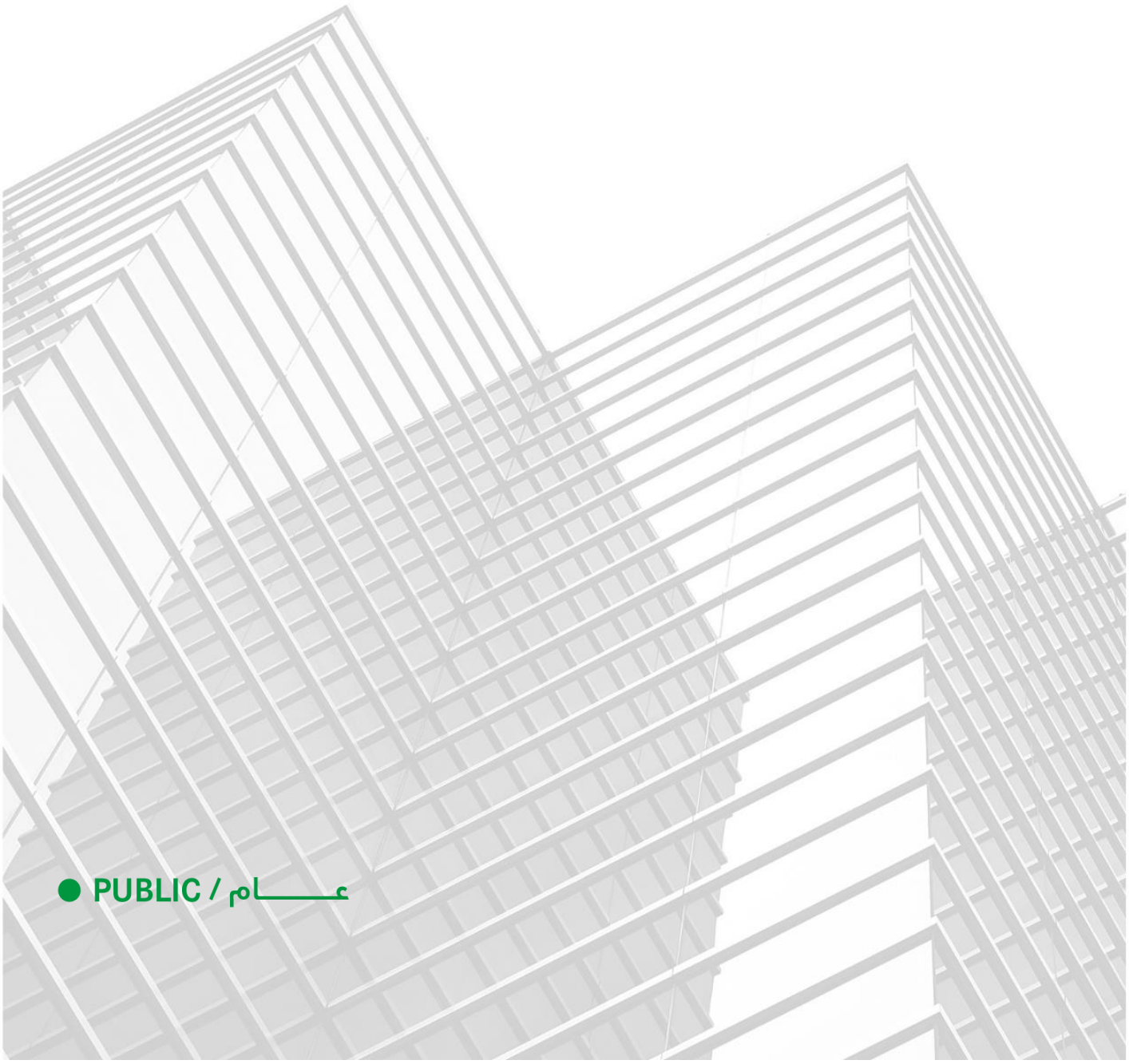
دائـــــرة الـصـــحـــة
DEPARTMENT OF HEALTH

POLICY ON BIOBANKING



● PUBLIC / عـــــــام

Document Title:	Policy on Biobanking		
Document Ref. Number:	DOH/Policy/RIC/POB/V1/2024	Version:	V1
New / Revised:	New		
Publication Date:	April, 2024		
Effective Date:	July, 2024		
Document Control:	DoH Strategy Sector		
Applies To:	DoH licensed healthcare providers, payers, stakeholders, academic institutes, research laboratories, and professionals involved in biobanking activities (collection, transport, access, among others) of human biological materials (cells, tissues, fluids, products) and the associated data generated from them in the emirate of Abu Dhabi.		
Owner:	Research and Innovation Center (RIC)		
Revision Date:	3 years after approval.		
Revision Period:	Within three years.		
Contact:	Sector: RIC@doh.gov.ae		

TABLE OF CONTENTS

1. Policy Purpose and Brief

This policy aims to establish a comprehensive framework that promotes the ethical, responsible, and standardized operation of biobanks in the emirate of Abu Dhabi, while harnessing the application of the best international quality standards for the collection, storage, distribution, and use of human biological samples and associated data for research and clinical purposes. The operability of biobanks should generate quality information to improve the healthcare system with personalized medicine and preventive public health strategies for the citizens of Abu Dhabi.

Biobanks have evolved into indispensable assets for advancing biomedical research and clinical practice. These facilities enable access to diverse human samples and information (such as genomic and clinical data), supporting the understanding of diseases and the development of novel diagnostic tools, precision medicine, and preventive public health strategies. Nevertheless, the effective operation of biobanks hinges on well-defined biosafety protocols and quality control procedures to ensure the preservation and integrity of the biospecimens throughout the entire process, encompassing collection, transportation, storage, and distribution. Additionally, robust data protection and privacy measures are essential to safeguard the personal information of the donors/participants.

By formulating this policy, the vision, goals, and priorities in the emirate of Abu Dhabi on biobanks are outlined in compliance with associated ethical, legal, social, and financial issues, which are necessary to benefit from them without causing harm to the population, and in a way that is tailored to the cultural context. This policy applies to the collection, storage, distribution, transportation, and use of human biological samples and associated data, as well as all stakeholders, healthcare providers, healthcare professionals, private entities involved in human research, government entities, academic institutions, researchers, scientists, and individuals providing or accessing biological materials and genomic data.

2. Definitions and Abbreviations

No.	Term / Abbreviation	Definition
2.1	**Abu Dhabi Healthcare Information and Cyber Security (ADHICS)**	A strategic initiative developed by the Department of Health of Abu Dhabi, that aims to enhance data privacy and security in Abu Dhabi's health sector.
2.2	**Accreditation**	System with a formal process for evaluating and recognizing the quality of an institution's services and competence. It is conducted by an official authorized organization.
2.3	**Advisory Board**	Body that provides non-binding strategic and scientific advice to the management of a biobank; It could cover scientific issues and ethical, legal, and societal issues (ELSI).
2.4	**Associated data**	Any information affiliated with human biological materials (biospecimens) including but not limited to research, phenotypic, clinical, epidemiologic, and procedural data, such as health records, family history, lifestyle, and genetic information (based on ISO 20387: 2018).
2.5	**Biobank**	Large collection of human biological materials (biospecimens) held for health and medical research purposes. Biobanks contain relevant associated data, such as personal and health information.
2.6	**Biobanking**	Process of acquisitioning and storing, together with some or all of the activities related to collection, preparation, preservation, testing, analysing and distributing defined biospecimens and associated data.
2.7	**Biospecimen**	A sample of human biological material that is stored in a biobank, such as but not limited to: urine, blood, tissue, umbilical cord blood, umbilical cord tissue, cells, DNA, RNA, proteins, or any derived subcomponents (e.g.: plasma, serum).
2.8	**Biosecurity**	Set of practices and measures designed to prevent the introduction and spread of harmful biological agents into the environment, such as pathogens, pests, or invasive species.

2.9	**Biosafety**	Set of practices and preventive measures aimed to protect humans, animals, and environmental health against potentially hazardous biological agents.
2.10	**Clinical Data Interchange Standards Consortium (CDISC)**	Global not-for-profit organization that actively develops data standards with the collective knowledge and experience of volunteers within the pharmaceutical industry
2.11	**Customer**	Healthcare providers, healthcare professionals, private entities involved in human research and development, government entities, academic institutions, researchers, scientists using biobank's resources for their intended purposes.
2.12	**Current Good Manufacturing Practice (cGMP)**	Set of rules governing the manufacturing, processing, packaging, and distribution of pharmaceutical and healthcare products, ensuring quality standards to guarantee product safety, efficacy, and compliance with regulatory requirements.
2.13	**Current Good Tissue Practice (cGTP)**	Set of quality standards and guidelines that govern the collection, processing, storage, and distribution of human tissues for medical use. cGTP ensures that tissues are safe, effective, and traceable, and that they meet regulatory requirements.
2.14	**Data breach**	The loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or any similar occurrence where data is accessed by unauthorized users or for unauthorized purposes whether electronic or not.
2.15	**Data Transfer Agreement (DTA)**	Legal contract that governs the transfer of data, that may include personal information, between a providing and a recipient institution, where obligations, restrictions, intended use, and measures for data protection are considered.
2.16	**Department of Health Abu Dhabi (DoH)**	The regulative body of the Healthcare Sector in the Emirate of Abu Dhabi ensures excellence in healthcare for the community by monitoring the health status of the population.
2.17	**De-identification**	Process that removes or masks all personal health identifiers (PHI) by codification or pseudonymization of samples and/or data.
2.18	**Donor/Participant**	Human individual who is the source of the biospecimen and personal data, which are stored in the biobank.
2.19	**Food and Drug Administration (FDA)**	The United States Food and Drug Administration is a federal agency of the Department of Health and Human Services.
2.20	**General Data Protection Regulation (GDPR)**	A set of European Union (EU) regulations that governs how the personal data of individuals in the EU may be processed and transferred.
2.21	**Good Clinical Laboratory Practice (GCLP)**	Standard for compliance by laboratories involved in the analysis of samples from clinical trials (Source: World Health Organization).
2.22	**Good Laboratory Practice (GLP)**	Set of rules and criteria for a quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are performed.
2.23	**Good Storage Practice (GSP)**	Set of rules that ensure quality storage of medical products in warehouses and adequate transportation of pharmaceutical products.

2.24	**Incidental findings**	Observations, results, or other findings that may occur during analysis but are unrelated to the primary goals of the analysis.
2.25	**Institutional Review Board (IRB)**	Independent body formally designated to review, approve, and monitor biomedical and behavioral issues involving humans with the aim to protect the rights and welfare of the human research subjects recruited to participate in research, in addition to the legal protection for the investigators and the facility itself. Sometimes referred as Independent Ethics Committee (IEC) or Research Ethics Committee (REC).
2.26	**Informed Assent**	Agreement given by a minor or a non-competent person to undergo the procedures related to the storage and use of their biological materials and/or associated data in a biobank. It does not represent a legal document, therefore requires the informed consent of the parent or legal guardian.
2.27	**Informed Consent (IC)**	Voluntary and documented agreement given by a donor to undergo the procedures related to the storage and use of their biological materials and/or associated data in a biobank. Informed consent requires a comprehensive understanding of the purpose, procedures, potential risks, and benefits associated with biobanking activities, including those to be used in future research.
2.28	**International Conference on Harmonisation Good Clinical Practice (ICH-GCP)**	International ethical and scientific quality standards for designing, recording, and reporting trials that involve the participation of human subjects.
2.29	**Laboratory Information Management System (LIMS)**	Software that supports laboratory operations, including workflow, tracking, security, mapping of samples, data exchange interfaces, among others.
2.30	**License**	A permission given by the Department of Health Abu Dhabi to practice a profession, activity or provide a healthcare service.
2.31	**Material Transfer Agreement (MTA)**	Legal contract that governs the transfer of biospecimens between a providing and a recipient institution, where rights, obligations, restrictions, intended use, and measures for the protection of the biospecimen and associated data are considered.
2.32	**Ministry of Health and Prevention (MOHAP) of the United Arab Emirates (UAE)**	Governing body responsible for the implementation of health care policy in all areas of technical, material, and coordination in the UAE.
2.33	**Organization for Economic Co-operation and Development (OECD)**	Forum where the governments of 38 democracies with market-based economies collaborate to develop policy standards to promote sustainable economic growth.
2.34	**Preservation**	Process of maintaining the integrity and quality of biospecimens over time by means of physical and/or chemical methods, such as freezing and fixation.
2.35	**Professional Qualification Requirements (PQR)**	Unified licensure requirements in the United Arab Emirates applied to license health professionals, as amended from time to time.
2.36	**Protected Health Information (PHI)**	Health information that relates to past, present, or future physical or mental health or condition of a patient; the provision of health care to a patient; or the past, present or future payment for the provision of health care to a patient.
2.37	**Pseudonymization**	Process that replaces or encrypts identifiable information, with added complexity to the protection of the personal data to enhance privacy and security.

2.38	**Quality Management System (QMS)**	Set of policies, processes and procedures required for planning and execution (production/development/service) in the core business area of an organization (e.g.: areas that can impact the organization's ability to meet customer requirements).
2.39	**Standard Operating Procedure (SOP)**	Written documents that provide detailed instructions for specific work processes in a company or organization.
2.40	**Stem cell**	Undifferentiated and unspecialized cell that has the capacity to regenerate (self-renewal) through cell division for long periods of time and which, under certain physiological or experimental conditions, can be induced to differentiate into specialized cell types (differentiation) with specific morphological characteristics and functions.
2.41	**Vulnerable participants**	Donors who may be compromised in their ability to give informed consent or those who may be subjected to coercion in their decision making. Including, but not limited to, people of determination, individuals with mental health disorders, prisoners, children under 18 years of age, patients with incurable diseases, among others.
2.42	**21 CFR Part 11**	Title 21 of the Code of Federal Regulations part 11 of the United States Food and Drug Administration (FDA) that regulates electronic records and electronic signatures.

3. Policy Content

3.1 Policy statement

The implementation and performance of human biobanks will be endorsed in the emirate of Abu Dhabi to foster research. This would increase the health status and quality of life of the population, contributing to biomedical knowledge and the prevention, diagnosis, and treatment of diseases, by promoting the best international practices for biobanking activities and in compliance with the regulations of Abu Dhabi.

Priorities and goals regarding the implementation and operability of biobanks in Abu Dhabi are detailed in **Appendix 1.**

3.2 Legislative regulation for licensure

3.2.1 The biobank shall operate under a license granted by the Department of Health (DoH) and maintain the licensure while biobanking activities are being conducted in accordance with federal and Abu Dhabi laws and regulations.

3.2.1.1 The biobank shall obtain a "License for Biobank Facilities" from the DoH prior to the constitution and operation of the facility. A schematized figure of the licensing process can be found in **Appendix 2**, along with the documents required for the facility's application submission.

3.2.1.2 Application and licensing fees shall be paid by the facility prior to review of the application.

3.2.1.3 This application shall be additionally reviewed by at least one of the following competent authorities, depending on the activities that will be conducted within the facility.

- For research and/or clinical purposes of cells, tissues, and fluids that are not umbilical cord blood, umbilical cord tissue, stem cells, or blood forming cells: **Abu Dhabi Health Research and Technology Committee (ADHRTC).**
- For research and/or clinical purposes of umbilical cord blood, umbilical cord tissue, stem cells and blood forming cells: **UAE Supreme Committee of Cord blood and Stem Cells.**
- For research and/or clinical purposes regarding infectious diseases biobanks: **Infectious Disease System – Abu Dhabi Public Health Center** (**IDS-ADPHC).**
- For research and/or clinical purposes of genetic information associated with human biospecimens, in addition to the above: **UAE Genomics Council.**
- For clinical trials (e.g.: treatments based on stem cells, vaccine trials), regardless of the biospecimen type or associated data and in addition to the above: **Abu Dhabi Health Research and Technology Committee (ADHRTC).**
- For commercial or patentable purposes, in addition to the above: **Ministry of Economy**.

3.2.1.4 After the authorities' approval of the application, DoH will grant a "Preliminary approval" to allow the biobank facility to fulfill the remaining requirements after paying the correspondent fees.

3.2.1.5 The biobank shall establish an Institutional Review Board (IRB) to review and supervise the management and operations of the biobanks, whose conformation and responsibilities shall comply with DoH standards and regulations regarding human subject research and the Healthcare workforce Bioethics Guideline.

3.2.1.6 The biobank shall provide a bank guarantee to obtain the license. The amount shall be determined by DoH and shall be deducted in the event of agreement violations and bankruptcy situations.

3.2.1.7 The licensure shall be renewed within the determined time by the competent authorities referred in clause 3.2.1.3. Operations shall only be performed under a valid DoH license.

3.2.1.8 Inspections shall be performed by DoH or DoH designated third parties to ensure continued compliance with requirements and regulations of Abu Dhabi. These inspections can be performed without notice.
3.2.1.9 Changes in the scope of the activities of the biobank shall be subject to review by DoH, who shall define the future actions that must be followed. New activities shall not be conducted until approval.

3.2.2 The processes performed must be accredited by international authorities, if the former is not possible, evidence of best international practices must be provided.
3.2.2.1 A list of the approved accreditation bodies for biobanks in Abu Dhabi are detailed in **Appendix 3**, where specific systems are required if umbilical cord blood or stem cells are under the scope of the facility.
3.2.2.2 Accreditation shall be acquired within 2 years after setting up the biobank or DoH license will be revoked.

3.2.3 Biobanks shall be registered in a local register administered by DoH.
3.2.3.1 The biobank is responsible for registering the facility in the Registry of Biobanks of Abu Dhabi, where the purpose, biobank director, legal representative, and the scope of the biobank are included.
3.2.3.2 DoH shall retain the registry of licensed biobanks to be used for governance, statistics, collaboration and research facilitation, or other information needed.
3.2.3.3 No identifiable information nor protective health information of the donors should be included in the registry.

3.2.4 Biobanks shall emit reports regarding their operability status on a biannual basis.
3.2.4.1 DoH shall establish a body, group, or committee to hold responsibility for the review and monitoring of the reports, such as a "Biobank Security Committee".
3.2.4.2 Standardized reports shall be developed by this body (or by DoH) that include, as a minimum, storage capacity, quality metrics and biospecimens stored.
3.2.4.3 Biobank is responsible for registering the requested information on time.

3.2.5 The biobank personnel shall be licensed by DoH to perform their activities under their scope of work with adequate qualifications and training.
3.2.5.1 The personnel involved in the procurement and processing of human biospecimens require a license by DoH under the PQR and must obtain clinical privileges in accordance with the applicable clinical privileges system issued by the DoH.
3.2.5.2 The employees shall have adequate knowledge and expertise in their field of work, where training and certification for cGTP, ICH-GCP, GLP, GCLP, GMP, and GSP shall be required, if applicable.
3.2.5.3 The personnel shall perform their activities respecting donor's privacy and confidentiality.

3.2.6 The biobank shall guarantee/aim to operate under the best international practices for biobanking.
3.2.6.1 Biobanks shall be collaborative with inspections from DoH or the DoH designated third party institutions (as per 3.2.1.8).
3.2.6.2 Biobanks shall define activities that will be conducted and provide evidence of operating under the best current international practices for biobanking.
3.2.6.3 Procedures shall be dynamic and able to adapt over time to new knowledge related to biobanks.
3.2.6.4 As authorities increasingly encourage or require the use of CDISC standards in regulatory submissions, biobanks involved in clinical research shall comply with these standards to meet regulatory expectations.

3.2.7 Export and import of biospecimens and associated data outside of the UAE is not allowed, unless DoH and MOHAP indicate otherwise.
3.2.7.1 In the possibility of export or import, it shall be performed under contractual and legal agreements defined in MTAs and DTAs, previously approved by DoH.
3.2.7.2 Export and import shall consider the protection of donor's privacy and rights therefore, data shall be anonymized.
3.2.7.3 Export and import of biospecimens and associated data for commercial purposes shall not be allowed by any means. They shall only be feasible for biomedical research purposes approved by DoH.
3.2.7.4 DoH may receive counselling from other institutions such as ADHRTC, UAE Genomics Council, UAE Supreme Committee of Cord blood and Stem Cells to make a decision, if required.

3.2.8 Closure of the biobank
3.2.8.1 The biobank activities can cease by a suspension from DoH or by the facility's own request.
3.2.8.2 The destination of biospecimens and data shall be established in the resolution of closure by DoH, where they can be destroyed, transferred to another biobank, or conserved in approved facilities for specific research projects.
3.2.8.3 Transfer to other facilities or biobanks shall be established through contractual agreements or a mechanism approved by DoH.
3.2.8.4 For DoH licensed umbilical cord blood and stem cells biobanks, both the stored biospecimens and their associated data should be accessible for at least 30 years after the last use or after the closure of the biobank.

3.3 Facility establishment requirements

3.3.1. Biobanks shall plan the location and design of the facility to operate within their scope, while ensuring best practices through quality and safety measures.
3.3.1.1. An adequate infrastructure for efficient storage, processing, and management of the biospecimens and associated data is required.
3.3.1.2. Biobanks shall be situated in a secure location with controlled access to minimize potential risks and ensure the safety and confidentiality of stored samples and data.
3.3.1.3. The facilities shall be designed to guarantee efficient workflow, proper ventilation, and compliance with safety regulations and standards.
3.3.1.4. The engineering plan and infrastructure of the biobank shall be approved by DoH.
3.3.1.5. Development of long-term strategic plans that consider the sustainability of the biobank. This includes financial planning, infrastructure expansion, and adapting to technological advancements.

3.3.2. Biobanks shall implement an environmental monitoring system to ensure that storage conditions are met and maintained.

3.3.2.1. The facility shall implement a continuous monitoring system (manual and automated) to track temperature, humidity, and other environmental factors critical for sample preservation.

3.3.2.2. Automated systems for storage and environmental monitoring are preferred to maintain high sample quality and efficient workflow.

3.3.2.3. Environmental conditions requirements are determined according to sample type, equipment functioning and intended purposes.

3.3.2.4. Real-time alerts for deviations of environmental conditions shall be considered in the environmental monitoring system.

3.3.3. Biobanks shall ensure optimal storage capacity for biospecimens in alignment with international standards and cutting-edge technology.

3.3.3.1. Adherence to internationally recognized standards and guidelines for the storage of biospecimens shall be followed. GSP shall be considered for all biospecimens, since they are human samples and intended for high quality research.

3.3.3.2. The conditions under which biospecimens are stored should be suitable for the intended use and purpose.

3.3.3.3. Biobanks shall have sufficient storage capacity and strategic initiatives to uphold potential future growth of the collections due to increased quantities, new sample types, or collaborative partnerships.

3.3.3.4. Utilization of storage racks and containers shall be suitable for the safe and organized storage of different types of biological samples while minimizing cross-contamination.

3.3.3.5. Storage areas shall be designed to avoid or minimize chemical contact or exposure to any possible source of infection.

3.3.3.6. Biobanks must have a secure data storage system with adequate capacity to safeguard electronic data storage, such as donor information, biospecimen metadata, associated data, and experimental details. Regular backup procedures and recovery plans should be included to prevent data loss or corruption. More details regarding data management and IT infrastructure are elaborated in clause 3.6.

3.3.4. Biobanks shall implement security measures to protect the confidentiality and integrity of biospecimens and associated data.

3.3.4.1. The biobank shall develop, establish and maintain security and data privacy requirements in accordance with the federal and Abu Dhabi laws and regulations.
- A centralized log management system shall be established, where all system, application, and security logs shall be stored and analyzed.
- All log information (system/application/security logs) shall be shared with DoH Healthcare Computer Emergency Response Team (CERT) on real-time basis.
- All biobanks shall deploy DoH's vulnerability management solution and support periodic scanning of systems and applications, and remediation mandates.

3.3.4.2. A robust access control system shall be implemented to restrict entry to authorized personnel only, based on roles and responsibilities. Access allowance or removals shall be promptly updated and registered.

3.3.4.3. Surveillance systems shall be implemented, such as security cameras and monitoring systems to record and oversee activities within the facility, enhancing security and deterring unauthorized access.

3.3.4.4. Alarm systems shall be established, tested, and maintained to adequately detect security breaches, unusual activities, and undesired environmental changes.

3.3.4.5. The biobank shall develop and implement a comprehensive risk management system to identify, assess, and mitigate potential risks to sample and data integrity.

3.3.4.6. An emergency plan response shall be developed and implemented to address security incidents such as natural disasters and power outages.

3.3.4.7. If data in external digital systems can be accessed through the biobank system (e.g.: electronic health records, research databases, demographic information systems, among others), procedures and policies shall be put in place to prevent unauthorized access to that data and to verify that accurate transmission from the point of data entry to reports (whether paper or electronic), assuring data integrity.

3.3.5. Biobanks' laboratory shall operate under the highest standards of quality, precision and ethical conduct to ensure the integrity of biospecimens and associated data.

3.3.5.1. Laboratory procedures shall comply with local and federal regulations, ethical principles, and international standards related to biobanking of human biospecimens and associated data.

3.3.5.2. An accredited laboratory (e.g.: ISO 15189) shall be assigned or designated to perform the relevant biobanking activities, such as collection and quality assurance.

3.3.5.3. Ensure that the necessary equipment and materials are available and operational to perform testing adequately. A maintenance schedule for all laboratory equipment and instruments shall be created and maintained following GCLP standards to ensure accuracy and reliability.

3.3.5.4. Biosafety and biosecurity measures shall be implemented according to a risk assessment.

3.3.5.5. Provide backup power solutions to critical equipment, ensuring the integrity of samples and data during power outages.

3.3.5.6. Approved medical devices should be used whenever possible, either from *Conformité Européenne* (CE) or Food and Drug Administration (FDA). If not, a commitment to obtain certification shall be made.

3.3.5.7. Accreditation should be obtained within two years from the start of operations, from any of the accreditation bodies listed in **Appendix 3.**

3.3.5.8. A traceability process/system shall be implemented from the collection of the biospecimen and associated data to the storage, distribution, transfer, and disposal.

3.3.5.9. Procedures for cleaning and infection control shall be put in place to guarantee quality and safe practices. These procedures shall be validated.

3.3.5.10. Biobanks shall have procedures to ensure that consumable supplies and reagents used conform to the required standards.

3.3.6. Biobanks shall implement a management system for biospecimens and associated data resources, that covers every step from the collection, processing, handling, storage, transfer, destruction and access, complying with quality standards and privacy regulations.

3.3.6.1. The biobank shall develop procedures covering the life cycle of biospecimens and associated data, from collection to storage, reception and distribution, transport and traceability, and preparation and preservation of the biospecimens.

3.3.6.2. The biobank shall use standardized procedures to ensure compatibility with other databases and interfaces for potential future collaborations. These procedures shall be validated and verified, where quality control monitoring and assessment shall be performed.

3.3.6.3. Collection strategies and methods shall be suitable for the intended use of the biospecimens and associated data or with the quality standards set by the biobank. Preanalytical variables shall be considered.

3.3.6.4. Biospecimens shall be collected and labelled in accordance with appropriate biosafety practices, subject privacy regulations, and the informed consent.

3.3.6.5. A labelling or coding system (e.g.: unique identifiers) shall be implemented to facilitate tracking and shall correctly link biospecimens to associated data. Biospecimens shall be accompanied by outer and immediate labelling texts.

3.3.6.6. Biobanks shall have policies for managing records and procedures defining data access, data collection methods, reporting, data quality control, and standardized medical terminology.

3.3.6.7. Biobanks shall develop SOPs for the storage and retrieval of biospecimens, considering the processes for addition, withdrawal, final disposal, and requests to access.

3.3.6.8. Biobanks shall develop SOPs for the transport of biospecimens that are suitable for their intended use and nature, considering shipping and transport temperature and conditions to ensure biospecimen integrity and safety.

3.3.7. A Quality Management System (QMS) shall be established in compliance with relevant quality standards, to ensure biospecimens and associated data are suitable for medical and/or research purposes, in accordance with the intended use.

3.3.7.1. A comprehensive document control system for the organization, review, and updating of standard operating procedures (SOPs), protocols, and other critical documents shall be developed.

3.3.7.2. The handling of the biospecimens and associated data shall be documented from the collection to the processing, storage, access, transfer, and disposal.

3.3.7.3. Quality should be monitored regularly according to a quality assurance program. This program shall be specific to how the quality will be assessed and should be reviewed by the laboratory quality officer/department on a routine basis.

3.3.7.4. Procedures to identify deviations and non-compliances shall be implemented, along with the procedure for preventive and corrective measures.

3.3.7.5. Biobank staff shall be trained prior to performing their duties and re-training shall be done as per accreditation standards. Competence shall be evaluated and documented.

3.3.7.6. Biobanks shall prepare for inspections by DoH, internal, and external audits to ensure compliance with quality standards.

A schematized figure of the facility requirements for human biobanks in Abu Dhabi can be found in **Appendix 4**.

3.4. Governance

3.4.1. An internal governance system shall be planned and implemented in accordance with the biobank's scope and in compliance with federal laws, Abu Dhabi laws and regulations, and international ethical principles.

3.4.1.1. It is recommended that the internal governance system is based on a dynamic approach able to adapt over time, new emergent technologies, research innovations, and regulatory dispositions.

3.4.1.2. The biobank shall define the principles that guide the facility's management, operability, and decision-making, including at least: transparency, consistency, equitability, fairness, accountability, and efficiency.

3.4.1.3. The governance system shall guarantee compliance with the biobanks' purpose and enhance trust among stakeholders, researchers, and participants.

3.4.1.4. The life cycle stages of the biospecimens and associated data shall be standardized in the governance system, where policies and procedures are developed and implemented to ensure the quality of the resources.

3.4.2. The biobank shall establish a clear organizational structure that delineates roles, responsibilities, and reporting relationships to ensure an effective governance framework and management.

3.4.2.1. An organizational chart shall be developed which defines the management of the biobank and the relationships between the personnel and external parties.

3.4.2.2. Specific responsibilities and roles shall be defined depending on the size, nature, and the institutional context, to establish legal commitments and duties. Some of these roles may include: a biobank director, a quality manager, a data manager, among others.

3.4.2.3. Committees shall be established to ensure adherence to the governance system by oversight mechanisms or advisory boards. The quantity, responsibilities, members, and size of the committees shall be defined by the biobank.

3.4.2.4. An employees' record shall be established and maintained, where information about job titles, employment information, training records, and registration at the correspondent legal bodies is included.

3.4.2.5. Training shall be provided to the personnel to keep up with the best updated practices on biobanking. Periodic re-training and competency assessments shall be performed as per standards.

3.4.2.6. Communication and training on legal and ethical aspects related to the biobank's activities shall be provided and assessed.

3.4.3. Internal documentation shall be developed and implemented to govern the operability of the biobank, which shall comply with the QMS. Some of these activities include, but are not limited to, informed consent, secure data management, return of results, access, incidental findings, among others.

3.4.3.1. Policies, guidelines, and procedures shall be developed by the biobank management based on their scope of application, nature, purpose, size, and best practices.
3.4.3.2. Every operational activity performed under the biobank facility shall be described in Standard Operating Procedures (SOPs).
3.4.3.3. Policies shall be developed for "access" and "data protection and privacy", since they are of high-level importance and shall be made publicly available.
3.4.3.4. All documents shall be reviewed in a time frame defined by the biobank. A 2-year time frame is recommended.

3.4.4. An ethical oversight mechanism that reviews the matters related to biobanking activities shall be established.
3.4.4.1. Biobanks shall establish an IRB responsible for reviewing and approving biobank activities, protocols, and informed consent procedures to ensure adherence to ethical standards.
3.4.4.2. The conformity of the IRB shall comply with the correspondent local and federal regulations.

3.5. Ethical, legal, and social implications (ELSI)

3.5.1. Biobanks shall foster the involvement of the community on biobanking activities and initiatives, considering the cultural context, inclusivity, and sharing the benefits arisen from accessing biobank's biospecimens and associated data.
3.5.1.1. Biobanks shall establish a community **engagement** program to consider the values, concerns, and perspectives of the population in the direction of biobanking activities and decision-making processes.
3.5.1.2. **Public trust** measures shall be considered to foster the voluntary participation of the population, such as transparent communication, open forums, among others.
3.5.1.3. **Cultural context** consultation with local leaders, social groups, and professionals about local ethical and/or legal guidance of specific social groups and cultural minorities shall be considered to obtain equal opportunities and to be aware of diverse perspectives.
3.5.1.4. Personal, religious, and culturally held beliefs and traditions should be respected in any research using biospecimens and associated data. Additionally, the biobanks shall track any relevant restrictions or instructions based on personal, religious, and culturally held beliefs and traditions in order to ensure that the donor's wishes are upheld.
3.5.1.5. Biobanks shall determine **benefit sharing** mechanisms to address how the benefits arising from the use of biobank's resources can be retrieved to the donors, communities, researchers, and the population by considering the applicable intellectual property regulations at the national level and as mentioned in this document.
3.5.1.6. **Education** on biobanks shall be provided to donors, stakeholders, and communities to promote informed decision-making processes, to highlight the importance and impact of biobanking, to foster participation on biobanking activities, and to guarantee ethical use of biospecimens and associated data.

3.5.2. Biobanks shall be committed to respecting the human dignity and autonomy of donors following international guidelines and ethical conduct on biobanking and DoH Healthcare workforce Bioethics Guideline.
3.5.2.1. An **informed consent** shall be obtained from the donors prior to their participation in the biobank, where they must be informed of the purpose of sample and data collection, risks, and potential benefits. This document shall be the ethical and legal base of biobanking that respects the autonomy and rights of the donors, such as the right to withdraw their consent. More details and requirements are addressed in 3.7.
3.5.2.2. Biobanks shall conduct the **recruitment** process with transparency, inclusivity, and fairness, implementing measures to guarantee voluntary participation without coercion or undue influence.
3.5.2.3. A policy for **return of results** shall be developed and implemented, where procedures shall consider the impact of incidental findings. Donors shall have the opportunity to decide whether to receive relevant research findings.
3.5.2.4. **Genetic information** shall be treated as protected health information and in compliance with local regulations of Abu Dhabi. The collection and use of this type of data shall be explicitly informed and explained to donors, where a policy to protect privacy and confidentiality shall be implemented to avoid potential discrimination based on genetic information.
3.5.2.5. Biobanks shall clarify the **ownership** rights of donated biospecimens and associated data based on national and institutional guidelines. Roles and responsibilities shall be outlined throughout all biobanking processes.

3.5.3. The collection, processing, handling, storage, transfer, destruction, and access to biospecimens and associated data shall comply with ethical and scientific standards and with local and federal regulations.
3.5.3.1. Biobanks shall define policies and/or procedures for the **long-term storage** duration of biospecimens and associated data. Acceptable uses shall be considered.
3.5.3.2. In the possibility of **international collaboration**, ethical, legal, and social implications shall be considered by the biobanks. These collaborations may only occur under approval by DoH.
3.5.3.3. Biobanks shall define their posture regarding the **commercialization** of potential outcomes derived from the access to biospecimens and associated data before any commercial collaborations commence, especially to communicate the posture to participants. Ethical and legal considerations shall be assessed.
3.5.3.4. Biobanks shall operate under **regulatory compliance** with international ethical standards, federal laws, and Abu Dhabi regulations that govern the collection, storage, and use of biospecimens and associated data. A set of guidelines and standards for biobanking are detailed in **Appendix 6**.
3.5.3.5. The involvement of pediatric populations on biobanking activities shall adhere to international ethical standards, where it shall be fostered only if research questions cannot be addressed by studies on adults and if the collection and use of the biospecimens and data do not represent a major physical and psychological burden.

3.5.4. Biobanks shall be committed to safeguard donors' identifiable information, protected health information, and associated data with rigorous measures during data management by implementing responsible practices.
3.5.4.1. Measures shall be implemented to uphold the **privacy, confidentiality, and security** of the collected data throughout biobanking activities. More requirements are assessed in 3.6.

3.5.4.2. Policies that govern the **access** to biospecimens and/or associated data shall be developed and made publicly available to foster research. The rights of donors shall be respected along with ethical considerations.

A schematized figure of the ELSI for human biobanks in Abu Dhabi can be found in **Appendix 5.**

3.6. Data protection, confidentiality and privacy

3.6.1. Biobanks shall obtain biospecimens and associated data under the agreements detailed in the informed consent.

3.6.1.1. An explicit informed consent or assent must be obtained prior to the obtention of the biospecimens, associated data and/or protective health information, which should comply with the requirements stated in 3.7.

3.6.1.2. Under certain circumstances (e.g.: only for research purposes and for already collected clinical samples), samples can be incorporated into biobanks from hospital or clinical settings without a consent, as long as anonymization and security measures are held in place and after DoH's approval.

3.6.1.3. The methods used for the collection of biospecimens and/or associated data shall adhere to international, federal, and Abu Dhabi laws and regulations; moreover, the collection process should not comprehend a greater risk than the potential benefit.

3.6.1.4. The collected data should be restricted to the stated in the informed consent, according to the purpose of the biobank or research.

3.6.2. Biobanks shall use de-identification or pseudonymization methods to ensure that donor's personally identifiable information and protected health information (PHI) is not disclosed.

3.6.2.1. The collection, management, access, and sharing of identifiable information shall be subject to strict measures of de-identification or pseudonymization to protect donor's identity privacy and confidentiality, so the participant's identity is unable to be determined.

3.6.2.2. The measures taken shall follow federal and Abu Dhabi laws and regulations for protected health information, as well as the linings for genetic information, and international best practices and laws.

3.6.2.3. A procedure that details the protection methods shall be elaborated, where implications regarding return of results, incidental findings, and re-identification must be considered. Tests should be performed to avoid any residual risks related to the selected method.

3.6.3. Biobanks shall develop an IT infrastructure and strategy to manage the data, defining requirements for accessing and safeguarding the information.

3.6.3.1. Robust data systems shall be implemented to address the requirements of the biobanks. An approved LIMS shall be put in place to ensure all information is logged, traceable, and secure.

3.6.3.2. The IT structure shall ensure the data is completely secured, up-to-date, and without manipulation.

3.6.3.3. Biobanks shall possess management software that enables tracking biospecimens and associated data through all biobanking activities. These resources shall be periodically evaluated to ensure they fulfill the criteria advised in best practices and the latest needs of the biospecimen resource.

3.6.3.4. The stored records and documents shall be periodically reviewed for veracity. The data shall not be deleted, modified, or transferred without authorization.

3.6.3.5. The biobanks shall take measures to maintain the confidentiality for documents that are unable to be separated from the personally identifiable information, such as the agreement of consent and declarations of participation withdrawal.

3.6.3.6. Personnel with access to confidential data shall be bounded by confidentiality agreements and shall be trained to perform their duties with transparency.

3.6.3.7. Biobanks shall elaborate a data breach guideline and clearly define processes for handling a suspected or confirmed data breach.

3.6.3.8. Data shall be retained for an established period of time, previously approved by DoH and legally justified.

3.6.3.9. All system tools and methods should be validated to ensure their accuracy in performing that task.

3.6.3.10. Initial validation of the informatics system should be well-documented ensuring data integrity, accurate process workflow, and adequate audit trail according to 21 CFR Part 11.

3.6.4. Biobanks shall establish an effective system to identify and track biospecimens and associated data through the entire biobanking process.

3.6.4.1. Standardized procedures for harmonization shall be put in place, where a uniform approach is used during the handling of the biospecimens and associated data to guarantee the reliability and comparability of samples.

3.6.4.2. A comprehensive and organized cataloging system to track and manage the inventory of biospecimens and associated data within the biobank shall be established, documenting sample characteristics, storage locations, and relevant metadata.

3.6.4.3. Strategies to ensure the appropriate linking of biospecimens to existing data (associated clinical information, processing data, results) shall be implemented. Procedures to guarantee quality control of data shall be considered.

3.6.5. Biobanks shall develop a framework for sharing biospecimens and data in compliance with federal and Abu Dhabi laws and regulations, donor's consent, and the biobank's purpose.

3.6.5.1. Biobanks shall put in place measures to prevent re-identification of pseudonymized and anonymized biospecimens and data prior by third parties.

3.6.5.2. Third parties' access to personal information shall be restricted and limited. Access to data shall be mediated by MTAs or DTAs developed by the biobanks, where confidentiality and privacy shall be guaranteed as well as the agreements of the informed consent.

3.6.5.3. Policies regarding intellectual property, ownership, and potential benefits from research to the community shall be developed and implemented.

3.6.5.4. Information about policies and procedures to access biospecimens and data shall be made public for the interested parties.

3.7. Requirements for consent

3.7.1. Biobanks shall comply with federal laws, Abu Dhabi laws and local regulations, DoH Healthcare workforce Bioethics Guideline, and internationally best ethical practices related to the consent process of human biobanks in Abu Dhabi.

3.7.1.1. The informed consent process shall be subject to the principle of voluntariness, where donors shall be provided with information about their rights, associated risks, and potential benefits related to the biobanking activities.

3.7.1.2. Influencing ELSI factors on donors' consent shall be explored and addressed, such as cultural, religious, and age-related aspects.

3.7.1.3. Additional considerations shall be integrated in the informed consent when commercial, stem cell, and genetic research is derived from using biobank's resources. Abu Dhabi and international guidelines shall be followed.

3.7.1.4. The informed consent form shall be written on paper or electronic format, in a language that is understandable to the donor. The person requesting consent should ensure that the participant fully understands the information.

3.7.1.5. Donors shall have adequate time and place to read the form, to understand the information, and to ask questions.

3.7.1.6. Biobanks shall optimize the consent process depending on their purpose, nature, and intended use. Different types of informed consent can be considered.

3.7.1.7. In cases where broader community participation is needed, consultation with the community, local leaders, and other professionals shall be conducted. The requirement for community participation in the consent process may also be specified in local ethical or legal guidelines.

3.7.1.8. Biobanks shall respect the autonomy of the participants through rules pertaining to obtaining informed consent, respecting the right to refuse and withdraw the consent, the right to know and not to know, the policy regarding re-contacting, incidental findings, and giving clinically relevant information.

3.7.2. Biobanks shall include a clause for future research in the informed consent, to provide details of the potential use of the biospecimens and associated data for different types of research not yet specified or developed.

3.7.2.1. Information of the potential uses, risks, and benefits related to the use of the biospecimens and/or associated data in future research shall be provided. Special emphasis must be placed regarding the long-term storage and use.

3.7.2.2. Donors shall determine the agreement or disagreement with the future use of their biospecimens and/or data. This decision shall be respected.

3.7.2.3. The biobank shall define consent review processes in accordance with applicable laws, including research ethics committees or comparable oversight mechanisms.

3.7.3. Biobanks shall define consent review processes in accordance with applicable laws, including research ethics committees or comparable oversight mechanisms.

3.7.3.1. These processes should be in place for use in cases where human biological materials or data are to be used in a manner not anticipated in the original informed consent process (e.g.: for determining when to seek re-consent) or if it is requested from the protocol of a clinical trial.

3.7.3.2. In some cases, a waiver of consent can be obtained from a research ethics committee or an appropriate authority, in accordance with applicable law and ethical principles pertaining to the protection of human subjects (e.g.: when a collection acquired many years ago can be re-used as a valuable resource for different purposes in biomedical research)

3.7.4. Donors shall be able to withdraw their consent at any time during the biobanking activities.

3.7.4.1. The biobank must provide information to donors regarding their right to withdraw their consent, which shall not have repercussions or negative consequences.

3.7.4.2. The withdrawal process shall be accessible and clear for donors. Donors can withdraw their consent without giving a specific reason.

3.7.4.3. The biobank shall notify donors of new available information that may impact their willingness to continue their participation on the biobanking activities. The communication and the donor's decision shall be documented.

3.7.4.4. Possible options for participants exercising their right of withdrawal are:

- *Option 1:* No further use. The biobank shall destroy all biospecimens, associated data and materials derived from them. The facility shall not contact the participant again.
- *Option 2*: No further contact. The biobank shall no longer contact the participant directly by any means but can continue to use the biospecimens and associated data already collected.
- *Option 3*: No further access. The biobank will not contact the donor or access the participant's medical records but can continue to use samples and data already collected. All this specific information must be described in the information sheet.

3.7.4.5. Procedures for destroying the biospecimens and/or associated data shall be implemented and explained. When biospecimens and/or associated data cannot be destroyed after withdrawal of consent or for long-term clinical monitoring, the biobank shall provide alternatives (e.g.: anonymization) to donors and explain why their samples and/or data are not retrievable.

3.7.5. Biobanks shall provide special considerations and safeguards when obtaining informed consent from vulnerable subjects.

3.7.5.1. The recruitment of vulnerable participants must respect the requirements of the Declaration of Helsinki. Vulnerable groups and individuals shall receive specifically considered protection, the purpose of the collection or procedure shall be responsive to the health needs of this group or individual.

3.7.5.2. In cases of demented or mentally incompetent donors, a relative or legally authorized representative could sign the consent form on the donor's behalf. The donor must be informed regardless of their age, medical, or mental condition.

3.7.5.3. Biobanks shall consult with legally authorized representatives and implement communication strategies to enhance understanding of the consent terms.

3.7.6. Biobanks shall comply with legal requirements when including biospecimens and/or associated data of deceased individuals.

3.7.6.1. Biobanks shall request consent from potential participants before their death or from relatives or legally authorized representatives after the participants' decease. This can be defined in a clause of the initial consent.

3.7.6.2. DoH shall dictate the applicable consent and legal requirements for these situations.

3.7.6.3. The uses of biospecimens and data, collected before or after death, that fall outside the scope of the original consent will require approval by the IRB.

3.7.7. The recruitment of pediatric subjects shall be subject to the approval of parents or legal guardians.

3.7.7.1. Biobanks shall consider the participation of the pediatric subjects in the consent process according to their age, maturity, and agreement to participate in an informed assent.

3.7.7.2. In addition to the child's assent, parents or an appropriate legal representative must provide consent on behalf of the child. Biobanks shall re-contact donors once they reach the local legal age of maturity to seek consent, if possible. For this purpose, a procedure ensuring that accurate contact information is maintained shall be defined.

3.7.8. Biobanks shall develop policies and/or procedures for the return of results and Incidental findings, which shall be included in the informed consent.

3.7.8.1. A return of results policy shall be developed to establish criteria, level of clinical significance, responsive actions, and counseling services or strategies when donors agree to receive the results arisen from research and use of the biospecimens and associated data.

3.7.8.2. Biobanks must allocate resources for re-testing potentially actionable results and contend with the difficulty of drafting common criteria for actionable results that cannot be strictly dictated by law.

3.7.8.3. Biobanks shall have guidelines or procedures to manage incidental findings, considering the protection of whistleblowers and the steps taken to address reported issues promptly and appropriately. These documents must be approved by the IRB.

3.7.8.4. Donors shall state their preferences regarding the possibility of the return of results and incidental findings.

3.8. Customer's fundamental rights and safeguards

3.8.1. Customers must comply with all relevant Abu Dhabi, federal, and international laws and regulations governing the use of biological samples and data.

3.8.1.1. Customers shall ensure that the use of biospecimens and/or associated data aligns with the original donor's consent, ethical standards, and guidelines related to their research activities or clinical purposes. Mechanisms shall be put in place by the biobank to maintain consistency of the proposed uses with the informed consent and scope of services, when applicable.

3.8.1.2. Customers must adhere to the policies and procedures outlined by the biobank, including any specific guidelines for sample and data usage.

3.8.1.3. Customers shall comply with the biobank's policy or procedure regarding return of results.

3.8.2. Customers shall have access to biospecimens and associated data in accordance with biobank's policies, regulations, and specified terms of MTAs and DTAs.

3.8.2.1. Customers have the right to expect high-quality services, including accurate sample information, reliable data, and adherence to agreed-upon timelines.

3.8.2.2. The conditions to access biospecimens and associated data shall be determined in MTAs and DTAs, previously approved by DoH, for already collected biospecimens.

3.8.2.3. Biobanks shall establish user fees to access human biospecimens, data, and services, to cover the costs of collecting, annotating, storing, retrieving, and processing the delivered biospecimens.

3.8.2.4. Customers shall have access to biobank resources in an equitable manner, without discrimination or bias due to nationality, affiliation, research approach, among others.

3.8.2.5. Customers are responsible for implementing robust security measures to protect the samples and data they access, preventing unauthorized access or breaches.

3.8.3. Customers shall be transparent about their research goals, protocols, and findings. Report back to the biobank on the outcomes of their research shall be encouraged.

3.8.3.1. Customers shall obtain DoH's written approval prior to publishing their studies and research results derived from the use of biobank's resources, where DoH's acknowledgement shall be included in publications or presentations.

3.8.3.2. Profits derived from the commercial use shall be given back to the human population groups or specific population groups.

3.8.3.3. Customers are encouraged to maintain open and transparent communication with the biobank, mainly regarding any challenges, changes in project scope, or additional requirements.

3.8.4. Contribution to the biobank's sustainability shall be fostered by returning the unused biospecimens or portions of it.

3.8.4.1. The return of unused portions of biospecimens shall be stated in the MTAs/DTAs. Although it is not mandatory, it shall be encouraged for a mutual beneficial relationship.

3.8.5. A customer-centric fee structure shall be elaborated for private biobanks with for-profit purposes.

3.8.5.1. Private biobanks (for-profit) shall mitigate the risk of unjustified or sudden price changes, providing details of cost-associated services and processes to customers and donors.

3.8.5.2. Biobanks shall clearly communicate the fee structure to customers, including the costs related to sample processing, data management, storage, or other services.

3.8.5.3. Customers and biobanks shall adhere to contractual agreements that detail the agreed-upon fees, provisions that specify their duration, and conditions under which they may change or be reviewed.

3.8.5.4. Customers shall be notified of proposed fee changes in advance, to allow them to plan accordingly.

3.8.5.5.

3.9. Relationships with public and private stakeholders

3.9.1. Biobanks shall establish effective relationships with public and private stakeholders to ensure compliance with ethical standards.

3.9.1.1. All interactions with stakeholders shall be subject to the highest ethical standards related to biobanking activities. Measures to enhance commitment towards ethical standards shall be implemented.

3.9.1.2. The rights and privacy of stakeholders shall be respected regardless of their nature, which may refer to donors, researchers, authorities, non-profit organizations, among others.

3.9.1.3. Biobanks shall allocate resources for community engagement strategies, as detailed in 3.5, to incorporate communities' perspectives and values into biobanking activities.

3.9.1.4. Biobanks shall implement measures to protect the privacy of donors, to avoid misuse and discrimination from private stakeholders.

3.9.2. The interactions between biobanks and private and public stakeholders shall be governed by the principles of transparency, accountability, and accessibility.

3.9.2.1. Stakeholders shall be provided with clear and accurate information regarding the biobank, its purpose, scope, organizational structure, decision-making mechanisms, financial or funding sustainability, and activities.

3.9.2.2. Donors shall be informed about how their biospecimens, and associated data will be used for research or clinical purposes.

3.9.2.3. The biobank shall share their policies and procedures that include interaction with stakeholders, such as access and data sharing.

3.9.2.4. Decision-making processes shall be informed to stakeholders. A feedback mechanism shall be implemented, where stakeholders can express their concerns, questions, and comments.

3.9.2.5. The biobank shall define how all previous information would be available to private and public stakeholders, ensuring transparent communication (e.g.: publishing on a website).

3.9.3. Collaboration among biobanks and stakeholders shall be encouraged to ensure the sustainability of the biobank and to create a mutually beneficial relationship.

3.9.3.1. Research findings shall be communicated to stakeholders and the community after obtaining DoH's written approval.

3.9.3.2. Collaboration with healthcare facilities could facilitate biospecimens collection and the gathering of information across the health system.

3.9.3.3. Collaborations with other biobanks could harmonize practices, improve standards, and foster large-scale research.

3.9.3.4. Health authorities and government agencies could address national health priorities by collaborating with biobanks.

3.9.3.5. Since international collaborations uphold opportunities for quality exchange of resources, data, and expertise, these should be fostered by ensuring the protection and privacy of donors' information.

3.9.4. Biobanks shall define the terms for collaborations that include intellectual property rights.

3.9.4.1. All potential research outcomes with commercial purposes shall comply with federal and Abu Dhabi regulations related to intellectual property rights.

3.9.4.2. Licensing agreements shall be made to determine the ownership of the intellectual property rights and the management of them.

3.9.4.3. The negotiation process of the licensing terms shall be conducted in a transparent manner, ensuring the benefits can be equitably distributed.

3.9.4.4. Benefit sharing measures for the community and/or donors shall be considered and implemented.

3.9.4.5. The interests and privacy of all parties involved shall be considered in the negotiation of agreements.

3.9.5. Biobanks shall build and preserve public trust to encourage community participation when private stakeholders access biobank resources.

3.9.5.1. The potential benefits arising from collaborations shall be highlighted in open forums, educational programs, or other activities.

3.9.5.2. Privacy and rights shall be guaranteed by strict measures, which stakeholders shall respect and adhere to**.**

3.9.5.3. Any selling or usage of specimens by third parties post applicable research shall be adequately communicated to the donor, according to the donor's choice concerning communication.

3.9.5.4. Biobanks shall develop and implement policies for handling potential conflict of interests with the communities, where the steps to identify, disclose, and manage them are clear and transparent.

3.9.5.5. The biobanks shall plan strategies to mitigate conflicts of interest, such as establishing independent advisory panels, third-party monitoring, or regular external audits.

4. Exempted from Policy Scope

This policy does not apply to the collection, storage, distribution, or use of non-human biospecimen, such as the ones derived from animals, plants, microbials, among others. Human biospecimens that are conserved for a specific purpose within an IRB approved investigational research are excluded, as long as they are not used beyond their scope and after the previously determined amount of time.

5. Policy Scope of Implementation

This policy applies to the collection, storage, transportation, distribution, and use of human biological samples and associated data, as well as all stakeholders, healthcare providers, healthcare professionals, private entities involved, government entities, academic institutions, researchers, scientists, and individuals providing or using their biological materials and genomic data.

6. Policy Roles and Responsibilities

Stakeholder name	Stakeholder Key Role
DoH	Collaborate with experts to stay updated on legal and ethical developments and amend regulations accordingly. Inspect and ensure biobanks comply with the stated requirements and regulations, at annual and ad-hoc basis.
Biobank	Comply with all regulations and ethical principles governing biobank activities in Abu Dhabi in relation to their purpose and scope.
Customer	Comply with the agreements and internal regulations of biobanks.

7. Relevant Reference Documents

No.	Reference Date	Reference Name	Relation Explanation / Coding / Publication Links
1.	2020	Council of Ministers' Decision No (6) Year 2020 on Endorsement of the Regulations of Cord Blood and Stem Cells Store Centers.	https://mohap.gov.ae/app_content/legislations/php-law-en-97/mobile/index.html
2.	2020	NetCord-FACT International Standards for Cord Blood Collection, Banking, and Release for Administration	https://www.factweb.org/forms/store/ProductFormPublic/seventh-edition-netcord-fact-international-standards-for-cord-blood-collection-banking-and-release-for-administration-free-download
3.	2017	Common minimum technical standards and protocols for biobanks dedicated to cancer research.	https://publications.iarc.fr/Book-And-Report-Series/Iarc-Technical-Publications/Common-Minimum-Technical-Standards-And-Protocols-For-Biobanks-Dedicated-To-Cancer-Research-2017
4.	2004	Human Tissue Act 2004	https://www.legislation.gov.uk/ukpga/2004/30/schedule/3/crossheading/power-to-grant-licence
5.	2000	Code of practice for tissue banks.	https://www.clinsurgeryjournal.com/articles/ascr-aid1063.pdf
6.	2004	Directive 2004/23/EC - Setting standards for tissues and cells of the European Parliament and of the Council.	https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:102:0048:0058:en:PDF
7.	2023	Biobank Sweden's translation of the Biobank Act (2023:38)	https://biobanksverige.se/wp-content/uploads/The-Biobank-Act-2023-38.pdf
8.	2021	Human Biobank Management Act CH Amended Date: 2021-01-20, Ministry of Health and Welfare.	https://law.moj.gov.tw/Eng/LawClass/LawAll.aspx?PCode=L0020164

9.	2018	ISO 20387- 2018 Biotechnology — Biobanking — General requirements for biobanking.	https://www.iso.org/obp/ui/en/#iso:std:iso:20387:ed-1:v1:en
10.	2021	Biobanking of Human Biospecimens Lessons from 25 Years of Biobanking Experience Second Edition.	https://doi.org/10.1007/978-3-030-55901-4
11.	2016	Federal Decree-Law No. (5) of 2016 on the Regulation of Human Organs and Transplantation.	https://mohap.gov.ae/app_content/legislations/php-law-en-094a/mobile/index.html#p=1
12.	2022	DOH Standard in Stem cell Therapies and regenerative medicine	https://www.doh.gov.ae/en/resources/standards
13.	2019	Federal Law No. (7) of Year 2019 Concerning Medically Assisted Reproduction	https://mohap.gov.ae/app_content/legislations/php-law-en-96/mobile/index.html
14.	2023	Al Jalila foundation. Dubai.	https://www.aljalilafoundation.ae/what-we-do/research/biobank/
15.	2009	OECD Guidelines on Human Biobanks and Genetic Research Databases (HBGRDs).	https://web-archive.oecd.org/2012-06-14/112430-44054609.pdf
16.	2017	ICH E18 Guideline on genomic sampling and management of genomic data - Scientific guideline	https://www.ema.europa.eu/en/ich-e18-guideline-genomic-sampling-and-management-genomic-data-scientific-guideline
17.	2016	NCI Best Practices for Biospecimen Resources	https://biospecimens.cancer.gov/bestpractices/2016-NCIBestPractices.pdf

8. Appendix

Appendix 1. Priorities and goals regarding biobanking activities in Abu Dhabi.

The following priorities and goals are set by DoH for human biobanks operating in Abu Dhabi (**Figure 1**):

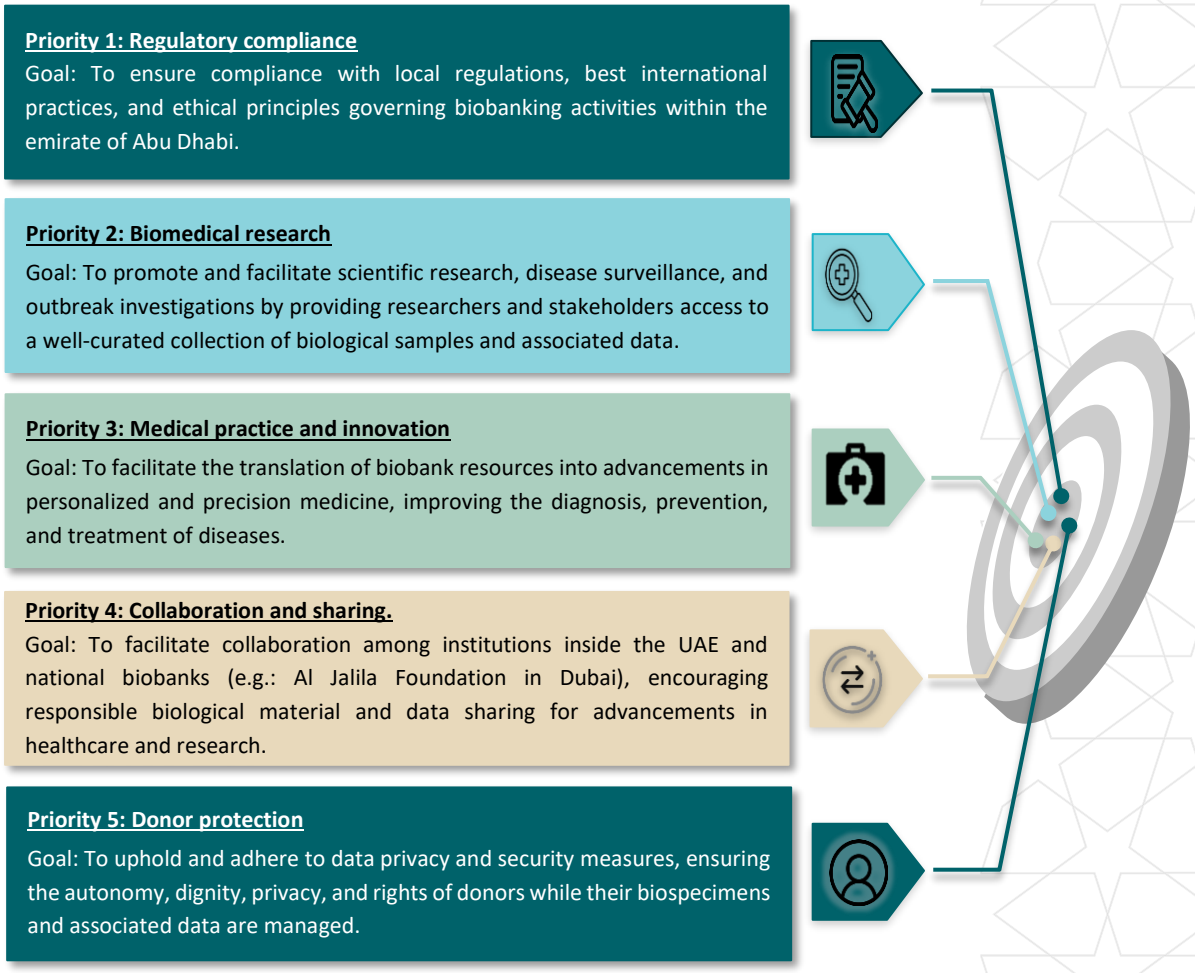


Figure 1. Priorities and goals regarding biobanking activities in Abu Dhabi.

Appendix 2. License for Biobank Facilities: Process for acquisition and facility's planning.

Human biobanks operating in Abu Dhabi shall apply for a license granted by DoH prior to starting their activities, this license shall be maintained and renewed as indicated by the authority. These licensing process steps are summarized in **Figure 2.**

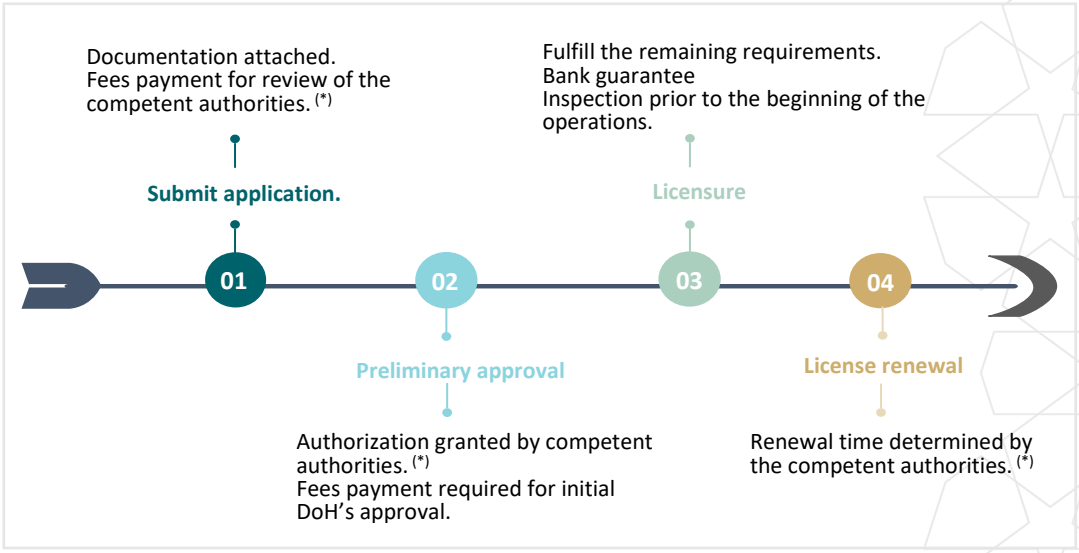


Figure 2. Licensing process for human biobanks in Abu Dhabi.

*Competent authorities comprise DoH and authorities listed in 3.2.1.3, depending on the biobank's purpose and scope.

The following information should be presented in the application submission (**Figure 2**: "Documentation attached"), as a minimum.

- Name of the biobank and address.
- Representative of the biobank, personal identification, and related information.
- Objectives of the biobank.
- Scope of application (biospecimens and data that will be handled).
- Organizational structure.
- Proposed employees and designated charges.
- Strategic plan for financing and sustainability of the biobank.
- Quality Management System.
- Biosafety and Biosecurity Manual.
- Internal regulation for the biobank operations.
- Internal regulation for the Independent Ethics Committee.
- Risk assessment.
- Accreditation plan.
- Scientific information, research and references that support the project.

Appendix 3. Accreditation systems for biobanks

One or more of the following accreditation systems must be attained by the biobank according to their established activities and the biospecimens handled within the facility. Specific accreditation systems for biobanks that store umbilical cord blood or stem cells are outlined below.

Table 1. Authorized Institutions for accreditation of biobanks in the emirate of Abu Dhabi

Institute's Name	Description
College of American Pathologist (CAP) – Biorepository Accreditation Program (*)	Organization of board-certified pathologists serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.
NETCORD -FACT (*)	The Foundation for the Accreditation of Cellular Therapy. Omaha, Nebraska - United State of America.
American Association of Blood Banks (AABB) (*)	AABB's Cellular Therapy Standards and Accreditation Program. AABB's mission is to develop standards for stem cell banking and other aspects of cellular therapies.
The Foundation for the Accreditation of Cellular Therapy (FACT) (*)	Non-profit corporation co-founded by the International Society for Cellular Therapy (ISCT) and the American Society of Blood and Marrow Transplantation (ASBMT) for the purposes of voluntary inspection and accreditation in the field of cellular therapy.
Joint Accreditation Committee ISCT-Europe & EBMT (JACIE) (*)	JACIE is Europe's only official accreditation body in the field of hematopoietic stem cell transplantation and cellular therapy. It promotes high-quality patient care and medical and laboratory practice through a profession-led, voluntary accreditation scheme.
ISO 20387- 2018	Biotechnology — Biobanking — General requirements for biobanking. Contains requirements designed to demonstrate the competence of a biobank's operation and the ability to provide biological material and associated data for research and development.
American Association of Tissue Banks (AATB)	The only accreditation program for tissue establishments, recognizing the highest commitment to the quality and safety of donated human tissue.

*: These accreditation systems are specifically required if stem cells, umbilical cord blood, and blood-forming cells are under the scope of the biobank. They are eligible but not mandatory for the remaining biospecimens and associated data, such as blood, cells, tissues, cellular products, and other fluids.

Appendix 4. Facility requirements for human biobanks in the emirate of Abu Dhabi.

The following figure (**Figure 3**) summarizes the central requirements that human biobanks operating in Abu Dhabi shall consider for their facilities.

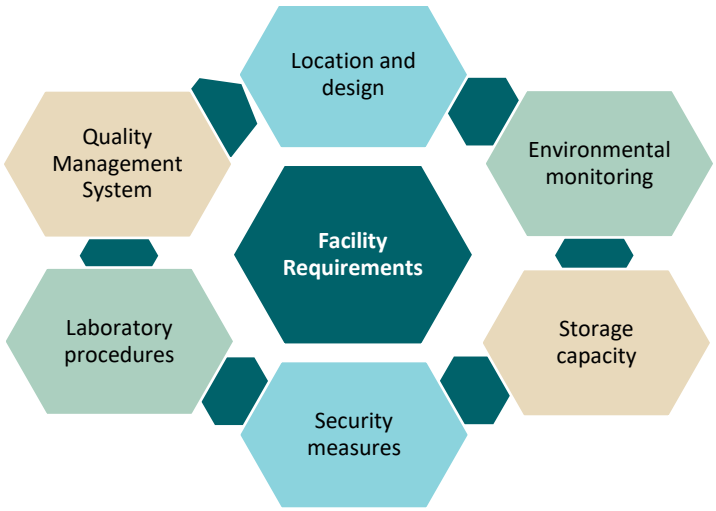


Figure 3. Facility requirements for human biobanks in the emirate of Abu Dhabi

Appendix 5. Ethical, legal, and social implications for human biobanks in the emirate of Abu Dhabi.

The following figure (**Figure 4**) summarizes ethical, legal, and social implications that shall be addresses by human biobanks operating in Abu Dhabi.

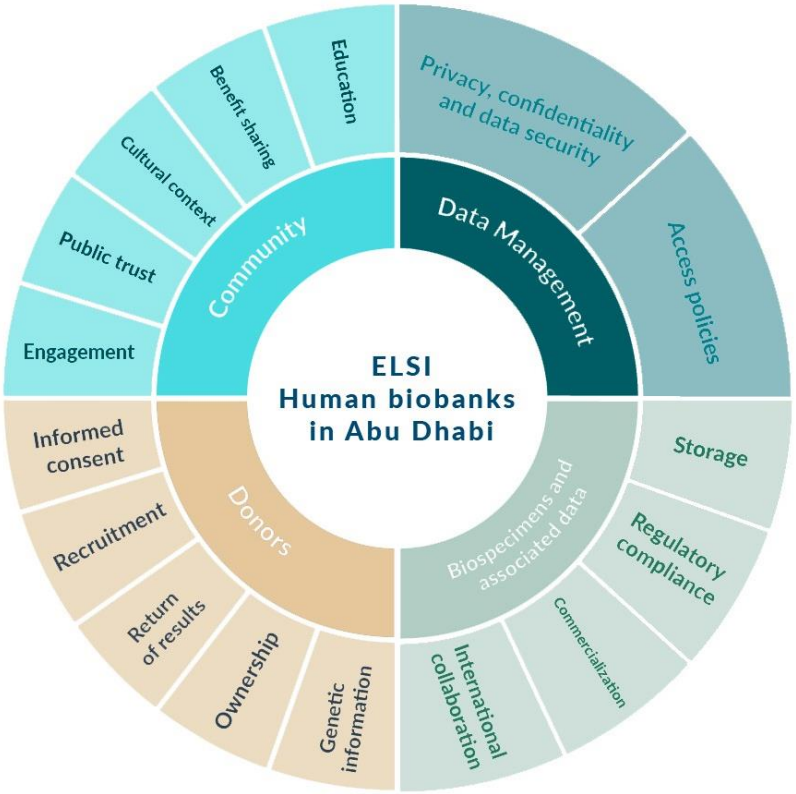


Figure 4. ELSI for human biobanks in Abu Dhabi.

Appendix 6. Organizations providing guidelines and standards for biobanking activities

Item	Name of the organizations	Relevant guidelines/ policies/standards	Websites
1.	Biobanking and Biomolecular resources Research Infrastructure-European Research Infrastructure Consortium (BBMRI-ERIC)	- Guidance on Ethical, Legal, and Societal Issues (ELSI) - Biobanking with Children – Resources and Good Practices - Ethics of AI Lab. - Guideline for Biobanks to comply with EU in vitro diagnostics regulation (2017).	www.bbmri-eric.eu
2.	Council of Europe (COE)	- Recommendation CM/ Rec(2016) 6 of the Committee of Ministers to member States on research on biological materials of human origin.	www.coe.int
3.	Council for International Organizations of Medical Sciences (CIOMS)	- International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002).	www.cioms.ch
4.	Global Alliance for Genomics and Health (GA4GH) Framework	- GA4GH Code of Ethics and Community Conduct (CECC). - Framework for responsible sharing of genomic and health-related data. - GA4GH vision: genomic and health-related data sharing in 2022.	https://www.ga4gh.org/
5.	International Society for Biological and Environmental Repositories (ISBER)	- ISBER Best practices: Recommendations for Repositories – 5th edition.	www.isber.org
6.	Organization for Economic Co-operation and Development (OECD)	- Guidelines on Human Biobanks and Genetic Research Databases (2009) - Best Practice Guidelines for Biological Resource Centers, OECD (2007). - Principles on Good Laboratory Practice (GLP).	www.oecd.org
7.	United Nations Educational, Scientific and Cultural Organization (UNESCO)	- International Declaration on Human Genetic Data (2003) - Universal Declaration on the Human Genome and Human Rights (1997) -	www.unesco.org
8.	National Cancer Institute (NCI) Biorepositories and Biospecimen Research Branch (BBRB)	- NCI Best Practices for Biospecimen Resources. (2016) - Genomic Data Commons (GDC).	www.biospecimens.cancer.gov
9.	World Medical Association (WMA)	- Human Biobanks and genetic Research Databases. (WMA Declaration of Taipei) - Declaration of Helsinki	www.wma.net
10.	World Health Organization (WHO)	- Guidelines on Human Cell, Tissue, and Organ Transplantation. - Ethical Guidelines for Health-related Research Involving Humans. - A call for global governance of biobanks. Bull World Health Organ. (2015).	https://www.who.int/
11.	European, Middle Eastern, and African Society for Bio preservation and Biobanking (ESBB)	- ESBB Guidelines. - Basic principles of biobanking: from biological samples to precision medicine for patients.	
12.	National Institutes of Health (NIH)	- NIH Genomic Data Sharing (GDS) Policy. - Guide for Human Biospecimen Storage and Tracking.	https://www.nih.gov
13.	International Society for Stem Cell Research (ISSCR)	- ISSCR Guidelines for Stem Cell Research and Clinical Translation. - Standards for Human Stem Cell Use in Research	https://www.isscr.org/
14.	International Organization for Standardization (ISO)	- ISO 20387:2018 – Biotechnology – Biobanking – General requirements for biobanking.	https://www.iso.org/home.html

		- ISO 15189:2022 – Medical laboratories – Requirements for quality and competence. - ISO/TC 276 – Biotechnology.	
15.	National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research	- The Belmont Report, ethical principles and guidelines.	https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html
16.	American Academy of Pediatrics (AAP)	- AAP guidelines. - Translational Research in Pediatrics: Tissue Sampling and Biobanking.	https://www.aap.org/
17.	Children's Oncology Group (COG)	- Guidelines for Pediatric Biobanking.	https://childrensoncologygroup.org/home
18.	International Rare Diseases Research Consortium (IRDiRC)	- IRDiRC Guidelines.	https://irdirc.org/
19.	American College of Medical Genetics and Genomics (ACMG)	- ACMG Standards and Guidelines. - ACMG Technical Standards for Clinical Genetics Laboratories.	https://www.acmg.net/
20.	The American College of Obstetricians and Gynecologists	- ACOG Committee Opinion No. 771: Umbilical Cord Blood Banking (2019).	https://www.acog.org/
21.	The Royal Collage of Pathologists of Australia (RCPA)	- Guideline: Subject: Biobanking.	https://www.rcpa.edu.au/
22.	Government of South Australia & South Australian Biobanking Working Group	- Guidance Document for Human Research Biobanks and Associated Data. Government of South Australia. (2018).	https://www.sahealth.sa.gov.au/