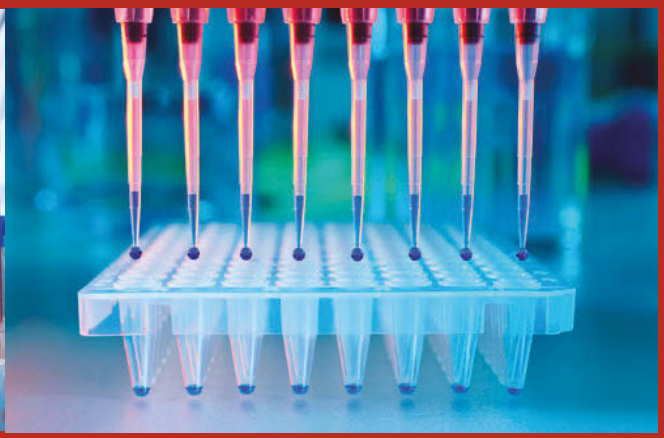
GUIDELINES FOR THE ESTABLISHMENT AND MANAGEMENT OF BIOBANK FOR HEALTH LABORATORY SYSTEM IN ETHIOPIA



ETHIOPIAN PUBLIC HEALTH INSTITUTE
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GUIDELINES FOR THE ESTABLISHMENT AND MANAGEMENT OF BIOBANK FOR HEALTH LABORATORY SYSTEM IN ETHIOPIA

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Addis Ababa, Ethiopia

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FOREWORD

Today, there is an increasing demand for biospecimens and the associated data for the implementation of laboratory quality assurance, various research projects and clinical purposes. Biospecimens collected, processed, and stored under optimal conditions at biobanks increasingly provide a crucial foundation for clinical and research purposes. The presence of biobanks in one country provides a source of information that opens up opportunities to learn more about the diagnosis, prevention, and treatment of diseases.

As part of their core function and routine activities, clinical and public health laboratories daily handle a vast amount of biospecimens and associated data through patient-based laboratory testing, surveillances and health-related researches. However, the specimens collected in different health facilities and research institutions have been stored under different environmental and safety conditions so that there is no standardized system for monitoring and management of biospecimens in the country. Because of the aforementioned reasons and facts, the establishment and administration of a biobank system for health laboratories in Ethiopia is required.

For the establishment and effective implementation of biobanking system and practices across the health laboratory system in Ethiopia, a guiding document is essential to assist in the standardization of processes, procedures and practices involved in the collection/receipt, analysis, storage, retrieval, and sharing of biospecimens and their associated data. This guideline has been enhanced with the latest scientific knowledge, best practices, and international recommendations for establishing and managing biobank to ensure full compliance with both national and international standards.

The establishment and management of biobanks will only be successful through dedicated support, collaboration, and concerted efforts of all stakeholders and partners. On its part, the Ethiopian Public Health is commited to lead and coordinate all efforts towards the seamless implementation of the guidelines and establishment of robust bio-banking system as an important resource for public health researches and laboratory quality assurance programs including evaluation of methods and technologies. Finally,I would like to thank all experts and organizations who have made significant contributions to the development of this important and timely guideline.

Mesay Hailu, PhD

Director General

Ethiopian Public Health Institute

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The Ethiopian Public Health Institute would like to acknowledge all the experts who have been instrumental in the preparation of these guidelines.

The institute would also like to recognizes the valuable contribution of all organizations and stakeholders to the development of this very important document. In this regard,its special thanks go to the Ministry of Health and its agencies, Regional Health Bureaus, Regional Public Health Institutes, Regional Reference Laboratories, development partner organizations, professional associations, the private sector, and academia.

CONTENTS

TERMS AND DEFINITIONS

- **Associated data:** The clinical, biomedical, pathological, epidemiological or other information related to individuals or patients who provided a sample.
- **Biobank:** are specialized organizations that collect, process, store, and distribute biological materials with the associated data obtained from humans and animals for future use in research.
- **Biological agent:** a microorganism, biological toxin, particle or otherwise infectious material, either naturally occurring or genetically modified, which may have the potential to cause infection, allergy, toxicity or otherwise create a hazard to humans, animals, or plants.
- **Biospecimen:** is a sample of material taken from humans, animals or plants that may be used for laboratory testing or for different research purpose.

1. INTRODUCTION

Biobank is a formal entity that collects and/or receives, processes, stores, and/or distributes specimens, as well as the data associated with them, for current or future use. Globally there is amassed a vast amount of specimen and associated data through patient-based laboratory testing and a wide range of health-related research, such as basic biomedical, epidemiologic surveys, clinical trials, population-based and disease-specific surveillance activities. To date, there is an increasing demand for biospecimens with associated clinical, biomedical, and public health data, which has resulted in the establishment of biobank in many countries.

Biobank is critical for supporting diagnostic development and health research in order to improve the health of the population. Biobanks are becoming a source of biospecimens and the associated data for further investigations and research projects. It plays an important role in facilitating the development and evaluation of diagnostic tests for diseases with epidemic potential and other global health priorities by providing access to biospecimens and data for quality assurance (QA) implementation including external quality assessment and quality control, diagnostic and test algorithm development, method evaluation, and researches. Biobanks have an important role in biological research in general and their impact on medical, societal, and economic issues.

To ensure the availability of high-quality biospecimens for future use, standardized methods for specimen collection/receipt, analysis, long-term storage, retrieval, and sharing must be developed. However, there is no standard national guidance to serve this purpose in Ethiopia. As a result, many institutions and investigators in the country relay on non-standardized systems for creating and managing their biospecimens repositories while several institutions lack the knowledge and practices of biobanking.

The collection, processing, storage and sharing of biospecimens as well as the associated data must be properly coordinated and organized. The establishment and implementation of an efficient, effective and sustainable biobanking system across the health laboratory system in Ethiopia needs a guiding document. The establishment and implementation of a biobank system should be based on international benchmarks and best practices that would address basic biospecimen management requirements including potential legal and ethical concerns, effective implementation and sustainability. This document is developed to guide the establishment and implementation of functional and sustainable biobank system and practices across health laboratory system in Ethiopia.

2. PURPOSE AND SCOPE

2.1. Purpose

The purpose of this document is to guide the establishment and effective implementation of biobanking system and practices across health laboratory system in Ethiopia. Guidelines captured in the document are aimed to assist in the standardization of processes, procedures and practices involved in the collection, receipt, analysis, storage, retrieval, and sharing of biospecimens and data associated with them.

2.2. Scope

This guideline intends to provide general guidance for the collection, transporting, processing, storage, sharing and disposal of biological materials across the health laboratory system in Ethiopia.

3. ORGANIZATION AND PERSONNEL

3.1. Governance

Biobank governance is the implementation and oversight of policies and procedures that govern its operations. The governance structure, design, and complexity of a biobank can vary greatly depending on its size, purpose, source of support, and institutional affiliation. The governance structure should be in accordance with applicable regulations, provide good stewardship of biobank specimen and data collections, including the adherence of Quality Management System (QMS), biosafety and biosecurity, and be part of a business plan that addresses long-term sustainability. A committee, board, or other group (governance oversight body) that serves to guide and advise the repository may provide governance oversight.

A governance framework and/or policy should be developed that includes a description of the composition and responsibilities of the governance oversight body. These policies and procedures should be comprehensive covering the full repository lifecycle and or processes. Transparency is the foundation of biobank stakeholder trust, which includes but is not limited to government agencies, donors, scientists, sponsors, and members of the public. Stakeholders should have access to information on repository governance, services offered, and fees assessed, if any, as well as the ethical, legal, and social foundations of the biobank's activities. The biobank governance plan should include the following elements:

- Clear line of governing arrangement that include technical and managerial personals, secured and designated infrastructure, monitoring and communication information systems.
- A transparent policy for accessing and use of specimens and data, including applicable requirements, limits, exclusions, and priorities.
- Provisions for safekeeping of the collection(s) including maintenance, security, and integrity of specimens and data.
- Business plan that contains essential steps for the continual functioning of the biobank including required infrastructures (staffing, facilities, equipment), services, specimen collection, processing, storage, quality control, distribution and governance framework.
- Determination of specimens to be collected and storage environment. The scientific purpose of the specimen collection should be defined prior to initiation to effectively plan for collection, processing, storage, disposal and downstream uses.
- Determination of customers served to ensure that specimens provided are collected and processed in a way that is likely to be beneficial to the public.

- A brief directive emphasizing that all biobank activities must be completed in accordance with International Organization for Standardization (ISO) 20387/2018, client, and regulatory bodies' requirements.
- Transparent and effective communication systems for internal and external customers to build and maintain trust among all the stakeholders.
- Determination of customers and services to be provided and put in place the appropriate requirements to ensure that high-quality specimens will be available.
- A road map that guides the biobank to implement all relevant and applicable legislation, regulations, and ethical norms.

3.2. Organizational Arrangement

The biobank should be directed by a person or persons with the competence and delegated responsibility for the services provided. A well-defined role and responsibilities should be defined for all managerial, technical and supportive staffs. For each role in the biobank, an organizational structure and clear job descriptions with lines of reporting should be documented. Personnel must be adequately trained to perform the tasks specified in their job description and must adhere to all repository policies and regulations.

Even though the organizational structure of the biobank may vary depending on its scope and objectives, the following operations must be taken into account.

- Leadership and managerial component that will oversee and manage the overall operations of the biobank to achieve the desired objective.
- Qualified and competent personnel should be assigned to ensure that all biobanks operations are in compliant with all applicable quality and/or ISO standards and regulations.
- Qualified and competent personnel should be assigned to ensure biosafety and biosecurity requirements are adequately implemented.
- The biobank should have adequate technical staffs with appropriate educational background and experience related to biological sample collection, processing, interpretation, storage and disposal.
- Technical procedures related to biospecimen management should be applied to ensure the integrity and reliability of biospecimens.
- There should be assigned person who manages required supplies and commodities for the continual operation of the biobank.

- A responsible team or person for data and information management should be represented within the biobank, as a safe data management and information system is essential.
- It is essential to have an equipment maintenance team or person with adequate skill and competency, such as biomedical and computer engineers, to handle biobank instruments in accordance with the manufacturer's instructions and prevent operations from being disrupted by equipment failure.
- It is critical for the biobank to consider a responsible body for legal and ethical issues in order to maintain privacy and confidentiality during the collection, storage, and use of biospecimens and associated data, as well as to adhere to and keep up to date on relevant international/national/ regional regulations, privacy regulations, and other local and community rules.
- The biobank should have a business plan for identifying the target customer(s) or business stakeholder needs, the infrastructures and services to serve the identified customer(s) and business needs, establishes proactive review of the biobank's ability to meet the needs, and a robust marketing plan to advertise the facilities and services within and outside the organization.
- It is important to have a biobank steering committee that will advise on scientific strategy and current developments and oversee the biosafety and biosecurity programs, as well as the biobank's collaboration with other biobanks.
- Biobank should establish transparent and effective means of communication system with partners, stakeholders, the community, and the population about current progress and activities performed.

4. FACILITY AND EQUIPMENT

An effective biobank operation requires a safe and functional working environment and equipment to ensure the safe-keeping of samples stored. The complexity and types of infrastructure and equipment depends on the type of material being stored, storage requirement, the projected retention periods, growth of the specimen numbers, and the use of the materials.

The storage system is fundamental to maintain high sample quality. The data and databases related to biospecimen annotation, quality, storage location, and use are important attributes of biobank infrastructure.

4.1. Facility for Biobank

- A biobank needs a designated area with particular design and elements to ensure the safekeeping of the material stored, support the equipment employed, and provide a safe and effective working environment.
- The design should include sufficient space to accommodate the material planned for initial, future and backup storage. The space should be adequate to allow for the safe mobility of persons, equipment, and samples as per the international best practices and standards.
- An area should be designated for biospecimen collection, receiving, tracking and shipping, immediate and interim processing, preparing and processing, packaging and labeling, reviewing, registration, controlling, storing and retrieving as well as for office activities.
- The biobank should have emergency exit and dedicative assembly point.
- There should be appropriate risk assessment and mitigation plan for responding to a wide variety of emergency situations related to biobank infrastructure.

4.2. Heating, Ventilation and Air Conditioning

4.2.1. Temperature and Humidity

- An ambient temperature and humidity should be monitored and maintained within defined limits.
- Adequate heating and air conditioning should be provided as needed.

4.2.2. Airflow and Circulation

- Sufficient space for air circulation should be provided to prevent excess moisture and condensation.

- Adequate ventilation and monitoring is required in biobanks where liquid nitrogen and dry ice are used to maintain adequate oxygen levels.
- The ventilation system should ensure that personnel are protected and that standards for the removal of specific harmful vapors are met.
- Appropriate monitoring devices (*e.g.,* oxygen and/or CO_2 monitors), preferably with auditory and visual alarms, should be combined with a dedicated exhaust system and installed within areas where low oxygen level might develop or harmful gases might accumulate.

4.3. Lighting

The biobank should have appropriate and sufficient lighting to provide a safe working environment and to allow materials to be accurately stored and retrieved. The lighting levels required will depend on the particular spatial environment where the samples are stored, the type of activity that is being performed, the volume and specimen type, and the labeling/ identification system employed.

In case of power loss, it is critical that emergency lighting with battery backup support and tied to backup power supply be available. It is beneficial to use small nightlights that plug into outlets that have a battery component for low-level illumination. Biobanks should also have portable lighting on hand to use as focused light sources, as needed. Emergency lighting should be tested on a regular basis and batteries checked on an annual basis and replaced as needed as a part of the overall safety and preventive maintenance plans.

4.4. Flooring

- Flooring surfaces should be appropriate for the equipment and refrigerants. It should be easy to clean and facilitate the movement of equipment when circumstances warrant.
- Special consideration should be given to the flooring where liquid nitrogen is used to avoid any hazard posed by it.
- Biobanks should consider providing anti-fatigue mats for staff in areas where personnel stand for prolonged periods of time without compromising the biosafety precautions.

4.5. Backup Power

- Automatic generator and/or uninterrupted power supply (UPS) should be available to maintain a continuous supply of electric power connected to biobank equipment and systems when utility power is not working.

- Functionality testing has to be conducted in a regular time of intervals to ensure their proper backup capabilities. The power generator system should be included in a frequent preventative maintenance plan.
- An attached alarm system (SMS, email, phone call, etc.) should be in place to manage the emergency power outage response as required.

4.6. Security and Access

- The biobank facility shall be equipped with restricted access control system to ensure bio specimens and data privacy as well as protection.
- The system has to prevent unauthorized access to the facility which should be only limited to biobank staff. Freezers should be locked at all times, and a record of access to samples and data has to be controlled. Access to the laboratory information management system should be password protected and activities in the system have to traceable to the individual performing a task to uphold confidentiality.
- The biobank facility should be under 24/7 Closed-circuit television (CCTV) surveillance.
- There should also security guards on a daily basis to safeguard the premises and report alarms as well as prevent physical intrusion of unauthorized individuals.
- The biobank should have a policy for handling visitors. Visitors to the biobank should sign a visitors' register followed by induction and are always accompanied by a staff member.

4.7. Fire Prevention System

- The biobank should have fire detection and prevention plan and appointed a team with the necessarily training and competency to safeguard the facility from preventative fires.
- The facility should be fitted with smoke detectors equipped with audible and visible alarms. Emergency break glass units to disconnect the electronic access control security system in the event of fire to allow staff to swiftly evacuate the building.
- Based on specific risk assessment, the nature of equipment and stored materials, appropriate fire extinguishing/suppression systems should be installed.
- The fire prevention system for the facility should undergo preventative maintenance, regular inspection and repairs of all electronic systems, equipment, electric works and cables as well as the proper storage of flammable liquids.

4.8. Emergency Preparedness and Response

The biobank should have an emergency preparedness and management plan to handle disasters that are natural (earth quick, flooding etc.) or man-made (war, terrorism etc.) that may threaten or cause death, injury or disease, damage to property, infrastructure or the environment. The plan should be verified through planned and unplanned drills where real life scenarios are simulated.

4.9. Equipment and Materials

The biobank should have functional equipment and materials used to collect, transport and store specimens at the appropriate temperature for the desired period.

4.9.1. Biospecimens Storage Equipment

- The biobank should have appropriate specimen storage capacities and equipment based on the type of sample and its requirements.
- Storage equipment should be accommodative for a variety of samples requiring short-term and long-term storage conditions.
- Equipment selections should take into consideration staffing requirements, quality issues, available resources and equipment support and maintenance requirements.
- The storage condition can be ultra-low-temperature (or low temperature) storage systems or ambient temperature storage systems.
- The biobank can use nitrogen freezers for a temperature below -80 °C, deep freezers for a temperature between 0 up to -80 °C and refrigerators (2-8 °C) for a temporary storage.

4.9.2. Backup Storage Capacity

The biobank should have adequate backup capacity for low temperature units to handle possible equipment failure.

4.9.3. Equipment Management

- A system for preventative and curative maintenance and repair of storage equipment, supporting systems and facilities should be in place.
- Equipment maintenance should be performed at regular and established intervals as per manufacturer's recommendation.
- Equipment exposed to infectious (or potentially infectious) materials should be properly disinfected and decontaminated by appropriate disinfectant.

- Calibration should be done for all equipment and device by certified and competent service providers per the manufacturer's recommendations.
- The proper performance of all equipment should be verified or qualified prior to use or following repairs that affect the instrument's measuring capabilities.

5. BIOSPECIMENS COLLECTION, TRANSPORTATION, AND PROCESSING

Biospecimens collection, transportation and processing must adhere to and follow procedures appropriate for the type of biospecimen being collected and its intended uses. It must be handled in accordance with the applicable biosafety guidelines. Close collaboration is needed among researchers, biobankers, patient advocacy groups, and the biotech and pharmaceutical industries to have proper biospecimen.

5.1. Biospecimens Collection and/or Reception

- All participants should be consented and aware before the commencement of biospecimen reception and/or collection.
- The biobank should receive quality assured biospecimens based on the established criteria. The leftover biospecimen collected for routine laboratory tests; may be reserved for biobank activity if the specimen type, volume, quality and other factors are fulfilled.
- Biospecimen should be collected considering factors such as age, gender, date of collection and other relevant factors.
- Multiple aliquots should be made and stored separately to minimize the risk of compromised sample integrity or freeze/thaw events.
- The time, temperature, and the person handling the sample should be documented /recorded every time the specimen is manipulated.
- All incoming and collected biospecimen to the biobank should be inspected based on the acceptance and rejection protocols.

5.2. Labeling

- Each biospecimen should have a unique identifier or combination of identifiers that are firmly affixed to the container, clearly and legibly marked, and able to cope up various storage conditions.
- Labels should strictly follow the protocol requirements and if these are not defined better to recommend to include the date of collection, time of collection, collector's initials, and test and/or protocol reference, participant ID, visit date and time. The information in the ID and the label must comply with applicable privacy policy.
- Labeled information on the specimen container and the log sheet and/or transmittal papers has to be verified to ensure the traceability.

5.3. Biospecimens Transportation

- Packaging and transportation of biospecimens must conform to the stringent applicable national and international guidance including International Air Transport Association/United Nation dangerous goods regulations for both in country and out of country transportations.
- International biospecimen transportation should consider signed Material Transfer Agreements.
- All personnel involved in packaging and transportation should be trained and certified.
- The facility should use best practices to protect biospecimens from factors that could influence specimen integrity (i.e., temperature, humidity, light, structural quality, and spill containment) and to provide protection to workers, individuals involved in the transportation of the biospecimens, and the environment.
- Every biospecimen collection, receiving and transferring or any service disruptions as well as accidental activity should be cautiously tracked and monitored.
- Biospecimen shipping should consider the shipping time, distance, climate, season, transportation method, regulations and type of biospecimen.
- All incoming and collected biospecimen to the biobank should be inspected based on the acceptance and rejection protocols.

5.4. Biospecimens Processing

- The biospecimen should be managed and accessed properly, detailed descriptions of supplies, equipment, methods, and processing for division of a biospecimen into multiple aliquots must be stated and managed properly.
- Maintaining biospecimen data in a safe and secure manner, shielding temperature-sensitive biospecimen, and successfully tracking biospecimen samples throughout their lifecycles.

6. BIOSPECIMEN STORAGE, RETRIEVAL, AND DISPOSAL

6.1. Biospecimen Storage

Biospecimen should be handled and stored according to procedures and protocols specific to the biospecimen type, the biomolecules, and its intended use.

- Biospecimen should be stored in functional, secure and calibrated storage equipment with limited access.
- Biospecimen storage condition and location should be documented appropriately.
- Biospecimen containing pathogens should be stored with great care and dedicated areas.
- The biobank should have a system to keep track of critical activities including sample thaws, reception and/or processing delays, sample destruction, processing, sample transfer inside the biobank, specimen distribution and return.
- A system should be established for the use of a unique identifier for equipment (freezer, refrigerator, storage cabinet, etc.) and for shelves, racks, boxes, as well as each location within the storage container.
- The biobank should establish and implement an electronic or paper-based biospecimen archiving system.

6.2. Biospecimen Storage Conditions

Standardized protocols should be applied consistently in storing biospecimens to ensure specimen integrity.

- Biobank storage conditions should comply with facility requirements and environmental conditions. Biospecimen should be stored under stabilized conditions to meet the requirements of potential future use.
- In selecting the biospecimen storage temperature, it is essential to consider the type of biospecimen, the intended period of storage, the frequency of use of biospecimens, the biomolecules and analyses of interest, the intended purpose of the biospecimen, whether the goals include preserving viable cells, the humidity level, the light intensity in the facilities, access to a continuous power supply, and backup systems.
- For short-term storage, refrigeration or freezing is preferable for biospecimens, while long-term storage requires ultra-low temperature or cryogenic storage.
- Retention time should be defined and practiced based on biospecimen type, nature and the intended use.

6.2.1. Lyophilization

Lyophilization /freeze-drying/ is an alternative method for the long-term storage of biospecimens.

- Lyophilization should be done according to the manufacture's instruction.
- The lyophilized material should be stored in sealed vacuum ampoules throughout the entire freeze–drying process.
- Lyophilization is not recommended for all cell types (i.e., some eukaryotic cells do not tolerate lyophilization).

6.2.2. Cryopreservation and Liquid nitrogen storage (LN2)

Cryopreservation is a process that preserves organelles, cells, tissues, or any other biological specimen constructs by cooling them to very low temperatures. It may damage cells and tissue by thermal stress, dehydration, and formation of water crystals. Liquid nitrogen (LN2) is an effective long-term storage platform, suitable for bio-banking facilities with thousands of stored samples, while -80^{o}C freezers support small and medium-sized biobank facilities. Cryopreservation is the most widely used method for the long-term storage of cells and cellular products, but has disadvantages such as high costs of equipment and reagents and need of a constant supply.

- Cryopreservation is the recommended standard for preservation of human biological samples for a wide range of research applications.
- Osmotic and dehydration injuries can cause harm when cryoprotective additives and vitrification treatments are exposed to and removed.
- To reduce the number of times a sample is thawed, frozen, or vitrified before use, it is crucial to choose aliquot sizes that are suitable for the specimens' planned uses.

6.2.3. Fixation and Preservation

- Formalin or alcohol fixation and paraffin embedding is the best method for morphological analysis, morphology-related methods, and immunohistochemistry.
- The biobank should use preservatives for biospecimens as an alternative method when adequate freezing procedures and storage facilities are not available.

6.3. Retrieval of Specimens from Storage

Samples should be retrieved from storage according to biospecimen resource procedures that safeguard sample quality. Retrieval of biospecimen for shipment or analysis requires strict

adherence to protocols for proper specimen inventory and tracking, as well as adherence to established safety standards in working with freezers and other storage equipment.

- Biobank should establish a system for biological material and associated data retrieval.
- An inventory for biospecimen and its associated data should be updated regularly upon storage and retrieval.

6.4. Disposal

A decision to dispose biospecimens and in biobank's storage may be made as a result of variety of circumstances such as retention time, equipment failure, samples that have undergone maximum freeze-thaw cycles and samples with spoiled contents, etc. The biobank should document and implement a procedure for disposing of biospecimens and its associated data in accordance with applicable national and international biosafety & biosecurity rules and regulations, institutional policies and guidelines.

7. QUALITY MANAGEMENT SYSTEM

The QMS for biobanks should be established, documented, implemented and maintained to comply with ISO 20387:2018 and other relevant standards.

7.1. Personnel Requirements

- There should be a system for reporting, documentation, and follow-up of any deviation, incident, or failure and all personnel should be trained and encouraged to report deviations as learning opportunities supporting quality improvement.
- Training and competency assessment programs should be established and implemented to ensure competent staffs are always available.
- Employees must undergo proper training in order to gain essential competence, and all training and competency-related documentation must be documented in the personnel profile.
- Responsible personnel for quality management implementation should be assigned to ensure biobank operations comply with quality standards.

7.2. Equipment and Supply Management

- The biobank should have system for the selection, procurement, installation, handling, transport, storage, use, maintenance, and decommissioning of equipment, in order to ensure proper functioning and to prevent contamination or deterioration.
- There should be a system for the selection, procurement, reception, storage, acceptance testing and inventory management of reagents and consumables.

7.3. Document and Record

- The biobank should have key quality documents including quality manual, guide line, different standard operating procedures (SOPs), job aids and formats.
- The quality manual should reference all the procedures required to ensure that QA objectives are fulfilled.
- There should be a document control system.
- Records and documents in the biobank should be kept in a secure/safe condition.
- Retention time for records should be established and maintained accordingly.

7.4. Internal Audit

- The biobank should conduct internal audit regularly to monitor the overall operations in the biobank process.

7.5. Quality Control

The biobanks should implement a quality control (QC) system based on the type of bio-specimens. But many of the QC processes are generic across all types of biobanks and they concern the four "pillars" or responsibilities of all collections which are:

- Each Biobank should establish, document and implement QC procedures throughout the biobank process.
- QC activities should be performed at planned intervals.
- Biobank should have appropriate QC materials (e.g. internal control material).
- QC material should be periodically examined to assess quality characteristics of the biological material - including stability, performance of processing methods and accuracy / precision of QC procedures.
- Biobanks should retain documented information of QC activities and results.
- QC results should be periodically analyzed for trends and used as input for the continuous improvement process.

8. BIOSAFETY AND BIOSECURITY

Biosafety and biosecurity activities are fundamental to protect employees, the community, and the environment from exposure or release of pathogenic biological agents. All biospecimens should be treated as though it is infectious and the biobank should adhere to the key biosafety/biosecurity principles.

8.1. Biosafety

- Biospecimens should be handled according to universal safety precautions.
- The biobank should adhere to the national biosafety policy, manual, and procedures.
- All biobanks that handle biospecimens should operate under the applicable standard.
- The biobank should assign responsible personnel to manage biosafety activities.
- The biobank should have a system for biosafety program audit and inspection.

8.2. Risk Assessment

The biobank is handling biohazardous specimens and preservative materials (CO_2, liquid nitrogen, dry ice, etc.) that are associated with various types of risks. Thus, the biobank should have risk management system and should conduct risk assessment regularly.

- The assessment should identify and prioritize assets (e.g. material, equipment, physical resource inventory; chemical, biological and radiological hazards), identify and define threats and vulnerabilities; determine risk levels, mitigation strategies; and assign and document potential events to risk levels.
- The risk assessment findings provide information on the selection of appropriate mitigation plan, including the application of biosafety levels and good microbiological practices, safety equipment, and facility safeguards that can help prevent hazards.
- The biobank should have a system for the control of common hazards through the application of:
    - Material safety data sheets (MSDS)
    - Chemical hygiene plan
    - Fire safety program
    - Radiological safety plan
    - Personal protective equipment specific for biospecimens and preservative materials (CO_2, liquid nitrogen, dry ice, etc.)

8.3. Decontamination and Spill management

The biobank should have a system for decontamination and spill management. Decontamination management should be based on the type of hazard. There should be an effective and efficient control mechanism of spills based on the type of spill occurred in the biobank.

8.4. Biosecurity

Biosecurity refers to the principles, technologies and practices that are implemented to secure pathogens, toxins and sensitive information from unauthorized access, loss, theft, misuse, diversion or intentional release. The biobank should develop and implement a biosecurity plan that safeguards the biospecimens. The plan should also include physical security, inventory management, and information system control.

8.4.1. Biobank Security

- Management and control of physical security should be based on a comprehensive risk assessment. Biobank entrances should have lockable doors that should not prevent exit in an emergency.
- Biobank access should be restricted to authorized personnel.
- The threat of theft and tampering with biospecimens especially for high consequence biological materials (agents, toxins, samples, and tissues) and sensitive information should be assessed, and appropriate steps should be taken to prevent these acts from happening.
- All personnel should be readily identifiable to guard from unauthorized access and workers should be provided with ready access to telephones, panic buttons or other emergency alert devices.
- Access to confidential information should be controlled (e.g. access codes). It is recommended for the biobank to be under closed-circuit television (CCTV) surveillance system.

8.4.2. Biospecimens Inventory

- The biobank should have inventory system for biospecimens and the associated data.
- The biobank should have a system for storage, indexing, access, control and inventory of biospecimens.
- The biobank should have a regular inventory of biospecimens.

8.4.3. Emergency and Incident Response

Biobank security considerations should be incorporated into incident and emergency response plans, investigation of incidents and implementation of corrective actions. The following need to be considered where there are higher risks of an incident or exposure to biological agents.

- A biobank should develop and implement a written emergency preparedness response plan.
- Planning for and sourcing of post-exposure prophylaxis and therapeutics should be available.
- The plan should be reviewed periodically and drills or simulation exercises should be conducted regularly to test and evaluate the effectiveness of the plan.

8.5. Waste Management

General precautionary waste disposal measures for hazardous waste should be followed, including but not limited to:

- Onsite waste handling and storage from biobank center should be in accordance with Waste Management National Guideline.
- All discarded biospecimens and contaminated waste should be made biologically safe before being taken from the laboratory facility.
- Transport of waste that has not been treated can be allowed, provided that the material is packaged and transported in a manner which considers hazardous waste statutory and regulatory requirements.
- Waste generated in a biobank area should be segregated into different categories, based on their potential hazard and disposal route (e.g. hazardous waste, non-hazardous waste) by the person who produces each waste item.

9. DATA MANAGEMENT

Appropriate data management of biospecimens is crucial to the overall usefulness of the biospecimen resource. Individual user relies on banked biospecimens for a wide variety of purposes, using different platforms and technologies. The biobank should be equipped with an electronic inventory system for the management and accounting of biological samples and their data. The physical storage of samples and their associated data should be configured and traceable on the password protected system, to ensure biomaterials and data privacy and protection. The biobank laboratory information management system (LIMS) enables tracking of sample usage, movement within the repository, retrieval and dissemination to clients, sample return from clients, and data search and query. To safeguard biobank data:-

- The biobank should have a system for unique identification of each sample. All activities of staff on the system should be traceable to an individual.
- An audit trail and periodic biobank inventory should be conducted. Data in the system should be frequently backed-up to protect against data loss.
- The biobank informatics infrastructure should be in place the overall data management operations of the biobank.

9.1. Data Collection

- Data associated with a biospecimen should be collected in accordance with applicable procedures and research protocols. Biospecimen resources should be collected and stored following applicable informed consent.
- All biospecimen associated data that include demographic data, sample type, size, collection time and date, clinical signs and symptoms and test results should be collected.

9.2. Data Tracking and Inventory System

9.2.1. Data Tracking

- Effective data tracking systems should be applied to track a biospecimen associated data in a regular interval.
- Specimen location should uniquely identify a location of each biological specimen in the biobank.
- Each location combination (e.g., freezer, rack, box, row, and column) should uniquely identify a location in the biobank. To validate specimen location, a randomly generated specimen number/list or other appropriate randomized system should be checked on a

subset of the samples on a regularly scheduled basis.

9.2.2. Data Inventory System

- The inventory system should track specimen type; vial or container type; volume or size; date and time of specimen collection, receipt and/or processing; processing method; storage temperature; preservatives, specimen location, available storage space, and any other characteristics needed.
- The inventory system should include a full audit trail of changes made to the database. This includes recording changes to both specimen data and system metadata.
- The audit trail should include but not be limited to: the original data; the changed data; who made the changes; how the change was made, date and time of change, and if possible, why the changes were made.
- This audit trail should be automatically recorded and available for read-only access.
- Record changes should not obscure previously recorded information in the audit trail.
- The inventory system must have the ability to produce reports.
- The inventory system should have the ability to save reports for future execution.

9.2.3. Data Security

- The biobank should establish and implement a system for safeguarding biospecimens and its associated data.
- Access to the computerized inventory system should be tightly controlled.
- Security roles with defined privilege levels should be assigned to individual users of the system.
- The system should provide a mechanism to log off users after a specified period of time when the system is idle.
- All database access attempts should be logged with the date and time of login and logout.

9.2.4. Data Quality, Validation and Backup

- A periodic audit of the database should be performed to ensure the quality of data.
- There should be a data validation system in the biobank to ensure accuracy of the system.
- The biobank should have a data backup system on secure remote servers at regular intervals to prevent data loss.
- Data backups should be validated on a regular basis to ensure the data can be accurately recovered.
- Data should be electronically convertible into formats that can easily be shared among collaborating institutions, where possible and appropriate. The inventory management

system should enforce all data integrity, security and audit trail requirements for external access.

9.2.5. Data Sharing and Communication

- An appropriate, ethical and accountable governance system is a key to ensure data and biological samples are shared in a trustworthy manner.
- The biobank should develop and implement a system for biospecimen and associated data sharing and communication. Transparent and effective lines of communication should be established among stakeholders.
- Biospecimens and associated data sharing should follow the available institutional policy and guidance.

10. LEGAL AND ETHICAL CONSIDERATIONS

Consideration of issues related to legal, ethical and governance is crucial in the establishment and management of biobanks. Key ethical issues include respecting the autonomy of human subjects, protecting human research participants from breaches of privacy and confidentiality, and minimizing individual and group harms. Standard practice dictates that consent or waiver of consent is required for the collection, storage, and future use of data/ biospecimens entered into an institutional biobank as granted by an independent Institutional Review Board (IRB) or the National Ethics Committee Studies that involve unlinked/anonymized biospecimens requires no initial review or determination by an IRB.

The collection, storage, dissemination, and access and use of biospecimens and associated data should be guided by the set of the national and/or institutional legal mandate and relevant policy frameworks to ensure that biospecimens and data are used in scientifically meritorious researches and establishing biospecimen resource governance. Biospecimens and associated data used for unintended purposes should lead to appropriate administrative and/or legal action in accordance with the national and/or institutional framework.

10.1. Biospecimen and Data Retention

Transparent policies governing the retention of biospecimens and data should be established and documented. In addition to the biospecimen and associated data retention policy such as usage agreements and material transfer agreements should specify and include information describing the retention. As biospecimen resources are precious, permanent or long-term retention is generally preferred. However, its governance should be implemented based on national and institutional policies, guidelines and procedures. Storage space, quality of biospecimen and data including foreseeable research utilities are also important considerations in the management and retention of biospecimen and associated data.

10.1. Conflicts of Interest

Biobanks are the sole property of the specific institutions they belong to. An institution should have written guidance or SOPs for the management of conflict of interest among project PIs, home institutes, funders and other partners with regard to transfer and ownership of biospecimen and associated data.

Biospecimen resources should implement transparent policies for maintaining the confidentiality and security of the biospecimens and associated participant data. Protecting the privacy of individuals who contribute biospecimens and on maintaining the confidentiality of

associated clinical data and information is of a high priority for biobanks. Timely and policy guided access to specimens and data is also crucial to foster activities.

10.2. Intellectual Property

Inventions or knowledge generated from research using annotated biospecimens may have commercial value and should be regulated by a separate arrangement between the owner of the biobank and the investigators.

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