EXPERT OPINION

Bioethics and Biobanking in Biomedical Research in Malaysia

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In the rapidly evolving domain of biomedical research, bioethics is a critical pillar that ensures the alignment of scientific advancements to ethical principles, societal values and human rights. The systematic collection of biological samples, processing and storage involved in precision medicine, epidemiological research and genetic studies are in need of a robust ethical governance and careful navigation in the biobanking practice. Addressing bioethical concerns is crucial, as Malaysia progresses to become one of the leaders in biomedical innovation. Discussions and the establishment of various ethical frameworks and national guidelines throughout the years have demonstrated Malaysia's commitment towards improving ethical oversights, regulatory clarity, and public trust in biomedical research and biobanking practices. However, challenges in areas such as informed consent, data privacy, equitable sharing of benefits and public trust in research institutions persist.

Biobanking, the storage of biological samples, is considered a cornerstone in biomedical research and it has revolutionised the study of human biology to an unprecedented scale. In this technology, biological specimens such as blood, tissue and DNA are collected, managed and stored in repositories to enable better understanding of disease mechanisms, identification of biomarkers and development of new treatments for diseases through original and pioneering research studies. In Malaysia initiatives to foster a robust biobanking infrastructure has led to the establishment of a Biobank Unit under the purview of the Institute for Medical Research (IMR) under the Ministry of Health in Malaysia (MOH) in 2019. Despite this, the ethical implications of biobanking are far-reaching and issues related to consent, sample ownership, secondary data use and fair distribution of research benefits are still being debated. A foundational guidance can be found in '*The Malaysian Guidelines on the Use of Human Biological Samples for Research*', published in 2015 by the MOH[1], but the ensuing ethical dilemmas that emerged in modern biobanking suggest the need for more comprehensive and updated regulations.

In light of these challenges and concerns surrounding ethical practices in research, some of the most pressing issues related to biobanking are discussed below.

Informed Consent

During the process of obtaining consent, it is important that donors-participants understand what will be done to the biological samples that they contribute. A valid informed consent is complex and Malaysia has currently adopted the *broad consent model*, which allows researchers to use biological samples for future research that are not specified but still within the ethical boundaries.[2] Apart from giving voluntary consent, it is important that donors -participants clearly understand the potential uses of their samples. A broad consent therefore poses a challenge as the validity of the consent can be questioned.

Genetic modification and commercial exploitation of biological samples in controversial research has always been the cause of fear and public apprehension. The proposal of a more stringent and ethical consent process is the *dynamic consent model* which allows donors-participants to continually update their preferences with regard to the use of their samples.[3] This alternative process may foster transparency and thus build trust between donors-participants and researchers including the biobank authorities. However, it is apparent that important infrastructure such as specific digital platforms for real-time donor-participant engagement including secure technology would be required in the implementation of this type of consent.

Data Privacy and Ownership

The privacy of data is a significant concern as biobanking is increasingly linked to genomic and genetic research. Re-identification of anonymised genetic data poses risks to donors-participants such as genetic discrimination, for instance, by insurance companies and employers. Issues of data security have notably become a barrier to public participation in biobanking initiatives. Thus, to prevent unauthorised access to private data and to preserve data integrity, secure data-sharing frameworks, blockchain or privacy technology driven by artificial intelligence (AI) would be required. Ownership rights are also imperative to ensure that donors-participants consent is obtained prior to third party sharing.

The recent amendment to the Personal Data Protection Act (PDPA) in Malaysia in 2024[4] is not only timely but necessary. The key changes made in areas such as data privacy, security and governance, have direct impact on bioethics and biobanking in research. The PDPA (Amendment) 2024, has now introduced crucial practices in the protection of personal data and some of them include mandatory data breach notifications to enhance transparency and accountability, and appointment of Data Protection Officers in research institutions. Biobanks handling large volumes of genetic or health data need to oversee compliance to data protection laws and expansion of definitions of sensitive personal data which now includes DNA, fingerprints and facial recognition data.[5]

Governance, Regulations and the Role of Ethics Committees

The biobanking landscape in Malaysia is in need of a clear, dedicated guideline and legislative framework. Donors-participants information is protected by the PDPA (Amendment) 2024 but issues pertaining to practices in biobanking are not specifically addressed. Groundwork has commenced for a National Biorepository Policy to establish standardised governance that will address challenges in storage of biological samples, access, privacy including commercialisation (National Sub-Committee for Laboratory Biosafety & Biosecurity, 2023).[6] At present, multiple biorepositories in the country are managed by government agencies, universities and private companies. The biobanks in most of these institutions and facilities have been operating under general laws such as Human Tissue Act 1974[7] that governs the use of human tissues and the previous PDPA 2010 to cover privacy and confidentiality aspects. The current Malaysian Guidelines on the Use of Human Biological Samples for Research (2015) are not legally binding and consent under the Human Tissue Act 1974 only applies to samples of deceased individuals and not living donors. There are concerns from the public that biological samples are being commercialised without donor-participant consent and exploitation of donated biological samples for financial gain.[8,9] Enforcement in the form of a dedicated biobank legislation, improved ethical guidelines and sustainable biobank models for research, diagnosis and public health are therefore vital.

Across the board, decisions from Institutional Review Boards (IRB) or Ethics Committees are sometimes delayed and there can be inconsistencies in the procedures used. Standardisation of ethical assessments and an efficient biobank governance that adhere to international ethical standards are crucial. Reviewers for ethical applications must also be trained to be well-versed in ethical considerations that are unique to biorepositories, genomic data privacy and storage of samples.

Standardisation

For purposes of universal standardisation of global biobanking, ISO 20387:2018 was developed by integrating guidelines from national and international biobank standards such as from the United Kingdom, Brazil, France and the Organisation for Economic Co-operation and Development (OECD). This ISO standard focuses on quality assurance of biological materials, data management and governance, standardisation of procedures for sample collection to distribution as well as risks assessments and sustainability of biobanks. With standardisation of processing protocols including rigorous quality control and regulatory compliance, it is now hoped that research using the biological samples can be reproducible, in turn promoting international collaborations for advancements in the field of study while at the same time increasing stakeholder confidence in biospecimen-based research.[10]

Artificial Intelligence (AI) and Biobanking Governance

The Ministry of Science, Technology and Innovation (MOSTI), published a guideline, 'National Guidelines on AI Governance & Ethics' in 2024, to ensure responsible application of artificial intelligence (AI) across healthcare and multiple sectors.[11] The use of AI in biobanking is no doubt necessary as it brings efficiency in data analysis but this also raises concerns on algorithmic bias, security vulnerabilities, and ethical accountability. Key ethical principles pertaining to biobanking as outlined in the guideline by MOSTI include fairness and non-discrimination (AI-driven analyses to be free from bias so as not to disadvantage certain populations), transparency and explainability (AI-generated results in genomic research to be interpretable for accountability in clinical decision-making), privacy and data protection (AI algorithms to adhere to strict privacy measures, preventing unauthorised access and data misuse) and most importantly, human oversight (AI to only enhance ethical and scientific rigor but must not replace human-decision making).

From the Islamic bioethics perspective, the use of human biological materials in research is regulated by principles that emphasises on consent, overall benefit to the society and the prevention of harm. With reference to 'Kompilasi Muzakarah MKI 2016' by Jabatan Kemajuan Islam Malaysia, the utilisation of biological samples e.g., adult stem cells, umbilical cord blood and residual embryos from *in vitro* fertilisation (IVF) treatments is allowed under Shariah law with the condition that informed consent has been obtained from the donor or guardian.[12] However, the commercialisation of those samples for non-therapeutic or business purposes is strictly prohibited, a stance that expresses the strong ethical position against exploitation. Biomedical research must have scientific rationale, have undergone ethical scrutiny and should only be performed by qualified researchers. These legal pronouncements affirm the conformity of Islamic Jurisprudence with universal standards of ethics and they provide the cultural and theological frameworks for regulation of biobanking and biomedical research in a Muslim-majority country like Malaysia.

The future of biobanking in Malaysia must ultimately prioritise transparency, ethical stewardship and public trust. Confidence in the biobanking governance can be nurtured by raising ethical literacy among the public, improving engagement with donors, participants and researchers as well as educating the larger society. An ethically robust and sustainable biobanking ecosystem can be achieved by bridging regulatory gaps and embracing technological innovations, propelling medical advancements, improvements to public health and precision medicine on both national and global scales.

As biomedical research advances, the 'Malaysian Guidelines on the Use of Human Biological Samples for Research' is currently being updated by the Biobank Secretariat at the National Institutes of Health, MOH, as a critical move toward ethical modernisation, instilling principles of dynamic consent, data sovereignty and fair benefit-sharing in national practice. This effort will ensure the harmonisation of Malaysia's biobanking environment with global standards and guidelines, ultimately strengthening trust, transparency, and scientific integrity in this age of precision medicine.

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