# Summary of principles underpinning the Draft Revised MTA

An MTA is a **legally binding** **contract** which means that 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 which can be serious.

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 depend~~s~~ on a shared understanding of terms and the contexts in which they are used.

The MTA Template includes a set of **six provisions that stipulate the type of info~~r~~mation 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.

The MTA Template provides a **sample agreement** to illustrate how to construct a sensible MTA. Not all the provisions in the sample will suit all research collaboration situations but all researchers should be able to operate well within the framework of the sample agreement.

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.

# PREAMBLE

This Template for a **Material Transfer Agreement (MTA)** is intended to provide the minimum standard for the required content for 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**.

It is intended that **Parties** may customise their **MTA** to suit the specific circumstances, provided that the minimum required elements described in 3. below are included.

The **Material Transfer Agreement** 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; how the **Material** will be used; the nature of the **Material**; the terms and conditions under which the **Material** may be used; 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.

*Note: where* ***Data*** *alone is shared, a Data Transfer Agreement (DTA) is appropriate. A DTA 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.*

# 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*

1.1. Agreement:- means this Agreement and all annexures and amendments thereto

1.2 Becomes Identifiable: - Means the Participant who provided the material can be personally identified

1.3 Benefit: - Includes acknowledgement of the Participant’s generosity; sharing access to information, use of research results, royalties, acknowledgement of the Provider for sharing access to the Material, 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, job creation, 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.

1.4 Benefit sharing: - means the process or act of sharing in a manner that is fair and equitable in the benefits as described above

1.5 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

1.6 Data: - means the information associated with the Human Biological

Material, including personal information, derived directly or indirectly during the conduct of the research

1.7 DoH 2015: - means *Ethics in Health Research: Principles, Processes and*

*Structures* 2nd edition 2015 Department of Health Republic of South Africa

1.8 Human Biological - means a biological sample from a person, living or deceased,

Material: including Deoxyribonucleic Acid (DNA), Ribonucleic Acid (RNA), blastomeres, polar bodies, cultured cells, embryos, gametes, progenitor stem cells, tissue, growth factors and blood specimens, and any modifications or derivatives thereof

1.9 Health Research Ethics - means a Health Research Ethics Committee (HREC) which is

 Committee: registered with the South African National Health Research Ethics

Council in terms of s 73(1) of the National Health Act 61/2003

1.10 Intellectual Property - means any creation of the mind that is capable of being protected

Rights: 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)

|  |  |
| --- | --- |
| 1.11 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  |
| 1.12 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 biological sample to be used for health research and / or teaching purposes  |
| 1.15 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  |
| 1.18 Provider:  | - means the institution or entity that transfers the Material  |
| 1.19 Recipient:  | - means the institution or entity that receives the transferred Material  |
| 1.20 Research Results:  | - means all products of the research, whether tangible or intangible;  |
| 1.21 Secondary Use of Material:  | - means use of the Material for purposes other than those for which the Participant originally gave permission, as described in the approved protocol (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  |

## 2. Each MATERIAL TRANSFER AGREEMENT must include

2.1Information 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; the duration of such use; where it will be stored and whether the remainder will be destroyed or returned.

2.2 Information about the **Parties** that identifies them and outlines the expectations, responsibilities of each.

2.3 Information about permissions, liability & representations.

2.4 Information about stewardship and distribution limitations.

2.5 Information about confidentiality, non-disclosure and publication expectations.

3.6 Information about appropriate use of **Material**, including biosafety concerns.

**3. SAMPLE AGREEMENT CONTENT:**

***NOTE: Boldface type = Defined terms for purposes of this document***

**THE PARTIES AGREE AS FOLLOWS:**

### 3.1 OBJECTIVE

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

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

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

3.4 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.

3.4 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**.

3.5 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]*.

3.6 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.*

## 4. OBLIGATIONS OF THE PROVIDER

4.1 The **Provider** must ensure that a **Participant** has provided **Informed Consent** for **Secondary Use of Material** in accordance with 3.3.7 of **DoH 2015** Guidelines and that the **HREC** has reviewed and approved the **Project** including the **Informed Consent** documentation.

4.2 The **Provider** must inform the **HREC** that a **Material Transfer Agreement** for the **Project** exists and will be approved by the relevant institutional authority.

4.3 Where **Material** is to be exported out of the Republic of South Africa, the **Provider** must obtain the necessary **Permit** for such export.

4.4 The **Provider** must inform the **HREC** and the **Participant** if the **Provider** is informed that the **Material** has **Become Identifiable** for any reason whatsoever.

## 5. OBLIGATIONS OF THE RECIPIENT

5.1 The **Recipient** may not use the **Material** for any purpose that is not described as part of the **Project** in Annexure A.

5.2 The **Recipient** may not transfer or otherwise provide access to the **Material** to any party not listed in Annexure A, without a **Project** amendment with written approval from the **HREC** and amendment of this **Agreement**.

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

## 6. ROLE OF THE HEALTH RESEARCH ETHICS COMMITTEE

6.1 The role of the **HREC** is as described in s 73 of the National Health Act 61 of 2003 and in **DoH 2015** Guidelines*.*

6.2 The **HREC** must require the **Provider** to state in the application for ethics review that a **Material Transfer Agreement** exists and will be approved by the relevant institutional authority.

## 7. BENEFIT SHARING

7.1 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**.

7.2 The minimum **Benefit** expected is that the **Recipient** will acknowledge (without violating confidentiality requirements) the generosity of the **Participant** in providing **Human Biological Material** to facilitate research.

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

## 8. DURATION OF AGREEMENT

This Agreement commences and becomes effective on the date it is signed by the authorised signatories and continues until the **Project** terminates.

## 9. TERMINATION OF PROJECT

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

9.2 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**.

## 10. DISPUTE RESOLUTION

10.1 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.

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

10.3 Where the **Parties** fail to achieve resolution within thirty (30) days of the dispute date, the dispute must be referred to the institutional authority of the respective Parties for resolution.

10.4 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.

10.5 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.

## 11. 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.*

11.1 **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.

11.2 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**.

11.3 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**.

11.4 The **Parties** agree to honour the intellectual property 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.

## 12. CONFIDENTIALITY

12.1 The **Parties** must take all reasonable steps to keep the identity of a **Participant** confidential and must protect and secure **Material** at all times.

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

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

12.3.1 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;

12.3.2 the Recipient can reasonably demonstrate was already in its possession at the time of disclosure;

12.3.3 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

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

## 13. 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.*

13.1 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.

13.2 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**. *Bear in mind this is not standard for pharmaceutical clinical trials*.

## 14. INDEMNITY

14.1 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.

14.2 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.

14.3 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.

14.4 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**.

## 15. OFFICIAL ADDRESS FOR COMMUNICATION AND NOTICES

15.1 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:

15.2 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:

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

15.4 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.*

## 16. GENERAL

16.1 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**.

16.2 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.

16.3 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**.

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

16.5 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.

## 17. 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.

## 18. COUNTERPART SIGNING OF THIS AGREEMENT

18.1 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.

89.2 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, in the presence of the undersigned witnesses, 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



















