv) establishing compliance strategies.

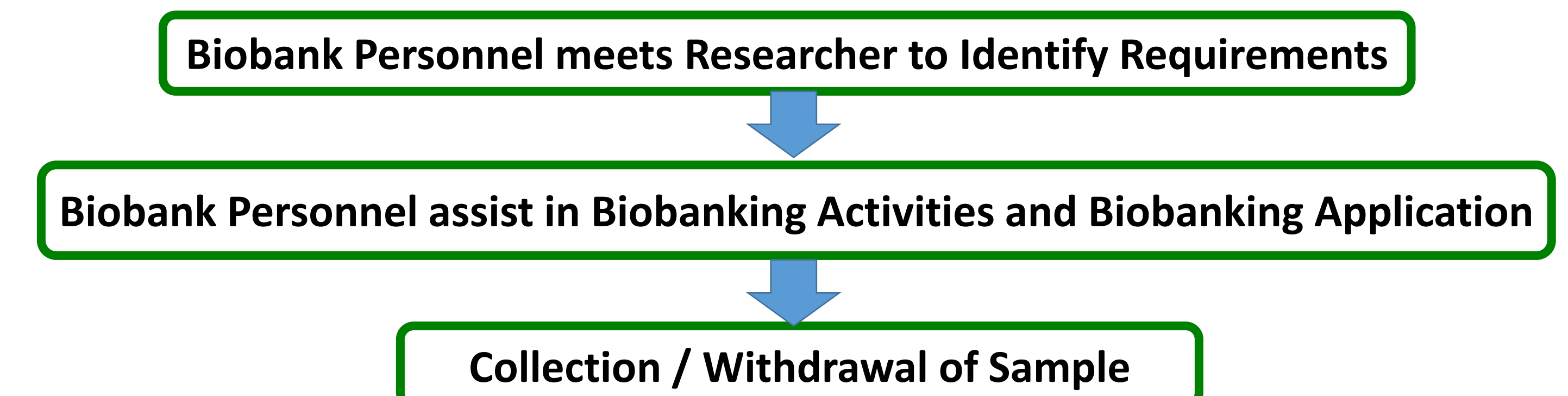
### (i) Biobank Registration Process



### (ii) Biobank Governance



### (iii) Biobank Workflow



### (iv) Compliance Strategies

- 1) Declaration of Compliance to HBRA Human Tissue Framework**
  - Any Biobank (primary or satellite bank) performing biobanking activity are required to perform annual self-declaration of compliance using “*Declaration of Compliance of Tissue Banking Activities including Handling of Legacy Tissue*” form.
- 2) Consent Requirements For Future Research**
  - A system is set up to ensure that the donor’s consent and health information are accurately tracked, thus ensuring the integrity of records of the consent and other information relating to the donor.
  - The Consent forms for Future Research are standardised across all SingHealth biobanks, and ensure all contained the mandatory elements in accordance to HTF.
- 3) Managing Contravention & SAE Reporting by BioBanks**
  - Contraventions and reportable Serious Adverse Event resulting from: (1) biobanking activity or (2) removal of human tissue conducted under the biobank’s supervision and control are submitted timely to MOH.
- 4) Operational Requirements of Biobanks**
  - Set up of a Quality Management System which address:
    - ❖ Equipment management.
    - ❖ Proper qualifications and trainings for biobank personnel.
    - ❖ Data management plans.
    - ❖ Measures to control the spread of communicable disease.
    - ❖ Development of policies and procedures (for lab processing, export, tissues handling).

## Result

Structured biobank governance framework and policies are developed to oversight the biobank operations. Policies for sharing of biospecimens and associated data are being developed in compliance with HBRA. The workflow pertaining to collection, storage, processing, access and utilization guidelines as well as compliance monitoring strategies are also set up.

The workflow includes harmonizing the operations across the primary biobank and satellite sites of biobank and the compliance oversight. Transparent and open communication are vital among stakeholders across institution, leading to trust and engagement.

## Conclusion

The biobank’s governing body, biobank business plan and documented policies covering the entire biobanking lifecycle have been established. The best practices, aligned to ISBER best practices, have been useful in raising the overall consistency and quality of specimens used in research.