**MTA TEMPLATE**

The **Material Transfer Agreement** **(MTA)** is a contract that governs the transfer of Human Biological Material and its Associated Data (collectively termed Material) between organisations and/or institutions, and which sets out what will be done with any Material supplied.

As a **MTA** is a **legally binding** **contract,** researchers must ensure that their institution’s research office legal people are involved. There are contractual implications and consequences when the contract is not upheld by the parties.

An MTA is an **ethical undertaking** by parties, which means that researchers must understand the ethical principles that inform their plans to do research, share the biological resource and data and to produce findings and other career-building outcomes like publications. There are ethical implications and consequences when researchers ignore ethical obligations to Participants and others who help to make their research and career-building possible.

The MTA Template includes a list of **definitions of terms** for purposes of the MTA. Where possible, the definitions are taken from existing legislation or ethics guidelines to prevent a proliferation of highly subjective interpretations of the terms. Standardisation depends on a shared understanding of terms and the contexts in which they are used.

The MTA Template includes a set of **provisions that stipulate the type of information that must be included in an MTA**. **This means that the Template is open to customisation for particular contexts, but the type of information that must be recorded is fixed.** Consequently, standardisation is possible within a flexible framework or template rather than insisting on a one size fits all approach.

Finally, the MTA Template includes two Annexures: **Annexure A** provides a summary of the intentions of the Parties for sharing and using the Material. **Annexure B** provides a description of how benefit sharing is to occur.

**GUIDANCE**

This Template for a **MTA** is intended to provide the minimum standard for the required content such an **Agreement** between Providers and Recipients of **Material**. It provides a framework in terms of which the **Parties** to a MTA may engage to record their **Agreement** regarding the transfer, use and other processing of the **Material**, and where each Party undertakes to engage with the other in the utmost good faith and to conduct itself in the highest ethical standards and comply with all applicable legislation, including but not limited to the legislative ban on the sale of or trade in tissues, gametes, blood or blood products. The understanding is furthermore that no Materials can be transferred for purposes of a research project that has not been approved by an NHREC registered HREC.

In the context of a clinical trial organised by a commercial sponsor, the intention is for an MTA based on this template to be entered into between the site responsible for the collection of Human Biological Material from participants in the clinical trial (the Provider) and the entity primarily responsible for performing any subsequent analysis of the Human Biological Material (the Recipient). In the event multiple entities are involved in the analysis, they should be referred to in Annexure A. The MTA entered into in this context between the Provider and the Recipient must ensure that the terms of the MTA align with the agreements between the clinical trial sponsor and the Provider and the clinical trial sponsor and the Recipient.

A rigid and prescriptive template is not suitable for different contexts, the aim is therefore to encourage standardisation of approach to the MTA, within a flexible framework, to ensure that important aspects are always included in the MTA, and that Human Biological Material and its Associated Data are treated with the proper respect and care.

It is intended that **Parties** may customise their **MTA** to suit the specific circumstances, provided that the minimum required elements described in this template are included.

**Each Material Transfer Agreement must include:**

1. Information that summarises the Project, describes the nature of the Material to be transferred; the quantities of the Material; the purpose for which it will be used; how the Material will be used; the terms and conditions under which the Material may be used; the duration of such use; where it will be stored and whether the remainder will be destroyed or returned, any modifications to the Material; whether third party transfers are permitted; whether benefit sharing arrangements are intended; intellectual property rights; and other legal requirements and/or regulatory guidelines or policies.
2. Information about the Parties that identifies them and outlines the expectations, responsibilities of each.
3. Information about permissions, liability & representations.
4. Information about stewardship and distribution limitations.
5. Information about confidentiality, non-disclosure and publication expectations.
6. Information about appropriate use of Material, including biosafety concerns.

*Note: where* ***Data*** *alone is shared, a Data Transfer Agreement (DTA) or Data Sharing Agreement (DSA) is appropriate. A DTA/DSA may have very similar content, depending on the circumstances and, therefore, this template may be used, with the necessary adjustments made to suit the circumstances.*

**ROLE OF THE HEALTH RESEARCH ETHICS COMMITTEE**

The role of the HREC is as described in s 73 of the National Health Act 61 of 2003 and in the Department of Health Ethics in Health Research 2024 Guidelines. In line with the Declaration of Taipei 2022, the HREC should review the Material Transfer Agreement to ensure that all ethical aspects have been addressed satisfactorily.

**MATERIAL TRANSFER AGREEMENT FOR HUMAN BIOLOGICAL MATERIAL AND ASSOCIATED DATA (MATERIAL)** (hereafter referred to as “MTA”)

**Entered into between**

**The Provider**

**and**

**The Recipient**

**On**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**[date]**

**MATERIAL TRANSFER AGREEMENT**

1. **DEFINITIONS**

*NOTE: Each MTA should include the definitions that are relevant to that MTA*

|  |  |
| --- | --- |
| * 1. Agreement:
 | * means this Agreement and all annexures and amendments thereto
 |
| * 1. Becomes Identifiable:
 | * means the Participant who provided the material can be directly personally identified
 |
| * 1. Benefit:
 | * includes sharing access to information, use of research results, publication rights, transfer of technology and Material and capacity building; and

 contribution to the socio-economic needs of the Republic and includes capacity development, technology transfer, enterprise development, social upliftment and products, or processes or services that embody or use the intellectual property; ex Publicly Financed Research and Development Act 51/2008 Reg 1. |
| * 1. Benefit sharing:
 | * means the process or act of sharing in a manner that is fair and equitable in the Benefits (as described above)
 |
| * 1. Biobank:
 | * an institution or unit thereof that stores and safeguards an organised collection of Human Biological Material and Associated Data from different individuals usually for an unlimited period of time for purposes of health research
 |
| * 1. Associated Data:
 | * means the information associated with the **Human Biological Material**, including personal information, derived directly or indirectly prior and during the conduct of the research **Project**
 |
| * 1. **NDoH 2024:**
 | * Means NDoH-2024-Health-Research-Guidelines-3rdEdition-v0.1
 |
| * 1. Human Biological Material:
 | * means a biological sample or tissue from a person, living or deceased, including Deoxyribonucleic Acid (DNA), Ribonucleic Acid (RNA), blastomeres, polar bodies, cultured cells, embryos, gametes, progenitor stem cells, growth factors and blood specimens, biopsy tissue and any modifications or derivatives thereof
 |
| * 1. Health Research Ethics Committee:
 | * means a Health Research Ethics Committee (HREC) which is registered with the South African National Health Research Ethics Council in terms of s 73(1) of the National Health Act 61/2003
 |
| * 1. Intellectual Property Rights:
 | * means any creation of the mind that is foregrounded or backgrounded and that is capable of being protected by law from use by any other person, whether in terms of South African law or foreign intellectual property law, and includes any rights in such creation, but excludes copyrighted works such as a thesis, dissertation, article, handbook or any other publication which, in the ordinary course or business, is associated with conventional academic work (per IPR definition in Publicly Financed Research and Development Act 51 of 2008)
 |
| * 1. Informed Consent:
 | * means the record of permission provided by the **Participant** to collect, store and use for further research purposes (as appropriate) the **Human Biological Material** sample under consideration
 |
| * 1. Material:
 | * means **Human Biological Material** and its **Associated Data**
 |
| 1.13 Material Transfer Agreement: | means a legally binding contract that governs the transfer of Material between organisations and/or institutions, which sets out: what will be done with any Material supplied; the nature of the Material; the terms and conditions under which the Material will be used; any modifications to the Material; benefit sharing arrangements; intellectual property rights; and other legal requirements and/or regulatory guidelines or policies |
| 1.14 Participant:  | * means the person who has provided a **Human Biological Material** to be used for health research and / or teaching purposes
 |
| * 1. Parties:
 | * means the **Provider** and the **Recipient**
 |
| 1.16 Permit: | * means the authorisation of the National Department of Health to transfer and / or export **Material**
 |
| 1.17 Project: | * means the health research project for which the **Material** will be used, including storage in a biobank for future use and that has approval from a registered HREC
 |
| 1.18 Provider: | * means the institution or entity that transfers the **Material**; there will be an initial provider in all cases and may be downstream providers in some projects
 |
| 1.19 Recipient: | * means the institution or entity that receives the transferred **Material**
 |
| * 1. Research Results:
 | * means all products of the research **Project**, whether tangible or intangible;
 |
| * 1. Secondary Use of Material:
 | * means use of the Material for health research purposes other than those for which the **Participant** originally gave permission, as described in the approved protocol and **Informed Consent** (see 3.3.7 of DoH 2015 *Ethics in Health Research Guidelines*)
 |
| 1.22 Steward: | * means a person or entity entrusted by the **Participant** to safeguard and protect the **Material** in accordance with 3.3 of DoH 2015 *Ethics in Health Research Guidelines*
 |
| 1.23 Termination Report | * means a report prepared by the **Recipient** and submitted to the **Provider** on termination of the **Project**
 |
| 1.24 Transfer of Material: | - means transport by the **Provider** of **Material,** whether physically or electronically, within the Republic of South Africa or across the national borders to provide access by the Recipient to that Material to produce data |

**THE PARTIES AGREE AS FOLLOWS:**

2.1 **OBJECTIVE**

 The objective of this **Agreement** is to record the intention ofthe **Parties** to transfer, use and process **Human Biological Material** and its **Associated** **Data**.

2.2 The **Provider** hereby transfers the **Material** as fully described in **Annexure A** to the **Recipient**, and the **Recipient** accepts the **Material** from the **Provider.**

2.3 The **Parties** agree that no **Material** may be transferred unless for the purpose of the **Project** as described in **Annexure A**.

2.4 The Human Biological Material are provided at no cost other than as specified in the research protocol.

2.5 The **Provider** remains the **Steward** of the **Material** and the **Participant** retains the right to determine **Secondary Use of Material** until such **Material** is destroyed.

2.6 Each party undertakes to engage with the other in utmost good faith and to adhere to the highest ethical standards and to comply with all applicable legislation, including the prohibition on sale of or trade in **Human Biological Material**.

2.7 The **Parties** record that, upon **Termination** of the **Project**, the **Material** will be *[insert the anticipated destiny of the unused Material e.g., destroyed or returned]*.

2.8 The **Parties** record that South African law and jurisdiction govern this **Agreement** when the Provider is in South Africa. Properly motivated exceptions may be possible, at the discretion of the Provider’s institution.

*Note: South African jurisdiction is to be preferred since the Human Biological Material is South African and Participants are South Africans.*

**3. OBLIGATIONS OF THE PROVIDER**

3.1 The **Provider** must ensure that a **Participant** has provided **Informed Consent** for Use and/or **Secondary Use of Material** in accordance with 3.3.7 of **DoH 2024** Guidelines and that the **HREC** has reviewed and approved the **Project** including the **Informed Consent** documentation.

3.2 The provider to ensure the donor signs the version of the consent that is approved by HREC

3.3 The **Provider** must inform the **HREC** that a **Material Transfer Agreement** for the **Project** exists

3.4 Where **Material** is to be exported out of the Republic of South Africa, the **Provider** must obtain the necessary **Permit** and other relevant authorizations for such export, or work together with other appropriate entities involved in the Project to ensure that these are obtained.

3.5 The **Provider** must inform the **HREC** and wherever possible the **Participant**/s if the **Provider** is informed that the **Material** has **Become Identifiable** for any reason whatsoever. This must be clarified as **Material** remain coded and hence potentially identifiable.

3.6 The Provider will furthermore take responsibility to make all possible efforts to protect the identity of the **Participant** and to limit harm to such Participant/s.

3.7 The **Provider** and **Recipient** must agree on appropriate procedures in instances where the **Participant** is no longer contactable.

3.8 “The Provider will deliver the materials to the Recipient as outlined in the research protocol approved by the HREC or according to the following schedule and in the following media/formats (if related to data)":

4. **OBLIGATIONS OF THE RECIPIENT**

4.1 The **Recipient** acknowledges that the Materials may contain sensitive and confidential information (associated data), which information the **Recipient** undertakes to protect and keep confidential.

4.2 The **Recipient** may not use the **Material** for any purpose that is not described as part of the **Project** in Annexure A, and/or **Informed Consent**.

4.3 The **Recipient** may not transfer or otherwise provide access to the **Material** to any party not listed in Annexure A, without a **Project** amendment approved in writing by the **HREC** and amendment of this **Agreement**.

4.4 The **Recipient** must inform the **Provider** without delay if the **Material** **Becomes Identifiable** for any reason whatsoever.

4.5 The Recipient shall ensure **Materials** are kept in a safe and secure place.

**5. BENEFIT SHARING**

5.1 The possible **Benefit** and **Benefit Sharing** arrangements must be discussed and negotiated between the **Provider** and the **Recipient** before **Material** is transferred to the **Recipient**.

5.2 The **Parties** must record their **Benefit Sharing** arrangement in **Annexure B**.

**6. DURATION OF AGREEMENT**

This **Agreement** commences and becomes effective on the date it is signed by the authorised signatories, and after the institutional HREC issues approval for the research **Project** and continues until the **Project** terminates (in accordance with clause 8).

**7. TERMINATION OF PROJECT**

7.1 When the **Project** terminates, for any reason whatsoever, the **Recipient** must provide the **Provider** with a **Termination Report**.

7.2 The **Termination Repor**t must include the reasons for termination, the status of the **Project** as at termination and the current status of the **Material**.

7.3 The **Parties** must clarify procedures for discontinued use and destruction of **Human Biological** **Material** after termination of the Project

**8. DISPUTE RESOLUTION**

8.1 Where a dispute arises between the **Parties** flowing from this **Agreement**, the **Parties** must engage as soon as possible to discuss and endeavour to resolve the dispute civilly and responsibly, by mutual agreement.

8.2 A dispute date must be recorded, i.e. the date on which the dispute was brought to the attention of the other Party.

8.3 Where the **Parties** fail to achieve resolution within thirty (30) days of the dispute date, the dispute must be referred a higher level of authority within the Parties’ organisations for resolution.

8.4 As a last resort, either party may litigate in accordance with South African law, in a South African court, in accordance with 3.6 above.

8.5 The **Parties** may agree to resolve such dispute by arbitration in terms of a separate arbitration **Agreement**, provided that such arbitration is in accordance with South African law, and takes place in South Africa, in accordance with 3.6 above.Exceptions can be made, if properly motivated, in accordance with 3.6 above.

**9. INTELLECTUAL PROPERTY**

*Note:* ***Intellectual property******rights*** *should preferably be dealt with in detail in a separate Research Agreement, Collaboration Agreement or Commercialisation Agreement. If no such separate agreement exists, the following basic default provisions can be used.*

9.1 **Intellectual Property** **Rights** must be dealt with in terms of relevant South African law, including but not limited to the Intellectual Property Rights from Publicly Financed Research and Development Act 51 of 2008.

* 1. All **Intellectual Property** **Rights** generally or exclusively created, derived, produced, enhanced, developed or discovered by the **Recipient** during the **Project**, including copyright therein and all associated documentation and processes, will be the property of the **Recipient** and the **Provider** will acquire no right, interest or proprietorship therein by virtue of this **Agreement**.
	2. Pre-existing intellectual property rights of a **Party** to this **Agreement** are and remain the property of that **Party**, and the other **Party** acquires no right, interest, or proprietorship therein by virtue of this **Agreement**.
	3. The **Parties** agree to honour the **Intellectual Property Rights** of the other **Party** by, amongst other measures, keeping all proprietary information and/or confidential information (which includes all **Associated Data**) in the strictest confidence, notwithstanding termination of this **Agreement** for any reason whatsoever.

 All relevant third-third party agreements must be listed in the MTA, attached to MTA.

**10. CONFIDENTIALITY**

10.1 The **Parties** must take all reasonable steps to keep the identity of a **Participant** confidential and must protect and secure **Material** at all times in accordance with the requirements of the Project and, if applicable, their obligations under separate contractual documents towards the entity responsible for the Project.

10.2 **Confidentiality** includes the properties, characteristics, content, composition, potential secondary uses and methods of use pertaining to the **Material**.

10.3 Obligations of confidentiality do not apply to information which: -

10.3.1 is in the public domain at the time of disclosure or which after disclosure enters the public domain, provided it does not enter the public domain by way of a breach of this Agreement.

10.3.2 the Recipient can reasonably demonstrate was already in its possession at the time of disclosure.

10.3.3 becomes available to the Recipient free from the obligation of confidentiality through a third party who did not acquire the information directly or indirectly from the disclosing party and who is not otherwise prohibited from disclosing such information; or

10.3.4 is independently developed by employees of the Recipient, its affiliates or subcontractors, without reference to the confidential information.

**11. AUTHORSHIP AND PUBLICATIONS**

*Note: Authorship and publication arrangements should preferably be dealt with in detail in a separate Research Agreement, Collaboration Agreement or Commercialisation Agreement. If no such separate agreement exists, the following basic provisions should be recorded.*

11.1 Authorship of publications flowing from use of the **Material** must comply with the International Committee of Medical Journal Editors (ICMJE) Authorship Guidelines (<http://www.icmje.org/icmje-recommendations.pdf>) in the absence of any institutional Authorship Guidelines.

11.2 The **Recipient** should provide a copy of the publication to the **Provider** and must acknowledge the Provider’s contribution of the **Material** unless otherwise requested by the **Provider**.

*Note: Please keep in mind the above examples clause do not reflect standard approach for clinical trials organised by a commercial sponsor*.

**12. INDEMNITY**

12.1 The **Provider** gives no warranty that the **Material** is fit for the purpose for which it is transferred, or that it has any particular qualities or characteristics.

12.2 Use of the **Material** is at the sole and exclusive risk of the **Recipient** which indemnifies and agrees to hold the **Provider** harmless against any and all losses that may arise in connection with the **Material** including loss or damage to the **Material** in transit.

12.3 The **Provider** accepts no liability to the **Recipient** for any claims arising from the **Recipient’s** use of the **Material**, save to the extent that limitation of liability is not permitted by the applicable law.

12.4 The **Recipient** must maintain adequate insurance cover against any claims, demands, losses, liability, costs or causes of action in respect of injury or death of any third party arising in connection with the **Material** and/or this **Agreement**.

**13. OFFICIAL ADDRESS FOR COMMUNICATION AND NOTICES**

13.1 The **Provider** chooses as its *domicilium citandi et executandi* for all purposes arising from this Agreement, the address specified below:

**Contact Person**:

Physical:

Postal:

Email:

13.2 The **Recipient** chooses as its *domicilium citandi et executandi* for all purposes arising from this Agreement, the address specified below:

**Contact Person:**

Physical:

Postal:

Email:

13.3 Either party may amend its *domicilium citandi et executandi* by means of written notice to the other party.

13.4 Any notice, request, consent or communication made between **Parties** pursuant to this **Agreement** must be in writing and may be delivered by email, hand, fax or prepaid registered post.

 *Note: Review the chosen method in light of prevailing communication constraints to choose the most practical and sensible method for ascertaining receipt of delivery.*

**14. GENERAL**

14.1 This **Agreement** embodies the entire agreement between the **Parties** and no provision may be altered or amended without the written mutual consent of the **Parties**.

14.2 Neither party may assign or cede any benefit, obligation or interest it may have in this **Agreement** to any other person without the prior written consent of the other party.

14.3 No extension of time or indulgence by any party in any way affects, prejudices or derogates from the rights of the party in any respect under this **Agreement** nor is it a waiver of any rights hereunder or a novation of this **Agreement**.

14.4 The rule that an **Agreement** is interpreted against the party that drafted it does not apply to this **Agreement**.

14.5 In the event of any provision of this **Agreement** being held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect any other provision of this **Agreement**, such provision being regarded as severable.

**15. AUTHORITY**

Each **Party** signing this **Agreement** and on behalf of a **Party** hereto, hereby warrants in his or her official capacity that he or she is duly authorised to do so.

**16. COUNTERPART SIGNING OF THIS AGREEMENT**

16.1 The **Parties** agree that this **Agreement** may be signed at different times and in different places, and in copy provided the content of the **Agreement** and signatures are exact replicas (counterparts) of the originals when put together.

16.2 The signed **Agreements** when put together constitute the binding agreement between the **Parties**.

**THUS DONE AND SIGNED** on behalf of the **PARTIES** by their duly authorised representatives, at the places appearing in the appropriate spaces below, on the dates as specified.

|  |
| --- |
| **Duly authorised and on behalf of the Providing Institution** |
| Full name: |
| Tel: |
| Designation:  |
|  |
| Signature:  |
| Signed at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ on this the \_\_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 20\_\_. |
|

|  |  |  |  |
| --- | --- | --- | --- |
| Witness 1: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Witness 2: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

 |

|  |
| --- |
| **Duly authorised and on behalf of the Recipient Institution** |
| Full name: |
| Tel: |
| Designation:  |
|  |
| Signature:  |
| Signed at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ on this the \_\_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 20\_\_. |
|

|  |  |  |  |
| --- | --- | --- | --- |
| Witness 1: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Witness 2: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

 |

**Annexure A**

**To be completed by the Provider and/or Recipient**

The **Provider** delegates responsibility to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[insert name of person ] who will obtain the necessary **Permit** and arrange the appropriate transport for the **Material** to be transferred

Description of **Project** in terms of which the **Material** will be used upon transfer:

Description of specific experimental tests that the **Material** will be subjected to upon transfer:

Parties other than the Recipient to whom the **Material** will be transferred in terms of the **Project**:

Quantity of **Material** to be transferred:

Preferred method of transfer of **Material**:

Period within which **Material** will be transferred:

Frequency of export of **Material**:

Process of destruction of **Material**:

How confidentiality will be maintained should **Research Results** be released into the public domain:

**Annexure B**

**Benefit Sharing Arrangement between the Recipient and Provider**