

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

MATERIAL TRANSFER AGREEMENT FOR HUMAN BIOLOGICAL MATERIALS¹

(hereinafter, “the Agreement”)

Signature Date -----

¹ This MTA has been approved by the Biobanks Ethics Committee of the University of the Witwatersrand Johannesburg. This document is an adaptation of one of the outcomes of Safia Mahomed’s PhD through the Steve Biko Centre for Bioethics, Faculty of Health Sciences, University of the Witwatersrand, with support from the Wits Biobanks Ethics Committee and Legal Office as at 1 January 2017. This document may be used but sources must be duly acknowledged.



Entered into by and between:

(Hereinafter, “the Provider”)

Registered physical and postal address of Principal Investigator:	Tel:
	Fax:
	Cell:
	Email:



(Hereinafter, “the Recipient”)

Registered physical and postal address of Recipient:	Tel:
	Fax:
	Cell:
	Email:



(Hereinafter, the Human Research Ethics Committee)

Registered physical and postal address of Human Research Ethics Committee:	Tel:
	Fax:
	Cell:
	Email:

PREAMBLE²

WHEREAS

- A. the Provider remains custodian of the Materials; and
- B. the Provider hereby transfers the Materials to the Recipient, and the Recipient accepts the Materials subject to the terms and conditions below; and
- C. each Party undertakes to engage with the other in the utmost good faith and to conduct itself in the highest ethical standards and comply with all applicable legislation, including but not limited to the legislative ban on the sale of or trade in tissues, gametes, blood or blood products; and
- D. the Parties agree to conduct themselves hereunder in compliance with the Human Research Ethics Committee (Medical), University of the Witwatersrand, Johannesburg (HREC) protocols on research on human biological materials; and
- E. understanding, therefore, that no Materials can be transferred for purposes of a research³ project that has not been approved by the HREC

² 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, intellectual property rights and other legal requirements, regulatory guidelines or policies.

³ 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.”

NOW THEREFORE, 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, and to provide for matters connected therewith.

2. DEFINITIONS

- 2.1 Agreement: - means this Agreement and all annexures thereto
- 2.2 Benefit: - means the benefit that will be received by the Provider from the use of the Materials by the Recipient. Benefits may include, 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: - means 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

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- 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 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 Human Research Ethics Committee (Medical) University of the Witwatersrand, Johannesburg ("HREC"): - means the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, Johannesburg which is registered with the South African National Health Research Ethics Council, whose purpose is to review and, where the proposals meet the ethical standards of the committee, approve all health research protocols⁴

⁴ 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."

- 2.11 Intellectual Property Rights: - means statutory and other proprietary rights resulting from creations of the human mind such as copyright, patents, scientific works and discoveries, and trademarks
- 2.12 Informed Consent: - means 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 and the Recipient in this Agreement
- 2.15 Project: - means the health research project for which the Materials will be used hereunder
- 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. Secondary uses must be approved by the HREC⁵
- 2.18 Signature Date: - means the effective date subject to 3.3
- 2.19 Termination Report: - means a report prepared by the Recipient and submitted to the Provider on termination of the Project. The Termination Report will

⁵ As secondary uses of Materials include health research as contemplated by section 1 of the NHA (ref: footnote 3) and as all health research ethics committees are required to review and approve health research proposals and protocols (ref: footnote 4), approval for secondary uses of Material must be obtained from a health research ethics committee.

include, inter alia, reason for termination, status of Project at termination and current state of Materials.

3. OBLIGATIONS OF THE PROVIDER

- 3.1 The Provider agrees to transfer to the Recipient the Materials more fully described in **Annexure A**, and in the quantity, packaging and by mode of transport as more fully described in **Annexure A**.
- 3.2 Should the Provider be informed that the Materials have become identifiable for any reason whatsoever, the Provider is responsible for informing the HREC and the relevant Donor(s) of same and for obtaining approval from the HREC and consent from the Donor(s), where reasonably possible, for any further uses of the Material.
- 3.3 This Agreement is subject to the suspensive condition that, and is of no force or effect unless and until, the HREC has approved the study of which the MTA forms a part of *and* the MTA.

4. ACKNOWLEDGEMENTS BY AND OBLIGATIONS OF THE RECIPIENT

- 4.1 The Recipient acknowledges that the Materials have been obtained and/or developed by the Provider, where applicable.
- 4.2 The Recipient acknowledges that the Materials are of health research value.
- 4.3 The Recipient may only carry out research according to the protocol approved by the HREC.
- 4.4 The Recipient will be responsible for obtaining the necessary permits and authorisations, and for arranging and bearing the costs of the appropriate transport for the Material to be transferred to the Recipient.

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- 4.5 The Recipient acknowledges that the Materials may contain sensitive and confidential information, which information the Recipient undertakes to protect and keep confidential.
- 4.6 Other than those parties stipulated in **Annexure A**, the Provider may not transfer or otherwise provide the Material to any party without approval of the HREC. Such approval will be on such written conditions as the Provider may deem fit in its sole discretion and will be agreed by the Recipient in writing.
- 4.7 Should the Materials become identifiable for any reason whatsoever, the Recipient must inform the Provider without delay.
- 4.8 The Recipient agrees to 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. USE AND PURPOSE OF MATERIAL

- 5.1 The Recipient warrants that the Materials will be used only for the purposes of the Project, as more fully described in **Annexure A**, attached hereto.
- 5.2 The Recipient agrees that the Material will be located at:
_____(entity details)
- 5.3 The Recipient shall not, without the written permission of the Provider, use the Materials for any purpose other than that permitted in terms of this Agreement.

6. BENEFIT SHARING

The sharing of benefits should be discussed and negotiated between the Provider and Recipient before Materials are transferred to the Recipient. The Parties agree to Benefit Sharing as detailed in **Annexure B**.

7. DURATION OF AGREEMENT

This Agreement will commence on the effective date and shall continue until the termination date.

8. TERMINATION OF PROJECT

8.1 In the event that the Project terminates, for any reason whatsoever, the Recipient will provide the Provider and the HREC with a Termination Report.

8.2 Termination of the Project will occur under one or more of the following circumstances:

8.2.1 the Project reaches completion;

8.2.2 the Project cannot be carried out by the Recipient for any reason whatsoever, including but not limited to the following:

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

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

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

8.2.2.4 either Party terminates the Agreement on reasonable notice;

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

8.3 On termination, the Recipient will immediately discontinue using the Material for any purpose whatsoever.

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- 8.4 Destruction, return to the Provider or transfer of Materials will be undertaken, or any other arrangements made, with the express approval of the HREC.

9. INFORMED CONSENT

Informed Consent requires that:

- 9.1 the Provider has obtained informed consent from the Donor(s) to provide Materials to the Recipient to undertake the Project as contemplated. In the event of Secondary Use of the Materials, the Donor(s) have consented thereto insofar as the Secondary Uses have been approved by the HREC.
- 9.2 the Donor(s) have been informed that, where reasonably possible, the Provider will inform them of developments or progress made by the Recipient in the Project and which is relevant to the Donor(s)' Informed Consent.
- 9.3 the Donor(s) have been informed and have accepted that on termination of this agreement, the Material will be returned to the Provider or destroyed, or any other arrangements made, as determined by the Provider under clause 8.
- 9.4 the Donor(s) are aware that all Materials and associated data are de-identified.
- 9.5 Disclosure to Donor(s) has been made in the event that Materials will be released into the public domain.
- 9.6 should the Recipient wish to conduct studies or use the Material for any other purpose than that approved by the HREC, the Provider must be notified in writing and HREC approval must first be obtained.

10. DISPUTE SETTLEMENT

- 10.1 All disputes between the Parties will be determined in accordance with the provisions of this clause 10.
- 10.2 Within a period of fourteen (14) days after the date on which the dispute arose (“the Dispute Date”) the Parties will meet to discuss the dispute and will endeavour to resolve the dispute amicably.
- 10.3 If the Parties are unable to resolve the dispute in terms of 10.2 within thirty (30) days from the Dispute Date the dispute will be referred to the Vice-Chancellor or a Deputy Vice-Chancellor of the University and the Chief Executive Officer of the Recipient or their duly appointed representative/s, who will use their best endeavours to resolve the dispute. Their determination will be final and binding and will be carried into effect by the Parties.
- 10.4 If the individuals described in 10.3 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 the South Gauteng High Court, Johannesburg, unless the Parties agree to resolve such dispute by arbitration in terms of a separate arbitration Agreement.

11. INTELLECTUAL PROPERTY

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

12. CONFIDENTIALITY

The Recipient agrees to keep the Materials secure and confidential at all times. Confidentiality includes, but is not limited to: the properties, characteristics, content, composition, potential secondary uses and methods of use of the Material. All information relating to the nature and processes of the research in whatever form, must also be treated as confidential. The identity of the Donor(s) must be protected and kept confidential at all times. Any publications, newsletters or oral

presentations must not divulge any details of the Donor(s) unless consent has been obtained for such use from the Donor(s).

13. PUBLICATIONS AND PUBLICITY

13.1 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.

13.2 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. 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.

13.3 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.

13.4 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.

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

14. LIABILITY

14.1 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.

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

14.3 Should either Party breach the terms of this Agreement, notwithstanding 7 (seven) days written notice to rectify the breach, this Agreement may be terminated by the aggrieved Party by written notice.

15. GENERAL

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

15.3 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.

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

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

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- 15.6 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.
- 15.7 The rule that an Agreement will be interpreted against the Party that drafted it shall not apply to this Agreement.
- 15.8 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.
- 15.9 The Recipient receives only the rights as set out in this agreement and these rights are not exclusive to the Recipient.
16. This MTA is null and void and of no force and effect unless and until the HREC has approved the research of which the MTA forms a part *and* the MTA.

Duly authorised and on behalf of the Provider:

Full name: _____

Designation: _____

Signature: _____

Signed at _____ on this the _____ day of _____, 2021

WITNESSES:

Witness 1: _____

Witness 2: _____



Duly authorised and on behalf of the Recipient:

Full name: _____

Designation: _____

Signature: _____

Signed at _____ on this the _____ day of _____, 2021

WITNESSES:

Witness 1: _____ Witness 2: _____

Duly authorised and on behalf of the Human Research Ethics Committee:

Protocol No.: _____

Principal Investigator: _____

Study Title: _____

Full name: _____

Designation: _____

Signature: _____

Signed at _____ on this the _____ day of _____, 2021

WITNESSES:

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



Annexure B

Benefit Sharing Arrangement between the Recipient and Provider

REFERENCES

POLICIES, ACTS, REGULATIONS & GUIDELINES

1. The Human Research Ethics Committee Medical (HREC) “Principles and Policies on Biobanks” University of the Witwatersrand.
2. Companies Act 71 of 2008.
3. Ethics in Health Research: Principles, Structures and Processes, Research Ethics Guidelines, Department of Health, (2004).
4. National Health Act 61 of 2003 together with Regulations to chapter 8 thereof.
5. OECD Guidelines on Human Biobanks and Genetic Research Databases.
6. Protection of Personal Information Act 4 of 2013.
7. Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals developed by members of the International Committee of Medical Journal Editors over the period 2011 to 2013. Accessed at: <http://www.icmje.org/icmje-recommendations.pdf> on 26 May 2014.
8. World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects.

MATERIAL TRANSFER AGREEMENT TEMPLATES

1. Draft Material Transfer Agreement adapted for the National Health Research Ethics Council, developed by Glaudina Loots (Director: Health Innovation – Department of Science and Technology).
2. Fred Hutchinson Material Transfer Agreement for Non Profit Organisations.
3. South African National Botanical Institute Agreement (B) for the Supply of Biological Material.
4. Uganda’s Standard Material Transfer Agreement.
5. UHN (Toronto) Technology, Development and Commercialisation Material Transfer Agreement.
6. UW TechTransfer Invention Licensing UW CFAR HIV Specimen Repository Materials Transfer Agreement (Not-for-Profit).
7. University College London Standard Material Transfer Agreement.
8. WITS Health Consortium Standard Material Transfer Agreement.

9. Informal discussion with Ms Marietjie Botes, Insurance attorney, 13 March 2014.

JOURNAL ARTICLES, RESOURCE MANUALS & OTHER TEXTS

1. Dhai A “Practical Ethics Guide for Researchers and Research Ethics Committee Members” (Steve Biko Centre for Bioethics), resource manual (2012).
2. Goebel JW et al “Legal and Ethical Consequences of international biobanking from a national perspective: the German BMB-EU Coop Project” European Journal of Human Genetics (2010) 18, 522-525.
3. Master Z & Resnik DB “Stem-cell tourism and scientific responsibility” European Molecular Biology Organisation Reports. 2011, 992-995.
4. Sathar A et al “Collaborative International Research: Ethical and Regulatory Issues Pertaining to Human Biological Materials at a South African Institutional Research Ethics Committee” Developing World Bioethics ISSN 1471-8731.
5. Schwab A “The Recipe for Overarching Regulation” American Journal of Bioethics.
6. Streltz WD, Bennet AB “Material Transfer Agreements: A University Perspective” Office of Research Administration, University of California.
7. Legal opinion by Norton Rose Fulbright titled “Legal opinion on the interpretation and applicability of the Intellectual Property Rights from Publically Financed Research and Development Act, 2008 and its Regulations to the Research and Development activities undertaken by Wits Health Consortium (Pty) Ltd” dated 30 April 2014.