
# Guidelines for Transfer of Biological Materials for Research and Quality Assurance Purposes in Zambia



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**Abbreviations**

MOH-Ministry of Health

NHRA-National Health Research Authority

REC-Research Ethics Committee

IRB-Institutional Review Board

NHREB-National Health Research Ethics Board

PI-Principal Investigators

MTA- Material Transfer Agreement

## 1.0 Background

The National Health Research Authority (NHRA) is a regulatory body established in Zambia by the Health Research Act of 2013. The Act provides for its functions and powers of regulating and promoting health research in Zambia. The ACT further provides for the establishment of the National Health Research Ethics Board (NHREB). The Board is responsible for regulating ethics on human and animal research in Zambia as provided for in the 'Guidelines for the Ethical Conduct of Health Research in Zambia.'

The governing body of the NHRA is the Council. According to the National Health Research Act, the Council has the mandate and powers to issue guidelines on the conduct of human research in collaboration with the Board.

In line with this mandate, the NHRA Council hereby issue the following guidelines to provide for the processes and key requirements for obtaining approval for biological materials transfer for the purpose of research and quality assurance. These guidelines are supplementary to Statutory Instrument No. 92 of 2018 on the National Health Research (Material Transfer) Regulations, 2018 and provide more information on the processes required for applying for and obtaining approval for transfer of biological materials.

## 1.1 Scope of the Guidelines

This document sets out guidelines for the Transfer of Materials for Health Research Purposes. The document is intended to be used by the National Health Research Authority (NHRA), National Health Research Ethics Board (NHREB), Researchers/ Research Institutions, appropriate key stakeholders as defined by the Health Research Act of 2013 and the general public. These guidelines shall apply for all Material Transfer Agreements certificates awarded by NHRA. This document should be read in conjunction with the Health Research Act no 2 of 2013, The

National Health Research (Material Transfer) Statutory Instrument No. 92 of 2018 Guidelines for the Ethical Conduct of Health Research in Zambia and other guidelines and documents that govern health research in Zambia.

### 1.2 Objectives of the Guidelines

The objectives of these guidelines are to:

a. To describe application procedures for request to transfer biological materials for research and quality assurance purposes.
b. To describe the process for review and approval of request for transfer of biological materials.
c. Provide for and describe the Material Transfer Agreement
d. To outline feedback procedures on applications for biological material transfers.
e. To outline applicable fees and payment procedures for biological material transfer.

### 2.1 Application for transfer of Biological Materials for Research Purposes.

An application for the transfer of biological materials for research purposes shall be made to the National Health Research Athority (the Authority) using designated forms available on the institutional website or upon request via the institutional email. The Authority shall consider the applications for transfer of biological materials for research puproses within 90 days of the date of receipt of the application. Where the Authority approves or rejects an applications for the transfer of biological materilas for research purposes, the Authority will inform the applicant within seven (7) business days. All applications for transfer of biological materials shall be made upon payment of **non-refundable fees** prescribed in section 2.4 of these guidelines.

### 2.2 Application For Transfer Of Biological Materials For Quality Assurance

In an event where an application for transfer of biological materials is required for quality assurance, the application shall be accompanied by the folllowing:

a. Standard operation procedures for the planned tests
b. A statement of agreement between the two laboratories
c. A plan for schedulred shipments of the quality assurance samples

The authority shall consider the applications for transfer of biological materials for quality assurance within thirty (30) days from the date of receipt of the application and will determine the number of the shipments for each approval for quality assurance samples. Each shipment shall bear the seal of the authority.

The authority shall where it approves or reject an application for transfer of biological materials for quality assurance purposes notify the applicant using applicable forms as stipulated in the National Health Research ( Material Transfer) Statutory Instrument within seven (7) days. Similarly, applications for transfer of biological materials for quality assurance purposes shall attract **non-refundable fees** prescribed in section 2.4 these guidelines.

**2.3 Material Transfer Agreement (MTA)**

A person who intends to import or export biological materials for research or quality assurance purposes shall fill out a material transfer agreement provided by NHRA. All parties involved in the application for a MTA shall ensure that confidentiality is maintaned by withholding identities of the participants. In an event of **termination** of the MTA, the parties shall destroy the samples unless the analysis is one which cannot be abandoned. The authority shall require publication to acknowledhe the source of the material.

The material transfer aggreement shall include terms relationg to:

a. Intellectual property rights
b. Rights to authorship

c. Benefitis to the health researcher, community or individual where applicable and
d. Access to data from the study

Notwithstanding, the provisions of sub-regulation(1) of National Health Research ( Material Transfer) Statutory Instrument, an agreement made on intellectual property rights, rights to authorship, sharing benefits and access to data shall not be inconsistent with any other written laws.

### 2.4.1 FEES

An application for material transfer for research or quality assurance purposes shall attract fees as stipulated in the National Health Research (Material Transfer) Statutory Instrument. The fees are categorised by source of income for the protocol from which an applicant is seeking approval for biological material transfer.The table below stipulates applicable fees for each catergory.

| Applicant | Units | Cost(ZMK) |
|---|---|---|
| Applicatiopn to transfer biological materials (students) | 3400 | 1020 |
| Application to transfer biological materials (Locally funded protocol) | 8350 | 2505 |
| Application to transfer biologicla materials ( International funded protocol) | 16700 | 5010 |

### 2.4.2 Payment Procedures

All payments for an application to transfer biological materials shall be made by making deposits into the National Health Research Authority bank account held with Zambia National Commercial Bank (ZANACO). An applicant shall attach the proof of payment to their application and await confirmation of receipt from NHRA. Upon confirmation, NHRA shall issue a GRZ receipt to the applicant and further submit the application for review to NHREB.

**Bank Details:**

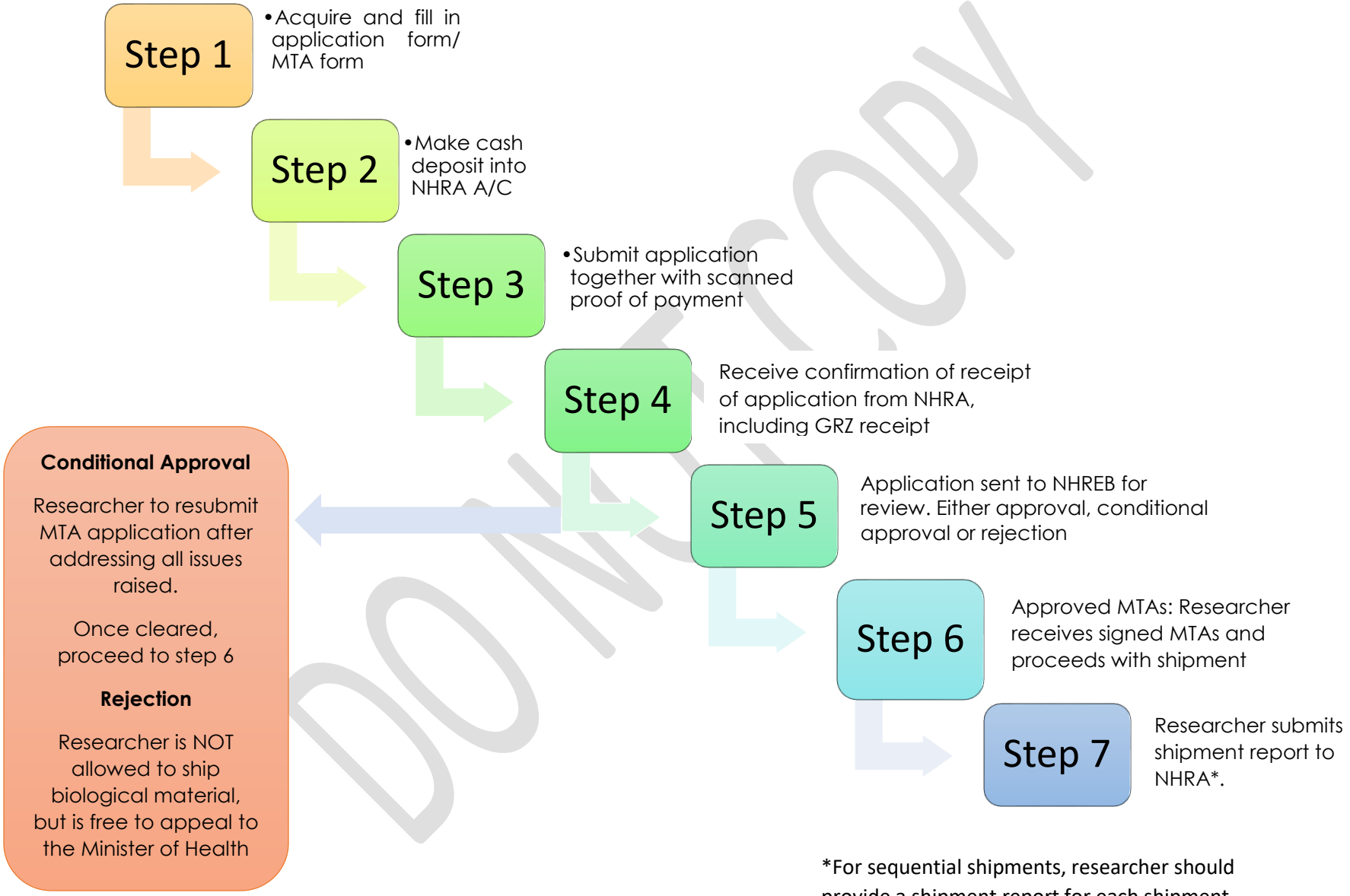
*National Health Research Authority – Trust Fund Account*

*Account No. 5586154300287*

*ZANACO*

*Woodlnds Branch*

### 3.0 Summary of application process




*For sequential shipments, researcher should provide a shipment report for each shipment made