**TEMPLATE**

**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' 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 Material 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;

2.7 Data: means any information, including personal information in any form derived 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 Material: means Material from a human being including but not limited to Materials 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 means a Health Research Ethics Committee which is registered with

Committee: the South African National Health Research Ethics Council;

2.11 Intellectual Property: means statutory and other proprietary rights resulting from

Rights: 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 Donor to 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;

2.13 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: means use of the Materials for health research purposes other

than the uses determined in the approved protocol;

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 as fully 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 a health research project that has not been approved by an HREC.

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 and the relevant Donor(s)should the Provider be informed that the Materials have become identifiable for any reason whatsoever.

4.3 The Provider must obtain informed 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)

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| --- |
|  |

**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 Use research 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 effective on 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 a Termination 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 consent for 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 Provider, or 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

and their 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;

13.3 The Provider and the Recipient shall treat all information relating to the nature and

processes of the research in 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/icmie- 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 íf posted by prepaid registered post, five (5) business days after the date of posting thereof; or

16.6.3 íf 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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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:

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

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

Project:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Quantity of Materials required to be transferred:

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Preferred method of transfer of Materials:

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Period within which Materials will be transferred:

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Frequency of exporting of Materials:

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Process of destruction of Materials:

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

**Annexure B**

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

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