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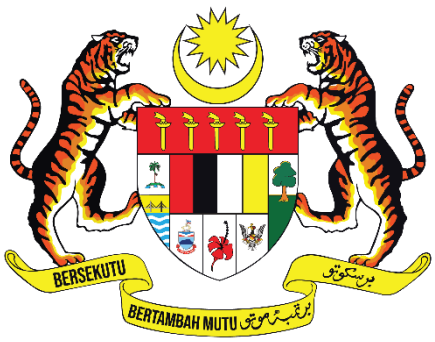
MINISTRY OF HEALTH MALAYSIA

MALAYSIAN GUIDELINES ON THE USE OF HUMAN BIOLOGICAL SAMPLES FOR RESEARCH

Second Edition



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FOREWORD

By Director General of Health

The Malaysian Guidelines on the Use of Human Biological Samples for Research have played a pivotal role in ensuring the ethical, safe, and responsible use of human biological materials in scientific research. As the landscape of biomedical research evolves rapidly, the need to adapt to new technologies, methodologies, and regulatory standards has become paramount. The new edition of these guidelines represents a critical step forward in addressing these changes while upholding the fundamental principles of respect, dignity, and rights for individuals contributing to scientific progress.

The world of medical and scientific research continues to transform, with advancements in genomics, biotechnology, and personalized medicine paving the way for innovative treatments and health solutions. However, with these advancements come new ethical challenges, particularly in relation to consent, privacy, and the potential for misuse of biological samples and data. As such, the guidelines remain an essential framework for ensuring that research using human biological samples is conducted with the highest standards of integrity, transparency, and respect for humanity.

This revised edition reflects extensive consultations with experts from diverse fields, including bioethics, law, and medicine, and incorporates the latest best practices and international standards. It offers clear, comprehensive, and practical guidance for researchers, institutional review boards, and policymakers, empowering them to navigate the complexities of modern research environments while safeguarding the welfare of individuals who voluntarily contribute to the advancement of knowledge.

As we look to the future of biomedical research in Malaysia and globally, the importance of maintaining a delicate balance between scientific progress and ethical responsibility cannot be overstated. These guidelines are a vital resource in achieving that balance. By following these principles, we ensure that the pursuit of knowledge remains aligned with the values of justice, respect, and care for humanity.

"I trust that this updated edition will continue to serve as a cornerstone for ethical research in Malaysia and beyond, promoting trust, accountability, and the responsible use of human biological samples in the service of science and public health."

Datuk Dr. Mahathar bin Abd Wahab
Director-General of Health
Chairperson, National Committee for Clinical Research
Ministry of Health Malaysia

FOREWORD

By Deputy Director General of Health
(Research & Technical Support)

I am pleased to present the updated Malaysian Guidelines for the Use of Human Biological Samples for Research, developed by the Ministry of Health Malaysia. This document reaffirms our commitment to ensuring that biomedical and health-related research in Malaysia is conducted with the highest standards of ethical integrity, scientific rigour, and respect for human dignity.

"Human biological samples are essential to the advancement of medical knowledge; however, their collection, storage, and use must be guided by strong ethical principles. These guidelines are intended to assist researchers and research ethics committees in addressing the legal and ethical considerations involved, thereby ensuring transparency, accountability, and maintaining public trust."

Based on international best practices and adapted to the Malaysian context, the guidelines address key areas such as informed consent, sample governance, confidentiality, data protection, and benefit-sharing. They are intended to support researchers, institutions, and research ethics committees in ensuring compliance with national standards while promoting responsible research conduct aligned with regulatory requirements.

We extend our sincere appreciation to the Working Committee and all contributors for their dedication, and we hope this document fosters ethical research and strengthens public confidence in biomedical research in Malaysia.

Datuk Dr Nor Fariza binti Ngah
Deputy Director General of Health
(Research and Technical Support)
Ministry of Health Malaysia

CHAIR OF WORKING COMMITTEE

It is with great honour and privilege that I present the Malaysian Guidelines for the Use of Human Biological Samples for Research, developed under the auspices of the Ministry of Health, Malaysia.

The use of human biological samples in research holds immense potential for advancing scientific understanding, improving healthcare outcomes, and guiding policy decisions. However, it also raises critical ethical, legal, and social considerations. The development of these guidelines was driven by the need to ensure that such research is conducted with the highest standards of integrity, respect for human dignity, and in full compliance with ethical and regulatory requirements.

This document was developed through inclusive consultation with experts from various institutions and backgrounds. Their collective expertise, insights, and commitment have been instrumental in shaping a comprehensive document that balances scientific advancement with the fundamental rights and welfare of individuals who contribute their biological samples for the benefit of society.

On behalf of the Working Committee, I extend my sincere appreciation to all who contributed to this important endeavour. It is our hope that these guidelines will continue to serve as a cornerstone of ethical biomedical research in Malaysia, promoting accountability, transparency, and respect for the individuals who make such research possible.

The valuable insights gathered throughout this process have enhanced the clarity, relevance, and applicability of the guidelines across diverse research settings in Malaysia.

I would like to extend my deepest appreciation to all members of the Working Committee, without whom this initiative would not have been possible. Your unwavering support and collaborative spirit have been the cornerstone of this achievement.

It is my sincere hope that these guidelines will be widely adopted and effectively implemented, thereby strengthening Malaysia's commitment to ethical research practices and contributing meaningfully to the global research landscape.

Dr. Hans Prakash a/l Sathasivam
Chair,
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Malaysian Guidelines for the Use of Human Biological Samples for Research
Ministry of Health Malaysia

EXTERNAL REVIEWERS' COMMENTS

"I am honoured to contribute to this revised edition, which reflects the ongoing commitment of the committee to uphold human dignity, privacy, and ethical standards in human sample-based research. With updates that align with current methodologies, ethical expectations, and regulatory frameworks, I hope these guidelines will continue to build trust between participants and the scientific community, ensure adherence to national and international regulations to elevate the overall standard of research related to the use of human biological samples."

Professor Dr. Normala Ibrahim
Dean
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Member of National Committee for Clinical Research

"Human tissue guidelines are essential frameworks designed to govern the ethical and legal, as well as responsible use of biological materials in research and education within the wider ecosystem of clinical practice. The guidelines ensure respect for donors' rights, promote transparency, and safeguard public trust by outlining the requirements for consent, storage, and usage. These guidelines specifically, are the result of a community of experts intended to help researchers and institutions navigate complex issues relating to privacy, ownership, and benefit sharing."

Dr Zisis Kozlakidis
Head of Laboratory Services and Biobanking,
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World Health Organisation

ACKNOWLEDGEMENT

The working committee would like to express our sincere appreciation to YBhg. Datuk Dr. Mahathar bin Abd Wahab, Director-General of Health, Malaysia, YBhg. Datuk Dr. Muhammad Radzi bin Abu Hassan, former Director-General of Health, Malaysia, and YBhg. Datuk Dr. Nor Fariza binti Ngah, Deputy Director-General of Health (Research & Technical Support), for their leadership, contributions, support, and commitment in driving the development of the latest edition of The Malaysian Guidelines on the Use of Human Biological Samples for Research. This task would not have been possible without the collective effort and support of numerous individuals, institutions, agencies, and organisations. We would like to sincerely thank all who have contributed directly and indirectly to the successful completion of these guidelines. It is our sincere hope that these guidelines will serve as an invaluable resource for the research community to further enhance and strengthen the Malaysian medical research ecosystem. We would also like to thank the Director-General of Health Malaysia for permission to publish this document.

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ABBREVIATIONS

AI	-	Artificial Intelligence
BLESS	-	Business Licensing Electronic Support System
CIOMS	-	Council for International Organizations of Medical Sciences
DTA	-	Data Transfer Agreement
FFPE	-	Formalin-Fixed Paraffin-Embedded
GCP	-	Good Clinical Practice
GDPR	-	General Data Protection Regulation
HIPAA	-	Health Insurance Portability and Accountability Act
ICH-GCP	-	International Council for Harmonisation Good Clinical Practice
IEC	-	Independent Ethics Committee
IP	-	Intellectual Property
IRB	-	Institutional Review Board
MCRCR	-	Malaysian Code of Responsible Conduct in Research
NCCR	-	National Committee for Clinical Research
NDAs	-	Non-Disclosure Agreements
PDPA	-	Personal Data Protection Act
PIS	-	Patient Information Sheet
SOP	-	Standard Operating Procedures
WHO	-	World Health Organization
WMA	-	World Medical Association

GLOSSARY

Acquisition	Act of obtaining possession and/or custody of biological material and/or associated data
Anonymisation of tissues/ samples	Process of removing all identifying information from specimens and data. In most cases, the possibility of re-identifying or re-contacting the participants/donors is negligible
Biobank	A legal entity or part of a legal entity that performs biobanking. The term applies more extensively to any entity focused on management and operations of specimens and associated data primarily intended for research purposes. Alternative terms may include biorepository, biological resource centre, tissue bank, and cell bank among many types of samples (refer “Type of Samples” in glossary).
Biobanking	Performing functions associated with a biobank. It can also be described as the process of acquisitioning and management, together with some or all the activities related to collection, preparation, preservation, testing, analysing, and distributing biological material as well as related information and data
Custodianship	Responsibility for safe keeping of samples and control of their use and eventual disposal in accordance with the terms of the consent given by the donor and any legal and good practice requirements. Custodianship implies some rights to decide how the samples are used and by whom, and the responsibility for safeguarding the interest of the donors.
Data Transfer Agreement	A Data Transfer Agreement (DTA) is a legal document outlining the terms and conditions under which data can be shared between organisations or individuals. It defines the rights of the data provider and the recipient with respect to the data and any derivatives.
De-identification	A process that removes any identifying information of a participant that can be connected to the samples or specimens.
Diagnostic Samples	Biological materials collected from individuals during diagnostic procedures, such as blood tests, biopsies, or image-guided procedures.

Human biological sample	The terms human biological material, human biological samples, human material, material, and samples are used interchangeably and refer to all biological materials of human origin, including (but not limited to) organs, tissues, bodily fluids, teeth, hair, and nails; as well as extracted genetic material such as DNA and RNA. This definition excludes established cell lines and laboratory-engineered constructs such as organoids.
Informed Consent	A voluntary agreement regarding a role a person will play in a research study after they are fully informed. This agreement shows that they are willing to participate voluntarily after having a full understanding of what the study entails, including the duration, risks, and benefits.
Institutional Review Board / Independent Ethics Committee (IRB / IEC)	A board, committee, or other group formally designated by an institution to review the ethical, legal, social, scientific, and financial implications of biomedical research involving humans as subjects, to approve the initiation of the research, and to conduct periodic reviews of such research. In some countries, this body is known as an institutional review board (IRB) or a research ethics board (REB).
Material Transfer Agreement	A Material Transfer Agreement (MTA) is a legal binding document that governs the transfer of materials between two parties. It defines the rights of the provider and that of the recipient with respect to the materials and any derivatives.
Participant/Patient Data	Data related to the individual participant/patient, including (but not limited to) their demographic data, medical history, current health status, treatment-related data, etc. That will be associated with the relevant biological samples.
Personal information	All identifiable information about individuals, living or dead. This includes written and electronic records and information obtained from samples.
Principal Investigator	A principal investigator (PI) is the lead researcher for a research project, typically in fields such as the sciences, laboratory studies, or clinical trials. The PI is responsible for overseeing the study, ensuring adherence to protocols and regulatory standards, and managing key aspects of the research, including protocol development, data analysis, and participant oversight.
Research Data	Collected and processed data derived from the analysis of the biological samples, used to generate insights and conclusions in the research study.

Standard Operating Procedures (SOP)	Step-by-step instructions to be followed routinely for the performance of designated operations or in designated situations to achieve efficiency, quality output, and uniformity of performance
Stored Biomaterials and Data	Biological samples and associated data that have been collected and stored for future research use.
Stem cell	A stem cell is an undifferentiated cell capable of developing into specialized cell types. They include embryonic stem cells (from early embryos), adult stem cells (from tissues like bone marrow), and induced pluripotent stem cells, which are adult cells reprogrammed to behave like embryonic stem cells. Stem cells are vital in biomedical research for their potential in tissue regeneration and disease modelling.

1.0 INTRODUCTION

Human biological samples are pivotal in advancing scientific knowledge and improving biomedical and translational research. In Malaysia's diverse biomedical research landscape, these samples are not only valuable for their scientific potential but are also essential for understanding the unique genetic, environmental, and cultural factors influencing health and disease among the Malaysian population.

All research utilising or involving human biological samples must obtain approval from an Institutional Review Board (IRB) or an Independent Ethics Committee (IEC). The ethical management of these samples is of utmost importance and requires rigorous adherence to ensure that the rights, dignity, and privacy of research participants are consistently respected. This is particularly crucial in Malaysia, where the diversity of the population demands a culturally sensitive approach to biomedical research. Effective research practices must therefore align with both local values and international ethical standards, fostering trust and cooperation between researchers and the community. They must also consider Shariah law and fatwa, specifically in handling human biological samples obtained from Muslims.

To ensure ethical integrity, it is essential that any cross-border transfer of human tissue for research is conducted under strict regulations that emphasise transparency and accountability. Access to biological materials should be limited to those dedicated to advancing scientific knowledge and ethical research, thereby preventing misuse, and upholding ethical standards.

These guidelines provide a comprehensive framework for the responsible use of human biological samples within the Malaysian research community. They address the entire lifecycle of sample management, encompassing acquisition, storage, analysis, transportation and sharing of samples, while adhering to national and international guidelines, best practices, regulations, and legislation. Key areas covered include ethical considerations, legal frameworks, privacy and data protection, operational protocols, sample and data management, and perspectives on sharing of samples and data. The current edition of the guidelines replaces all previously published editions.

By adhering to these guidelines, researchers in Malaysia will be able to uphold the principles of beneficence and justice to conduct research with the utmost integrity and credibility. This document serves as a guiding framework that emphasises the importance of ethical considerations, stakeholders' responsibilities, and best practices for sample management in every aspect of research involving human biological samples. It reflects Malaysia's

commitment to excellence and integrity in research, ensuring that the pursuit of scientific advancement also prioritises the well-being and rights of its citizens.

As we delve into the complexities of human biology, the Malaysian Guidelines on the Use of Human Biological Samples for Research stand as a testament to the nation's dedication to fostering ethical research practices that benefit society at large.

2.0 SOURCE/TYPES OF HUMAN BIOLOGICAL SAMPLES FOR RESEARCH

Human biological samples are substances collected from humans that provide critical biological information for scientific analysis and medical research. These include a variety of materials such as tissues, organs, cells, blood, genomic material, proteins, hair, nail clippings, urine, stool, saliva, or other bodily fluids that are essential for insights into human health, disease mechanisms, and therapeutic responses. This section details the different manners in which these human biological samples are sourced.

2.1 Stored/Archived Samples Collected During Routine Investigation/Treatment

The utilisation of these types of samples for research is pivotal for driving forward scientific discovery and enhancing healthcare outcomes. Leftover diagnostic samples refer to biological materials remaining after clinical testing procedures, including blood tests, biopsies, and image-guided procedures. Pathology archives contain a wealth of stored biomaterials and data amassed from routine diagnostics, presenting valuable prospects for scientific exploration across numerous disciplines. The use of the leftover samples for further research also needs to undergo an ethical approval process as it was initially harvested for different purposes. Therefore, guidelines are essential to uphold integrity and regulatory compliance, ensuring the conscientious and ethical utilisation of these materials and associated data in research endeavours.

2.2 Prospectively Collected Samples for Specific Research Projects

Prospectively collected samples and data specifically for research studies represent a cornerstone of rigorous scientific inquiry and medical advancement. Unlike leftover diagnostic samples and pathology archives, prospectively collected materials are intentionally gathered for research purposes from consenting individuals.

2.3 Prospectively Collected Samples for Biobanking (Future Research)

Prospectively collected samples and data for future research, commonly stored in biobanks, represent a strategic reservoir for ongoing and future scientific investigations without specific research in mind. These repositories meticulously gather biological materials and associated information from consenting individuals, underlining a forward-looking approach in biomedical research. Biobanks house a diverse range of samples, including tissues, genomic material, and associated data, curated to facilitate longitudinal studies and address emerging scientific questions. Ethical protocols govern their establishment and operation, ensuring transparency,

participant privacy, and the responsible stewardship of resources. By leveraging these biobanks, researchers can explore new frontiers in precision medicine, diagnosis, prognosis, disease prevention, and therapeutic innovation, ultimately enhancing global health outcomes through robust and sustainable biomedical research practices.

2.4 Legacy Samples from Previous Research Projects

Legacy samples refer to leftover or surplus biological materials (and clinical data) collected during previous research studies that are no longer needed for the original study but can be repurposed for future scientific inquiries (secondary use). These materials may include blood, tissue, genetic data, and participant health information. Repurposing these samples maximise their utility, optimizes research efforts, reduces redundancy, and encourages interdisciplinary collaboration. This approach accelerates scientific discovery and contributes to advancements in healthcare practices globally.

However, the use of legacy samples raises significant ethical concerns that require stringent oversight. Their utilisation must comply with ethical guidelines, donor consent, and legal standards, ensuring confidentiality, consent, and regulatory compliance. By adhering to these frameworks, researchers can responsibly continue scientific exploration and potentially drive new healthcare advancements.

2.5 Samples Obtained from Biobanks

Samples and data stored in biobank facilities are essential resources for advancing scientific research and medical innovation. These repositories systematically collect, preserve, and manage biological samples and associated data to support a wide range of research endeavours. The materials stored in biobanks, including blood/blood derivatives, tissue samples, genetic material, bodily fluids, and related data, provide valuable insights into health and disease. Biobanks may be categorized into several types, including population-based, disease-specific, and cohort-linked biobanks, each tailored to address specific research needs from broad population health studies to focused investigations of diseases. By consolidating and efficiently managing these resources, biobanks enhance research productivity, promote interdisciplinary collaboration, and accelerate scientific discoveries. When ethically managed and carefully maintained, these resources adhere to strict guidelines to ensure confidentiality, informed consent, and regulatory compliance. Ultimately, biobanks play a pivotal role in advancing biomedical research and improving global health outcomes, supporting both broad and targeted research initiatives.

2.6 Samples Removed from Deceased Individuals

Samples removed from deceased individuals represent a unique and ethically sensitive resource for biomedical research. These samples, which may include tissues, organs, or fluids, are collected post-mortem with the intention of advancing scientific knowledge and medical understanding. Ethical considerations, religious and cultural sensitivities, and regulatory protocols govern the respectful and responsible use of these materials, ensuring consent, confidentiality, and the dignity of the deceased. By studying samples removed from the deceased, researchers can explore disease mechanisms, investigate genetic predispositions, and develop treatments that benefit future generations. This research avenue not only expands our scientific insights but also contributes to innovations in healthcare, potentially offering insights into diseases that affect human populations worldwide.

According to the National Fatwa Council of Malaysia, the use of tissues, parts, or organs from the deceased for research is permissible, provided it adheres to specific ethical guidelines. First, respect for the individual is crucial, meaning that consent must be obtained from the deceased or their family. Additionally, the confidentiality and privacy of the deceased must be strictly protected throughout the research process. Researchers must also weigh the risks and benefits, ensuring that the potential positive outcomes outweigh any possible harm. This should include considerations for the genetic privacy and rights of family members of deceased participants.

Importantly, the whole deceased body of Muslims should not be used for research. Furthermore, tissues or organs cannot be used for any form of genetic alteration, as this is not permitted.

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3.0 GUIDING PRINCIPLES

Principle 1: Respect for Persons

How should consent be obtained? Consent should be obtained through a process that includes clear, understandable explanations and the opportunity for participants/donors to ask questions. This process must also accommodate language preferences and literacy levels, ensuring fully informed consent, whether it is obtained digitally, physically, or verbally (recorded).

What information should be provided to sample donors? Researchers should inform participants/donors about the purpose of the research, the types of samples to be collected and analyses to be conducted, the conditions under which the samples will be stored and used, potential risks and benefits, and their rights to withdraw consent at any time. Information on how samples will be disposed/destroyed if consent is withdrawn should also be included.

How can researchers ensure ongoing consent throughout the research process, especially as new information or technologies emerge? Researchers should, as much as that is possible and applicable, implement mechanisms for re-consent when significant changes occur or new information emerges that could affect participants' willingness to continue. Researchers should inform participants of significant new findings during the research that might affect their willingness to continue participation.

What procedures should be in place to handle participants' questions or complaints during the study? Researchers should establish a clear, accessible procedure for handling inquiries and grievances. A method usually employed by researchers would be providing the contact details of the principal investigator. An institutional contact point should also be provided (where possible) to ensure continuity and accountability in cases where the principal investigator is unavailable or has changed affiliations.

What additional considerations are needed for vulnerable populations? Safeguards should be enhanced for vulnerable groups to ensure consent is voluntary and informed, protecting against coercion and undue influence. Vulnerable populations should be included when necessary and have the access to contribute to the right research. (Please refer to Section 6.2.2 of this document for examples of “vulnerable groups”)

How can we respect participants who are unable to give consent? For individuals unable to give consent (e.g., minors, incapacitated adults), consent must be obtained from legally authorised representatives in accordance with local regulations. Ethical considerations must ensure that the research is likely to benefit the group represented by the participant.

Principle 2: Beneficence and Non-Maleficence

What constitutes a proper risk-benefit analysis for research involving human biological samples? The analysis must assess whether the potential benefits to participants and the broader society justify the risks involved. Measures should be put in place to minimise physical, psychological, and privacy risks to participants.

How should biological samples be collected and stored to minimise harm? Researchers must specify standardised procedures for the collection, labelling, transportation, and storage conditions of biological samples, such as maintaining specific temperature and humidity controls. Respect for persons should include proper handling of their samples and associated data.

How should researchers handle incidental findings that might affect a participant's health? Researchers should have a protocol in place for managing incidental findings. (Please refer to Section 6.5 of this document for further information).

What measures are in place to ensure that benefits and risks are continually reassessed throughout the research? Institutional review boards / Independent ethics committees are tasked with the continuous monitoring of studies to ensure risks and benefits remain balanced and acceptable.

How is participant confidentiality protected in research using biological samples? Participant confidentiality is safeguarded by de-identifying samples and data, employing robust security measures for data storage, and limiting data access to authorised personnel only.

Principle 3: Fairness and Justice

How can researchers ensure equitable selection of participants? Participant selection should be based solely on the scientific needs of the study ensuring fair and transparent criteria are applied. Vulnerable populations and hard-to-reach communities should be included when necessary and have the access to contribute to the right research.

What strategies should be used for fair benefit sharing? Researchers should ensure that the benefits of the research are shared with those who participated in the study. This can include providing feedback, offering health monitoring, investing in community health initiatives, and ensuring transparency about the potential outcomes and benefits of the research.

What mechanisms can be implemented to ensure transparency in participant selection and benefit sharing? Transparency can be ensured by publicising research protocols and

selection criteria, and by making them available online through institutional websites when appropriate, particularly when required by funders or regulatory bodies.

How do we address the risk of exploitation in vulnerable populations? Special measures must be taken to ensure that vulnerable populations are not disproportionately involved in research unless the research is directly beneficial to the group and the risks are proportionate to or lesser than the potential benefits. Studies specifically on vulnerable populations should be co-designed to avoid exploitation, and consider the vulnerable population's perspectives of needs and benefits rather than solely the researcher's interest and perspective of benefit. The IRB/IEC should take cognizance of these sensitivities and possible conflicts of interest.

Principle 4: Scientific Integrity

What are the requirements for the ethical review of research involving human biological samples? All research proposals must undergo review and approval by an IRB/IEC, which evaluates the scientific validity, ethical soundness, and compliance with both local and international guidelines and regulations.

What standards must be maintained during the collection, handling, and storage of biological samples to ensure scientific integrity? Standards that align with recognised national and international guidelines and/or best practices must be upheld during all stages of sample management. These standards should align with recognised national and international guidelines, including those for the collection, labelling, transportation, and storage. Regular audits and quality checks should be mandated.

How do researchers ensure reproducibility and transparency of their research findings? By adhering to international standards such as International Council for Harmonisation Good Clinical Practice (ICH-GCP) guidelines and the Malaysian Guidelines for Good Clinical Practice, as well as local regulations and guidelines from the Malaysian Ministry of Health and other relevant authorities, which advocate for rigorous documentation and methodological transparency.

What protocols are in place for dealing with allegations of scientific misconduct? Most institutions and funding bodies require a formal process for reporting and investigating misconduct. Each institution is responsible for ensuring such processes are set in place in their respective institutes.

Principle 5: Ethical Oversight

When is ethical approval required for research involving human biological samples? Ethical approval is required for all research involving human participants and/or their biological samples and/or participant data, and it must be obtained before the research begins.

How are ethical oversight committees kept independent and unbiased? It is recommended that such committees include diverse members with no vested interests in the specific research.

Principle 6: Legal and Regulatory Compliance

What are the key legal requirements for research involving human biological samples in Malaysia? Researchers must comply with the Human Tissues Act 1974, the Personal Data Protection Act 2010, and follow guidelines issued by the Malaysian Ministry of Health and other relevant authorities. The accountability of the processes to maintain the quality and preservation of samples, and the transparency of application and approval processes in the usage of the samples must be observed.

How do researchers handle changes in legal and regulatory standards during a long-term study? Regular updates from regulatory bodies and ongoing consultation with legal experts ensure compliance with current laws.

What are the implications of international collaborations in terms of compliance with different legal systems? Compliance with both local and international regulations is required, with agreements on jurisdictional issues clarified at the outset of collaboration.

If there are human biological samples obtained from a Muslim, are there any specific regulations to be complied with? Shariah law and fatwa should be adhered to such as in stem cell research, genetics research and handling of the samples from a Muslim.

Principle 7: Privacy and Confidentiality

How can researchers protect participant privacy and confidentiality? Ensuring participant's privacy and confidentiality involves implementing strict data de-identification, maintaining secure data storage facilities, and restricting facilities and data access to authorised personnel only. Regular training on confidentiality and data protection should be provided by research institutions to ensure compliance with ethical and legal standards.

What are the best practices for data management and security? Key practices include utilising encrypted databases to store sensitive information securely, implementing strict

access controls to ensure that only authorised personnel can access the data, and conducting regular security audits. These practices help in maintaining the integrity and confidentiality of the data collected and stored as part of research involving human biological samples. Duration of data storage should be explicitly mentioned in the informed consent (if applicable).

What steps are taken to ensure that privacy is maintained when research data are shared or published? Use of de-identified data sets and secure data sharing methods, as mandated by the Personal Data Protection Act 2010 of Malaysia.

How do researchers respond to data breaches or unauthorised access to confidential information? Implementation of immediate breach notification procedures and remedial actions as required by local data protection laws and international best practices.

Principle 8: Conflict of Interest

What constitutes a conflict of interest in research involving human biological samples? A conflict of interest occurs when personal, financial, or other considerations have the potential to compromise or bias professional judgement and objectivity in research.

How should conflicts of interest be managed? Researchers must disclose all potential conflicts of interest to the IRB/IEC or oversight committee responsible for the research. Effective management strategies should be established, including third-party oversight where necessary, to mitigate any potential influence on the research integrity.

What systems are in place to monitor conflicts of interest over the duration of the research? Regular declaration of interests and third-party audits, as recommended by international guidelines and Malaysian research governance frameworks.

How do conflicts of interest influence the publication and dissemination of research results? Conflicts of interest must be declared upon manuscript submission and during all public communications to maintain transparency and trust in published findings.

Principle 9: Integrity and Quality of Samples

What procedures are there for verifying the source and quality of biological samples? Procedures typically include chain-of-custody documentation and quality control checks, as per local and international standards, guidelines, and best practices.

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4.0 ETHICAL CONSIDERATION AND LEGAL FRAMEWORK

4.1 Ethical considerations

The collection, testing, storage, utilisation, and disposal of human biological samples present numerous ethical and legal challenges. All research utilising human biological samples will require approval from an IRB/IEC. While some of these challenges are unique to specific applications or contexts, the following ethical framework will address themes that are broadly relevant.

4.1.1 Respect for human lives and the human body

Respecting individuals and their bodies by allowing them to make informed decisions regarding contributions of their samples for research is important. Treating people with dignity means honouring their choices regarding how their tissue is collected and used. This necessitates obtaining informed and voluntary consent. All researchers have an ethical duty to help ensure the best outcomes for participants.

4.1.2 Appropriate consent models

Consent for tissue donation and its use should be voluntary and informed, ensuring individuals understand the proposed research and its implications. Explicit consent is generally required for research use unless waived by an IRB/IEC. Individuals should be informed if leftover tissue may be used for additional research or kept for future research (samples will be kept in biobank) and they retain the right to withdraw its use for research. A broad consent model may be used if samples are procured for biobanking. Volunteers should have the option to decline involvement and withdraw from the research process at any time. See section 6.0 for further details on consent.

4.1.3 Transparency while protecting patient privacy

Transparency is essential for building public trust, especially in the processes of obtaining and distributing human biological samples and data for research. Similarly, protecting the confidentiality of patients' information is a cornerstone of ethical practices in both medical treatment and research. Though challenging, maintaining confidentiality throughout each stage, from the collection and processing to the reporting, storage, biobanking and distribution of human biological samples is essential. Donor/Participant identifiers must be removed prior to release to approved end-users. Any exception to this should be in line with applicable ethical and legal requirements, be clearly justified and documented.

4.1.4 Prohibition on buying or selling human biological samples but permissible commercialisation practices

It is unethical to purchase, offer to purchase, or sell human biological samples for research. Such trade in human biological samples for monetary payment commodifies the body, is viewed as unethical because it diminishes respect for the human body, opens vulnerable individuals to exploitation, and contravenes the spirit of altruism that tissue donation embodies. Commercialisation of research outcomes (e.g., patents or commercialized products) introduces ethical ambiguity regarding benefit-sharing fairness and participant consent. As such, commercialisation of discoveries from research is permissible if it adheres to strict ethical guidelines. This includes ensuring that any potential commercial benefits arising from the research are managed and shared fairly, particularly if the research involves multiple partners/stakeholders. The possibility of commercialisation should be included in the informed consent process (if feasible). Intellectual property rights and commercialisation of research are acknowledged as a possibility, but this should happen only when adhering to clear ethical standards and principles.

4.2 Statutory Regulation

In Malaysia, although there is no single, specific legislation regulating the use of human biological samples in research, several applicable laws and regulations govern research related activities. The following statutes provide relevant guidance for the operation and ethical conduct of research involving human biological samples.

4.2.1 Human Tissues Act 1974, Act 130

This guideline acknowledges that while the Human Tissues Act 1974 (Act 130) may not fully address contemporary challenges such as genetic data protection, biobanking, and advanced consent models, it remains a relevant framework for governing activities involving human tissues in Malaysia. The Act regulates the donation and use of human tissues for therapeutic purposes, research, education, and other medical applications, with Section 2(1) specifically outlining the conditions for utilising human tissue for research, provided it aligns with the donor's wishes. The scope of this guideline is to offer practical and ethical guidance within the boundaries of the existing legislation. Proposals for amending or updating the Act fall outside the scope of this document. However, the guideline aims to address current issues by integrating best practices and ethical principles that align with international standards where applicable

4.2.2 Personal Data Protection Act 2010, Act 709

The Malaysian Personal Data Protection Act 2010 (Act 709) (PDPA) applies to any private company, statutory body or individuals who process personal data for commercial purposes. This act aims to protect individuals' personal data and empowers them to manage how such information is obtained, used, and shared. The PDPA outlines specific precautions that organisations must adhere to when collecting, retaining, using, and disclosing personal data. The Personal Data Protection Act (Act 709) does not apply to the federal and state governments. However, federal and state governments must comply with current Acts, Circulars, Regulations and Guidelines of the Government when processing personal information. Further information regarding the implementation and enforcement of this Act can be obtained from the Personal Data Protection Commissioner (PPDP), an agency under the Digital Ministry.

4.2.3 Patents Act 1983, Act 291

The Patents Act 1983 (Act 291) sets the guidelines for patenting inventions and applies to research involving human biological samples. Inventions derived from human biological samples, such as treatments and diagnostic methods, can be patented if they meet the criteria set out in Act 291. According to Section 11 of Act 291, "*An invention is patentable if it is new, involves an inventive step and is industrially applicable*." Section 12 of Act 291 has described the meaning of "invention" as follows:

i. "An invention means an idea of an inventor which permits in practice the solution to a specific problem in the field of technology."
ii. "An invention may be or may relate to a product or process."

However, as described in Section 13 of Act 219, there are several "non-patentable inventions" though they may be inventions within the meaning of section 12 of Act 219. The following shall not be patentable:

i. "discoveries, scientific theories, and mathematical methods;"
ii. "plant or animal varieties or essentially biological processes for the production of plants or animals, other than man-made living microorganisms, microbiological processes, and the products of such microbiological processes;"
iii. "schemes, rules, or methods for doing business, performing purely mental acts, or playing games;"
iv. "methods for the treatment of human or animal body by surgery or therapy, and diagnostic methods practised on the human or animal body:"

Research policies on intellectual property should ensure compliance with what has been described in the Patents Act 1983 (Act 291) and further information regarding the administration and enforcement of this Act can be obtained from the Intellectual Property Corporation of Malaysia (MyIPO).

4.2.4 Access to Biological Resources and Benefit Sharing 2017, Act 795

As a party to the Convention on Biological Diversity and the Nagoya Protocol, Malaysia has enacted the Access to Biological Resources and Benefit Sharing Act 2017 [Act 795] as Malaysia's legal framework for regulating access to biological resources including human genetic resources. Notably, while the Nagoya Protocol explicitly excludes human genetic resources, Act 795 takes into account national circumstances and a broader approach by including human genetic resources (see Sections 12(2)(f) and 15(3)(f)). In fact, Section 4 defines a 'resource provider' as an individual from whom a biological resource, including genetic resources, is obtained. The Act stipulates that access may only be granted through permits, while ensuring that benefits arising from such access are shared fairly and equitably. At the same time, it provides safeguards to prevent any use that conflicts with existing laws, ethical standards, or the broader public interest. The Ministry of Natural Resources and Environmental Sustainability is collaborating closely with the Ministry of Health to develop relevant regulations, considering the needs stipulated in Act 795.

4.2.5 Prevention and Control of Infectious Disease Act 1988, Act 342

The Prevention and Control of Infectious Diseases Act 1988 (Act 342) is designed to manage and control infectious diseases through measures such as isolation, quarantine, and health interventions. While its primary focus is on disease prevention and control, the Act indirectly impacts the use of human biological samples in research by regulating their collection and use, especially during outbreaks when public health measures are in place. Act 342 supports the development of health and safety guidelines for handling biological samples to ensure safety and prevent the spread of infectious agents. Although the Act does not provide specific ethical guidelines for research, it complements other regulations and ethical frameworks that govern the use of human biological samples, ensuring that research practices comply with ethical standards and legal requirements to protect individuals' rights and obtain proper consent.

4.2.6 Biosafety Act 2007, Act 678

The Biosafety Act 2007 (Act 678) regulates the release, importation, exportation, and contained use of living modified organisms produced through modern biotechnology as well as the release of their products. The Act aims to protect human, plant, and animal health, the

environment, and biological diversity. Any activity involving living modified organisms with the application of in vitro techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of the nucleic acid into cells or organelles or fusion of cells beyond the taxonomic family is regulated under this law. However, there are some exemptions provided under the First Schedule of the Biosafety (Approval and Notification) Regulations 2010 that may apply. Researchers should consult with their respective Institutional Biosafety Committee or the Department of Biosafety Malaysia with regards to exemptions. Further information regarding this Act can be obtained from the Department of Biosafety under the Ministry of Natural Resources and Environmental Sustainability.

4.2.7 Data Sharing Act 2025, Act 864

This Act provides a structured regulatory framework for the sharing of data among public sector agencies. Further information regarding this Act can be obtained from the Ministry of Digital, Malaysia.

4.3 Guidelines for conduct of Research utilising Human Biological Samples

Existing legislation, such as the Human Tissue Act 1974, apply specifically to deceased bodies, while the PDPA 2010 governs data protection for commercial entities. Nevertheless, several international and local guidelines are applicable for the conduct of research across both public and private sectors. The Declaration of Helsinki, established by the World Medical Association (WMA), sets forth ethical principles for medical research involving human subjects. Additionally, the International Ethical Guidelines for Health-related Research Involving Humans, prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), must be adhered to in all relevant research activities. Malaysia has established several guidelines to ensure the ethical conduct of research is aligned with international standards. These guidelines provide frameworks for researchers to maintain high ethical and scientific standards throughout the conduct of research.

4.3.1 Malaysian Guideline for Good Clinical Practice (GCP)

Good Clinical Practice (GCP) is a recognised ethical and scientific guideline aimed at ensuring the rights, safety, and well-being of clinical trial participants, consistent with the Declaration of Helsinki. The latest version of the Malaysian Guideline for Good Clinical Practice (GCP) is the Fourth Edition, published in 2018. This edition was developed by the National Committee for Clinical Research (NCCR) in response to the growing complexity and number of clinical trials in Malaysia. The Malaysian Good Clinical Practice (GCP) Guidelines, provide a

comprehensive framework that aligns with the International Conference on Harmonisation (ICH) E6(R2) guidelines.

These guidelines cover the design, conduct, recording, and reporting of clinical trials involving human subjects. Researchers are obligated to safeguard the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of participants throughout the clinical trial process. This includes ensuring compliance with regulatory, ethical, and procedural requirements set forth by local authorities and international standards.

The GCP guidelines also emphasise the need for GCP training and certification for all clinical trial investigators and research personnel in Malaysia to uphold ethical and scientific standards. Investigators are required to demonstrate their qualifications through education, GCP certification, and relevant experience, providing necessary documentation to sponsors, Institutional Review Boards (IRBs), Independent Ethics Committees (IECs), and regulatory authorities.

Furthermore, the guideline offers detailed instructions on the roles of the Drug Control Authority (DCA) and the National Pharmaceutical Regulatory Authority (NPRA), who oversee the approval and regulation of clinical trials in Malaysia. It also addresses the preparation and management of clinical trial agreements, budgets, insurance, and indemnity coverage, and outlines the specific steps for conducting both Industry-Sponsored Research (ISR) and Investigator-Initiated Research (IIR). These comprehensive guidelines are crucial for ensuring the protection of trial participants, maintaining the integrity of the research, and ensuring compliance with both international and local standards in clinical research.

4.3.2 The Malaysian Code of Responsible Conduct in Research

The Malaysian Code of Responsible Conduct in Research (MCRCR) is a comprehensive guideline that promotes ethical and responsible research practices in Malaysia. The Second Edition, published on March 19, 2021, enhances the previous guidelines to better align with international standards while considering local ethical, cultural, and legal contexts.

The MCRCR emphasises principles such as integrity, honesty, accountability, and transparency in research. It covers various aspects, including good research practices, training and responsibilities of researchers, and the duties of research entities. By fostering a culture of ethical behaviour, the code aims to prevent research misconduct and ensure that researchers are well-trained in ethical standards and research methodologies.

4.3.3 The National Standards for Cord Blood Banking and Transplantation

The National Standards for Cord Blood Banking and Transplantation provide a comprehensive framework for the collection, processing, testing, storage, and utilisation of cord blood for both clinical and research purposes. These standards ensure that cord blood, a valuable source of haemopoietic stem cells, is managed with strict quality control, safety measures, and ethical compliance. Key elements include donor eligibility assessment, informed consent, proper documentation, and traceability, ensuring that all samples are collected, processed, and stored in accordance with established regulatory requirements to safeguard donor and recipient welfare.

In the context of research, these standards emphasise biosafety, ethical considerations, and regulatory compliance to ensure the responsible use of cord blood samples. Researchers are required to adhere to stringent protocols for sample handling, transportation, storage, and data confidentiality to maintain scientific integrity and compliance with ethical principles. By following these national standards, research involving cord blood aligns with both national and international ethical guidelines, promoting transparency, accountability, and public trust in biomedical research.

4.4 Ownership or Custodianship of Human Biological Samples

The topic of biological samples ownership is often debated; legally and ethically. Ethically, a researcher cannot own a human body or a part of that human body (whether alive or deceased). The concept of stewardship or custodianship is more appropriate in this context. Once a sample/data has been obtained from a participant/patient, the appropriate custodian is the institution that collects the samples and data. Researchers may collect the biological samples, but the institution where the samples are kept or managed is ultimately the custodian.

Custodianship comes with responsibilities for the safekeeping of biological samples, controlling their use and secondary use, arranging for maintenance and access, transferring to third parties (if applicable), and eventual disposal (if required), all in line with legal and ethical requirements as well as the expectations of the participant/patient. Depending on how the institution is governed, custodianship may lie with the institute director, biobank manager, or a designated committee within the institution/organisation. (Please also refer to Section 5.1 of this document)

Any transfer or change in custodianship should be in line with the relevant consent documents and should be approved by the relevant IRB/IEC as well as documented through legally binding agreements.

4.4.1 Responsibility

Formal responsibility for custodianship of human biological samples should lie with the institution, hospital, or university rather than with individual researchers. This provides participants and users with confidence and trust when contributing samples for research and it also makes it easier for institutions to manage samples when an individual researcher leaves the institution. The custodian is responsible for ensuring that biological samples are collected, processed, stored, reported, distributed, and disposed of in a prescribed manner, in accordance with the guidelines set by the respective institution. They must also ensure that biological samples are utilised according to the content of the informed consent.

4.4.2 Intellectual Property (IP) and Commercialisation

Intellectual property (IP) rights refer to the legal protections granted to individuals over their intellectual creations, including those arising from research and development activities. These rights safeguard the ownership of products derived from the application of an individual's work or skills to biological samples. It is essential that the intended use of biological samples, including any potential IP rights that may arise, is clearly outlined in the informed consent documents. Participants must fully understand what they are consenting to, particularly regarding the use of their biological samples and any IP generated from them.

Additionally, participants should be informed about the custodianship of their biological samples and associated data, including what will occur if custodianship is transferred to a third party, if applicable. This ensures transparency and respect for the participant's rights.

For comprehensive information on IP regulations, protection, and enforcement in Malaysia, the Intellectual Property Corporation of Malaysia (MyIPO) serves as the central government agency responsible for overseeing IP matters. Further details can be accessed through the official MyIPO website (https://www.myipo.gov.my/en/).

4.4.3 Accessibility

To ensure optimal use and avoid unnecessary duplication of research effort and waste of resources, it is essential to make the biological samples and its data available for sharing with other researchers. Approval from both the IRB/IEC and custodian of the samples and/or data is absolutely required prior to access to samples and/data whether samples/data will be

transferred within or outside of Malaysia. Appropriate material and/or data transfer agreements should be used to define the rights and responsibilities of the provider and that of the recipient with regard to the material (human biological sample) and any derivatives as well as the life cycle of the human biological sample that is being used for research. The transfer of biological samples and data internationally should be in accordance with applicable laws, regulations, and policies. Human biological samples from Malaysia should only be sent out of the country if:

i. The required technology is not yet available in Malaysia and there is no alternative method or
ii. Testing in a central facility is crucial to the integrity of the study

This aspect must be carefully considered by the Malaysian research team and the IRB/IEC to ensure there is genuine justification for it, with particular consideration on the possibility of exploitative gathering of local samples by international teams. The IRB/IEC should urge the respective institute to acquire or adopt such technology into Malaysia instead, as it benefits the nation in the long term. For clinical trials or studies that require testing at a central facility outside the country, the laboratory manual for the study should also be submitted to the IRB/IEC for review and approval. Additionally, samples sent overseas with IRB/IEC approval should not be retained overseas for future research or biobanking purposes. An equitable benefit-sharing approach should be adopted where feasible, especially in cases where discoveries such as drugs or diagnostics are developed using Malaysian samples.

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5.0 MAJOR STAKEHOLDERS AND RESPONSIBILITIES

The ethical use of human biological samples in research involves various stakeholders each with specific roles and responsibilities. This section defines and outlines the roles and responsibilities of primary stakeholders, namely: Institutions, Investigators, IRB/IEC, Sponsors, Regulatory Authorities on Human Subject Research, Participants, and Biobanks /Tissue Repositories.

5.1 Institution

5.1.1 Definition

An institution in this context refers to any public or private organisation or entity where research activities are conducted. This can include hospitals, universities, research institutes, and other entities involved in medical and health-related research.

5.1.2 Responsibilities

i. Ensure compliance with local and international ethical guidelines, regulations, and legislation.
ii. Provide necessary infrastructure and resources for secure handling, storage, and disposal of human biological samples.
iii. Ensure research activities involving human samples are reviewed and approved by an appropriate IRB/IEC.
iv. Facilitate ongoing training and support for personnel in ethical research practices.
v. Manage and take appropriate action against researchers who breach research conduct or ethical guidelines to maintain the integrity of the research environment.

5.2 Investigator

5.2.1 Definition

Investigators are individuals, typically researchers or scientists, who lead or conduct the research. They are directly responsible for the design, implementation, and management of the research study.

5.2.2 Categories of Investigators

i. Principal Investigator (PI):

- The primary individual responsible for the design, conduct, oversight, and management of the research project.
- Ensures overall compliance with ethical, regulatory, and scientific standards.

ii. Co-Investigator:
- Works alongside the principal investigator to assist in the research design and implementation.
- Shares responsibility for managing the research study and may handle specific key tasks or participant groups.

iii. Sub-Investigator:
- A member of the research team designated and supervised by the Principal Investigator at a specific research site.
- Responsible for conducting research-related procedures and making critical research-related decisions (including roles such as clinicians, medical personnel, associates, residents, or research fellows).

iv. Collaborating Investigator:
- Contributes expertise and shares responsibility in specific aspects of the research, such as data analysis, specialised testing, or subject recruitment.
- Typically involved in multicentre studies or interdisciplinary research projects.

v. Foreign collaborators
- Foreign collaborators must understand Malaysian laws, regulations, and guidelines before being involved in the research.
- Roles and responsibilities should be clearly outlined in the Research Agreement and any other relevant documents.

5.2.3 Responsibilities

i. Design and conduct research according to ethical principles such as respect, beneficence, non-maleficence, and justice.
ii. Obtain informed consent from participants, ensuring understanding of risks and rights.
iii. Maintain confidentiality and anonymity of participants.
iv. To declare any perceived or anticipated conflicts of interest. Promptly report any adverse events or compliance issues to the overseeing Ethics Committee.
v. To be responsible when obtaining, managing, and disposing samples according to institutional policies and practices.

5.3 Institutional Review Boards / Independent Ethics Committees

5.3.1 Definition

An Independent Ethics Committee (IEC) or an Institutional Review Board (IRB) is a group tasked with reviewing proposed research studies to ensure they are ethically and scientifically acceptable and that the rights and welfare of participants are protected.

5.3.2 Responsibilities

i. Review and approve research proposals based on ethical and scientific validity.
ii. Monitor ongoing studies for compliance with ethical standards.
iii. Serve as an advisory body to address any ethical issues raised by participants or others affected by the research.
iv. Ensure thorough documentation and adherence to informed consent processes.
v. Protect the rights of human subjects in research, ensuring that participants' welfare, privacy, and autonomy are safeguarded throughout the study.
vi. Evaluate and mitigate risks associated with dual-use research of concern, particularly in studies involving genetic or infectious disease research that could be misused for harmful purposes.

5.4 Sponsor

5.4.1 Definition

Sponsors are organisations or individuals who finance the research. This can include governmental agencies, private companies, or non-profit organisations.

5.4.2 Responsibilities

i. Fund research that adheres to ethical standards.
ii. Ensure that the necessary resources are available to maintain high standards of safety and ethics throughout the research.
iii. Monitor research progress and compliance, working in collaboration with institutions and investigators.
iv. Report research findings transparently and ensure public access to results.

5.5 Regulatory Authority on Human Subject Research

5.5.1 Definition

This refers to the governmental bodies or agencies responsible for regulating and overseeing human subject research to ensure compliance with all applicable laws and ethical guidelines.

5.5.2 Responsibilities

i. Enforce laws and regulations related to human subject research
ii. Approve or reject research studies based on ethical, legal, and scientific considerations
iii. Conduct audits and inspection of research projects to ensure ongoing compliance with regulations
iv. Provide oversight to protect the rights and welfare of research subjects

5.6 Participants/Donor

5.6.1 Definition

Participants, also known as donor, volunteers or subjects, are individuals who consent to contribute their biological samples and associated data for research purposes. They play a critical role in the advancement of medical research.

5.6.2 Responsibilities

i. Provide informed consent after receiving all necessary information about the study purposes, procedures, risks, benefits, and rights
ii. Communicate openly with researchers about any concerns or adverse effects experienced during the study
iii. Comply with study protocols as agreed upon after informed consent

5.7 Biobanks

5.7.1 Definition

A legal entity or part of a legal entity that performs biobanking. The term applies more extensively to any entity focused on management and operations of specimens and associated data primarily intended for research purposes. Alternative terms may include biorepository, biological resource centre, tissue bank, and cell bank among others.

5.7.2 Responsibilities

i. Ensure ethical acquisition and management of biological samples in accordance with local and international guidelines, best practices, and legislation.
ii. Maintain detailed records and documentation regarding sample & data acquisition and informed consent
iii. Collaborate with researchers to provide samples that meet study criteria and ethical standards
iv. Monitor compliance with ethical and regulatory requirements concerning sample use and participant privacy and confidentiality
v. Ensure that quality control processes are in place for both samples and data

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6.0 INFORMED CONSENT AND PARTICIPANT RIGHTS

6.1 Overview of Informed Consent

Informed consent is the process by which a participant voluntarily confirms willingness to participate in specific research after being fully informed of all relevant aspects that could influence their decision. This consent is documented through a written, signed, and dated informed consent form. The Declaration of Helsinki asserts that "the subjects must be volunteers and informed participants in the research project."

Obtaining informed consent is a continuous process that begins with the initial contact with prospective participants and continues throughout the study. By informing prospective participants, repeatedly explaining procedures, answering their questions, and ensuring they understand each aspect of the study, investigators elicit informed consent and demonstrate respect for the participant’s dignity and autonomy.

Consent should be voluntary and is achieved when an individual's participation decision is free from undue influence. Various factors can impact the voluntariness of consent. Some of these factors stem from within the participants, such as mental health conditions, while others arise externally, like power imbalances between participants and researchers/clinicians. Conditions such as severe illness or economic hardship may threaten voluntariness, yet they do not automatically preclude individuals from providing voluntary consent. It falls upon research ethics committees to assess each protocol individually to determine if any influences on voluntary consent exceed the threshold of being undue and, if so, to identify appropriate safeguards.

6.2 Types of Consent

6.2.1 Specific and Broad Consent

Specific consent refers to obtaining consent for a particular research study, similar to obtaining consent for a specific medical treatment. It pertains to the situation in which an individual is enlisted to participate in a specific research project or when their biological samples or personal data are requested for a specific project. There is no suggestion that the consent given would automatically include permission to use biological materials or personal information in future research unless specifically requested.

Broad consent covers all potential future uses of research material for which consent is granted. It is important to note that broad informed consent is not a blanket approval for unlimited use of bodily material. Instead, it sets certain boundaries on how the material can be

used in the future. 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 for storage and future use (biobanking)
- Consent for access to medical records and information for data relevant to biobanking
- Consent for re-contacting the subject for more data

Where there is no consent for future research, leftover or surplus material should be destroyed or returned to the original providing institution according to institutional policies after the IRB/IEC approved study ends. Participants should be provided the option to opt out of specific uses.

When evaluating a research proposal, an IRB/IEC should be able to determine whether specific consent is necessary or if previously obtained broad consent suffices.

6.2.2 Consent Involving Vulnerable Persons

Research subjects, including healthy volunteers, can be considered inherently vulnerable due to unknown safety and efficacy of the investigational product and potential negative impacts from social, cultural, economic, psychological, and medical factors. Some vulnerabilities are easily identifiable, such as individuals with diminished mental capacities, while others may not be easily identified, such as homeless or economically disadvantaged individuals. Additionally, subjects may become more or less vulnerable as their health status and life circumstances change, making them more or less susceptible to the study.

According to the Council for International Organizations of Medical Sciences (CIOMS), “Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. This may occur when persons have relative or absolute impairments in decisional capacity, education, resources, strength, or other attributes needed to protect their own interests.”

Examples of vulnerable persons include but are not limited to, children, pregnant individuals, individuals with diminished mental capacity, prisoners, institutionalised persons (including orphans), patients in emergencies, the economically disadvantaged, and individuals unable to give consent.

The Declaration of Helsinki mandates that research subjects who are legally incompetent, physically, or mentally incapable of giving consent, or legally incompetent minors must obtain informed consent from a legally authorised representative. These groups should only be

included in research if it is necessary to promote the health of the population they represent and if the research cannot be conducted on legally competent individuals. Special provisions may be required when comprehension is severely limited, such as in cases of immaturity or mental disability. Each class of potentially vulnerable subjects should be evaluated individually, but respect demands that these individuals be given the opportunity to choose whether to participate in research to the extent they are able. Respect for persons also requires seeking permission from others to protect the subjects from harm, acknowledging their wishes, and involving third parties to safeguard them. The authorised person acting on behalf of the subject should be allowed to observe the research and withdraw the subject if it appears in the best interest of said participant.

6.2.3 Consent for Research Involving Patients

It is crucial to distinguish between a patient's consent for medical treatment or a diagnostic test and an individual's consent for research participation. When consenting to treatment, a patient weighs potential risks, like side effects, against anticipated benefits for their well-being. In contrast, research participation typically does not offer direct personal benefits, with any benefits being for society's collective good. Consequently, risks in research must be minimised, as the participant's consent is essentially altruistic.

There is a risk of therapeutic misconception, where individuals mistakenly believe research will directly benefit them medically. Therefore, it is essential to separate consent for treatment or diagnostic procedures from consent for research participation. An impartial third party should obtain research consent. Still, when not feasible, the IRB/IEC may allow the researcher or physician to obtain consent, provided measures address conflicts of interest, and ensure patient welfare

6.2.4 Consent for Research Involving Minors/Children or Adolescents

According to the laws of Malaysia Act 21: Age of Majority Act 1971 and Child Act 2001 [Act 611], an individual who is unmarried and below 18 years of age does not have the capacity to give valid consent. Minors can range from very young children lacking the capacity to consent to adolescents capable of understanding and deciding on research participation. While parents typically make decisions for minors, they must prioritise the child's welfare and best interests. Participation in research without direct benefit to minors should involve minimal risk and align with their best interests. Researchers should justify why they cannot involve older participants, respect minors' evolving autonomy, and inform them about the generous nature of their participation.

Consideration must also be given to children who were minors at the time when the research was conducted and subsequently reached the age of maturity. Their right to reconsider their consent must be implemented. Assent for minors aged less than 7 years is usually not required as they are deemed incapable of comprehending the research process. Assent for minors aged 7 to less than 18 years is required and investigators must first obtain the permission of the parents or guardians for the participation of the minor in the research and to solicit assent from the minor. However, emancipated minors can consent to participation in research without the permission or consent of the parent or guardian.

Minors may indicate assent orally or sign an assent form. As a rule, the participant should sign an assent form. When assent has been obtained orally, investigators are responsible for providing documentation or proof of assent. In general, clinical trials involving minors should begin only after informed assent has been obtained and documented in addition to informed consent from the parents or legal guardian.

6.3 Use of Electronic and Digital Informed Consent in Research

Informed consent is a vital ethical requirement in research, ensuring participants understand the study's nature, procedures, risks, and potential benefits before voluntarily agreeing to participate. Traditionally obtained through paper forms, informed consent can now be facilitated electronically, offering several advantages.

Benefits: Electronic and digital consent streamlines the process, saving time and enhancing accessibility, particularly for participants in remote areas. It can improve comprehension by using multimedia tools such as videos and interactive quizzes, making the information more engaging and easier to understand. Digital records are also more secure and easier to manage.

Challenges: Despite these benefits, there are challenges to consider. Not all participants have access to the necessary technology, and varying levels of digital literacy can affect their ability to understand and navigate electronic consent forms. Security and privacy are critical; researchers must ensure data protection and compliance with regulations like the Personal Data Protection Act 2010 (PDPA) as well as national and institutional guidelines and policies. Ethical concerns also persist, such as ensuring true informed consent and addressing power imbalances.

Implementing electronic and digital informed consent effectively requires selecting appropriate tools. Researchers could choose electronic consent platforms that are user-friendly, secure, and compliant with regulatory requirements. Ensuring compliance and security involves

implementing strong encryption methods for data storage and transmission and conducting regular audits and updates.

6.4 Waiver of Consent

i. Requests for waivers of informed consent must be thoroughly justified, with the rationale clearly outlined in the protocol document.
ii. The decision to waive consent by an IRB/IEC should align with the guidelines set forth by the Council for International Organizations of Medical Sciences (CIOMS), which stipulate: "Investigators must not commence research involving human subjects without obtaining individual informed consent from each participant or a legally authorised representative unless a research ethics committee has granted explicit approval."
iii. Before seeking a waiver of informed consent, investigators should initially explore whether informed consent could be adapted to preserve participants' ability to comprehend the general nature of the research and make a voluntary decision regarding participation.
iv. The IRB/IEC may entertain the possibility of modifying or waiving informed consent for research if ALL the following conditions are met:

- The research cannot be feasibly or practically conducted without the waiver or modification;
- The research holds significant societal value;
- The research presents minimal risks to participants; and
- No personally identifiable information is gathered.

Additional provisions may apply when waivers or modifications of informed consent are approved in the context of specific research.

6.5 Clinically Significant Incidental Findings

A clinically significant incidental finding arises when research uncovers a health-related issue for a participant unrelated to the study's primary purpose. Research findings are preliminary and not conclusive. If research data hints at a health condition needing confirmation and possibly treatment, the researcher is not held responsible and results are not returned to participants unless stated otherwise in the informed consent. Depending on the circumstances, the researcher may inform the attending clinician if the findings are significant or clinically relevant/actionable. Results to be returned to individual participants should have both:

- Clinical validity, e.g., strong evidence of the correlation with a disease or condition.
- Analytical validity, e.g., proven through a reference method

If a clinically relevant discovery is uncovered but the research participant's preference for receiving such information is uncertain, researchers must decide whether the possible damage of returning the incidental finding outweighs the anticipated benefits. Individual research results should be returned to the participant only if a relevant clinical support structure can be made available to the participant (e.g. in the case of genetic results, a genetic counsellor should be made available). Research institutions should ensure policies on incidental findings are in place and this should be clearly defined in the informed consent documents.

Participants should be given the opportunity to choose whether they wish to receive research results, and they should give consent for the return of results.

Approval by an IRB/IEC should be in place before attempting to return any research results to participants, their families, or physicians.

6.6 Withdrawal of Consent

Participants should be able to withdraw from the study at any time without need to explain their decision, with no penalty or prejudice to any treatment they are receiving. During the consent-taking process, they should be informed of the procedures for withdrawal and any potential repercussions or risks associated with withdrawing from the study. If there is a possibility that they would experience direct injury as a result of their withdrawal, they should also be notified of any follow-up monitoring and treatment methods.

Samples or data that have been utilised, dispatched, or published are not retractable if consent is withdrawn. From the time of withdrawal, the study should not use any existing samples or data provided by the participant. Additionally, a documented report should be provided to the participants confirming that their remaining samples or data have been destroyed.

6.7 Handling of Language Barriers and Literacy Issues

The primary issue in healthcare communication in Malaysia arises from the country's diverse linguistic and cultural landscape. With multiple languages such as Bahasa Melayu, Mandarin, Tamil, English, and various indigenous languages, effective communication between healthcare providers and patients is challenging. Ensuring all participants understand the consent they are providing is crucial, especially when language barriers and literacy issues are present. Effective strategies to address these challenges include:

- **Translations**: Provide consent forms in multiple languages commonly spoken in Malaysia, such as Bahasa Melayu, Mandarin, Tamil, and English. This ensures that participants who are not proficient in one language can still comprehend the information. Utilise professional translators familiar with the research context to ensure accuracy and cultural sensitivity. Consider back-translation methods, where a different translator re-translates the document to check for consistency and accuracy.
- **Simplified Language**: Use clear, simple, and jargon-free language in both the original and translated consent forms. Avoid technical terms and complex sentences that may confuse participants.
- **Verbal Explanations**: Provide verbal explanations of the consent information in person or via video/audio recordings in the participants' native languages. Allow participants to ask questions and seek clarifications. Ensure the availability of interpreters during the consent process to facilitate communication.
- **Visual Aids**: Use visual aids, such as diagrams, flowcharts, and infographics, to illustrate key points of the consent form. Ensure these visual aids are culturally appropriate and easily understandable.
- **Pilot Testing**: Conduct pilot testing of the consent process with a small group of participants from the target population. Gather feedback on the clarity and comprehensibility of the consent forms and make necessary adjustments based on this feedback.

6.8 Re-consent

Re-consent is required in the following situations:

- When the proposed research is not covered by the initial consent given at the time of biological material collection, unless an IRB/IEC waives the re-consent requirement;
- If the biological material was collected from a minor under 18 years of age who did not have decision-making capacity at the time and therefore did not personally consent, or consented jointly with a parent. If obtaining re-consent is not feasible, the IRB/IEC may have the discretion to waive the requirement based on relevant waiver criteria;
- For research considered sensitive, such as studies involving gametes and embryos, or human-animal combinations.

6.9 Pre-Death Consent

Pre-death consent refers to the process by which individuals provide consent for the use of their biological materials (such as tissues, blood, or organs) for research before their death in accordance to Human Tissues Act 1974. This is particularly important in research contexts where samples may be collected or used after the individual has passed away. Pre-death

consent ensures that individuals maintain control over their biological materials even after death. Many religious and cultural norms govern the collection of postmortem tissue for research. For example, consent for the use of the whole body is not valid for Muslims, as the donation of the entire body for research purposes is prohibited under Shariah law.

For individuals under the age of 18, the process of pre-death consent requires additional considerations. As minors are not legally able to provide full informed consent, consent must be obtained from a parent or legal guardian, who will act in the best interest of the child. Depending on the child's age and understanding, assent may also be sought. All research involving minors must adhere to strict ethical guidelines, ensuring the protection of the child's rights, welfare, and privacy. Even if consent was obtained prior to death, authorization may be required from the next of kin and/or a legally authorized representative in accordance with relevant laws.

The possibility of obtaining pre-death consent should be detailed out in a research protocol that is being submitted for IRB/IEC approval.

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7.0 COLLECTION AND MANAGEMENT OF SAMPLES

7.1 Enrolment

To ensure the integrity and reliability of research outcomes, the enrolment phase, a critical component in sample management, requires strict adherence to ethical guidelines and established methods. Ethical considerations, including informed consent and compliance with IRB/IEC policies/regulations, guide participant recruitment, which involves defining eligibility criteria and employing diverse strategies while avoiding coercion. Rigorous documentation and record-keeping protocols safeguard participant information, while clear communication channels and engagement foster transparency and responsiveness. Training programs for research staff ensures standardised implementation of enrolment procedures, with regular quality assurance checks to monitor compliance. By adhering to these guidelines and recommended practices, researchers uphold the ethical conduct and validity of sample acquisition during the enrolment phase.

7.2 Collection

Various biological samples can be collected and preserved for research purposes and the collection methods vary based on the sample type and intended use. Researchers or biobanks that collect biological samples must adhere to Standard Operating Procedures (SOPs) for acquisition, labelling, handling, storage, and distribution of biological samples. Samples collected from Muslims should be specifically coded, in terms of the religion, as they need to follow specific disposal methods. Researchers must adhere to and follow appropriate procedures according to the type of biological samples being collected and its intended uses when collecting samples from participants for research purposes.

7.3 Storage

Proper guidelines for biological samples storage are crucial for several reasons, all of which help ensure the integrity, reliability, and usefulness of the samples for research purposes.

7.3.1 Preservation of Sample Integrity

Proper sample handling and storage conditions, including temperature, humidity, and light exposure, are crucial for maintaining the quality and stability of biological samples over time. If samples are not stored under optimal conditions, they can degrade, compromising their usefulness for research. Researchers depend on the integrity of these samples to draw accurate conclusions. High-quality, well-preserved samples ensure reliable and valid research findings, ultimately supporting the success and credibility of scientific studies. Many research

projects span several years or even decades, requiring that samples be stored in a manner that preserves them throughout the project's duration.

7.3.2 Regulatory Compliance

Adhering to regulatory guidelines and standards is crucial for legal and ethical compliance, which can affect the legitimacy of the research.

7.3.3 Facilitating Sample Tracking and Management

Effective tracking and management systems ensure that samples can be traced from collection through to analysis, which is vital for maintaining the chain of custody and for audit purposes.

7.3.4 Minimising Contamination Risks

Contamination can ruin biological samples and render them useless for research. Therefore, measures should be put in place to mitigate these risks.

7.3.5 Ethical Considerations

Ethical storage practices reflect respect for the individuals who donated their biological samples and help maintain public trust in biomedical research and/or biobanking. Data and sample sovereignty is something that is of extreme importance to a country. Samples from Malaysian participants should not be biobanked or stored outside of Malaysia for future research/use. The export of human tissue samples for research to other countries poses significant risks, particularly in terms of the loss of control over the samples once they leave the local jurisdiction. Researchers and institutions often have limited oversight of how the samples are used after they are sent overseas, leading to concerns that they may be repurposed for unintended or unapproved studies. This lack of accountability can result in situations where the contributing researchers and communities are not informed about the ongoing use or analysis of their samples. There is also a risk that samples, once exported, may be destroyed or lost without proper documentation or feedback to the original institution. These concerns highlight the ethical uncertainties surrounding the export of human tissue samples for research, particularly when the control and oversight of the samples are transferred to external institutions. (Please also refer to Section 4.4.3 of this document)

7.3.6 Storage Systems

Storage systems for refrigerators/freezers require careful design and safety considerations to ensure optimal functionality and personnel safety. Equipment maintenance, repair, and replacement are critical for sustaining operational reliability. Implementing preventative

maintenance at regular intervals, annual calibration of instruments, and maintaining comprehensive records are fundamental practices. Qualified personnel should handle equipment maintenance and repair, and contingency plans for equipment replacement with stocked spare parts should be in place.

Additionally, the implementation of a real-time monitoring system for storage equipment such as refrigerators, freezers, and liquid nitrogen tanks is highly recommended. This system should provide continuous monitoring and generate regular reports, ensuring that any deviations in temperature or system functionality are promptly addressed. If financially feasible, such monitoring systems will enhance reliability, safety, and efficiency. By adhering to these structured practices, facilities can optimise environmental storage systems for sustained performance and safety.

7.4 Inventory

Effective systems for tracking samples should be established to ensure accurate tracing of samples from collection sites through transportation, processing, and throughout their lifecycle at the repository. Key components of these systems include sample identifiers or labels and inventory systems for tracking samples.

7.5 Transfer (Import/Export of Human Biological Samples)

The transfer of human biological samples for research purposes should be governed by stringent guidelines to ensure samples integrity, security, and safety. However, existing guidelines cover most aspects of transportation and storage for diagnostic purposes. When it comes to transport of human biological samples for research in Malaysia, certain issues and circumstances would need to be addressed.

Importantly, both the sender and receiver of human biological samples must obtain necessary approvals from the relevant national and institutional authorities prior to importing/exporting human biological samples. In addition to that, it is advisable to have a data and material transfer agreement prior to transportation of samples.

For the transfer of human biological samples for research purposes in Malaysia, including inter-institutional transfers, both the sender and receiver must obtain necessary approvals from institutional bodies, such as the IRB/IEC, to ensure ethical oversight and compliance with national and institutional guidelines and best practices. Custodianship, rather than ownership, of the samples must be clearly defined through a Material Transfer Agreement (MTA) prior to transfer of samples. The MTA should explicitly outline each the roles and responsibility of both sender and receiver.

Sending of human biological samples overseas for research purposes should only be considered if the technology is unavailable in Malaysia or if the study protocol necessitates testing at a central laboratory that is outside of Malaysia, which may be the case with some clinical trials. This, however, should be evaluated on a case-by-case basis by the IRB/IEC. To facilitate IRB/IEC evaluation, the researcher must submit the clinical trial laboratory manual together with the study protocol if it involves sending samples overseas. Samples should be discarded after the specific analysis is completed, and the storage of samples overseas for future use should be strictly prohibited.

If temporary storage outside of Malaysia is required for the current study, this must be explicitly stated in the study protocol submitted for IRB/IEC approval. Researchers and institutions must ensure that samples sent overseas are used solely for the approved study, and leftover or unutilised samples should either be returned or destroyed as specified in the IRB/IEC approved protocol.

In the context of transporting clinical specimens and infectious substances, several key roles are defined and play crucial roles in ensuring safe and efficient transportation of human biological samples. The Sender, also known as the consignor or shipper, initiates the process and could be the researcher, investigator, clinician, etc. Their responsibility includes properly packaging and labelling the specimens according to guidelines outlined in resources such as the Guidelines for The Safe Transport of Clinical Specimens and Infectious Substances in Malaysia. The Packaging Supplier provides the necessary packaging materials to ensure secure transport, following specific guidelines as per the aforementioned Malaysian guidelines. The Carrier, which may encompass logistician teams, courier companies, airline freight forwarders, and other transport operators, handles the physical transportation of the specimens, adhering strictly to safety protocols detailed in regulatory guidelines. Lastly, the Receiver, also referred to as the consignee, accepts the samples upon arrival, ensuring they are promptly processed and stored according to prescribed procedures. Each role plays a critical part in maintaining the integrity and safety of clinical specimens during transport, ensuring compliance with international standards and local regulations.

Permits to import or export human biological samples may be procured through the Malaysian Business Licensing Electronic Support System (BLESS) system (https://www.bless.gov.my). BLESS is a comprehensive online portal that facilitates the application, processing, and approval of various business licences and permits, including those related to the import and export of human biological samples. The BLESS system streamlines the application and approval process, reducing the time and effort required to obtain licences and permits, while ensuring transparency and real-time tracking of application status. Compliance with the Prevention and Control of Infectious Diseases Act 1988 (Act 342) is mandatory, as the Act

regulates the handling of biological samples to prevent the spread of infectious diseases. Additionally, the guidelines *Garis Panduan Pengimportan atau Pengeksportan Mayat atau Mana-Mana Bahagiannya* outlines specific requirements for importing and exporting human remains or body parts, including necessary health and safety protocols, documentation, and procedures. Together, these regulations ensure that all activities adhere to Malaysian laws and standards, safeguarding public health and preventing illegal practices.

7.5.1 Packaging

When transferring samples from collection points to their destination, they may encounter various challenges like movement, vibrations, temperature fluctuations, humidity changes, and pressure shifts. Therefore, it is crucial that the packaging used for transportation is strong and of good quality to withstand these typical stresses and impacts.

For detailed instructions on sample packaging and labelling, please refer to Section 6 and 7 of the Guidelines for The Safe Transport of Clinical Specimens and Infectious Substances in Malaysia.

7.5.2 Transportation

Proper guidelines for transporting samples are crucial. They ensure the safety of personnel involved by minimising exposure to infectious agents and protect the wider community from potential outbreaks. These guidelines also prevent contamination of samples during transit, thereby maintaining the accuracy and reliability of diagnostic testing. Compliance with established protocols ensures adherence to legal and regulatory requirements, averting potential legal issues and penalties. Efficient adherence to guidelines streamlines the transportation process, reducing errors, delays, and mishandling risks. Ultimately, adhering to proper guidelines not only safeguards public health but also contributes to the overall safety and effectiveness of healthcare and laboratory operations.

For transportation guidelines, please refer to Section 8 and 9 of the Guidelines for The Safe Transport of Clinical Specimens and Infectious Substances in Malaysia.

7.6 Disposal, Sharing or Release

The disposal, sharing and release of human biological samples should be clearly spelled out in research protocols. Institutionally, there should be appropriate standard operating procedures (SOPs) in place and end user (researchers) agreements which outline the relevant processes and responsibilities for disposal, sharing, and/or release of biological samples with researchers within or outside of the institution. Any samples (solid material) obtained from

Muslims should be buried according to their conditions. (Please refer to the Annex for further reference). Burial of specimens requires further concern on environmental and waste management. Institutes should periodically evaluate the processes, and procedures on when and how to dispose of human biological samples or make them available for sharing with other researchers/institutions.

Institutions and researchers could consider Islamic perspectives on the disposal of human biological samples, as outlined in the *Bayan Linnas Siri ke-170* by the *Pejabat Mufti Wilayah Persekutuan*. The guidelines for the disposal of human biological samples after a study are as follows: For tissues and organs (solid materials), if the participant is still alive, any leftover or surplus material should be buried. If the participant is deceased and the body has already been cleansed according to Islamic rites, the leftover or surplus material should also be buried. However, if the participant is deceased but the body has not yet been cleansed, the leftover material should be cleansed first and then buried. Currently, there is no clear definition regarding the disposal of liquid biological materials such as blood and saliva. Therefore, the current practice of disposing of these materials by incineration is considered permissible.

Researchers must put the biological samples and its data to the best possible scientific use considering the best interest of the participants and for public benefit. When samples are being shared, the sharing plan must be consistent with the permissions described in the informed consent and should have been IRB/IEC approved. The use of the biological samples beyond the initial intended use as described in the informed consent during acquisition of samples, is subject to evaluation and approval from the IRB/IEC. The sharing of human biological samples across borders, particularly those involving genetic material and infectious diseases, raises significant ethical as well as biosecurity and biosafety concerns.

Biosecurity refers to the measures and protocols designed to protect against the accidental release or misuse of pathogenic biological agents. Sharing samples across borders introduces several biosecurity concerns, such as risk of pathogen release, bioterrorism risks, and there is a need for robust systems to track and monitor the movement of high-risk samples to ensure they are handled properly and used only for legitimate research purposes. Biosafety concerns focus on the practices, equipment, and facilities designed to ensure that biological research is conducted safely. Key concerns which include laboratory standards, worker safety, and transport and shipping.

To reiterate, it is ethically and scientifically important to ensure that the research conducted with shared samples is scientifically valid and contributes to the advancement of knowledge and public health. According to the Nagoya Protocol, the sharing plan for biospecimens must align with the permissions detailed in the informed consent, and any use beyond the initially

intended purpose requires additional IRB/IEC approval. The Nagoya Protocol emphasises fair and equitable benefit-sharing arising from the utilisation of genetic resources, ensuring transparency and legal certainty for both providers and users.

Best Practices for safe sharing include conduct of thorough risk assessments to evaluate the potential hazards associated with the sample and development and adherence to SOPs for handling, transportation, and disposal of biological samples. Institutions should ensure that these procedures comply with the latest safety standards, train all personnel involved in handling of infectious samples, and work closely with national and international regulatory bodies to ensure compliance with all relevant guidelines and to stay informed about best practices and emerging risks.

Addressing these biosecurity and biosafety concerns is essential to ensure that the sharing of samples contributes positively to global health research and does not pose unnecessary risks to individuals or communities.

7.7 Data Management Practices

This section outlines guidelines for managing data derived from human biological samples in research. It ensures ethical handling, participant privacy, and data integrity, aligning with international standards such as the General Data Protection Regulation (GDPR), Health Insurance Portability and Accountability Act (HIPAA) and Malaysian laws including the Personal Data Protection Act (PDPA) of 2010.

7.7.1 Data Collection

Ethical data collection involves obtaining informed consent from participants and ensuring the methods used comply with legal and ethical guidelines. Data should be collected in a transparent, reproducible, and justifiable manner to respect the rights and privacy of individuals. Detailed documentation of data collection processes and ethical approvals is essential.

7.7.2 Data Accuracy and Quality

Ensuring data accuracy and quality involves implementing standardised procedures, regular validation, and thorough audits. High-quality data is reliable, complete, and precise, requiring continuous monitoring and updating to correct any errors. This includes maintaining detailed records of data provenance and integrity checks.

7.7.3 Data Storage - Sovereignty & Data Residency

Data sovereignty refers to the idea that data is subject to the laws and governance structures within the nation it is collected or stored.

Data residency pertains to the physical or geographical location of an organisation's data.

Data must be stored in compliance with local and international laws governing data sovereignty and residency. This ensures data remains within legal jurisdictions that provide appropriate protections and governance. Organisations must be aware of and adhere to regulations on cross-border data transfers and the location of data storage facilities.

7.7.4 Data Security

Implementing robust data security measures is critical to protect against breaches and unauthorised access. This includes physical security measures as well as electronic safeguards such as encryption, access controls, firewalls, audit trails, and regular security audits. Security protocols should be regularly updated to address new threats, ensuring the integrity, confidentiality, and availability of data. Protocols for immediate notification and rectification in case of breaches should be established.

7.7.5 Data Confidentiality

Non-Disclosure Agreements (NDAs) are essential when external parties handle data including, but not limited to, Personally Identifiable Information (PII). NDAs ensure that vendors are legally obligated to maintain confidentiality, implement security measures, and restrict data access to authorised personnel only. This helps protect sensitive information from unauthorised disclosure or misuse.

7.7.6 Data Sharing and Access

Policies for data sharing and access must balance openness and collaboration with privacy protection. Data should be accessible to authorised parties under well-defined conditions, ensuring compliance with ethical standards and legal regulations. Transparency in data access policies and adherence to consent agreements are crucial. Use encrypted data transmission methods for sharing data, especially when involving international stakeholders.

7.7.7 Data Retention and Disposal

Data retention policies should specify how long data is kept and the conditions for its disposal. Data should be retained only as long as necessary for its intended purpose, complying with

legal and regulatory requirements. Secure disposal methods, such as data wiping or physical destruction, are necessary to protect privacy when data is no longer needed.

7.7.8 Use of Artificial Intelligence (AI) in Research

The use of AI in research must adhere to ethical guidelines, ensuring transparency, fairness, and accountability. AI algorithms should be validated to prevent bias and discrimination, with efforts to support algorithmic transparency and ensure datasets used for training are free from bias and discrimination. Continuous monitoring and ethical oversight are required to maintain the integrity and trustworthiness of AI-driven research.

7.8 Training and Competency of Personnel

Training is critical to ensuring the ethical, safe, and effective handling of biological samples and data. All personnel involved in sample collection, management, and processing must receive comprehensive training tailored to specific research needs, institutional policies, and regulatory requirements. Aside from initial training covering all relevant aspects, ongoing training is essential to keep staff informed about regulatory updates, technological advancements, and best practices, ensuring their continued competence throughout the research process.

Personnel should be well-versed in institution-specific protocols and procedures to ensure consistency and safety. This includes adherence to regulatory guidelines and maintaining accurate documentation of all sample-related activities. Training should also ensure compliance with privacy and data protection regulations, ensuring that participant confidentiality is respected at all times.

Additional training is necessary for handling unique or culturally sensitive samples and data, ensuring ethical management and respect for participants' rights. Regular assessments and certifications should be conducted to evaluate staff competency, and refresher courses should be offered periodically to maintain high standards of practice.

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8.0 GENETIC, OMICS AND EPIGENETIC RESEARCH

Genetic, omics, and epigenetic research are interconnected fields, each offering unique insights into the complexities of biological systems. Together, they are revolutionizing our understanding of health, disease, and the interplay between our genes and the environment.

Genetic research focuses on the study of genes, their structure, function, and variation. It examines how genetic information is inherited, expressed, and altered, providing insight into the biological basis of inherited traits and diseases. With the advent of powerful sequencing technologies, genetic research has advanced significantly, enabling the identification of genes associated with various conditions, including cancers, neurological disorders, and autoimmune diseases.

Omics research is an umbrella term for a suite of scientific disciplines that explore large-scale data on biological molecules. These include genomics (the study of the genome), proteomics (the study of proteins), metabolomics (the study of metabolites), and transcriptomics (the study of RNA molecules).

Epigenetic research delves into the study of changes in gene expression or cellular phenotype that do not involve alterations to the underlying DNA sequence. Epigenetic modifications, such as DNA methylation and histone modification, can be influenced by environmental factors and lifestyle choices, making epigenetics a critical field for understanding how external influences can impact gene expression and contribute to diseases like cancer, aging, and metabolic disorders.

Together, these areas of research are paving the way for personalized medicine, targeted therapies, and a deeper understanding of human biology. They offer transformative potential for diagnosing, treating, and preventing diseases, as well as for enhancing our knowledge of evolutionary processes and development

While having great potential to benefit humanity, genetic and genomic research also has the potential to stigmatise individuals, communities, or groups, who may experience discrimination, be treated unfairly or inequitably, or suffer other harms based on their genetic information. As such, ethical considerations must always guide research utilising these methods to ensure that societal benefits gained are maximised while minimising harm. It is imperative that the research output especially genetic and genomic data, are used ethically, focusing on enhancing the well-being of individuals, families, and ethnic groups rather than stigmatising or discriminating against them.

8.1 Ethical Considerations

All such research requires ethical review and approval by IRB/IEC, preferably through a Full Board Review process. Participation in such research, whether involving direct/indirect engagement, the provision of biological materials, or personal data, must be voluntary, and researchers must obtain informed consent from participants, explaining the purpose, risks, benefits, and potential implications of such research, while prioritising participant autonomy and safeguarding sensitive genetic information.

The informed consent process should explicitly communicate if genetic or genomic studies will or may be performed using the participants specimens. The participant/donor should also be informed about the measures put in place to manage and protect the genomic/genetic data as well as policies on data sharing as this has implications on the privacy and confidentiality of participants/donors. An explanation on the nature of whole-genome research, with its difficulty in guaranteeing their anonymity with complete certainty should also be provided.

Participants/Donors should also be informed about the potential commercial utility arising from such research. The informed consent process should also explicitly state whether the individual participant/donor directly benefits from the commercialisation of the research data/output. This ensures that individuals are fully aware of how their genetic and/or genomic data will be used, who will have access to it, and any potential risks involved.

When significant clinical findings arise during such research, researchers must inform the participants affected, provided they have indicated a preference to receive such information. Individual research results should be returned to the participant only if a relevant clinical support structure can be made available to the participant (e.g. in the case of genetic results, a genetic counsellor should be made available). (Please also refer to Section 6.5 of this document)

It is crucial that secure data management practices must be implemented throughout the lifecycle of genetic information, adhering to strict data retention policies and access controls.

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9.0 HUMAN STEM CELL RESEARCH

This section provides some brief information on human stem cell research. For further information and guidance please refer to the latest edition of the Malaysian Guidelines for Stem Cell Research and Therapy 3rd Edition (2024).

9.1 Sources of Stem Cells

i. **Embryonic Stem Cells (ESCs):** Derived from embryos, these cells are pluripotent and can develop into any cell type in the body. Human ESCs are typically obtained from embryos created through in vitro fertilisation (IVF) and are used in various research and therapeutic applications.

ii. **Adult Stem Cells**: Derived from tissues such as bone marrow, adipose tissue, or blood of consenting adults. Include hematopoietic stem cells (from blood cells), mesenchymal stem cells (from bone, cartilage, and fat cells), neural stem cells (from nerve cells), epithelial stem cells (from cells in the lining of the digestive tract) and umbilical cord blood.

iii. **Induced Pluripotent Stem Cells (iPSCs)**: Generated from adult cells reprogrammed to an embryonic-like state.

9.2 Ethical Consideration

All research involving human stem cells, including foetal tissue, human gametes and embryos must receive prior approval from an IRB/IEC. This review ensures that the research meets ethical standards and regulatory requirements. Researchers must obtain informed consent from all donors. This consent must be:

i. **Voluntary**: Donors must participate willingly without any coercion.

ii. **Informed**: Donors must be fully informed about the nature of the research, its purposes, procedures, potential risks, and benefits. If the materials are intended for storage and future use in research, consent should also be obtained for this purpose.

iii. **Documented**: Consent must be documented appropriately, and donors should have the right to withdraw their consent at any time.

9.3 Therapeutic Cloning

Therapeutic cloning, where stem cells are used to create tissues or organs for transplant without creating a fully developed human being, may be permissible under the following strict conditions:

i. The primary purpose is medical treatment and life preservation.

ii. The process must not involve creating a cloned human being.
iii. National laws, cultural sensitivities, and ethical guidelines must be strictly adhered to.

9.4 Research Oversight and Monitoring

Continuous oversight and monitoring by IRBs/IECs are required to ensure compliance with approved protocols and ethical standards. This includes regular reporting and auditing of research activities.

9.5 Clinical Translation

For stem cell research with eventual intended clinical use, should consider the following:

1. **Preclinical Studies**: Rigorous preclinical testing to demonstrate safety and efficacy.
2. **Clinical Trials**: Approval from relevant regulatory bodies is required before commencing clinical trials. These trials must be conducted in phases to ensure thorough evaluation.
3. **Regulatory Approval**: Post-trial therapies must obtain regulatory approval based on the evidence of safety, efficacy, and quality.

9.6 Data Management and Sharing

1. Researchers must maintain accurate and comprehensive records of all research activities.
2. For further information, please refer to Topic 7 Sample and Data Management Recommended Guidelines and Practices.

9.7 Compliance with Legal and Ethical Standards

Researchers must comply with all relevant national and international laws, guidelines, and ethical standards. This includes respecting cultural and societal norms related to human research

Use of Embryonic Stem Cells

- Permissible under strict conditions, such as using surplus embryos from in-vitro fertilisation, spontaneously aborted, or aborted based on a doctor's advice (for reasons permitted by Islamic law) with proper consent.
- It is prohibited to take embryonic stem cells from a foetus and use them if the foetus was intentionally aborted.

- Research should not extend beyond the pre-implantation stage (14 days).

(Please refer to the *Keputusan Muzakarah Jawatankuasa Fatwa Majlis Kebangsaan Bagi Hal Ehwal Agama Islam Malaysia berkaitan Pengklonan dan ART* dated 22 February 2005)

Use of Foetal Tissue

- Permissible if the tissue is obtained with proper consent and respect for the foetus and if it aims to benefit human health.

Use of Human Gametes (Sperm and Ovum)

- Permissible under certain conditions, including informed consent and ethical review.
- Creating embryos solely for research is not permitted.

9.8 Training and Education

Researchers and staff involved in stem cell research must receive appropriate training and education on ethical practices, regulatory requirements, and scientific methodologies related to stem cell research.

9.9 Best Practice in Obtaining and Utilising Stem Cells

i. For adult stem cells, permission must be obtained from the donor, and if from a child, permission must be obtained from the parents/legal guardian, and the procedure must not cause harm.
ii. Permission must be obtained from the parents to obtain the placenta and umbilical cord blood of a baby,
iii. A spontaneously aborted foetus or a miscarriage due to medical advice or because of medical treatment allowed by law, provided parental consent is obtained. It must not be from a foetus intentionally aborted or aborted without medical reasons allowed by law.
iv. The surplus embryos that are stored frozen from assisted fertility technology IVF and the treatment and research are conducted before reaching the blastocyst (*alaqah)* stage.
v. Excess embryos obtained through IVF must be from legally married couples and cannot be implanted into the womb of another woman to avoid lineage mixing.
vi. Stem cells from embryos intentionally created using Somatic Cell Nuclear Transfer technology are not permitted to prevent exploitation and any form of misuse.

vii. Therapeutic cloning for medical purposes, such as creating specific cells or replacing damaged organs, considering the permissible boundaries of the law and cultural sensitivities, may be allowed but would be based on the judgement of the IRB/IEC

viii. Research must be conducted legally, with clear, scientific research proposals handled by researchers who are genuinely skilled, trustworthy, and responsible.

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10.0 BIOBANKING & PROSPECTIVE COLLECTION OF SAMPLES FOR FUTURE RESEARCH

Biobanks are vital resources for biomedical research. A biobank is a repository that collects, stores, and manages biological samples such as blood, saliva, urine, tissues, and cells, as well as molecular derivatives from these samples, for use in research. These repositories support various research fields, including genomics, proteomics, and metabolomics, by providing researchers with access to a vast array of biological samples and associated data, significantly reducing the time and resources needed for large-scale studies.

Biobanks significantly accelerate research by providing ready access to high-quality samples and data. This facilitates large-scale studies, such as genome-wide association studies, which require data from thousands of individuals. By systematically collecting and storing these samples and data, biobanks provide a foundation for high-quality, reproducible research, fostering scientific discoveries and innovations in healthcare. However, the use of these resources raises ethical considerations, including privacy issues, the validity of informed consent, and the ownership of biological information.

10.1 Governance & Custodianship

i. Governance: Institutional Biobanks should have a governance framework and policies on access to and utilisation of samples and data, transparency, safety, and security. Biobanks should operate on the basis of custodianship of samples and data and not ownership. Depending on how the institution is governed, custodianship may lie with the institute director, biobank manager, or a designated committee within the institution/organisation. Except as required by law, the custodian must not disclose samples or data to third parties for non-research purposes. This restriction remains in effect even after the custodian's term or employment ends.

ii. IRB/IEC Approval: Any research intending to use samples and data from biobanks must obtain approval from an IRB/IEC for their research.

iii. Purpose Communication: The intended use and foreseeable applications of the samples and data must be clearly defined and communicated to contributors of biological materials, institutions, and researchers.

10.2 Data Privacy and Protection

Processing of sensitive personal information within biobanks must comply to relevant Legislation, Circulars, Regulations, and Guidelines when processing personal information. The custodian must ensure the protection of participants' rights as stipulated by law. Researchers should only access coded or anonymized samples and data and must not attempt to re-identify participants.

10.3 Informed Consent

i. Consent Process: Informed consent must be obtained before any human biological materials are collected for research. If the materials are intended for storage and future use in research, a separate consent for biobanking should also be obtained. During the consent process, participants must be informed about possible future uses of their samples or data.

ii. Subsequent Use: New consent must be obtained if the subsequent use of samples or data is inconsistent with the original consent.

- Respect the wishes of participants who do not want to be contacted.
- If contact attempts fail, use of samples requires evaluation by the IRB/IEC to ascertain if a waiver of re-consent would be appropriate. (Please refer to Section 6.4 of this document)

iii. Re-consent Requirements: Re-consent is required in the following situations:

- When the proposed research is not covered by the initial consent given (unless waived by an IRB/IEC).
- If the biological material was collected from a minor below 18-years of age who did not possess decision-making capacity at the time.
- For research deemed sensitive, such as involving human eggs and embryos, or human-animal combinations.

10.4 Collection and Storage of Biological Samples and Information

De-identification and Coding: Human biological materials and data must be promptly de-identified and coded according to data privacy standards, with access to codes limited to those legally accountable for breaches.

Storage Duration: Institutions should formulate policies for the duration of sample and/or data storage and this should ideally be communicated to the donors/contributors.

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ANNEX

The sanctity of life is of the utmost importance in Islam as mentioned in the Quran:

> "And Truly We have conferred dignity on the children of Adam, and carried them by land and sea by various means of transportation. And We have provided them with good things and exalted them above many of Our creations."
>
> (Surah al-Isra', 17: 70)

Hence any effort to enhance quality of life and to alleviate illnesses is noble in Islam. Allah SWT also mentions that:

> "…and that whoever saves a human life, it shall be as though he had saved the life of all mankind…"
>
> (Surah al-Maidah, 5: 32)

The endeavour to save a life cannot be conducted except after mastering the knowledge and skills. The Prophet SAW mentioned:

مَنْ تَطَبَّبَ وَلَا يُعْلَمُ مِنْهُ طِبٌّ فَهُوَ ضَامِنٌ[1]

> Meaning: He who undertakes the treatment of others, without preparing himself and causes loss of life or damage is held liable.
>
> (Recorded by Abu Daud)

'Preparation' in this hadith includes the effort of conducting research. This hadīth is a great reminder to the physicians to ensure their ability to conduct their tasks and obligations. Their credibility is proven through their qualifications including acquiring 'knowledge, balance, confidence, patience, forbearance, fear of wrongdoing, and similar professional characteristics, besides mastering the use of the tools of the profession.'[2]

In handling samples obtained from a Muslim, shariah law and fatwa should be adhered to. Shariah emphasizes that a dead body earns honour and dignity as much as when he/she is alive regardless the religion. The Prophet SAW mentioned that:

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[1] Abū Dāud, Abū Sulayman Ibn al-Ashʿath, Sunan Abī Dāud, ed. by ʿAbd al-Ḥamīd, Muḥammad Maḥy al-Dīn, vol. 4, (Beirut: Al-Maktabah Al-ʿAṣriyyah, n.d.). p. 195. Bāb fī man taṭabbaba bi ghayr ʿilm faʾaʿnt (Chapter Who Medically Treats a Person without Knowledge, He Held Liability). Al-Albānī notes this is a good (ḥasan) Ḥadīth.

[2] Shamsuddin Muḥammad ibn Abī Bakr ibn Qayyim al-Jawziyyah, Al-Ṭibb Al-Nabawī, pp. 112-114.

عَنْ جَابِرِ بْنِ عَبْدِ اللهِ رَضِيَ اللهُ عَنْهُمَا قَالَ مَرَّ بِنَا جَنَازَةٌ فَقَامَ لَهَا النَّبِيُّ صَلَّى اللهُ عَلَيْهِ وَسَلَّمَ فَقُمْنَا بِهِ، فَقُلْنَا: يَا رَسُولَ اللهِ إِنَّهَا جَنَازَةُ يَهُوْدِيّ، قَالَ: "إِذَا رَأَيْتُمُ الْجَنَازَةَ فَقُوْمُوْا".[3]

Meaning: Jabir ibn Abdullah reported: A funeral passed by us and the Messenger SAW stood up. We told him, “O Prophet, this is a Jew funeral.” He replied, “When you see a funeral, please stand up.”

(Recorded by al-Bukhari)

The Prophet SAW also reminds us to handle the deceased with care.

كَسْرُ الْعَظْمِ الْمَيّتِ كَكَسْرِ عَظْمِ الْحَيّ فِي الْإِثْمِ[4]

Meaning: Breaking the bone of the deceased is tantamount to breaking it when he was alive.

(Recorded by Ibn Majah)

Here are juristic rulings regarding therapeutic cloning and stem cell research, the disposal of Muslim body parts, tissues, and foetuses and the donation of the whole deceased body for research purposes.

Juristic Rulings on Therapeutic Cloning and Stem Cell Research

The 67th Conference of Fatwa Committee of the National Council of Islamic Affairs that was held on 22 February 2005 had discussed the juristic rulings on Therapeutic Cloning and Stem Cell Research and unanimously decided that:

1) Therapeutic cloning for medical treatment, for instance, to create certain cells or to replace damaged organ is permissible provided that the sharīʿah precautions are considered.

2) Using frozen embryo or extra embryo In Vitro Fertilisation (IVF) process is permissible for research purpose. However, permission must be granted from the married couple who are under treatment. The research on the embryo must be done before the embryo reaches the ʿalaqah stage (blastocyst).

3) The permission for pre-embryonic research other than therapeutic purposes shall be

[3] Al-Bukhari, Ibn Hajar al-’Asqalani, Kitab Janāzah, Bab al-Qiyām li al-Janāzah
[4] Ibn Mājah, Sunan Ibn Mājah Kitab al-Janāʾiz, Bab Fī nahy ʿan kasri ʿiẓām al-mayyit.

obtained from the parents. The sample of the research cannot be implanted in the womb of any woman, including the wife.

4) It is permissible to do research on pre-embryos to determine the genetic disease of high-risk parents, and the embryo without disease alone may be implanted in the womb of the mother during the period of legitimate marriage. It is impermissible to conduct any research for commercial purposes or unrelated to maternal or foetal health.

5) Genetic engineering treatments on pre-embryos involving the modification of natural human features such as hair, hair colour, intellect, height, and so on including gender selection are illegal. However, gender selection is permissible, provided the gender factor may cause a serious genetic disease that can lead to death.

6) The research must be conducted legally, and the proposal must be unambiguous and scientifically sound. The research shall be conducted by professional, skilled, trusted and responsible researchers.

7) Stem cells from the sources listed below are permissible to be utilised for medical treatment or lawful scientific research:

    a. Adults, if they have given permission and they are not exposed to any harm.
    b. Children, if their parents have given their permission for some legitimate reason, and at the same time, these children are not exposed to any harm.
    c. Placenta and umbilical cord, if the parents have given their permission for that.
    d. Miscarried foetus, for some lawful treatment purposes, and with the parents' permission, and not with a foetus that was deliberately aborted without any lawful medical reason.
    e. Surplus inoculums from the test-tube babies if available and donated by the parents with their permission. Stem cells from deliberate inoculation of an ovum and spermatozoa of the female and male donors via the technology of Somatic Cell Nuclear Transfer (SCNT) is not permissible based on the principle of sadd al-dharā`iʿ (to stop any harmful effects).

Juristic Ruling on the Disposal of Muslim Body Parts, Tissues, and Foetuses

The 110th Conference of Fatwa Committee of the National Council of Islamic Affairs that was held on 27 and 28 March 2017 discussed the juristic rulings on the Disposal of Muslim Body Parts, Tissues and Foetuses and unanimously decided, among others, are:

1) Any body parts that are cut off from the living body, need to be buried without being washed and prayed for.

2) Any body parts or tissue of Muslim deceased that are cut off from the corpse that has been bathed and prayed, should be buried without being prayed. If it is unknown whether the corpse has been prayed or not, the body part or tissue should be bathed and prayed before it is buried.

3) For a miscarriage baby (neonatal death) and there are signs of life such as crying, movement and others, the deceased should be handled by being bathed, shrouded, prayed, and buried just like other funerals.

4) If the foetus is stillborn, and there is no sign of life, it must be bathed, shrouded, and buried without prayer.

Guidelines of the Disposal of Human Biological Samples

1) Surplus of samples or remnants that are no longer needed for research should be disposed.

2) Identification of samples obtained from a Muslim should be recognised by a specific code based on religion when it was first stored and labelled.

3) Samples obtained from a Muslim, should be buried if there is no danger of spreading disease or health hazard.

4) Samples should be buried only, if it is obtained from a Muslim who is still alive or obtained from a deceased that has been bathed and prayed.

5) Samples should be bathed, prayed, and buried, if it is obtained from a Muslim but the status of living is unknown.

6) Liquid samples, do not need to be buried.

7) Consultation should be made with:

    a. The States' Department of Islamic Affairs (Jabatan Agama Islam Negeri-negeri) for them to manage the burial process and to identify place of burial such as at specific graveyard or a dedicated and safe area.

b. The Department of Environment related to burial of any specimen stored in formalin or chemical to ensure environmental safety such as burial at an area at least 100 meters away from water resources, residential area, wells, and dams.

Juristic Rulings on the Donation of the Whole Deceased Body for Research Purposes

The 105th Conference of Fatwa Committee of the National Council of Islamic Affairs which was held on 3-5 February 2014 discussed the juristic ruling on the Donation of the Whole Deceased Body for Research Purposes and unanimously decided as follows:

1) After reviewing the report prepared by the research team of University Malaya, based on the facts, deliberation, and views presented in the report, Muzakarah decided to accept and ascertain the research findings.

2) Muzakarah would like to emphasise that the initial juristic ruling for the donation of the whole body or a deceased is prohibited because Islam puts high respect for the human body, live or dead. There are many injunctions regarding this context, such as the acts of tahjiz al-mayyit (preparation of corpse), i.e. washing the corpse, shrouding, praying and burial, and prohibition of chopping the corpse, and so on.

3) In the Malaysian context, Muzakarah views that the donation of a Muslim's whole body or a deceased and the need to use the deceased for research purposes do not reach the mandatory level. There are other alternatives to fulfil the need to use the dead body for research purposes. So long there is an alternative to fulfil the need, it must be done without having to permit the donation of the Muslim whole body or deceased.

4) Therefore, Muzakarah decides that the donation of the Muslim whole body or deceased for research purposes is forbidden and impermissible based on the arguments as follows:

    a. The principles of sanctity of the corpse and respecting the dead body must be adhered to, based on an Islamic legal maxim:

    الأَصْلُ فِي الْعِرْضِ التَّحْرِيمِ

    Meaning: The original condition related to dignity is prohibition.

    b. This legal maxim is based on a hadith of the Prophet SAW:

    فَإِنَّ دِمَائَكُمْ وَأَمْوَالَكُمْ وَأَعْرَاضَكُمْ بَيْنَكُمْ حَرَامٌ كَحُرْمَةِ يَوْمِكُمْ هَذَا فِي شَهْرِكُمْ هَذَا فِي بَلَدِكُمْ هَذَا

Meaning: Verily, your blood, property, and dignity are sacred to one another just like the sanctity of this day of yours, in this month of yours, and in this city of yours. (Hadith narrated by al-Bukhari and Muslim)

c. The sanctity of the deceased is an obligation yet the donation of the body infringes this sanctity.

The need to use the Muslim whole body or deceased for research purposes is not at the crucial or emergency level because there are still other alternatives to fulfil the requirement

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