Noguchi Memorial Institute for Medical Research
Institutional Policy

Number : Mgt-067-1.0

Title : Specimen Management Policy

Department : All Departments

This policy supersedes: None or older versions
Draft, Photocopied, and Obsolete versions of this document are not to be used.

EFFECTIVE: 14th June 2024

Table of Contents

1. Purpose/Expected Outcome

Specimens are regularly collected, analyzed, and stored for research, and or diagnostic purposes. It is essential that every specimen reaches the relevant test area safely in optimum condition and in a timely manner, stored securely, analyzed optimally, and disposed appropriately.

This policy will put in place systems to ensure the appropriate collection, receipt and management of specimen at NMIMR, UG.

2. Scope

The policy covers specimen collection, transport, handling, receipt, storage, analyses and disposal by NMIMR, UG.

It also applies to staff, who at any point handle or make decision in relation to specimen.

The policy covers human, animal, plant, environmental specimen, recombinant and genetic material.

3. Responsibility

3.1 Institute Management Committee (IMC)

The IMC shall:

- provide resources and policy direction for specimen management in the Institute.
- Manage risks associated with specimen management in the Institute.
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3.2 Heads of Department (HoD)

Heads of Department shall:

a. Maintain overall responsibility for specimen management in the department.
b. Manage risks associated with specimen management in the department.
c. Ensure the implementation of specimen management and its improvement for all projects within the department.

3.3 Institutional Quality Office (IQO)

The IQO shall:

a. Coordinate the development and implementation of procedures for specimen management.

b. Coordinate the generation of records to guarantee adequate management of specimen.
c. Ensure implementation of specimen management in all departments in the Institute.

3.4 Principal Investigators (PI)

Each PI shall:

a. Maintain overall responsibility for specimen management under respective projects.
b. Manage risks associated with specimen management under respective projects.

4 Policy Objectives

NMIMR, UG's objectives in relation to specimen management are to:

a. Protect the integrity of research output associated with specimen.
b. Improve biosafety, biosecurity and prevent bioterrorism associated with specimen in the Institute.
c. Protect the health and safety of staff handling specimen in the Institute.

5 Policy Statements

5.1 General

Staff who will be in direct contact with study participants/clients, biohazardous material or work in the clinical or laboratory setting shall undergo appropriate biosafety and occupational training, appropriate tests and obtain immunizations related to their specific job requirement.

Principal Investigators (PI) and research team members shall ensure facilities and equipment utilized in obtaining, processing, and storing biospecimen meet appropriate quality standards

5.2 Specimen collection and transport

5.2.1 All persons collecting specimen shall have the appropriate training and practice necessary precautions for collecting biospecimen.

5.2.2 Specimen collection and transport shall be in strict accordance with approved research protocol and institutional procedures for specimen collection and transport.

5.2.3 All collected specimen shall be unequivocally identifiable. Any protected health and personal information shall be kept confidential and secured in accordance with national and institutional policies and procedures.

NMIMR, UG shall reserve the right to reject specimen which are not collected and transported in accordance with approved procedures.

5.3 Specimen receipt and storage

5.3.1 Only specimen which are clearly traceable to the source shall be received into the Institute. Where the traceability of specimen is required to be withheld for legal and or security reasons, such reasons shall be referred to the Director for approval.

5.3.2 All specimen leaving the Institute to external entities shall have an approved Material Transfer Agreement (MTA) as provided by the Institute's Office of Research Support (ORS) and the IRB. Such specimen will include all samples generated from research work ongoing in the Institute.

5.3.3 All MTAs shall be exclusively endorsed by the Director.

All specimen shall be stored under optimal conditions in accordance with approved project and/or institutional requirements.

5.4 Examinations

5.4.1 Staff conducting test in the institute shall follow approved testing procedures to guarantee quality test outputs.

5.4.2 Specimen examination shall be carried out using methods, which, have been verified or validated for the intended test.

5.4.3 All examinations carried out in the Institute shall be documented in accordance with the Institute's document control requirements.

Examination processes shall be conducted to ensure the validity of examination outcomes.

5.5 Specimen archival

5.5.1 The NMIMR, UG shall have systems to archive items (specimen and reagents) to ensure that the integrity of the stored items are continually maintained.

5.5.2 The NMIMR, UG does not archive specimen in perpetuity. Retention times for specimen shall be specified at the time of storage subject to review by the Institutional Quality Office (IQO) and Cold Room Representatives (CRRs).

5.6 Specimen disposal

5.6.1 The institute through its Health and Safety Committee (HSC) and Institutional Safety Office (ISO) shall ensure storage and disposal facilities for hazardous materials and biological waste are appropriate to classification of the materials in the context of any statutory or regulatory requirement (Health and Safety Manual)

6 Attachments

N/A

7 Related documents

- Risk management policy
- Personnel management policy
- Equipment policy
- Information security policy
- Research Ethics policy
- Scientific misconduct policy
- Health and safety manual

8 References

N/A

9 Policy Revision History

N/A

10 Approval Page

Approved by Director
Name: Prof. Dorothy Yeboah-Manu

Signature:  Date: 10th June 2024

11 Policy Revision History

Policy #: Mgt-067-1.0
Triennial Review Date: 13th June 2027
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