BIOBANK RESEARCH REGULATIONS AND GUIDELINES FOR LOW-AND MIDDLE-INCOME COUNTRIES IN SOUTHEAST ASIA: A SCOPING REVIEW

Chin Kuen Yei[1], Mohammad Firdaus Bin Abdul Aziz[2], Ng Kee Seong[3]

1. *Master of Health Research Ethics (MOHRE), Faculty of Medicine, University of Malaya*
2. *Faculty of Law, University of Malaya.*
3. *Faculty of Medicine, University of Malaya*

Background Information:

Biobank is a collection of human biological materials and data generated by specimen analysis. They are crucial resources for biomedical research. Recent years have seen a surge in efforts by low-and middle-income countries (LMICs) involved in biobank research, and this includes countries in Southeast Asia (SEA). There have been active global collaborative biobank research projects, which involve sharing of human biological material (HBM) and data. Future and secondary uses of collected biological materials raise ethical concerns with respect to informed consent, privacy, and international HBM and data sharing. Therefore, it is important to address these ethical concerns with proper guidelines and regulations.

Project Objectives:

- To characterize the existing governance documents that address the ethical oversight of biobank research in LMICs in selected SEA countries (Malaysia, Thailand, and the Philippines)
- To identify areas where those documents converge or diverge in comparison to international guidelines.

Materials and Methods:

- A scoping review using the six-stage framework by Arksey and O'Malley, to examine the extent, range and nature of research activity and to identify research gaps in the existing documents.
- PRISMA-ScR (Preferred Reporting Items for Systematic reviews and Meta-analyses extension for scoping reviews) checklist to increase methodological transparency and uptake of research findings

Results:

Among the SEA countries, only Malaysia, Thailand, and the Philippines are selected due to the absence of human biobank research in Cambodia, Myanmar, and Laos and the limitation in documents in the English language for Vietnam and Indonesia. In total, 26 documents were identified for final analysis.

Informed Consent

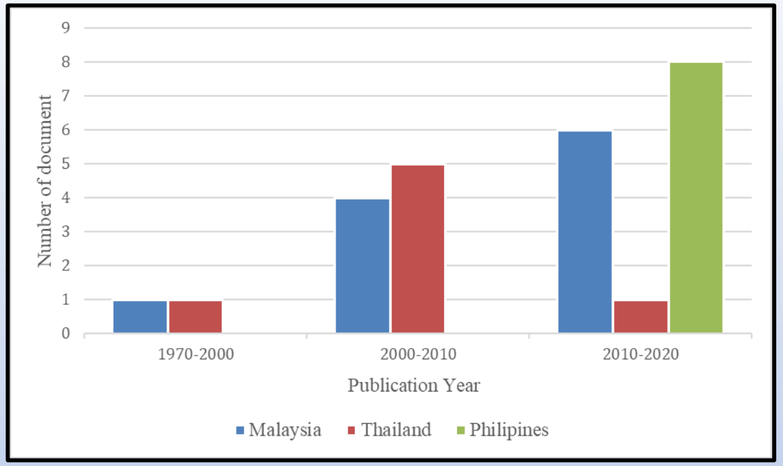
- Heterogeneity identified in the types of informed consent used for biobank research
- Guideline in Malaysia recommends blanket consent and multi-layered consent, Thailand recommends broad consent, and the Philippines recommends specific consent.
- Thailand and the Philippines follow the recommendation by the Declaration of Taipei by the World Medical Association and the CIOMS Guidelines i.e., broad and specific consent.

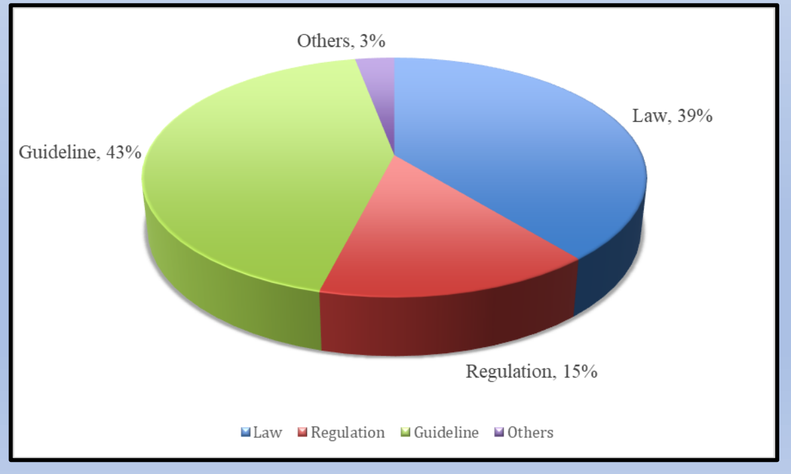
Privacy and Security Mechanism

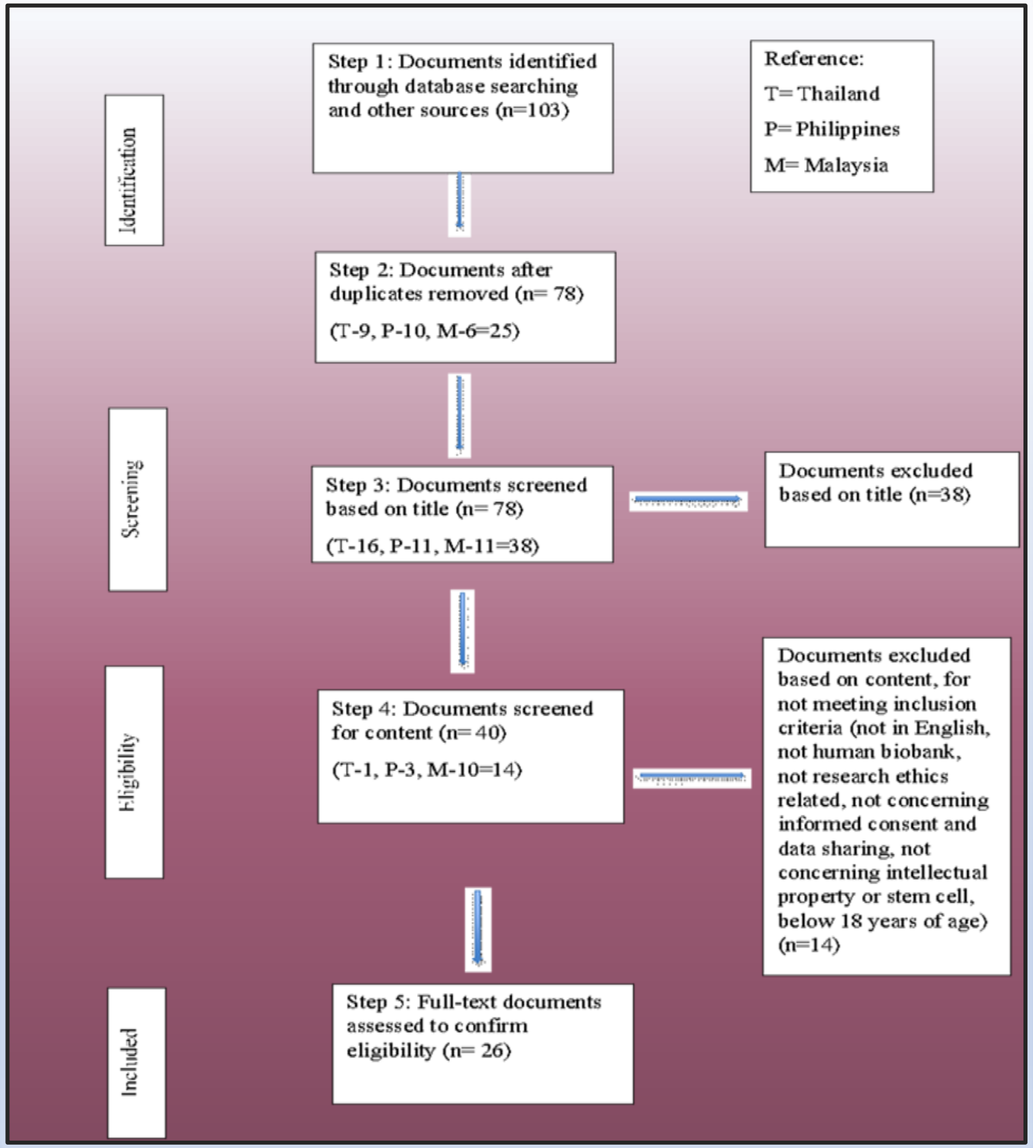
- All jurisdictions recommend process of coding and anonymisation before sharing the HBM and data for secondary uses.
- For sharing of HBM and data, the data protection laws applied in Thailand and the Philippines but the Malaysian data protection law does not apply to the public sector.

International Sharing of HBM and Data

- Material Transfer Agreement is required in Thailand and the Philippines but this position is not clear in Malaysia.
- In general, the positions on privacy and security mechanism and international sharing of HBM and data are in line with the international guidelines.







PRISMA Flow Diagram For Document Selection

Categories/Codes	*Malaysia*	*Thailand*	*Philippines*
Regulations on Research and Biobank	No law, but guidelines from the national level.	No law, but guidelines from the national committee	National Health Research Act mandates the formation of Ethical Guidelines with renewal every 5 years.
Research Oversight Mechanism	Oversight via ethics approval.	Oversight via ethics approval.	Oversight via ethics approval.
Informed Consent	Multi-layered consent and blanket consent Withdrawal of consent allowed Waiver allowed by Ethics Committee if: - Anonymised samples - Stored or archived samples	Broad Consent Withdrawal of consent allowed Waiver allowed by Ethics Committee if: - Difficulty to obtain consent - Consent violates privacy - Consent causes damage to physical and mental health.	Specific Consent Withdrawal of consent allowed Waiver allowed by Ethics Committee if: -subsequent use is not consistent with original informed consent - anonymous samples - samples that have no identifiers
Privacy and Security Mechanism	Coded and require anonymization	Require deidentification.	Generally coded and require anonymisation. 2nd and 3rd party use only on anonymised samples. Mechanism of de-identification is specified.
	Disclosure of types of information decided by the researchers at the proposal stage. No disclosure to third parties.	Disclosure of individual is required if affecting the health of the donor or informed in advance during consent taking	No disclosure of individual results to the donor unless stated in the initial informed consent. No disclosure to unauthorized third parties.
International HBM and Data Sharing	No specific guide	Material Transfer Agreement is required for sharing of HBM.	Material Transfer Agreement is required for sharing of HBM.

Summary of the Findings

Topics	*Malaysia*	*Thailand*	*Philippines*	*WMA Declaration of Taipei*	*CIOMS Guideline*
Types of Consent	-Multi-layered consent -Blanket consent	Broad Consent	Specific Consent	Not specified but blanket consent is not feasible	Specific or broad consent Tiered consent for disclosure of results
Withdrawal of Consent	Allowed	Allowed	Allowed	Allowed	Allowed
Waiver of Consent by Ethics Committee	Allowed if: - Anonymised samples - Stored or archived samples	Allowed if: - Difficulty to obtain consent - Consent violates privacy - Consent causes damage to physical and mental health.	Allowed if: -subsequent use is not consistent with original informed consent - anonymous samples and no identifiers	Allowed if: -serious and immediate threat to protect the health of the population	Allowed if: -Archived samples and data with strong justifications from researchers: 1. impracticable to locate the donor 2. research has important social values 3. minimal risks
Anonymisation	Coded and require anonymization	Require deidentification.	Generally coded and require anonymisation. Mechanism of de-identification is specified.	Not mentioned	Coded and require anonymization Only can share coded or anonymised data with researchers.
Material Transfer Agreement (MTA)	No specific guide	MTA is required for sharing of HBM.	MTA is required for sharing of HBM.	MTA is required for sharing of HBM or data.	MTA is required which includes the following contents: -duration of use -what happens to sample at the end of use -responsibilities of each party.

Summary of the Findings Compared With International Standards

Conclusion

- The most significant finding is the heterogeneity of the informed consent models for biobank research suggested in the guidelines in Malaysia, Thailand, and the Philippines.
- The Malaysian position for blanket consent conflicts with international guidelines whereas the Philippines and Thailand follows the recommended broad or specific consent.
- The positions adopted for privacy and security mechanism, and sharing of HBM and data are rather homogenous and follow most of the standards in the international guidelines.
- The policymakers should ensure that the regulations are reviewed periodically to accommodate changes and provide guidance that is certain, unambiguous, and up-to-date for novice researchers in biobank research and ethics committee members.
- Given the “regulatory patchwork” pattern, Malaysia and Thailand could adopt the national research law such as the Philippines whereby all relevant policymakers in different ministries would be involved to review the regulatory periodically.
- As this study does not include empirical interviews with policymakers or other key stakeholders, it is difficult to account for the differences in the regulations and ethical governance regarding biobank research across the three jurisdictions.
- Future empirical studies should be carried out to address the inadequacies of the regulatory framework in these countries in comparison with international guidelines.

References:

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