



MATERIAL TRANSFER AGREEMENT AND CONFIDENTIALITY AGREEMENT

made and entered into between:

The **SOUTH AFRICAN MEDICAL RESEARCH COUNCIL**, a statutory science council established and operating in terms of the South African Medical Research Council Act, No. 58 of 1991, herein represented by **Professor Glenda Gray** in her capacity as President of the Council,

through its **NON-COMMUNICABLE DISEASES RESEARCH UNIT**, represented by **Professor Andre Pascal Kengne** in his capacity as Director of the Unit

From: Office of the President, PO Box 19070, Tygerberg 7505, South Africa

(hereinafter "Receiving Party / Recipient")

And

INSTITUTIONAL DETAILS

(hereinafter "Disclosing Party")

PREAMBLE

Whereas each Party as a Disclosing Party has in its possession certain Confidential and / or Material relating to the Purpose;

And Whereas each Party as a Disclosing Party has agreed to disclose certain of this Confidential Information and / or Material to the Receiving Party subject to the Receiving Party agreeing to the terms of confidentiality set out herein;

1 INTERPRETATION AND DEFINITIONS

In this Agreement, unless inconsistent with, or otherwise indicated by the context:

- 1.1 The headings of clauses are intended for convenience only and shall not affect the interpretation of this Agreement;
 - 1.2 Words in the singular include the plural and vice versa;
 - 1.3 Words importing any one gender include each of the other genders;
 - 1.4 A reference to a natural person includes a legal person;
 - 1.5 "Parties" means the parties to this Agreement and "Party" shall mean one of them;
 - 1.6 The "Disclosing Party" is the proprietor and / or owner and / or is lawfully entitled to and / or has a legal right to the "Confidential Information" and / or Material as defined below;
 - 1.7 The "Receiving Party / Recipient" means either Party receiving any Confidential Information and / or Material from the Disclosing Party and shall include its members of staff, students and contractors;
 - 1.8 "Confidential Information" shall include, but shall not be limited in its interpretation to all intellectual property, patents, copyrights, trademarks, inventions, utility models and like, rights, secret knowledge, and further means every other form of intellectual property right, which also includes any improvement(s), specialist technical information or expertise, data, material (including biological materials), organisms- as well as non-patentable inventions, irrespective of the way and manner of being published, or the way it is written or recorded whether it is captured on a computer, developed or created, as well as specifications, formulae, systems, methods, process, information, inventions, which means any invention that describes new and inventive and can be applied or implemented in agriculture or trade, as well as inventions described in the specifications of patents of/and applications for patents that is protected against any claims thereof and all rights that is internationally protecting, including, but without limitation, the right to obtain legal protection regarding that, in whatever form it is available, and patents, which mean all registered patents and/or applications to patents listed in the world, together with all rights to, in any other country in the world apply
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for such patent protection and/or receive such protection, technical information and specifications, manufacturing techniques, designs, circuit diagrams, instruction manuals, blueprints, electronic artwork, samples, devices, demonstrations, formulae, know-how, show-how, information concerning materials, marketing and business information generally, financial information and other materials of whatever description in which the Disclosing Party has an interest in being kept confidential;

- 1.9 “Commencement Date” means the date of signature of the party signing last;
- 1.10 “Material” means the material to be transferred, together with any parts or sub-units, descendants, progeny, mutants, mutations or other derivatives thereof, to the Recipient as defined in clause 6 hereunder;
- 1.11 “Dataset library” means the document that accompanies the Material document file, listing the variables contained in the Material document file, along with the definition and unit measure of each variable;
- 1.12 “Pooling” means merging the Material received from various sources;
- 1.13 “Computer database” means electronic version of the pooled data which will be kept centrally, at the South African Medical Research Council (SAMRC), Non-Communicable Diseases Research Unit (NCDRU) in Cape Town, South Africa;
- 1.14 “Deidentified” means that the identifiable variables related to the participants will be removed prior to submission of the Material to the head office of the consortium;
- 1.15 “Purpose / Project” means Material, data and information relating to **NAME OF THE STUDY**

NOW THEREFORE it is hereby agreed that: -

2 OWNERSHIP OF THE CONFIDENTIAL INFORMATION AND ASSESSMENT

- 2.1 The Receiving Party acknowledges that all right, title and interest in and to the Confidential Information and / or Material vests in the Disclosing Party and that it has no claim of any nature in and to the Confidential Information and / or Material.
- 2.2 The Disclosing Party and Receiving Party specifically undertake, in the event of any new invention(s) that may be conceived or reduced during the conduct of and pursuant to the Project, to use their best endeavours to negotiate in good faith and with due regard to the relative contributions of each Party to such a new invention, a joint invention agreement, which agreement shall *inter alia* provide for, on an equitable basis, the sharing between them of new patent costs, the percentage of their respective ownership in such new patent(s) and their respective income and invention responsibilities, provided also that both Parties retain the right to commercialise independently of the other Party.
- 2.3 Confidential Information and / or Material disclosed under this Agreement shall at all times remain the property of the Disclosing Party. The Confidential Information will be used for

Not-for-profit research purposes only and in accordance with the terms and conditions of this Agreement.

- 2.4 No license or other rights in or to the Confidential Information and / or Material is granted by this Agreement or any disclosure under this Agreement except as provided herein.
- 2.5 This Agreement does not confer by implication *estoppel* or otherwise any license or other rights under any of the Patents, patent applications, Confidential Information, trademarks-and/or secrets, or other proprietary rights of either Party.
- 2.6 All Confidential Information and / or Material made available under this Agreement, including copies thereof, shall be returned to the Disclosing Party (or, upon such Party's request or consent, destroyed) upon the first to occur of:
 - 2.6.1 completion of the Purpose(s) set forth in this Agreement; or
 - 2.6.2 at the request of the Disclosing Party; or
 - 2.6.3 at the cancellation of this Agreement by any party without any reason.
- 2.7 The Receiving Party shall immediately report, in writing, to the Disclosing Party, any improvements and modifications that it might make to the Material and/or the Confidential Information. The Receiving Party shall promptly inform the Disclosing Party, in writing of any inventions, whether patentable or otherwise, resulting from the Receiving Party's direct use of the Material and/or Confidential Information. In the event that the Disclosing Party elects not to seek patent protection on inventions conceived or reduced to practice using the Material, the Receiving Party shall have the right of first refusal to file patent applications on behalf of the Receiving Party for said inventions.

3 PERIOD OF CONFIDENTIALITY

- 3.1 The provisions of this Agreement shall remain in force for the duration of this Agreement and a period of three (3) years after the termination thereof.

4 NON-DISCLOSURE

- 4.1. The Receiving Party undertakes to maintain the confidentiality of any Confidential Information, whether the access thereto was granted before or after the Commencement Date of this Agreement. The Receiving Party will not disclose or permit to be disclosed to any person any aspect of such Confidential Information other than as specifically for the Purpose allowed in this Agreement.
 - 4.2. The Receiving Party shall take all such steps as may be necessary to prevent the Confidential Information falling into the hands of an unauthorised third party.
 - 4.3. The Receiving Party shall not make use of any of the Confidential Information in the development, manufacture, marketing and/or sale of any goods without the prior written consent of the Disclosing Party.
 - 4.4. The Receiving Party shall not use or disclose or attempt to use or disclose the Confidential Information for any purpose other than as intended herein.
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- 4.5. The Receiving Party shall not use or attempt to use the Confidential Information in any manner which will cause or be likely to cause injury or loss to the Disclosing Party.
- 4.6. The Receiving Party shall by written notice to the Disclosing Party specify which of the Receiving Party's employees, officers or agents will have any access to the Confidential Information and those individuals whose access are approved by the Disclosing Party shall sign this agreement or a copy hereof in acknowledgement that they are also in the individual capacity bound by the terms and conditions of this agreement. In addition, the Receiving Party shall be jointly and severally liable for any breaches of such individuals of any provision contained herein.

5 EXCEPTIONS

- 5.1 The rights and obligations agreed to in clause 4 above shall not apply to information which:
 - 5.1.1 is in fact lawfully in the public domain available at the Commencement Date; or
 - 5.1.2 lawfully comes into the public domain after the Commencement Date otherwise than as a result of the conduct of the Receiving Party or one of its employees or agents; or
 - 5.1.3 the Receiving Party is obligated to produce as a result of an order by a court, judicial or administrative authority or pursuant governmental action, provided that the Disclosing Party shall have been given prior written notice of such court order, governmental action and opportunity to appear and object, or
 - 5.1.4 The Receiving Party obtains from a third party not under any confidentiality obligation to the Disclosing Party respecting such information, or
 - 5.1.5 The Receiving Party at the time of disclosure already has in its possession and in which is not subject to any obligation of secrecy on their part, to the other party, or
 - 5.1.6 The Receiving Party can prove from its records to have been independently generated and/or developed by it without reference to any information it has received pursuant of this Agreement.
- 5.2 The onus of proving the facts necessary to sustain any one of the exceptions listed in subparagraphs 5.1.1 to 5.1.6 rests with the Receiving Party.

6 TRANSFER OF MATERIAL

- 6.1 This agreement concerns the following deidentified Material to be provided to the Recipient only if captured in the **[Name of study]**:
 - 6.1.1 Demographic and general information, including gender, age, level of education, employment, income (estimate of total household income), indicators of the study setting (rural vs. urban), variables reflecting the design (if complex design used),
 - 6.1.2 Behavioural measurements, including tobacco use, alcohol consumption, diet and dietary salt intake, physical activity, personal and family history of (raised blood pressure, diabetes, raised total cholesterol, cardiovascular disease, chronic kidney

- disease), received lifestyle advice, list of chronic medication use (including traditional medicine),
- 6.1.3 Past medical history, including any previous dialysis treatment for acute kidney injury,
 - 6.1.4 Physical measurements, including blood pressure and heart rate, weight, height, waist circumference, hip circumference, blood glucose, blood lipids,
 - 6.1.5 Measures of kidney function, including creatinine, urea, urinary albumin excretion, urinary protein creatinine ratio, cystatin C,
 - 6.1.6 Measures of chronic kidney disease impact, including serum electrolytes (Na⁺, K⁺, Cl⁻, calcium, phosphates), haematological profile, serum protein,
 - 6.1.7 Other biological markers, including markers of inflammation (high-sensitivity C-reactive protein (hsCRP), fibrinogen, or other biological markers measured),
 - 6.1.8 Kidney imaging, including for example ultrasound of the kidney, echogenicity and corticomedullary differentiation,
 - 6.1.9 Histology of kidneys, including renal biopsies.

7 THE RESEARCH PROJECT

- 7.1 The manner in which, and the extent to which the Material may be used by the Recipient are as follows:

The deidentified Material, obtained from [Collaborators' institution] will be merged with the existing database from other contributing studies. The merged database will be used in the analysis to answer research questions; which will be predetermined by the core research group.

- 7.2 In the framework of this Agreement, the Parties may transfer Material to one another, which transfer shall be subject to the conditions of this Agreement. Parties shall list such Material also as Annexure to this Agreement and shall keep the Annexure up to date after each transfer of Material.
- 7.3 The Receiving Party shall utilise the Material solely for the conduct of the Project and shall in no case seek or have any person or corporate body seeking any commercial use of the Material or any other material that could not have been made but for the Material, unless explicitly agreed upon in this Agreement.
- 7.4 The Receiving Party shall not transmit by any means whatsoever all or part of the Material to any third party without the prior and written consent of the Disclosing Party.
- 7.5 The Receiving Party shall ensure that the importation, transport, use, maintenance and disposition of the Material will be conducted in strict accordance with and in compliance

with all laws and regulations both local, nationally and internationally, including regulations for work with recombinant Material.

- 7.6 In the event where human tissue or products of human origin are implied by this Agreement, the Parties undertake to comply with the regulations related to human tissue or products of human origin, as enacted in the RSA Act on Human Tissue 65 of 1983, as amended and/or any other relevant act(s) and/or regulation(s) and in this regard to get the necessary approval from the Ethics Committee of either and/or both Parties, prior to the transfer of such human tissue or products of human origin.

8 PUBLICATION RIGHTS

- 8.1 In the framework of this Agreement, the *defacto* member/s of the Disclosing Party will act as co-author/s to all publications generated using Material supplied by the Disclosing Party. If the Material supplied by the Disclosing Party is not used in a publication, the *defacto* member/s will not be included as a co-author.
- 8.2 Any publication, document and/or paper arising out of joint work conducted by the Parties pursuant to this contract must acknowledge both the Disclosing Party and the Recipient.
- 8.3 The use of the name, logo and/or official emblem of a Party on any publication, document and/or paper by any Party shall require prior permission of the Party whose emblem will be utilised. It must however be ensured that the official emblem and logo of the respective Parties are not misused.

9 WHOLE AGREEMENT

- 9.1 This document constitutes the whole of this Agreement to the exclusion of all else.
- 9.2 No amendment, alteration, addition, variation or consensual cancellation of this Agreement will be valid unless in writing and signed by both Parties hereto.

10 WAIVER

- 10.1 No waiver of any of the terms or conditions of this Agreement will be binding for any purpose unless expressed in writing and signed by both Parties and any such waiver will be effective only in the specific instance and for the purpose given.
- 10.2 No failure or delay on the part of the Disclosing Party in exercising any right, power or privilege will operate as a waiver, nor will any single or partial exercise by the Disclosing Party of any right, power or privilege preclude any other or further exercise thereof or the exercise of any other right, power or privilege.

11 SEVERABILITY

- 11.1 In the event that any of the provisions of this Agreement are found to be invalid, unlawful, or unenforceable such terms shall be severable from the remaining terms, which shall continue to be valid and enforceable.

12 NON-EXCLUSIVITY

- 12.1 Nothing in this Agreement shall be deemed to constitute or imply that the Disclosing Party grants any licence, immunity or intellectual property rights to the Receiving Party or that the Disclosing Party is obliged to enter into any further Agreements with the Receiving Party.
- 12.2 It is explicitly agreed upon by the Parties that the provision and disclosure of Confidential Information from the Disclosing Party to the Receiving Party is non-exclusive as the Disclosing Party, in his sole discretion, is entitled and free in any manner it chooses to act with Confidential Information in any way the Disclosing Party sees fit, and whatever the decision, including the disclosure of Confidential Information to any third party for any other similar reason, is in the sole discretion of the Disclosing Party.

13 BREACH

- 13.1 If a party to this agreement ("the breaching party") breaches any material provision of this agreement, the other party ("the aggrieved Party") shall be entitled to deliver to the breaching party a written notice requiring the breaching party to rectify that breach within 30 days of receipt.
- 13.2 If the breaching party remains in breach of such provision within 30 days after receipt of the notice, the aggrieved party shall be entitled (without derogating from any of its other rights or remedies under this agreement or at law)
- 13.2.1 To sue for immediate specific performance of any of the defaulting party's obligations under this agreement, whether or not such obligation is then due, or
- 13.2.2 To cancel this agreement, in which case written notice of the cancellation shall be given to the defaulting Party, provided that the remedy of specific performance or damages would not adequately prevent the aggrieved party from being prejudiced.

14 WARRANTIES AND INDEMNIFICATION

- 14.1 Each Party agrees to indemnify, defend and hold harmless the other Party and its directors, employees, researchers and students against any and all claims of or liabilities to third parties, including fees, expenses and costs of claims and suits for any such third parties loss, damage, injury, or loss of life, if such claims or liabilities arise directly or indirectly from the omission or performance of the indemnifying party's rights or obligations arising out of this Agreement. A Party is released from this obligation as far as the aforementioned is

caused by gross negligence or malicious intent of the other Party or any of its employees, researchers and/or students.

- 14.2 The Parties shall not be liable against one another for any damages or loss of profit in connection with this Agreement unless this is caused by gross negligence or malicious intent of a Party, its licensees or any of its directors, employees, researchers or students.
- 14.3 Notwithstanding any other provisions and/or terms and conditions referred to herein, the Disclosing Party does not warrant that the use of the Materials does not or will not infringe any patent nor is the Disclosing Party under any obligation to obtain or provide licenses that may be required for the use of the Materials by the Receiving Party. The Material is experimental in nature and is provided by the Disclosing Party with no warranties, express or implied, including any warranty of merchantability, title, or fitness for a particular use. The Receiving Party will indemnify the Disclosing Party and hold the Disclosing Party harmless from any claims or liabilities that might arise as a result of the Receiving Party's use of the Material.

15 MISCELLANEOUS

- 15.1 Any notice required or permitted to be given to the parties hereto is properly given if delivered, in writing, in person to the addresses on the first page of the Agreement or to such other addresses as may be designated in writing by the parties from time to time during the term of this Agreement.

16 DISPUTES

- 16.1 The Parties shall use reasonable endeavours to solve any dispute that will arise in connection to this Agreement by mutual arrangement. Any disputes between the Parties arising under or relating to this Agreement shall be first presented to senior management representatives of the respective Parties for resolution, who will attempt to resolve the matter amicably and promptly. If the Parties do not come to any solution, the Party by whom any legal action is instituted, will be entitled to choose the jurisdiction of a competent court as *dominis litis*.

17 JURISDICTION

- 17.1 This Agreement shall be governed by South African law and the Parties hereby irrevocably agrees to the jurisdiction of the High Courts of South Africa in respect of any dispute flowing from this Agreement.

Signed at _____ on this _____ day of _____

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(Signature of "Recipient")

Signed at _____ on this _____ day of _____

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(Signature for "Disclosing Party")
