**DATA TRANSFER & SHARING AGREEMENT PERTAINING TO THE SUPPLY OF CONFIDENTIAL**

**RESEARCH DATA** (hereafter referred to as “DTA”)

**Entered into between**

**The Provider**

**and**

**The Recipient**

**On**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**[date]**

**MATERIAL TRANSFER AGREEMENT**

1. **DEFINITIONS**

*NOTE: Each DTA should include the definitions that are relevant to that DTA*

|  |  |
| --- | --- |
| * 1. Agreement:
 | * means this Agreement and all annexures and amendments thereto
 |
| * 1. Becomes Identifiable:
 | * means the Participant who provided the data can be directly personally identified
 |
| * 1. Benefit:
 | * includes sharing access to information, use of research results, publication rights, transfer of technology and data and capacity building; and

 contribution to the socio-economic needs of the Republic and includes capacity development, technology transfer, enterprise development, social upliftment and products, or processes or services that embody or use the intellectual property; ex Publicly Financed Research and Development Act 51/2008 Reg 1. |
| * 1. Benefit sharing:
 | * means the process or act of sharing in a manner that is fair and equitable in the Benefits (as described above)
 |
| * 1. Associated Data:
 | * means the information associated with the data, including personal information, derived directly or indirectly prior and during the conduct of the research **Project**
 |
| * 1. DoH 2024:
 | * means *South African Ethics in Health Research Guidelines: Principles, Processes and Structures 2024, 3rd edition.* Department of Health Republic of South Africa
 |
| * 1. 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. Intellectual Property Rights:
 | * means any creation of the mind that is foregrounded or backgrounded and 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. Informed Consent:
 | * means the record of permission provided by the **Participant** to collect, store and use for further research purposes (as appropriate) the **Data** under consideration
 |
| 1.10 Data Transfer Agreement: | * means a legally binding contract that governs the transfer and sharing of Data between organisations and/or institutions, which sets out: what will be done with any Data supplied; the nature of the Data; the terms and conditions under which the Data will be used; any modifications to the Data; benefit sharing arrangements; intellectual property rights; and other legal requirements and/or regulatory guidelines or policies
 |
| 1.14 Participant:  | * means the person who has provided Data to be used for health research and / or teaching purposes
 |
| * 1. Parties:
 | * means the **Provider** and the **Recipient**
 |
| 1.16 Permit: | * means the authorisation of the National Department of Health to transfer and / or share Data.
 |
| 1.17 Project: | * means the health research project for which the Data will be used, including storage in a registry or repository for future use and that has approval from a registered HREC
 |
| 1.18 Provider: | * means the institution or entity that transfers or shares the ***Data***; there will be an initial provider in all cases and may be downstream providers in some projects
 |
| 1.19 Recipient: | * means the institution or entity that receives the transferred **Data**
 |
| * 1. Research Results:
 | * means all data of the research **Project**, whether tangible or intangible;
 |
| * 1. Secondary Use of Data:
 | * means use of the Data for health research purposes other than those for which the **Participant** originally gave permission, as described in the approved protocol and **Informed Consent** (see 3.1.10 of NDoH 2024 *South African Ethics in Health Research Guidelines*)
 |
| 1.22 Steward: | * means a person or entity entrusted by the **Participant** to safeguard and protect the Datain accordance with NDoH 2024 South African Ethics in Health Research Guidelines)
 |
| 1.23 Termination Report | * means a report prepared by the **Recipient** and submitted to the **Provider** on termination of the **Project**
 |
| 1.24 Data Transfer & Sharing: | - means sharing of data by the **Provider** of **Data,** whether physically or electronically, within the Republic of South Africa or across the national borders to provide access by the Recipient to that data |

**2.**

**THE PARTIES AGREE AS FOLLOWS:**

2.1 **OBJECTIVE**

 The objective of this **Agreement** is to record the intention ofthe **Parties** to transfer, share, use and process **Data**.

2.2 The **Provider** hereby transfers/ shares the **Data** as fully described in **Annexure A** to the **Recipient**, and the **Recipient** accepts the **Data** from the **Provider.**

2.3 The **Parties** agree that no **Data** may be shared unless for the purpose of the **Project** as described in **Annexure A**.

2.4 The Data are provided at no cost other than as specified in the research protocol.

2.5 The **Provider** remains the **Steward** of the **Data,** and the **Participant** retains the right to determine **Secondary Use of Data** until such **Data** is destroyed.

2.6 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 **Data**.

2.7 The **Parties** record that, upon **Termination** of the **Project**, the **Data** will be *[insert the anticipated destiny of the data e.g., destroyed or returned]*.

2.8 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 Data is South African and Participants are South Africans.*

**3. OBLIGATIONS OF THE PROVIDER**

3.1 The **Provider** must ensure that a **Participant** has provided **Informed Consent** for Use and/or **Secondary Use of Data** in accordance with 3.1.10 of **NDoH 2024 South African Ethics in Health Research Guidelines** and that the **HREC** has reviewed and approved the **Project** including the **Informed Consent** documentation.

3.2 The provider to ensure the donor signs the version of the consent that is approved by HREC

3.3 The **Provider** must inform the **HREC** that a **Data Transfer Agreement** for the **Project** exists

3.4 Where **Data** is to be exported out of the Republic of South Africa, the **Provider** must obtain the necessary **Permit** and other relevant authorizations for such export or work together with other appropriate entities involved in the Project to ensure that these are obtained.

3.5 The **Provider** must inform the **HREC** and wherever possible the **Participant**/s if the **Provider** is informed that the **Data** has **Become Identifiable** for any reason whatsoever. This must be clarified as **Data** remain coded and hence potentially identifiable.

3.6 The Provider will furthermore take responsibility to make all possible efforts to protect the identity of the **Participant** and to limit harm to such Participant/s.

3.7 The **Provider** and **Recipient** must agree on appropriate procedures in instances where the **Participant** is no longer contactable.

3.8 “The Provider will deliver the data to the Recipient as outlined in the research protocol approved by the HREC or according to the following schedule and in the following media/formats ":

4. **OBLIGATIONS OF THE RECIPIENT**

4.1 The **Recipient** acknowledges that the Data may contain sensitive and confidential information (associated data), which information the **Recipient** undertakes to protect and keep confidential.

4.2 The **Recipient** may not use the **Data** for any purpose that is not described as part of the **Project** in Annexure A, and/or **Informed Consent**.

4.3 The **Recipient** may not share or otherwise provide access to the **Data** to any party not listed in Annexure A, without a **Project** amendment approved in writing by the **HREC** and amendment of this **Agreement**.

4.4 The **Recipient** must inform the **Provider** without delay if the **Data** **Becomes Identifiable** for any reason whatsoever.

4.5 The Recipient shall ensure **Data** are kept in a safe and secure place.

**5. BENEFIT SHARING**

5.1 The possible **Benefit** and **Benefit Sharing** arrangements must be discussed and negotiated between the **Provider** and the **Recipient** before **Data** is shared with the **Recipient**.

5.2 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 after the institutional HREC issues approval for the research **Project**, and continues until the **Project** terminates (in accordance with clause 8).

**7. TERMINATION OF PROJECT**

7.1 When the **Project** terminates, for any reason whatsoever, the **Recipient** must provide the **Provider** with a **Termination Report**.

7.2 The **Termination Repor**t must include the reasons for termination, the status of the **Project** as at termination and the current status of the **Data**.

7.3 The **Parties** must clarify procedures for discontinued use and destruction of **Data** after termination of the Project

**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 a higher level of authority within the Parties’ organisations 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, in accordance with 3.6 above.Exceptions can be made, if properly motivated, in accordance with 3.6 above.

**9. 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.*

9.1 **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.

* 1. 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**.
	2. 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**.
	3. The **Parties** agree to honour the **Intellectual Property Rights** 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.

 All relevant third-third party agreements must be listed in the DTA, attached to DTA.

**10. CONFIDENTIALITY**

10.1 The **Parties** must take all reasonable steps to keep the identity of a **Participant** confidential and must always protect and secure Data in accordance with the requirements of the Project and, if applicable, their obligations under separate contractual documents towards the entity responsible for the Project.

10.2 **Confidentiality** includes the properties, characteristics, content, composition, potential secondary uses and methods of use pertaining to the **Data**.

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. 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.*

11.1 Authorship of publications flowing from use of the Data must comply with the International Committee of Medical Journal Editors (ICMJE) Authorship Guidelines (<http://www.icmje.org/icmje-recommendations.pdf>) in the absence of any institutional Authorship Guidelines.

11.2 The **Recipient** should provide a copy of the publication to the **Provider** and must acknowledge the Provider’s contribution of the **Data** unless otherwise requested by the **Provider**.

*Note: Please keep in mind the above examples clause do not reflect standard approach for clinical trials organised by a commercial sponsor*.

**12. INDEMNITY**

12.1 The **Provider** gives no warranty that the **Data** is fit for the purpose for which it is shared, or that it has any particular qualities or characteristics.

12.2 Use of the Data 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 **Data** including loss or damage to the **Data being shared.**

12.3 The **Provider** accepts no liability to the **Recipient** for any claims arising from the **Recipient’s** use of the **Data**, save to the extent that limitation of liability is not permitted by the applicable law.

12.4 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 **Data** and/or this **Agreement**.

**13. OFFICIAL ADDRESS FOR COMMUNICATION AND NOTICES**

13.1 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:

13.2 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:

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

13.4 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.*

**14. GENERAL**

14.1 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**.

14.2 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.

14.3 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**.

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

14.5 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.

**15. 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.

**16. COUNTERPART SIGNING OF THIS AGREEMENT**

16.1 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.

16.2 The signed **Agreements** when put together constitute the binding agreement between the **Parties**.

**THUS DONE AND SIGNED** on behalf of the **PARTIES** by their duly authorised representatives, 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 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 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 sharing of the **Data** to be transferred

Description of **Project** in terms of which the **Data** will be used upon sharing:

Description of specific studies that the **Data** will be subjected to upon sharing:

Parties other than the Recipient to whom the **Data** will be shared in terms of the **Project**:

Quantity of **Data** to be shared:

Preferred method of sharing of **Data**:

Period within which Data will be shared:

Frequency of export of **Data**:

Process of destruction of **Data**:

How confidentiality will be maintained should **Research Results** be released into the public domain:

**Annexure B**

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

**Annexure C**

**Project Staff**

Forms part of the Agreement (Disclosure of the information shall be restricted to the following individuals:)