DEPARTMENT OF HEALTH

NO. 719 **20 JULY 2018**

National Health Act, 2003 (Act No. 61 of 2003)

Material Transfer Agreement of Human Biological Materials

Material Transfer Agreement of Human Biological Materials is hereby published for public notice. All the providers and recipients of the biological material for use in research or clinical trials under the auspices of the Health Research Ethics Committees shall use the Material Transfer Agreement of Human Biological Materials.

Dr Aaron Motsoaledi, MP
Minister of Health
Date: 27/8/2018

MATERIAL TRANSFER AGREEMENT FOR HUMAN BIOLOGICAL MATERIALS

(hereinafter referred to as, "the Agreement")

Entered into and between

The Providing Institution
(hereinafter referred to as, "the Provider")

and

The Recipient Institution
(hereinafter referred to as, "the Recipient")

and

The Human Research Ethics Committee
(hereinafter referred to as, "the HREC")

THE PARTIES AGREE AS FOLLOWS

1. OBJECTIVE

The objective of this Agreement[1] is to set out a framework within which the Parties will engage in the transfer, use and other processing of the Materials.

2. DEFINITIONS

2.1 Agreement: - means this Agreement and all annexures and amendments thereto;

2.2 Benefit: - means, amongst others, the sharing of information;use of research results;royalties; acknowledgement of the Provider as the source of the Materials; publication rights; transfer of technology or Materials;and capacity building;

2.3 Benefit sharing: - means the process or act of sharing in the benefits that derive from the Project in a manner that is fair and equitable;

2.4 Biobank: - an institution or unit thereof that safeguards an organised collection of Human Biological Material and associated data from different individuals, which are usually kept for an unlimited period of time, for the purposes of health research;

2.5 Country: - means the Republic of South Africa;

2.6 Custodian: - means a person or entity entrusted by the Donor with safeguarding and protecting the Materials;

[1]A Material Transfer Agreement is a contract governing the transfer of materials between organisations and/or institutions, which sets out: what will be done with any material supplied; whether the material will be used in humans or not; the quality of the material; the terms and conditions under which the materials will be used; any modifications to the material; third party transfers; benefit sharing arrangements; intellectual property rights; and other legal requirements and/or regulatory guidelines or policies.

2.7	Data	- means any information, including personal information in any formderived directly or indirectly during the conduct of research or clinical care;
2.8	Donor	- means a person who has donated Materials to be used for health research purposes and / or teaching;
2.9	Human Biological Materials	- means Material from a human being including but not limited to Deoxyribonucleic Acid (DNA), Ribonucleic Acid (RNA), blastomeres, polar bodies, cultured cells, embryos, gametes, progenitor stem cells, tissues and growth factors and any modifications or derivatives thereof;
2.10	Health Research Ethics Committee	means a Health Research Ethics Committee[2] which is registered with the South African National Health Research Ethics Council;
2.11	Intellectual Property Rights:	- means statutory and other proprietary rights resulting from creation of the human mind such as copyright, patents, scientific works, discoveries and trademarks;
2.12	Informed Consent:	- means a formal agreement that a Donor (with legal capacity to do so) signs to give permission for donation of Materials, after being informed about the project and includes an on-going information sharing process which allows a Donorto consent to participate and determine whether and how their Materials will be utilised in the Project, as approved by the HREC from time to time;

[2] Section 73(1)&(2) of the NHA stipulates that:

"(1) Every institution, health agency and health establishment at which health research is conducted, must establish or have access to a health research ethics committee, which is registered with the National Health Research Ethics Council.

(2) A health research ethics committee must-

(a) review research proposals and protocols in order to ensure that research conducted by the relevant institution, agency or establishment will promote health, contribute to the prevention of communicable or non-communicable diseases or disability or result in cures for communicable or non-communicable diseases; and

(b) grant approval for research by the relevant institution, agency or establishment in instances where research proposals and protocol meet the ethical standards of that health research ethics committee."

2.13 Materials - means Human Biological Materials and Data;

2.14 Parties: - means the Provider, the Recipient and the HREC;

2.15 Project: - means the health research project for which the Materials will be used;

2.16 Research Results: - means all products of the research, whether tangible or intangible;

2.17 Secondary Use[3] - means use of the Materials for health research purposes other than the uses determined in the approved protocol; and

2.18 Termination Report: - means a report prepared by the Recipient and submitted to the Provider on termination of the Project.

3. AGREEMENT

3.1 The Provider hereby transfers the Materials to the Recipient, and the Recipient accepts the Materials from the Provider asfully described in **Annexure A.**

3.2 The Parties agree to conduct themselves hereunder in compliance with South African laws and policies, that no Materials shall be transferred for purposes of ahealth research[4] project that has not been approved by an HREC.

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[3] As secondary uses of Materials include health research as contemplated by section 1 of the NHA (footnote 2) and as all health research ethics committees are required to review and approve health research proposals and protocols (footnote 3), approval of secondary uses of Material must be obtained from a health research ethics committee.

[4] According to section 1 of the National Health Act 61 of 2003 (NHA):
"health research includes: any research which contributes to knowledge of –
(a) The biological, clinical, psychological or social processes in human beings;
(b) Improved methods for the provision of health services;
(c) Human pathology;
(d) The causes of disease;
(e) The effects of the environment on the human body;
(f) The development or new application of pharmaceuticals, medicines and related substances; and
(g) The development of new applications of health technology."

3.3 The Provider remains custodian of the Materials; and the donor remains the owner of the material until such materials are destroyed.

3.4 Each Party undertakes to engage with the other in the utmost good faith and to conduct itself with 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.

3.5 This Agreement is subject to the suspensive condition that, and is of no force or effect unless and until, the HREC has approved the Project of which this Agreement forms a part and the HREC has approved this Agreement.

4. OBLIGATIONS OF THE PROVIDER

4.1 The Provider must obtain the necessary permits and authorisations for export of Materials.

4.2 The Provider shall inform the HREC andthe relevant Donor(s)should the Provider be informed that the Materials have become identifiable for any reason whatsoever.

4.3 The Provider must obtaininformed consent from the Donor(s), where reasonably possible,and approval from the HREC, for any further uses of the Material.

5. OBLIGATIONS OF THE RECIPIENT

5.1 The Recipient may only carry out research according to the protocol approved by the HREC.

5.2 The Recipient shall protect and keep the Material confidential.

5.3 The Recipient may not transfer or otherwise provide the Material to any party, other than those parties listed in **Annexure A**, without approval of the HREC.

5.4 Should the Materials become identifiable for any reason whatsoever, the Recipient must inform the Provider without delay.

5.5 The Recipient shall deliver feedback to the Provider on the development and progress made with regard to the Project by supplying the Provider with updated information where relevant and in terms of applicable ethical and legal requirements.

5.6 The Recipient agrees that the Material will be located at:

(entity details)

6. OBLIGATIONS OF THE HREC

6.1 The obligations of the HREC are to:

6.1.1 review and approve research proposals and protocols that require the transfer of Materials;

6.1.2 review and grant approval of this Agreement to ensure that it adequately safeguards the Material and the ethical requirements set out herein; and

6.1.3 review and approve all Secondary Useresearch of the Material transferred.

6.2 The HREC will be the last party to sign this Agreement and will only do so, after all the provisions set out herein, have been satisfied.

7. BENEFIT SHARING

7.1 The sharing of benefits should be discussed and negotiated between the Provider and Recipient before Materials are transferred to the Recipient.

7.2 The Parties agree to Benefit Sharing as detailed in **Annexure B**.

8. DURATION OF AGREEMENT

This Agreement will commence and become effectiveon the date it is signed by the HREC and shall continue until the Project terminates.

9. TERMINATION OF PROJECT

9.1 When the Project terminates, for any reason whatsoever, the Recipient shall provide the Provider and the HREC with aTermination Report.

9.2 The Termination Report will include, *inter alia*, reasons for termination, the status of the Project as at termination and the current status of the Materials.

9.3 Termination of the Project may occur under one or more of the following circumstances:

9.3.1 the Project reaches completion;

9.3.2 the Project cannot be carried out by the Recipient for the following reasons:

9.3.2.1 the Donors withdraw consentfor use as contemplated hereunder and in such numbers as to render continuation of the Project impracticable or impossible;

9.3.2.2 the Recipient entity dissolves, winds-up or ceases to continue operating for any reason whatsoever;

9.3.2.3 the HREC withdraws approval for the Project in its entirety;

9.3.2.4 either Party terminates the Agreement on reasonable notice; or

9.3.2.5 a *force majeure* makes continuance of the Project impracticable or impossible.

9.4 The Recipient will,on termination of the project, immediately discontinue using the Material for any purpose whatsoever.

9.5 Destruction, return to the Provideror transfer of Materials will be undertaken by the recipient, or any other arrangements made,with the express approval of the HREC.

10. INFORMED CONSENT

10.1 The Provider must obtain an informed consent from the Donor(s) to provide Materials to the Recipient to undertake the Project as contemplated.

10.2 The Provider must furnish the completed consent form from the donors together with the project protocol to the HREC for approval.

10.3 The Provider must submit the informed consent form for Secondary Uses of the Material to the HREC should the need arise for Secondary Use.

10.4 The Provider must inform the donors of developments or progress made by the Recipient in the Project and which is relevant to the Donor(s) Informed Consent.

11. DISPUTE SETTLEMENT

11.1 Should a dispute arise between the Parties in connection with this Agreement, the Parties must,within a period of fourteen (14) days after the date on which the dispute arose (the Dispute Date) meet to discuss the dispute and endeavour to resolve the dispute amicably, by mutual agreement.

11.2 If the Parties are unable to resolve the dispute in terms of 11.1 within thirty (30) days from the Dispute Date, the dispute will be referred to the senior management of the respective Parties for resolution.Senior management will use their best endeavours to resolve the dispute andtheir determination will be final and binding and will be carried into effect by the Parties.

11.3 If senior management of the respective Parties are unable to resolve the dispute within a period of thirty (30) days after it has been referred to them, either Party may institute action in accordance with South African laws, in a South African court, unless the Parties agree to resolve such dispute by arbitration in terms of a separate arbitration agreement.

12. INTELLECTUAL PROPERTY

Intellectual property will be dealt with through relevant laws related to the applicable protocol and underlying third party agreements,as far as there are any.

13. CONFIDENTIALITY

13.1 The Recipient shall keep the identity of the Donor(s)and the Materials secure and confidential at all times.

13.2 Confidentiality includes, but is not limited to the properties; characteristics; content; composition; potential secondary uses; and methods of use of the Material.

13.3 The Provider and the Recipient shall treat allinformation relating to the nature and processes of the researchin whatever form confidential.

14. PUBLICATIONS & PUBLICITY

14.1 Authorship of publications emanating from the use of the Materials hereunder must be in keeping with the International Committee of Medical Journal Editors Authorship Guidelines (http://www.icmje.org/icmje-recommendations.pdf) as amended from time to time.

14.2 Where the Recipient wishes to publish any information concerning the Project (in either oral or written form), the Provider must be notified and provided with a copy of the publication at least ten(10) days prior to submission of the proposed publication.

14.3 The Provider must inform the Recipient whether any information related to the publication must be removed or included and provide reasons to substantiate the removal or addition of such information.

14.4 The Provider must be supplied with a final copy of the publication before publication by the Recipient. The Recipient must acknowledge the Provider's contribution of the Material unless otherwise requested by the Provider.

14.5 Neither Party shall use the name of the other Party or its employees in any advertisement, press release or other publicity without prior written approval of the other Party.

14.6 Notwithstanding the above, and where relevant, publications must be subjected to the applicable protocol and relevant third party agreements.

15. INDEMNITY

15.1 The Provider gives no warranty that the Materials are fit for the use and purpose for which they are transferred hereunder, or that they have any particular qualities or characteristics.

15.2 The Provider will not be liable to the Recipient for any claims or damages arising from the Recipient's use of the Material.

16. DOMICILIA AND NOTICES

16.1 The Provider choose as its *domicilium citandi et executandi* for all purposes arising from this Agreement, the addresses specified below:

Attention:
Physical:
Postal:
Telefax:
Email:

16.2 The Recipient choose as its *domicilium citandi et executandi* for all purposes arising from this Agreement, the addresses specified below:

Attention:
Physical:
Postal:
Telefax:
Email:

16.3 The HREC choose as its *domicilium citandi et executandi* for all purposes arising from this Agreement, the addresses specified below:

Attention:
Physical:
Postal:
Telefax:
Email:

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

16.5 Any notice, request, consent or communication made between Parties pursuant to this Agreement shall be in writing and shall be delivered by hand, or sent by prepaid registered post or by fax or email.

16.6 A notice, request, consent or communication is presumed unless the contrary is proven, to have been given:

16.6.1 if hand delivered during business hours on a business day, on the day of delivery;

16.6.2 if posted by prepaid registered post, five (5) business days after the date of posting thereof; *or*

16.6.3 if sent by email, on the first business day following the day of sending of such email.

16.7 Notwithstanding anything to the contrary contained or implied in this Agreement, a written notice or communication actually received by one of the Parties from another including by way of facsimile transmission, shall be adequate written notice or communication to such party.

17. GENERAL

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

17.2 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 and the approval of the HREC.

17.3 Neither Party is regarded as having waived, or is precluded in any way from exercising any right under or arising out of this Agreement by reason of such Party having at any time extended any extension of time for, or having shown any indulgency to, the other Party with reference to any performance of any obligation under this Agreement, or having failed to enforce, or delayed in enforcing any right of action against the other Party.

17.4 This Agreement constitutes the sole record of the Agreement between the Parties in regard to the subject matter hereof and replaces any prior Agreement, which may exist between the Parties.

17.5 No Party will be bound by any representation, express or implied term, warranty, promise or the like not recorded in this Agreement.

17.6 Any amendments to this contract are of no force and effect unless reduced to writing and signed by the Parties.

17.7 No extension of time or indulgence by any Party will be deemed in any way to affect, prejudice or derogate from the rights of the Party in any respect under this Agreement nor will it in any way be regarded as a waiver of any rights hereunder or a novation of this Agreement.

17.8 The rule that an Agreement will be interpreted against the Party that drafted it shall not apply to this Agreement.

17.9 In the event of any one or more of the provisions of this Agreement being held for any reason to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect any other provision of this Agreement, and this Agreement shall be construed as if such invalid, illegal or unenforceable provision was not a part of this Agreement, and the Agreement shall be carried out as nearly as possible in accordance with its original terms and intent.

17.10 The Recipient receives only the rights as set out in this agreement and these rights are not exclusive to the Recipient.

18. 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 by such Party to do so.

19. COUNTERPART SIGNING OF THIS AGREEMENT

19.1 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.

19.2 The signed Agreements when put together shall constitute a 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 _____ 2018.
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 _____ 2018.
Witness 1: _____ Witness 2: _____

Duly authorised and on behalf of the Human Research Ethics Committee
Full name:
Tel:
Designation:
Signature:
Signed at _____ on this the _____ day of _____ 2018.
Witness 1: _____ Witness 2: _____

Annexure A

To be completed by the Provider and/or Recipient

The Responsible Party who will obtain the necessary permits and authorisations and arrange appropriate transport for the Material to be transferred is:

_____

_____

Description of health research project under which the Materials will be used on transfer:

_____

_____

Specific experimental tests that the Materials will be subjected to on transfer:

_____

_____

Parties other than the Recipient to whom the Materials might be transferred as required by the Project:

_____

Quantity of Materials required to be transferred:

_____

Preferred method of transfer of Materials:

_____

Period within which Materials will be transferred:

_____

Frequency of exporting of Materials:

_____

Process of destruction of Materials:

_____

How confidentiality will be maintained should Materials be released into the public domain:

_____

Annexure B

Benefit Sharing Arrangement between the Recipient and Provider