THE ROADMAP TO ESTABLISHING THE NATIONAL BIOREPOSITORY POLICY FOR MALAYSIA

A 2023 TECHNICAL REPORT

BY THE WORKING COMMITTEE FOR THE ESTABLISHMENT OF THE NATIONAL BIOREPOSITORY POLICY FOR MALAYSIA

UNDER THE NATIONAL SUB-COMMITTEE FOR LABORATORY BIOSAFETY AND BIOSECURITY, NATIONAL LABORATORY TECHNICAL ADVISORY COMMITTEE (LTAC)

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ACKNOWLEDGEMENT

We would like to thank the Director General of Health Malaysia for his permission to publish this technical report. We also acknowledge the direct and indirect contributions of the directors of institutions and staff members from all participating laboratories for their invaluable and meaningful development of this technical report for the establishment of the National Biorepository Policy for Malaysia.

TECHNICAL REPORT

A. INTRODUCTION

Malaysia, like any country in the world, will continuously be facing outbreaks of infectious diseases of known and unknown origin of the pathogen. The rapid development of diagnostics is crucial to accurately and quickly identify the etiological agent of the disease. Using COVID-19 as an example, the MOH reference laboratories have benefitted from SARs-CoV-1 virus isolates shared by one of the biorepositories in Malaysia for the rapid development and deployment of the SARS-CoV-2 diagnostic protocol. This demonstrates the importance of a biorepository network, access, and sharing of well-characterized biospecimens to facilitate diagnostic development and evaluation and improve the diagnosis and prevention of disease. The biorepository resources can also be used for treatment and to promote health-related product technology.

Several biorepositories currently exist in Malaysia, under the purview of various stakeholders. In each biorepository, the biospecimens and, associated data and information are stored in an organized system. As designated biorepositories, the biorepositories will involve the collection and storage of biological materials associated with medical/ data and epidemiological data, which has unique coding and retrievable, unique and it is meant for a continuous or long-term duration. Therefore, all biorepositories must be run in best practices, safe and secured, well maintained, and sustainable.

The utility and value of biorepositories in Malaysia should potentially be maximized through the decentralized biorepository model or concept. This can be accomplished through an establishment of a biorepository governance framework. The biorepository network should be managed according to the guiding principles of transparency, equitable access, ethics, and respect for national laws and regulatory framework as well as policy, that support country ownership and sustainability. By adopting the Nagoya Protocol and Access To Biological Resources And Benefit Sharing Act 2017 on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization of the convention

on biological diversity, sharing of specimens from national biorepositories can be rewarded through mechanisms such as equitable access to diagnostics.

B. PURPOSE

1. To establish a policy for National Biorepository Malaysia.
2. To develop a sustainable model for a regional network of country-owned biorepositories incorporating standardized methods for collection, characterization, and archiving of specimens, and characterization of isolates to facilitate and accelerate diagnostics development and evaluation for COVID-19 and other diseases of epidemic potential.
3. To ensure that biorepository facilities shall be managed safely and securely in compliance with all the national regulations and policies as well as internationally recognized standards and regulatory frameworks.
4. To ensure that the values of biorepositories shall be leveraged through the formation of an appropriate governance framework.

C. SCOPE OF THE NATIONAL BIOREPOSITORY POLICY FOR MALAYSIA

This policy applies to all facilities that collect, process, catalog, store, retrieve, and distribute biological material, derived from humans, animals, insects (arthropods), plants, and environments such as,

a) urine, blood, tissue, cells
b) DNA, RNA, protein
c) microbial culture
d) cell line
e) genome sequences and data

D. GAP ANALYSIS IN MALAYSIA

1. Biorepositories Regulatory Framework in Malaysia

In Malaysia, there is no legislation specifically regulating biorepositories and its related activities. However, there are relevant and applicable laws and regulations that can be found in several statutes, such as the Human Tissue Act 1974, the Personal Data Protection Act 2010, and the Patents Act 1983 which specify issues that are related to the operation of biorepositories. The Human Tissue Act 1974 although not specifically formulated for the operation of biorepositories, does provide some rules related to the biorepository activities. The Personal Data Protection Act 2010 generally addresses the issue of privacy and confidentiality of personal data. Nevertheless, the Act can be applicable to address the same issue when biological samples are processed to produce data. The Patents Act 1983 generally provides the rules on a patent of an invention, however, the Act applyis also relevant in regulating biorepository activities when there is work derived from the biological samples in the biorepositories. The following sections will further describe these legislations application in addressing the identified ethical issues.

In addition, the Ministry of Health (MOH) introduced a national guideline that primarily regulates the operation of biorepositories in the country, namely the Malaysian Guidelines on the Use of Human Biological Samples for Research (hereinafter referred to as National Guidelines), published in 2015. The national guidelines partly mentioned the regulations on biorepositories and its activities in Malaysia. The preamble of the guidelines states that,

"These guidelines aim to draw attention to important ethical issues that should be considered when:

- Conducting research involving the planned prospective collection of human biological samples including those for bio-banking."[1]

In addition, the provisions on legal and ethical issues surrounding biorepositories are well provided under Paragraph 3.3 of the guidelines. However, given guidelines are not

[1] Malaysian Guidelines on the Use of Human Biological Samples for Research (Malaysia) Preamble.

legally binding, it only serves as guidance to the Institutional Review Board / Independent Ethics Committee (IRB/IEC) on the general principles and approaches to ensure ethical issues related to the use of human biological samples for research are appropriately addressed.[2] Nevertheless, the IRB/IEC is expected to comply with the general guidelines.[3] The following sections will also examine the application of the national guideline in addressing ethical issues.

2. Consent

In related to the consent issue, Section 2(1) of the Human Tissue Act 1974 provides the rule for the utilization of human body parts for research purposes, provided that the use is in accordance with the donor's request. The Section provides that,

> "(1) If any person, either in writing at any time or orally in the presence of two or more witnesses during his last illness, has expressed a request that his body or any specified part of his body be used after his death for …research, the person lawfully in possession of his body after his death may, … authorized the removal from the body, …the specified part, for use in accordance with the request"[4]

However, it can be said that the Section has its limitation, as the permission to utilize the human body parts is only applicable to a body of a deceased, but not to a living person.[5]

In addition, Paragraph 3.3.1 of the guidelines states that approval from the IRB/IEC together with informed consent must be obtained before conducting any study. Furthermore, in Paragraph 3.3.2, the guidelines outline the different types of informed consent that can be obtained,

> "If the researcher plans to store and use the tissues for future research, a multi-layered consent with several options should be obtained. The request for consent may include:
>
> - Consent to the specific planned research
> - Consent for storage and future use

[2] Ibid.
[3] Ibid.
[4] Human Tissues Act 1974 (Act 130) (Malaysia) s 2(1).
[5] Human Tissues Act 1974 (Act 130) (Malaysia) Preamble.

- Consent for access to medical records and information for data relevant to the bio-banking
- Consent for re-contacting the subject for more data"[6]

The guidelines also provide the types of information needed to be furnished to the participants when obtaining informed consent. Paragraph 5 of the guidelines states that,

"…researchers must provide potential study subjects with the following information,

- the purpose of the research
- possible future research including the type of studies, type of diseases that could be investigated, possible impact of research, and benefits
- type and amount of tissue taken (as well as location)
- the manner in which the tissue will be taken, the safety & invasiveness of acquisition, and the duration of storage
- the potential uses for the tissue including any commercial uses
- the safeguards to protect the individual's privacy and confidentiality
- identifying information attached to a specific tissue, and its traceability
- how the use of the tissue could affect privacy
- the right to withdraw and arrange for disposal of tissues and data"[7]

Above all, it can be inferred from the Malaysian Guidelines on the Use of Human Biological Samples for Research that Malaysia adopted a specific and informed consent as its consent model.

3. Privacy and Confidentiality

Section 2(2)(a) of the Personal Data Protection Act (PDPA) provides that,

"Subject to subsection (1), this Act applies to a person in respect of personal data if—

[6] Malaysian Guidelines on the Use of Human Biological Samples for Research (Malaysia) para 3.3.2.
[7] Malaysian Guidelines on the Use of Human Biological Samples for Research (Malaysia) para 5.

(a) the person is established in Malaysia and the personal data is processed, whether or not in the context of that establishment, by that person or any other person employed or engaged by that establishment; …"[8]

In this case, the researcher or owner of data must adhere to the rules as stated in the PDPA which include among others, (I) sensitive personal data should not be processed unless with explicit consent,[9] (ii) the data cannot be disclosed unless consent was obtained,[10] (iii) there must be practical steps from loss or misuse of data,[11] (iv) data cannot be kept longer than the intended purpose,[12] (v) there must be reasonable steps to protect the data,[13] and (vi) the donors must be given access to their data.[14]

Above all, it can be said that the PDPA addresses most of the legal and ethical issues related to the use of data derived from biobanking activities. However, the provisions are only applicable if the data is used in commercial transactions.[15] Hence, the public biobank does not fall within the ambit of the law until when it involves in a commercial transaction[16].

On the issue of privacy and confidentiality, Paragraph 6.1 of the Malaysian Guidelines on the Use of Human Biological Samples for Research provides advice on maintaining the confidentiality of biological data, where it states that the personal identifiers should be removed as far and as early as possible so as not to link the results of the tests to identifiable individuals.

Furthermore, the key principles on personal information were outlined within the same paragraph, which include, (I) personal information must be treated as confidential, (ii)

[8] Personal Data Protection Act 2010 (Act 709) (Malaysia) s 2(2)(a).
[9] Personal Data Protection Act 2010 (Act 709) (Malaysia) s 40 (1)(a).
[10] Personal Data Protection Act 2010 (Act 709) (Malaysia) s 8.
[11] Personal Data Protection Act 2010 (Act 709) (Malaysia) s 9(1).
[12] Personal Data Protection Act 2010 (Act 709) (Malaysia) s 10(1).
[13] Personal Data Protection Act 2010 (Act 709) (Malaysia) s 10(2).
[14] Personal Data Protection Act 2010 (Act 709) (Malaysia) s 12.
[15] Personal Data Protection Act 2010 (Act 709) (Malaysia) s 2(1).
[16] "Commercial transaction" according to s 4 of the Personal Data Protection Act 2010 means, "any transaction of a commercial nature, whether contractual or not, which includes any matters relating to the supply or exchange of goods or services, agency, investments, financing, banking and insurance, but does not include a credit reporting business carried out by a credit reporting agency under the Credit Reporting Agencies Act 2010."

all medical research using identifiable personal information must be approved by an IRB/IEC, (iii) all personal information must be coded or anonymized as far as early as possible in the data processing, (iv) principal investigators are responsible for ensuring that procedures and security arrangements are sufficient to prevent breaches of confidentiality, and (v) researchers must decide which information or results will be made to the people involved.[17]

Finally, to ensure the guarantee of data protection, Paragraph 6.2 of the guidelines also stated that the level and process of anonymization should be approved by the IRB/IEC and there must be a clear and stringent privacy framework to ensure the protection of data.

4. Ownership and Intellectual Property Rights

The Human Tissue Act 1974 provides the rule on ownership of human body parts of a deceased. The Act stipulates that the hospital or any other person authorized by the deceased shall have the lawful possession of the human body and parts. Section 4 of the Act provides that,

"…the person having the control and management of the hospital or any other person authorized by him shall be deemed …to be a person in lawful possession of the body."[18]

According to the Malaysian Guidelines on the Use of Human Biological Samples for Research, the biological samples should be held under the custodianship of the biobank. It is stated under Paragraph 7 of the guidelines that the custodianship of research samples lies with the institution that collects the samples. Nevertheless, Paragraph 7.1 of the guidelines also provides some responsibilities to the custodian of the biological samples namely to protect and regulate the use, storage, access, transfer, and disposal of the tissues. Finally, on the issue of intellectual property rights, The Patent Act provides that, the work derived from the biobank samples, such as treatment by way of surgery or therapy and the diagnostic method practiced and its products can be counted as patentable invention as long as it meets three criteria. Section 11 of the Act provides that,

[17] Malaysian Guidelines on the Use of Human Biological Samples for Research (Malaysia) para 6.1.
[18] Human Tissues Act 1974 (Act 130) (Malaysia) s 4.

"An invention is patentable if it is new, involves an inventive step, and is industrially applicable."[19]

Meanwhile, the Act also defines an "invention" stating it as "an idea of an inventor which permits in practice the solution to a specific problem in the field of technology".[20] This invention may be or may relate to a product or process.[21]

Furthermore, Paragraph 7.2 of the guidelines provides that policy regarding intellectual property arising from the research should follow applicable rules and regulations. Hence, the Patents Act 1983 is applicable for that matter.[22]

5. Return of Feedback

On the issue of return of feedback to the donor, the Malaysian Biobank Guidelines under Paragraph 3.3.3 provides that,

"Researcher should decide at the beginning on the type of information that will be made available to the patients and/or the community and this should be indicated in the submission to the IRB/IEC and included in a subject information sheet."[23]

The guidelines did not specify the duty of care of researcher in the two instances i.e. incidental findings and individual research results. It can be inferred from the guidelines that the duty of care of the researcher only exists if it is indicated in the submission to the research ethical committee, ie the IRB/IEC, and is included in the subject information sheet.

6. Impact of Commercialisation of Biobank on Public Trust

According to the Malaysian Guidelines on the Use of Human Biological Samples for Research, it can be observed that the current approach does not prohibit biobanks to commercialize samples. Paragraph 7.2 of the guidelines provides that,

[19] Patents Act 1983 (Act 291) (Malaysia) s 11.
[20] Patents Act 1983 (Act 291) (Malaysia) s 12(1).
[21] Patents Act 1983 (Act 291) (Malaysia) s 12(2).
[22] Reference made to s 2 of the Patents Act 1983, for patents applications and registrations.
[23] Malaysian Guidelines on the Use of Human Biological Samples for Research (Malaysia) para 3.3.3.

"Biological samples should not be used for financial gain or sold to a third party, without prior permission from the donor or the legal representative."[24]

This clearly shows that the commercialization of samples by biobank is possible as long as the sample donors are duly informed and give consent for such activity.

7. Comparisons with Other Jurisdictions

The jurisdictions taken as comparisons are Europe, the United Kingdom, Australia, and Singapore. As stated beforehand, this section emphasizes a comparison with the United Kingdom's biobanking regulatory framework.

Table 1: Comparisons between Malaysia's Biobanking Regulatory Framework with other jurisdictions based on regulatory instruments used.

Jurisdictions	Jurisdictions	Jurisdictions	Jurisdictions
Malaysia	- No specific legislation (utilizing applicable statute i.e. Human Tissue Act, Personal Data Protection Act, and Patents Act)	- Non-binding, merely advises (Malaysian Guidelines on the Use of Human Biological Samples for Research)	- Respective biobanks/institutes (e.g. Institutional Research Board, IRB/ Institutional Ethics Committee, IEC)
United Kingdom	- No specific legislation (utilizing applicable statute ie Human Tissue Act, Data Protection Act	- Binding for UK Biobank (UK Biobank Ethics and Governance Framework)	- Respective biobanks (ie UK Biobank Ethics Committee)
Australia	- No specific legislation	- Binding at the national level (National Statement on Ethical Conduct in Human Research, NHMRC)	- Human Research Ethics Committee under NHMRC
Singapore	- Human Biomedical Research Act 2015	- Ethics Guidelines for Human Biomedical Research (Bioethics Advisory Council)	- Respective biobanks/institutes (ie institutional Research Board, IRB)

[24] Malaysian Guidelines on the Use of Human Biological Samples for Research (Malaysia) para 7.2.

E. Biorepository Status in Malaysia

The *Biorepository Status In Malaysian Laboratories: A Questionnaire 2023 survey* was conducted to obtain information and determine the current status of existing biorepositories in Malaysia. Official letters and questionnaires in Google form format link were sent via mail and email on 14 and 21 March 2023 for ease of access and dissemination to all laboratories. The responses were analyzed and the results are as below:

1. Existing Biorepositories in Malaysia

a. A total number of 40 feedback responses were obtained from the questionnaire. Fifteen (15) respondents declared that they have a Biorepository/Culture Collection/Biobank.

b. Among the biorepositories, five (33%) are under Governmental Agency & Research Institute while another five (33%) belong to Public Universities. In addition, there are also collections from private companies (three, 20%), a private hospital (one, 7%), and a private university (one, 7%).

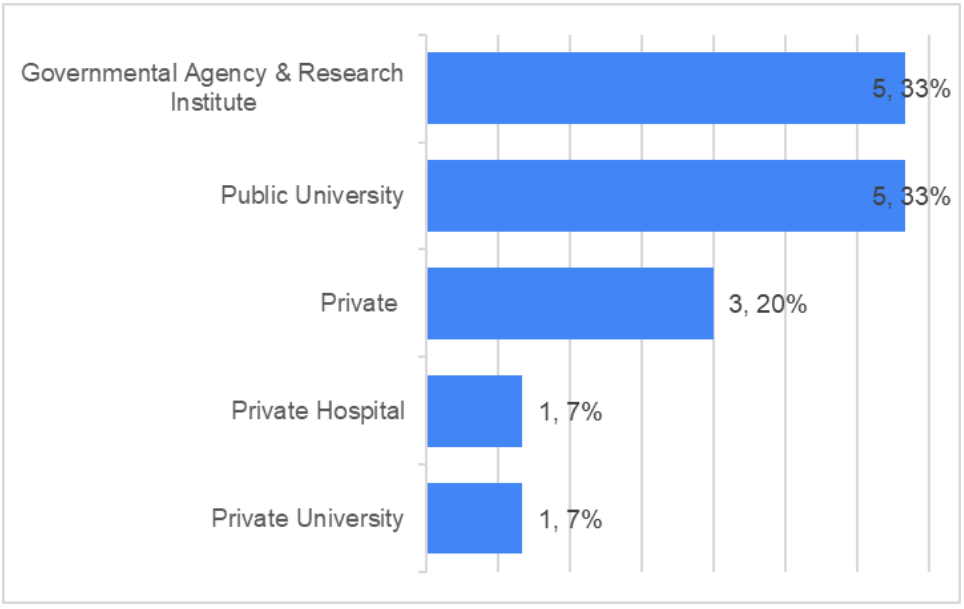

Figure 1: Percentage of biorepositories manage by various agencies.

c. List of 15 biorepositories:

Agencies	No.	Name of Biorepository/Culture Collection/Biobank	Acronym	Organization
Governmental Agency & Research Institute	1.	Malaysia Genetic and Living Culture Collection	MGLCC	National Institutes of Biotechnology Malaysia (NIBM)
	2.	FRIM Microbial Culture Collection	FRIM-MCC	Forest Research Institute Malaysia (FRIM)
	3.	IMR Culture Collection	IMRCC	Institute for Medical Research (IMR), National Institute of Health
	4.	Malaysia Plant DNA Bank	MyDNA	Forest Research Institute Malaysia (FRIM)
	5.	MARDI Microbial Culture Collection	MMCC	Malaysian Agricultural Research and Development Institute (MARDI)
Public University	6.	Microbial Culture Collection Unit, Institute of Bioscience	UNiCC	Universiti Putra Malaysia
	7.	UKM Culture Collection	UKMCC	Universiti Kebangsaan Malaysia
	8.	The Malaysian Cohort Biobank	TMC BIOBANK	Universiti Kebangsaan Malaysia
	9.	Biobank HCTM-UMBI	BIOBANK HCTM-UMBI	Universiti Kebangsaan Malaysia
	10.	University of Malaya Algae Culture Collection	UMACC	Universiti Malaya
Private Company	11.	None	None	Bionexus Gene Lab Sdn. Bhd.
	12.	None	None	Lablink (M) Sdn. Bhd.
	13.	None	None	Radilab Diagnostics Sdn Bhd
Private Hospital	14.	Microbiology Unit	None	Normah Medical Specialist Centre
Private University	15.	UTAR Biobank	UTAR Biobank	Universiti Tunku Abdul Rahman

d. The majority of biorepositories respondents are within the Klang Valley (nine in Kuala Lumpur and five in Selangor), and only one from Sarawak.

e. Out of the total biorepositories, three (3) do not have sufficient or no funds for long-term sustainability. The other twelve (12) biorepositories are funded either by the parent organization, respective ministries, self-funded (e.g.: income from services), and/or from various other R&D funding.

2. Scope and Functions

a. The highest percentage of the collections is for research purposes at 44%. This is followed by the conservation of biodiversity (24%), providing services (24%), and teaching (8%).

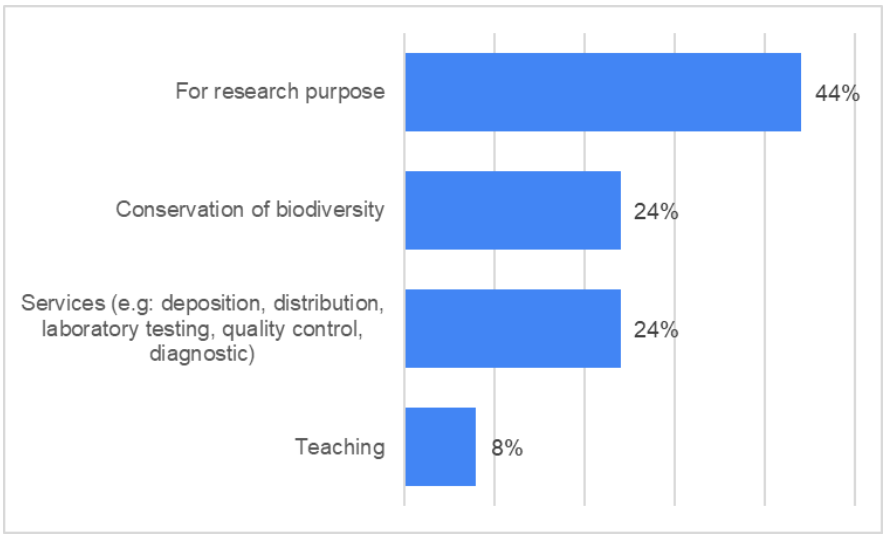

Figure 2: Percentage for purpose of collections establishment

b. The majority of the biomaterials maintained in the collection were isolated by the institutions' scientists (33%). In addition, the biomaterials were also obtained from hospitals/clinics (23%), individual scientists in Malaysia (23%), collections/research institutions abroad (7%), collections/research institutions in Malaysia (7%) as well as purchased strains (7%).

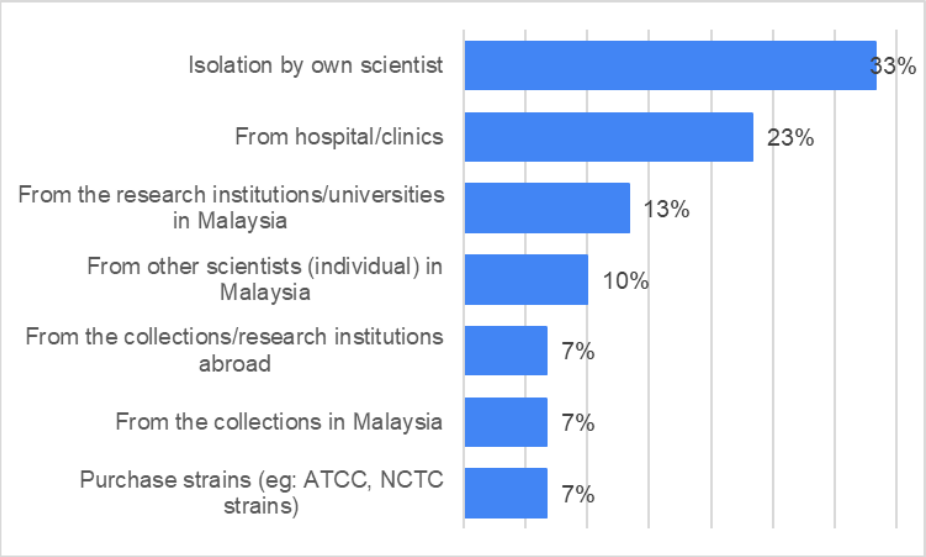

Figure 3: Percentage for the source of biomaterial in the collection

c. Five biorepositories store only microorganisms (e.g. bacteria, fungi, yeast). Other biorepositories maintain various types of biomaterials such as biospecimen (e.g urine, blood, tissue, cells, fecal), molecular materials (DNA, RNA, protein, plasmid, plasmid host, vector), algae, and microalgae. Two (2) biorepositories also manage genome sequences and databases.

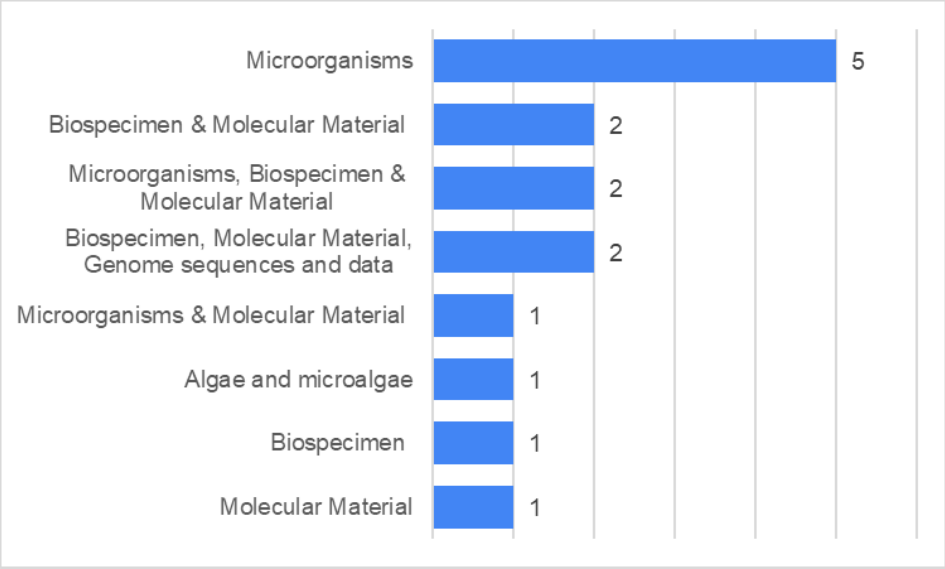

Figure 4: Number of biorepositories managing various types of biomaterials

d. The number of biomaterials in all 15 biorepositories is summarized below:

No.	Type of biomaterial	Approximate number of biomaterials
1.	Microorganisms	9,900 strains
2.	Biospecimen (urine, blood, tissue, cells, fecal)	More than 7,100,776 specimens in 1 ml cryotube (from approximately 170,000 participants/patients)
3.	Molecular Material (DNA, RNA, protein, plasmid, plasmid host, vector)	28,587 samples
4.	Algae and microalgae	250 strains

5. For deposition services, four (4) biorepositories offer both Safe and Public Deposit options. Six (6) biorepositories offer only Safe Deposit and another five (5) do not provide any such service. None of the biorepositories provide Patent Deposit service.
6. A total of twelve (12) biorepositories were conducting a distribution of their biomaterials. Distribution is made to the public, to research team members only, to research collaboration, and/or to organization staff only. However, the other three (3) biorepositories are not for distribution and are exclusively for their use.
7. Other types of services offered by biorepositories are identification and antibiotic sensitivity test for clinical samples, various laboratory tests, identification of microorganisms, preservation of microorganisms, (meta)-genome sequencing and analysis, microbial community profiling, biochemical content characterization, total viable count, training, and consultation.
8. Nine (9) biorepositories already implemented Material Transfer Agreements (MTA) for the distribution of biological material, while two (2) are still in the process of developing their MTAs. Four (4) biorepositories do not have or have applied MTA in managing their biorepositories.
9. Eight (8) biorepositories have obtained the certification or accreditation to the scopes including ISO 9001:2015, ISO 15189:2012 Medical Laboratory, and/or ISO/IEC 17025 — Testing and calibration laboratories. One (1) biorepository is a member of the Joint Commission International (JCI). The other six (6) biorepositories do not possess any certification/accreditation.

F. Different models of policy governance, advantages and disadvantages

No	Type	Function	Advantages	Disadvantages	Example of institutions/countries using this model
1	**Centralized model**	A single biorepository location or facility of all biological specimens and strains collected from multiple sources over the country	• Allow for the consolidation of resources, including expertise, infrastructure, and funding. • Enhanced sample diversity; Sample from various sources increases the diversity and representativeness of the biorepository • Cost savings in infrastructure, equipment and staffing	• Logistical challenges- Samples need to transport from various collection sites to a central facility (degradation, increased costs) • Risk of sample loss, mishandling, or catastrophic events such as equipment failures or natural disasters- a large number of samples in a single location.	1) **UK Biobank:** Is a large-scale biobank project with a central storage and processing facility in Stockport, Greater Manchester. 2) **National Cancer Institute's Cooperative Human Tissue Network (CHTN):** The CHTN is a centralized network of six regional biorepositories in the United States 3) **Korean Biobank Project:** The Korean Biobank Project is a government-funded initiative in South Korea.

No.	Type	Function	Advantages	Disadvantages	Example of institutions/countries using this model
2	**Regional model**	Samples are collected, processed, stored, and managed in multiple regional or local facilities. Each region has its repository, and the samples collected within that region are stored and managed locally	• Accessibility and proximity; within a specific geographic area to have easy access to the stored samples- reduces transportation costs. • Regional biorepositories have the potential to better represent the genetic and phenotypic diversity of local populations. • Having multiple regional repositories reduces the risk of catastrophic events.	• Fragmentation of resources- including expertise, infrastructure, and funding. • Standardization challenges: Ensuring consistent protocols, quality control measures, and data management practices across multiple regional repositories can be more challenging than in a centralized model	1) **Cancer Research UK (CRUK) Stratified Medicine Programme:** regional biorepositories across several locations in the United Kingdom. 2) **German National Cohort (GNC):** a large-scale population-based study in Germany. Samples are collected and stored at multiple regional study centers. 3) **Quebec Breast Cancer Biobank (QBCB):** Collecting & storing breast cancer samples from the province of Quebec.

No.	Type	Function	Advantages	Disadvantages	Example of institutions/countries using this model
3	**Decentralized or network model**	Biological samples are collected, processed, stored, and managed across multiple independent facilities or institutions. Each facility maintains its own repository and manages its operations autonomously, while collaborating within a larger network.	• Offers increased accessibility to samples as they are stored in multiple locations; access samples more conveniently, reducing transportation costs and time delays • Provide redundancy, ensuring that samples are preserved even if one facility experiences issues or disruptions	• Challenges in standardization and harmonization of SOPs and data management practices across multiple facilities. • Each facility within the network may operate with limited resources, including funding, infrastructure, and expertise. • Ensuring data consistency, privacy, and security can be more challenging in a distributed network	1) **BioBank Japan:** It consists of multiple biobanks across the country, each managed by a university or research institute. 2) **International Cancer Genome Consortium (ICGC):** global collaboration involving multiple institutions and countries. 3) **Biobanking and BioMolecular resources Research Infrastructure - European Research Infrastructure Consortium**

No.	Type	Function	Advantages	Disadvantages
4	**Sequencing network**	Biological samples, along with their associated genomic or genetic data, are collected, stored and managed in a network of interconnected facilities that specialize in high-throughput sequencing.	• Integration of sequencing and biobanking: allows for the preservation and management of biological samples while leveraging the latest sequencing technologies to generate genomic data from those samples. • Efficient utilization of resources/cost savings - efficient utilization of sequencing resources, as multiple facilities within the network can share and distribute the sequencing workload. • Collaboration and data sharing: The sequencing network model promotes collaboration and data sharing among the participating facilities	• The sequencing network model may require high storage capacity compared to traditional biorepositories • Data privacy: requires robust data management systems and strict adherence to ethical and legal guidelines to protect participant privacy and ensure secure data sharing.

G. Challenges to Consider When Choosing the Model for Setting Up Biorepositories

1. Establishing a national biorepository requires significant infrastructure and resources, including physical space, specialized equipment, personnel and funding. This includes long-term sustainability.
2. Standardizing protocols, sample handling, storage conditions and data management across multiple collection sites is crucial for maintaining sample quality and ensuring data comparability.
3. Establishing clear governance structures and ethical frameworks is critical to ensure that the collection, storage and use of samples adhere to ethical and legal guidelines.
4. Quality Control and Quality Assurance- are crucial to ensure sample integrity and data accuracy.

H. Guiding principles

Key Principles for Ethical Guidance in Biological Specimen Collection and Archiving includes, but is not limited to:

1. Ethical requirements
    a) Subject information sheet
    b) Informed consent and protection for patients, donors and recipients.
    c) Protection of patients, donors and recipients.
    d) Biological specimen commercialization or non-profit approach
    e) Imperative ethics to protect health
    f) Processing or processing of biological specimens [DNA, RNA, serum, plasma and cell lines (cell lines)]
    g) Genetic research on biological specimens
2. Access & benefit sharing
    a) Application to use samples
    b) Specimen Database
    c) Ownership and custody of specimens
    d) Ownership of commercialized research products
    e) Intellectual property rights

I. Consensus and Recommendations

1. The Committee recommends the establishment of a consortium for biobanking in Malaysia.
2. It was agreed that Malaysia cannot adopt a centralized model of biobanking.
3. It was agreed that a specific policy is needed in Malaysia.
4. It was agreed that an independent biorepository entity should be established in Malaysia.
5. It was agreed that the biorepository in Malaysia should adhere to relevant acts or guidelines.
6. There was a willingness expressed to share samples.
7. The purpose of the biobank is not for profit-making but rather to have measures in place for cost recovery.