



The Mycetoma Research Center
University of Khartoum
WHO Collaborating Center
on Mycetoma & Skin NTDs

The Mycetoma Research Center Biobank Sample Ownership and Utility Policies & Standard Operational Procedures

The Mycetoma Research Center Biobank

Sample Ownership and Utility Policies & Standard Operational Procedures

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Date: May 04, 2023



Background



The Mycetoma Research Center Biobank aims to responsibly collect, store, and share biological samples for mycetoma-related research.

This policy clearly defines ownership rights, ethical use, and equitable access, ensuring the biobank operates transparently and maintains high standards of integrity, scientific value, and respect for donor rights.





The Policy Objective



Ethical Sample Collection

Ensuring that all samples are collected with informed consent, emphasising the importance of privacy, confidentiality, and respect for participants' rights.



The Policy Objective



Clear Ownership Policies

Defining ownership rights, particularly regarding donor rights, the institution role, and the rights of researchers accessing the samples.



The Policy Objective



Fair and Transparent Sample Access

Establishing guidelines for internal and external researchers to access biobank samples while maintaining scientific integrity.



Equitable Benefit Sharing

The Policy Objective



Ensuring that research findings, particularly any commercial benefits or discoveries, are shared in a manner that benefits the wider community, especially the local population affected by mycetoma.



The Police Objective



Compliance with Regulations

Adhering to international and national legal frameworks, including human research ethics, intellectual property laws, and bioethics standards.



**SOP 1:
Sample Collection, Consent,
and Ownership**

Objective

To ensure that all biological samples are collected ethically and with informed consent while clarifying ownership of the samples.



**SOP 1:
Sample Collection, Consent,
and Ownership**

Sample Collection Procedures

Collect samples following approved protocols, adhering to Good Clinical Practice (GCP) and Good Medical Laboratory Practice (GMLP).

Ensure that participants fully understand the research purpose and that participation is voluntary, without coercion.

Clearly explain the potential use of samples, including future research studies and any potential commercialisation.



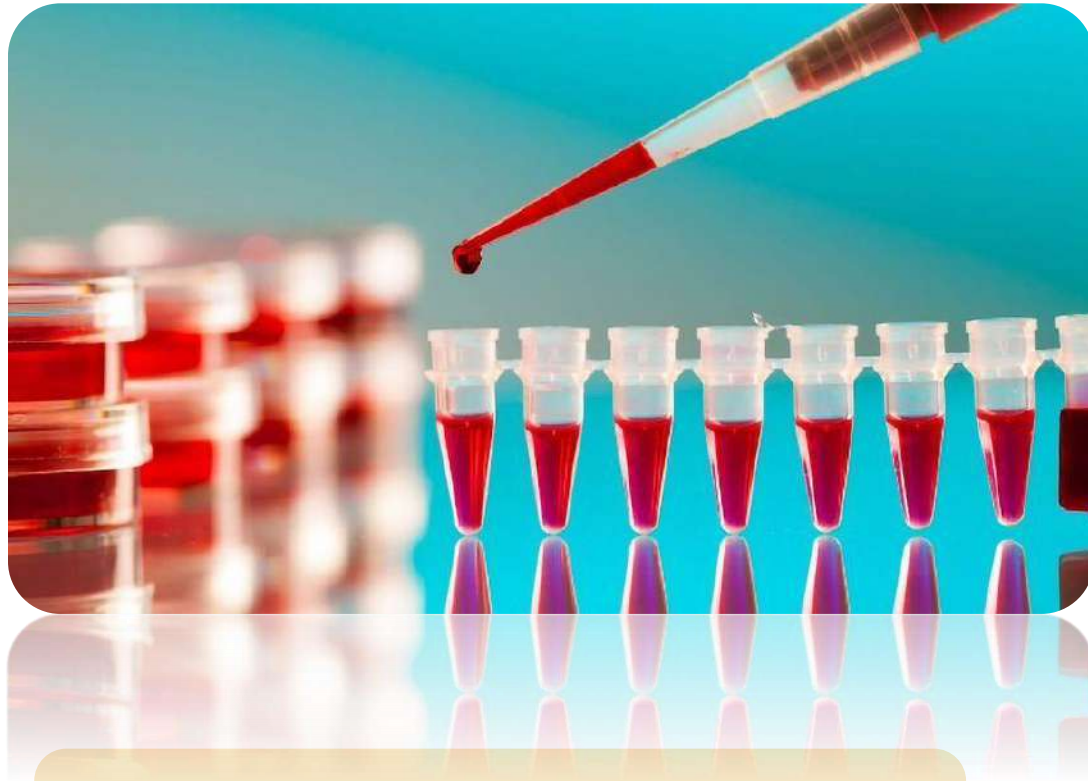
**SOP 1:
Sample Collection, Consent, and
Ownership**

Informed Consent

Obtain written informed consent from all participants before sample collection.

Provide participants with information about sample ownership, potential future use, and their rights to withdraw consent at any time without consequences.

Retain consent forms securely, with unique identification codes assigned to each donor to ensure confidentiality.



**SOP 1:
Sample Collection, Consent, and Ownership**

Ownership

Biological samples remain the property of the Mycetoma Research Center Biobank

Participants retain the right to withdraw their samples and data at any point.

Researchers are granted temporary custodianship when they access the samples, but ownership remains with the biobank.



**SOP 2:
Sample Use and Access
Policy**

Objective

To provide clear guidelines on how researchers can access biobank samples for scientific research while ensuring ethical use and oversight.

Internal and External Access



**SOP 2:
Sample Use and Access
Policy**

Internal Researchers

Provide streamlined access to samples for internal researchers affiliated with the Mycetoma Research Center.

External Researchers

External researchers must submit a formal application detailing the study design, objectives, and sample use. Review and approval by the Biobank Management Committee are mandatory.



**SOP 2:
Sample Use and Access
Policy**

Material Transfer Agreements (MTA)

All external parties accessing biobank samples must sign an MTA, which outlines conditions of use, restrictions, and intellectual property rights.

The MTA should define ownership and state that samples are for research purposes only and cannot be commercialised without further agreements.



Ethical Use and Compliance

Ensure that research using biobank samples is in line with national and international ethical guidelines.

Require institutional review board (IRB) or ethics committee approval for all research projects accessing samples.

**SOP 2:
Sample Use and Access Policy**

Data and Results Sharing



Encourage the sharing of results generated from biobank samples, promoting transparency and collaboration.

Mandate that all research findings are deposited into the Mycetoma Research Center's data repository, with appropriate recognition to the biobank.

**SOP 2:
Sample Use and Access Policy**



**SOP 3:
Data Protection, Privacy and Confidentiality**

Objectives

To protect the privacy and confidentiality of donors while ensuring that their data is securely stored and accessed only by authorised personnel.

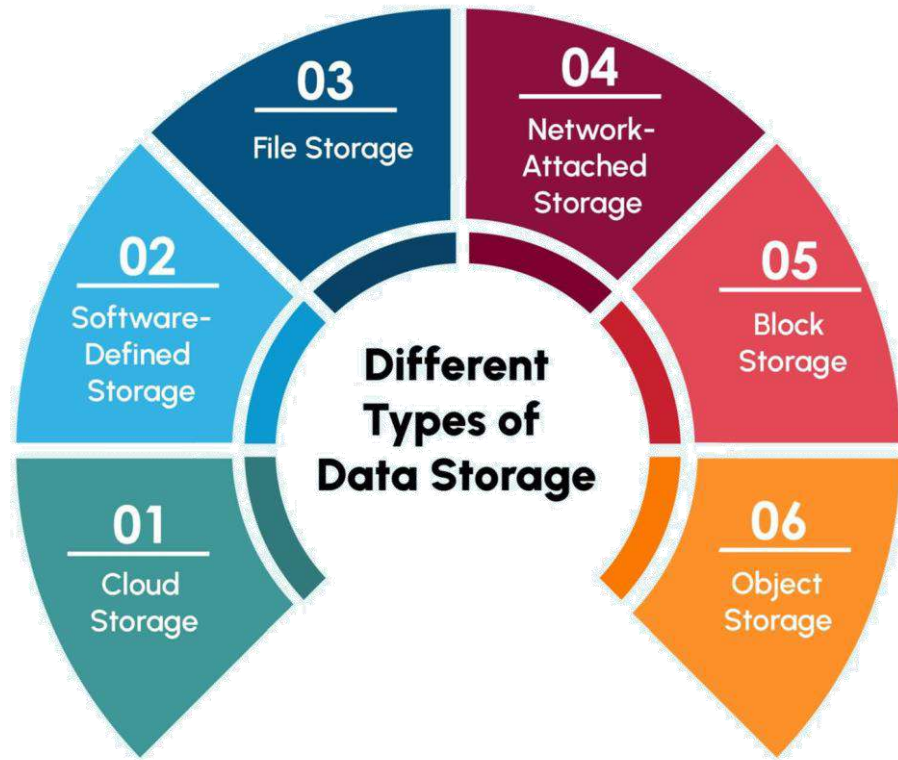
Anonymisation



**SOP 3:
Data Protection, Privacy and Confidentiality**

Anonymise all donor information before samples and associated data are released to researchers.

Use unique identifiers to link samples to donors while ensuring that personal data is kept separate and inaccessible to researchers.



**SOP 3:
Data Protection, Privacy
and Confidentiality**

Data Storage

Store all sample-related data in a secure, password-protected database.

Only authorised personnel should have access to donor-identifying information.

Conduct regular audits and security checks to ensure data integrity.

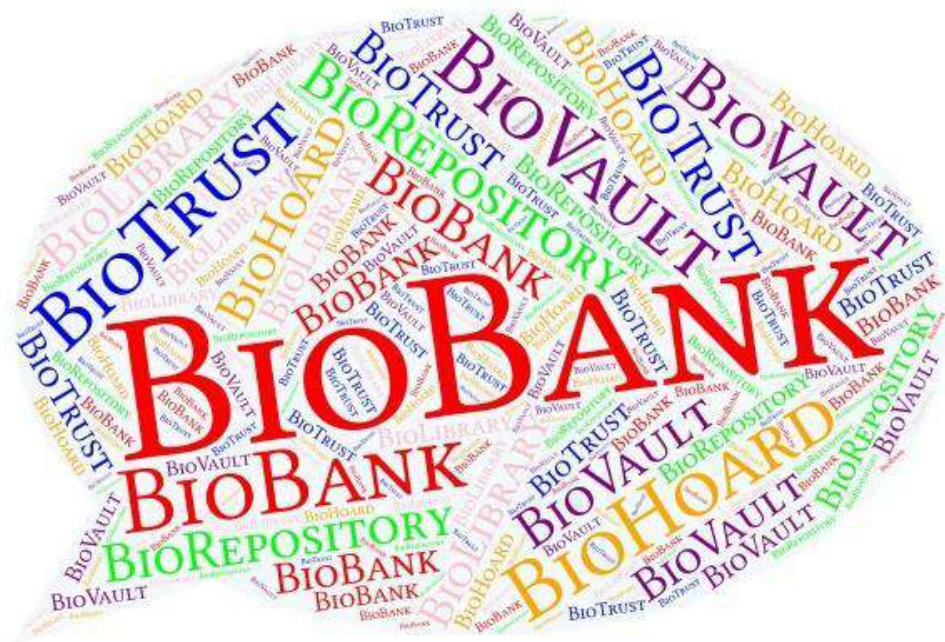


Data Breach Protocol

In the event of a data breach, implement immediate corrective actions and notify affected participants if their personal information is compromised.

SOP 3:

Data Protection, Privacy and Confidentiality



Objective

To establish a procedure for donors to withdraw their samples from the biobank and for the proper disposal of samples no longer needed.

SOP 4:
Sample Withdrawal and Disposal



**SOP 4:
Sample Withdrawal and Disposal**

Sample Withdrawal

Donors have the right to withdraw their consent and request that their samples and associated data be destroyed at any time.

Upon withdrawal, ensure that all records related to the sample are deleted and a report of withdrawal is maintained for audit purposes.



Sample Disposal

Ensure proper disposal procedures according to national biohazard waste regulations for samples that are no longer needed or if a donor requests withdrawal.

Record the destruction of each sample, ensuring it is carried out by trained personnel under supervision.

SOP 4:
Sample Withdrawal and Disposal



Objective

To ensure that any benefits arising from the use of biobank samples are shared equitably, particularly with communities affected by mycetoma.

**SOP 5:
Benefit Sharing and Intellectual Property**



**SOP 5:
Benefit Sharing and
Intellectual Property**

Commercialisation and Intellectual Property

If research using biobank samples leads to intellectual property (IP), patents, or commercial products, establish mechanisms for sharing these benefits with the biobank and affected communities.

IP rights should be clearly defined in the MTA before research begins, ensuring that discoveries are handled transparently.



Monitoring and Review

Conduct regular audits of the Biobank's adherence to these SOPs.

Review and update policies annually to reflect changes in ethical guidelines, laws, and technological advancements in biobanking.

References

- **General Data Protection Regulation (GDPR)**
- **Health Insurance Portability and Accountability Act (HIPAA)**
- **International Ethical Guidelines for Biomedical Research Involving Human Subjects**
- **MRC Scientific Research Ethics Guidelines 2024-**
https://mycetoma.edu.sd/?page_id=4949

Approval

These Standard Operating Procedures have been prepared, reviewed and approved by:

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On May 4, 2023.