Science for Prosperity

National Commission for Science, Technology and Innovation

NATIONAL GUIDELINES FOR THE DEVELOPMENT OF BIOLOGICAL MATERIAL TRANSFER AGREEMENTS

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FOREWORD

The National Commission for Science, Technology and Innovation (NACOSTI) is established under the Science Technology & Innovation Act, 2013. NACOSTI is the successor of the National Council for Science and Technology. The mandate of NACOSTI is to regulate and assure quality in the science, technology and innovation sector and advice the Government in matters related thereto.

In an effort to contribute to the realization of NACOSTI's mandate and adherence to ST&I Act and ST&I Regulations 2014, the Commission prepared the Guidelines for biological Materials Transfer Agreements to guide parties transferring biological materials from one institution to the other as well as outside the country.

The transfer of other types of materials will require adaptations. The Guidelines should therefore be adapted in order to suit the specific circumstances of each single transaction.

The Guidelines outlines the following: the process of authorization of biological material transfer; Material Transfer Agreement template; and six schedules for describing the biological material to be transferred, the purpose of transfer; budget, checklists, approvals from other regulatory bodies, and biological material agreement implementing form.

Using these Guidelines, IERC are expected to ensure that the applicants prepare comprehensive Material Transfer Agreements for submission to NACOSTI for consideration for approval.

The Commission will provide guidance on the implementation of all the provisions of these Guidelines and will accord all the support required to ensure that institutions deliver the expected outcomes that we all desire.

PROF. TOM PETER MIGUN OGADA
CHAIRMAN, NACOSTI BOARD

ACKNOWLEDGEMENT

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Finally, special thanks go to the stakeholders for their valuable that enriched the Guidelines.

DR. MOSES K. RUGUTT PhD, OGW.
DIRECTOR GENERAL

ABBREVIATIONS AND ACRONYMS

DNA	-	Deoxyribonucleic Acid
IERC	-	Institutional Ethics Review Committee
MTA	-	Material Transfer Agreement
NACOSTI	-	National Commission for Science, Technology and Innovation
NBC	-	National Bioethics Committee
RNA	-	Ribonucleic Acid
ST&I	-	Science, Technology and Innovation

INTRODUCTION

The mandate of the National Commission for Science, Technology and Innovation (NACOSTI) is to regulate and assure quality in the Science, Technology and Innovation Sector and advice the Government in matters related thereto. The Science, Technology and Innovation Act of 2013 (ST&I Act) under section 12 (3) states that any person undertaking or intending to undertake research in science and technology in the country, or who accesses, handles, or transfers any material or technology or moves it within, from or into the country, shall apply to NACOSTI for the grant of a license in accordance with the ST&I Act.

The ST&I Act under Section 15 (1) stipulates that: Any person who :- (a) accesses, handles, transacts, transfers or moves any specified technology or any material necessary for scientific research within, into or from Kenya without a licence issued under the Act; or (b) contravenes the provisions of section 12, commits an offence and shall, in addition to any other penalty which may be provided for in the ST&I Act or any other written law, be liable on conviction to a fine not exceeding five (5) million shillings or to imprisonment for a term not exceeding four years, or both.

Further, ST&I Act under section 6 (1) (p) provides for the development and enforcement of codes, guidelines and regulations in accordance with the policy determined under the ST&I Act for the governance, management and maintenance of standards and quality in research systems. In response to these provisions NACOSTI has developed these Guidelines on biological Material Transfer Agreement (MTA)

Material Transfer Agreement

A biological Material Transfer Agreement (MTA) is a generic term for documents used in the context of the transfer of any kind of biological material (human, animal and plant tissues, microbes) from one institution to another, nationally and internationally. Since these materials are a valuable resource, there is need for an agreement to be signed between the provider and the recipient of the biological material, hereby referred to as the MTA. The Agreement is binding to both parties.

The Agreement lays down the terms and conditions of transfer of the biological material, sets out the rights and obligations of both the Provider and the

Recipient. It also aims to facilitate access to biological materials and to allow fair and equitable sharing of the benefits derived from their use. Any deviation from the defined terms and conditions of a MTA without prior written approval from both parties is a violation of the binding contract and the Provider may invoke the Governing Law clause and formally punish the Recipient, or may reach an amicable settlement with the Recipient. The MTA to be used must conform to the relevant laws of Kenya and other international obligations.

Authorization of Material Transfer

The process of authorization of biological material transfer shall be undertaken as indicated below.

The Provider Scientist will:

1. Apply to a duly accredited Institutional Ethics Review Committee (IERC) for transfer of biological material. IERC will examine the application ensuring the rights of the source of the MATERIAL including the completeness of the application.
2. Upon recommendation by IERC, apply to NACOSTI which will consider the recommendations to ensure that the shipment is justified and does not infringe on the rights of individuals, communities and the country. NACOSTI will register the application and issue a no objection letter for the material transfer to proceed for approval by the other relevant organizations for shipment.
3. In case of human MATERIAL, the applicant shall submit the application to the Ministry responsible for health for a shipment permit.
4. In case of plant, animal or microbial MATERIAL, the applicant shall submit the application to the relevant Government agencies responsible for agriculture, livestock, wildlife, environment or national heritage for a shipment permit.

MATERIAL TRANSFER AGREEMENT TEMPLATE

This Material Transfer Agreement is made this…….day of ……. between ……..of address…….. (Herein referred to as the RECIPIENT) and …… of address…… (Herein referred to as the PROVIDER) Collectively, referred to as the 'PARTIES'.

WHEREAS, the ' PROVIDER' desires to transfer certain Materials (as defined below) to 'RECIPIENT' and Recipient desires to conduct research using the Materials; NOW, THEREFORE, in consideration of the mutual promises set forth in this Agreement, the Parties hereby agree as follows:

1. **Definitions**

a) Provider Institution: an organization providing the original material. The name and address of this party will be specified on the MTA implementing form.

b) Provider Scientist: A scientist employed and authorized by the Provider Institution. The name and address of this party will be specified on the MTA Implementing Form.

c) Recipient Institution: Organization receiving the original material.

d) Recipient Scientist: A scientist employed and authorized by the receiving institution. The name and address of this party will be specified on the MTA Implementing Form.

e) Original Material: Biological material sent by the Provider. Original material, progeny, and unmodified derivatives. The material shall not include (a) modifications, or (b) other substances created by the Recipient through the use of the material which are not modifications, progeny, or unmodified derivatives.

f) Progeny: Unmodified descendant from the material, such as virus from virus, cell from cell, or organism from organism.

g) Unmodified Derivatives: Substances created by the Recipient, which constitute an unmodified functional sub-unit or product expressed by the original Material. Some examples include: subclones of unmodified cell lines, purified or fractionated subsets of the original material, proteins expressed by DNA/RNA supplied by the Provider, or monoclonal antibodies secreted by a hybridoma cell line.

h) Modifications: Substances created by the Recipient which contain/incorporate the material.

i) Commercial Purposes: The sale, lease, license, or other transfer of the material or modification to a for-profit organization, which may include use of the material or modifications by any organization, including manufacture products for general sale, for screening compound libraries, to produce or manufacture products for general sale, or to conduct research activities that result in any organization. However, industrial sponsored academic research shall not be considered a use of the material or modifications for commercial purposes per se, unless any of the above conditions of this definition are met.

j) Confidential Information: information, date or material in written or other tangible form related to the material that is identified as confidential at the time of disclosure. Confidential information does not include information that is:

a) Generally known to the public at the time of disclosure to the Recipient;
b) Already in recipient's possession at the time of disclosure by the Provider;
c) Disclosed to Recipient on a non-confidential basis by a third party having the right to make such disclosure;
d) Independently developed by Recipient without the use of the Confidential Information disclosed by the Provider as evidenced by written records; or
e) Required to disclose by law or relevant regulation.

2. Use of the Biological Material

The Recipient and the Recipient Scientist agree that the material:

i. Is to be used solely for the purpose for which it is intended;

ii. Will not be used in human subjects, clinical trials or for diagnostic purposes involving human subjects without written consent of the Provider;

iii. Is to be used only at the Recipient organization and only in the Recipient Scientist's laboratory under the direction of the Recipient Scientist or others working under his/her supervision; and

iv. Any use of biological material other than as provided in (iii) above, will require a new MTA.

3. Ownership of the Property

i. The Provider shall retain tangible ownership of the material, including any material contained or incorporated in modifications.

ii. The Recipient shall retain ownership of:

a) Modifications (except that, the Provider retains ownership rights to the material included therein),

b) Those substances created through the use of the material or modifications, but which are not progeny, unmodified derivatives, or modifications).

If either ii (a) or ii (b) above results from the collaborative efforts of the Provider and the Recipient, the two parties shall have joint ownership.

4. Confidentiality

Any confidential information disclosed by the Provider to the Recipient shall be treated as confidential and maintained in confidence by Recipient for (…...) years after disclosure. Recipient shall not disclose any confidential information of Provider, except to its own personnel who have a need to know. Without limiting the foregoing, Recipient agrees to take the same methods to prevent the unauthorized use of disclosure of confidential information of Provider as it takes to protect its own confidential information or proprietary information.

5. Distribution

No biological material may be transferred from the Provider without approval and authority of NACOSTI.

6. **Disclosure and Intellectual Property Rights**

i. **Disclosure**: The Recipient shall promptly notify the Provider of any potential patentable discoveries or inventions made through the use of material whether or not made within the specified limits of the approved research use. The Recipient shall promptly supply the Provider with a copy of invention disclosure.

ii. **Intellectual Property:**

a) The Recipient acknowledges that the material is or may be the subject of intellectual property protection. Except as provided in this Agreement, no express or implied licenses or other rights are provided to the Recipient under any patents, patent applications, trade secrets or other proprietary rights of the Provider, including any altered forms of the material made by the Provider. In particular, no express or implied licenses or other rights are provided to use the material, modifications, or any related patents of the Provider for commercial purposes.

b) The Recipient may file patent application(s) claiming inventions made by the Recipient through the use of the material, but agrees for joint patent applications.

7. **Warranty and Licenses**

i. Any Material delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. The Provider *makes no representations and extends no warranties of any kind, either expressed or implied. There are no express or implied warranties of merchantability or fitness for a particular purpose, or that the use of the* MATERIAL *will not infringe any patent, copyright, trademark, or other proprietary rights.*

ii. If the Recipient desires to use or license the use of material or modifications for commercial purposes, the Recipient agrees, in advance of such use, to negotiate in good faith with the Provider to establish the terms of the commercial license. It is understood by the Recipient that the Provider shall have no obligation to grant such a license to the Recipient, and may grant exclusive or non-exclusive commercial licenses to others, or sell or assign all or part of the rights in the material to any third party

(ies), subject to any pre-existing rights held by others and obligations to the Government of Kenya.

iii. Without written consent from the Provider, the Recipient and/or the Recipient Scientist may not provide modifications for commercial and/or noncommercial purposes.

iv. The Recipient, at their discretion, may also either destroy the modification or remain bound by the terms of this agreement as they apply to modifications;

8. Liability

The Recipient assumes all liability for damages which may arise from use, storage or disposal of the material. The Provider will not be liable to the Recipient for any loss, claim, or demand made by the Recipient, or made against the Recipient by any party, due to or arising from the use of the material by the Recipient, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the Provider.

9. Publication of Research Results

This Agreement shall not be interpreted to prevent or delay publication of research findings resulting from the use of the material or the modifications. The Recipient Scientist agrees to joint authorship of research findings and provide appropriate acknowledgement of the source of the Material in all publications.

10. Termination

This Agreement shall terminate on the earliest of the following dates:

a) When the material becomes generally available to third parties, for example, through reagent catalogs or public depositories, or
b) On completion of the Recipient's existing/prevailing research with the material, or
c) At the expiry of thirty (30) days written notice by either party to the other, or
d) On the date specified in the implementing form, provided that:

i. If termination shall occur under (a) above, the Recipient shall be bound to the Provider by the least restrictive terms applicable.

ii. If termination shall occur under (b) or (d) above, the Recipient will discontinue use of the material and will, upon direction of the Provider, return or destroy any remaining material.

iii. In the event that the Provider terminates this Agreement under (c) above other than for breach of this Agreement or for cause such as an imminent health risk or patent infringement, the Provider will defer the effective date of termination for a period of up to one (1) year, upon request from the Recipient, to permit completion of research in progress. Upon the effective date of termination, or if requested, the deferred effective date of termination, Recipient will discontinue its use of the material and will, upon direction of the Provider, return or destroy any remaining material. The Recipient, at their discretion, will also either destroy the modifications or remain bound by the terms of this agreement as they apply to modifications.

11. Applicable Law

This agreement shall be governed by and construed in accordance with the laws of Kenya. The Recipient agrees to use the material in compliance with all applicable statutes and regulations, relating to public health, environment and animals.

12. Dispute Resolution

Any dispute, disagreement or question arising out of or relating to or in consequence of this Agreement or relating to its construction or performance shall be referred to and finally resolved by arbitration in Kenya in accordance with the provisions of the Arbitration Act, 1995 of the Laws of Kenya by an arbitrator appointed in writing by the parties or if they cannot agree upon a single Arbitrator then each party shall appoint an arbitrator within fourteen (14) days after having been required to do so by either of the parties. In the case where the appointed Arbitrators fail to agree on an Umpire to be appointed in writing by such appointed Arbitrators before entering upon the reference, an umpire shall be appointed by the chairman for the time being of

the Chartered Institute of Arbitration, Kenya Branch, on the application of the appointed Arbitrators. The Umpire shall sit with the Arbitrators and preside at their meetings and the making of an award shall be a condition precedent to any right of action against either party. The language of the arbitration shall be English. Each party shall bear its own cost of preparing and presenting its case. The costs of Arbitration (including fees and expenses of the Arbitrators) shall be shared equally between the parties unless the award provides otherwise.

13. Force Majeure

Non-compliance by a Party with this Agreement due to any cause beyond the reasonable control of the Party, such as war, civil commotion, destruction of production facilities and materials, fire, flood, earthquake or storm, labor disturbances, shortage of materials, failure of public utilities or common carriers (each, an event of "Force Majeure"), shall not constitute a breach of this Agreement. That Party shall be excused from performance under this Agreement to the extent and for the duration of such event of Force Majeure, provided, however, that it first notifies the other Party in writing thereof and that it uses reasonable efforts to cause such event of Force Majeure to abate.

14. Further Assurances

Each Party shall execute such other instruments, give such further assurances, and perform acts reasonably necessary or appropriate to effectuate the provisions of this Agreement.

15. No Third-Party Beneficiary

This Agreement is for the sole benefit of the Parties and does not confer any rights on any third party.

16. Complete Agreement

This agreement constitutes all agreements between the parties both written and oral with respect to the subject matter hereof. All prior agreements respecting the subject matter hereof either written or oral, expressed or implied between parties are hereby cancelled.

IN **WITNESS WHEREOF**, the Parties have executed this Agreement on this.....day of .....20……..

SIGNED by the said …… … …… … …… ….)
)
)
)
)
)
)
)
SIGNED by the said … … … … ….....… …...)

FIRST SCHEDULE

The Biological Material to be Transferred

[*Describe the Biological Material to be Transferred*]

SECOND SCHEDULE

The Purpose of the Biological Material to be Transferred

THIRD SCHEDULE

The Budget

[Where applicable]

FOURTH SCHEDULE

Checklist

1. A duly signed cover letter
2. A duly completed and signed Biological Material Agreement Implementing Form
3. A copy of the initial and current IERC approval letter for the associated study
4. A copy of approved consent document/s

FIFTH SCHEDULE

[Post NACOSTI approval]

A copy of the initial and current approval letters from relevant government ministries and other regulatory bodies

SIXTH SCHEDULE

Biological Material Agreement Implementing Form

The purpose of this form is to provide a record of the biological material transfer, to formalize the agreement between the Provider Scientist (identified below), and the Recipient Scientist (identified below) organization has accepted and signed an unmodified copy of the MTA. The Recipient organization's Authorized Official also will sign this form if the Recipient Scientist is not authorized to certify on behalf of the Recipient Organization (and the Authorized Official of Recipient, if necessary), should sign three copies of this form and return one signed copy to the Provider. The Provider Scientist will forward the material to the Recipient Scientist upon receipt of the signed copy from the Recipient organization. This implementing form is effective when signed by all parties. The parties executing this form certify that their respective organizations have accepted and signed the copy of the MTA, the terms of the MTA, for the transfer specified above. Please fill in all of the blank lines below.

Title of Research:

……

……

IERC assigned protocol number:

……

NACOSTI assigned reference number:……

Original material: (describe and quantify)

……

……

Intended use(s) of the material:
……

Termination date: ……..

Amount of optional transmittal fee: (indicate currency)
……..

Provider (Organization providing the original material):

a. Name of organization:……

b. Name of Authorized Official: ……..

c. Address: ……...

d. Authorized Signature: …… Date: ……..

Provider Scientist:

a. Name and title: ……

b. Address: …….

c. Signature: …….Date: …….

Recipient Scientist:

a. Name and title: ……..

b. Address: ……

c. Signature: ……Date: ……

Recipient organization certification (organization receiving the original material):

I hereby certify that the Recipient Organization has accepted and signed (initialing modifications) a copy of the MTA.

a) Name of organization: ……...

b) Name of Authorized Official: ……...

c) Address: ……..

d) Authorized Signature: …… Date: ……

e) In response to the terms of the research protocol titled: ……