PRELIMINARY COMMENTS about the SOUTH AFRICAN MTA 1.1

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Evolution of this document

This document evolved from a consultative workshop called by the National Department of Health in April 2019 to discuss the concerns raised by the NHREC and many other parties in response to the gazetting of a standard MTA in July 2018. The objective of the workshop was to clarify the intention of the National Department of Health (NDoH) that the MTA Template was intended to be a *guide* rather than an imposed blueprint, that users may *customise* the MTA to suit their particular circumstances, provided that the necessary basic elements are included and adhered to. The evolved document fulfils the objective and provides clear guidance on how to construct an appropriate MTA. It is thus sensible to name this revised MTA **the South African MTA 1.1** to indicate the difference between it and the gazetted version.

Many people attended that consultative workshop. Unfortunately I do not have access to an attendance register. However, it is to be specifically noted that this document is the product of a collaborative effort which began in April 2019 when good progress was made towards achieving agreement about the preferred content of a national template for a practically useful MTA for South African researchers to use when intending to share Human Biological Material and its Associated Data with collaborators within and outside of South Africa's national borders. Unfortunately, however, the document was not finalised due to reallocation of personnel resources as part of the response to COVID-19.

It is to be hoped that formal finalisation of the document will follow in due course; in the meanwhile, efforts are being made to encourage a standardised approach to the MTA to ensure that important aspects are included and that this precious resource - Human Biological Material and its Associated Data - is treated with appropriate respect and care. I continued the work started at the consultative workshop in April 2019 and consulted with various people to check for flaws and gaps. In particular, I acknowledge Dr Lyn Horn (UCT ORI), Prof Donrich W Thaldar, Dr Marietjie Botes (UKZN) and Prof Annalise Nienaber (UP). To ensure further consultation, the plan is to engage with institutional research offices, health research ethics committees (HRECs) and other interested parties via virtual workshops to gain insight into whether the MTA 1.1 is suitable for finalisation.

Update:

Two virtual workshops were held (2 November 2020 and 20 November 2020) at which clarifications and queries were discussed and further input from colleagues in research contract offices was received. The MTA has been further revised (mostly textual edits) and will be recirculated to attendees of the virtual workshops and other interested parties with the advice that it should be used henceforth. The MTA should be viewed as a living document in that it is open to further review and revision; it is a flexible guide with firm outer parameters that seeks to ensure that the minimum standards for an MTA are covered. To that end, users are requested to make notes over the coming months when textual improvements are required or substantive flaws or gaps are identified so that the guide can be amended as constructively necessary.

25 November 2020

PREAMBLE

The South African Material Transfer Agreement (SA MTA 1.1) is intended to provide the minimum standard for the required content of such an Agreement between Providers and Recipients of Material. It is based on the South African MTA gazetted in July 2018 and provides a detailed framework in terms of which the Parties to an MTA may engage to record their customised Agreement regarding the transfer, use and other processing of the Material.

It is intended that Parties may customise the MTA to suit their specific circumstances, provided that the minimum required elements described below in paragraph 2 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 are shared, a Data Transfer Agreement (DTA) is appropriate. A DTA may have content very similar to that of an MTA, depending on the circumstances and, therefore, this guide may be used for that purpose, with the necessary adjustments made to suit the circumstances.*

1. Summary of principles underpinning the MTA 1.1

An MTA is a legally binding contract which means that researchers must ensure that their institution's research office lawyers are involved. There are contractual implications and consequences when such a contract is not upheld by the parties thereto, 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.

SA MTA 1.1 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 these terms. Standardisation depends on a shared understanding of terms and the contexts in which they are used.

SA MTA 1.1 includes a set of six provisions that stipulate the type of information that must be included in an MTA. This means that SA MTA 1.1 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.

SA MTA 1.1 provides a sample agreement to illustrate how to construct a practically useful 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, SA MTA 1.1 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.

2. Essential Information for each MATERIAL TRANSFER AGREEMENT

1. Information that summarises the Project, describes the nature of the Material to be transferred; the quantities of the biological sample to be transferred; the purpose for which the samples and/or data will be used; the duration of such use; where the samples and data will be stored and whether the remainder of the samples will be destroyed or returned.
2. Information about the Parties that identifies them and outlines the expectations and responsibilities of each.
3. Information about permissions, liability and representations.
4. Information about stewardship and distribution limitations.
5. Information about confidentiality, non-disclosure and publication.
6. Information about appropriate use of samples and data, including biosafety concerns.

3. Role of the Health Research Ethics Committee

The role of the HREC is as described in section 73 of the National Health Act 61 of 2003 and in DoH 2015 Guidelines. That is, its role is to conduct the ethics review of the proposed project. To ensure the link between ethics review and the MTA is evident, the HREC should require the Provider to state in the application for ethics review that a Material Transfer Agreement exists and will be approved by the relevant authorised institutional authority. An HREC is not authorised to approve an MTA.

SAMPLE AGREEMENT FOR GUIDANCE PURPOSES

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

Entered into between

the Provider

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and

the Recipient

On

_____

[insert date]

1. DEFINITIONS

NOTE: This list is provided to assist users. It is not exhaustive. Each MTA should include the definitions that are relevant to that MTA, including additional definitions that do not appear in this list that will describe the intentions and expectations of the Agreement.
The purpose of definitions in the MTA is to ensure that parties understand fully what they are agreeing to.

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 technolog and Material; and capacity building; and/or A 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 (see 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	Commercial use:	- means the sale, lease, license, or other transfer of the Material or Modifications for profit-making purposes
1.7	Data:	- means the information associated with the Human Biological Material, including personal information, derived directly or indirectly during the conduct of the research or from other activities
1.8	DoH 2015:	- means *Ethics in Health Research: Principles, Processes and Structures* 2nd edition 2015 Department of Health Republic of South Africa
1.9	Human Biological Material:	- means a biological sample from a human being, living or deceased, 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
1.10	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

1.11	Intellectual Property Rights:	- means any creation of the mind 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)
1.12	Informed Consent:	- means the record of permission provided by the Participant to collect, use for research, store, share with research partners, and/or use for further research purposes, as appropriate, the Material under consideration *Note: This definition is intended to be general and inclusive for purposes of this Agreement, and is not intended as a standard of legal or ethical compliance. Parties must ensure that they comply with relevant legal and ethical norms regarding Participant consent.*
1.13	Material:	- means Human Biological Material and its Associated Data which may include 'personal information' as defined in the Protection of Personal Information Act 4 of 2013 *Note: If only Human Biological Material samples are to be transferred, the definition should be altered to be limited to Human Biological Material.*
1.14	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
1.15	Modification	- means substances created by the Recipient which contain or incorporate the Material
1.16	Participant:	- means the person who has provided a biological sample to be used for health research and / or teaching purposes
1.17	Parties:	- means the Provider and the Recipient
1.18	Permit:	- means the authorisation of the National Department of Health to transfer and / or export Material
1.19	Project:	- means the health research project for which the Material will be used, which may include storage in a biobank for future use
1.20	Provider:	- means the institution or entity that transfers the Material
1.21	Recipient:	- means the institution or entity that receives the transferred Material
1.22	Report	- means a report prepared by the Recipient and submitted to the Provider about the outcome of the research or upon termination (natural end) of the Project

1.23	Research Results:	- means all new modifications by the Recipient of the Material, whether tangible or intangible;
1.24	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*)
1.25	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*
1.26	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. SAMPLE AGREEMENT CONTENT

THE PARTIES AGREE AS FOLLOWS:

2.1 The objective of this Agreement is to record the intention of the Parties to transfer, use and otherwise process Material.

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 a Project as described in Annexure A.

2.4 The Provider remains the Steward of the Material and the Participant retains the right to determine whether to permit Secondary Use of the Biological Sample .

2.5 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 Material.

2.6 The Parties record that, upon completion of the Project, the remaining unused biological sample will be *[insert the anticipated destiny of the unused biological sample e.g. destroyed or returned]*.

3. OBLIGATIONS OF THE PROVIDER

3.1 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.

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

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

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

4. OBLIGATIONS OF THE RECIPIENT

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

4.2 The Recipient may not transfer or otherwise provide access to the Material to any party not listed in Annexure A, without the Provider first applying in writing to the HREC for a Project amendment and ensuring written amendment of this Agreement and appropriate authorisation.

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

5. BENEFIT SHARING

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

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

5.3 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 continues until the **Project** terminates.

7. COMPLETION OF PROJECT

7.1 When the Project is completed or terminated for any reason whatsoever, the Recipient must provide the Provider with a Report.

7.2 in the case of termination, the Report must describe the reasons for termination, the status of the Project as at termination and the current status of the Material.

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 to the institutional authority of the respective Parties 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.

9. GOVERNING LAW

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.

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.

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. INDEMNITY

11.1 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.

11.2 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.

11.3 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.

11.4 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.

12. 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.

12.1 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.

12.2 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.

12.3 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.

12.4 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.

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) as well as the Committee on Publication Ethics (COPE) (https://publicationethics.org/) 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. OFFICIAL ADDRESS FOR COMMUNICATION AND NOTICES

14.1 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:

14.2 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:

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

14.4 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.

15. GENERAL

15.1 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.

15.2 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.

15.3 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.

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

15.5 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.

16. 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.

17. COUNTERPART SIGNING OF THIS AGREEMENT

17.1 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.

17.2 The Parties agree that counterpart signatures may be secure electronic signatures.

17.3 The Parties agree that the signed Agreements, when put together, constitute the binding agreement between them.

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.

SIGNATURES PAGE FOLLOW

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