**MATERIAL AND DATA TRANSFER AGREEMENT**



Radboud Biobank

**Human Material and Associated Personal Data**

**Radboud Biobank**

This agreement (hereinafter referred to as “Agreement”) is made and entered by and between:

**Stichting Radboud universitair medisch centrum** established at Geert Grooteplein 10 P.O. Box 9101 6500 HB Nijmegen, the Netherlands, legally represented by the undersigned, hereinafter referred to as “RUMC”

and

<…>, having its principal office at <…>, <…>, legally represented by the undersigned, hereinafter referred to as “Recipient”.

RUMC and Recipient hereinafter also individually referred to as “Party” and together as ‘Parties’.

**Considering that:**

a) RUMC has obtained Original Material and Associated Personal Data as described in further detail hereunder;

b) RUMC has been requested to provide Recipient with its Original Material for use by Recipient’s Scientist for the purpose of the Recipient’s Research Project as described below;

c) The purpose and means of the Recipient's Research Project have been determined by Recipient;

d) RUMC agrees to provide its Original Material and Associated Personal Data and Recipient agrees to receive those subject to the terms and conditions specified below;

e) RUMC furthermore has certain Confidential Information concerning its Original Material as specified hereunder;

f) Such Confidential Information of RUMC is considered to be secret and confidential by both Parties and may constitute a valuable commercial asset to RUMC;

g) RUMC is willing, subject to the terms and conditions hereof, to respectively supply Original Material, Information and Associated Personal Data for no other purpose than the performance of the Research Project, as described below (the “Purpose”’).

|  |  |
| --- | --- |
| Recipient's Scientist: | RUMC’s Scientist |
| *Name: <…>*  *Address:*  *Tel: +*  *Fax:+*  *e-mail:* | *Name: <…>*  *Address:*  *Tel:* *+*  *Fax:* *+*  *e-mail:* |

**Article 1. Definitions**

For purposes of this Agreement

* 1. *“Original Material”* shall mean human material, as provided by RUMC to Recipient under this Agreement, and as further specified in Annex I to this Agreement.
  2. “*Material*” shall mean Original Material, Progeny and Unmodified Derivatives.
  3. “*Progeny*” shall mean unmodified descendant from the Material, such as cell from cell or organism from organism.
  4. “*Unmodified Derivatives*” shall mean substances created by the Recipient which constitute an unmodified functional subunit or product expressed by the Original Material. Some examples include: Original Material or unmodified portions thereof fixed as tissue sections or in arrays, and unmodified proteins, RNA, or DNA extracted from the Original Material.
  5. “*Modifications*” shall mean substances created by the Recipient which contain/incorporate the Material but are not Unmodified Derivatives. Some examples include: genetic modifications or manipulation of cells extracted from the Original Material.
  6. “*Associated Personal Data*” shall mean all coded personal information, related to the Material, including clinical and pathological characterization of the Subject , provided by RUMC to Recipient or developed by Recipient under this Agreement, as further specified in Annex I to this Agreement. The Associated Personal Data constitutes pseudonymized personal data under the GDPR.
  7. *”Recipient's Research Project”* shall mean the research project specified in Annex II to this Agreement.
  8. *“Dependent Inventions” shall mean any and all inventions that are conceived and reduced to practice by Recipient in the conduct of Recipient’s Research Project and that incorporate or claim the Material, irrespective of whether such inventions are patentable or not.*
  9. *“Effective Date” shall mean the date of the last signature on this Agreement.*
  10. *"Confidential Information" shall mean all information -not being Associated Personal Data- , know-how, data, grant applications, method of work, techniques, expertise* of RUMC*, regarding the Material,* *its characteristics and RUMC’s research concerning the Material*, *whether of a scientific, technical, engineering, operational, or economic nature, supplied to or obtained by RUMC or Recipient in written form, in the form of drawings or in the recording of oral conversation, or samples.*
  11. *“Unsolicited Findings” shall mean the new finding that particular Material carries in its information that is considered of immediate importance for the future health of the Subject or its family members.*
  12. *“GDPR” shall mean the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation),*
  13. *“Applicable Data Protection Law” shall mean the GDPR and any additional locally applicable data protection legislation.*
  14. *“Subject(s)” shall mean the patient or other person who is the donor of the Original Material.*

**Article 2. Ownership and use of Material, Confidential Information and Associated Personal Data**

**2.1** The Original Material will be transferred to the Recipient, to be used in the Recipient’s Research Project. Recipient shall not acquire ownership rights to the Material under this Agreement. For the avoidance of any doubt, the control (in Dutch: zeggenschap) of the Material remains at all times with the Subject, with the Parties solely acting as a custodian of the Material.

**2.2** Recipient shall use the Material, Confidential Information and Associated Personal Data solely for the non-commercial purposes of the Recipient’s Research Project specified in Annex II to this Agreement. All use of the received Material, Confidential Information and Associated Personal Data by Recipient in the Recipient’s Research Project shall be under the direction of Recipient 's Scientist, and shall only be carried out by persons working under Recipient 's Scientist's direct supervision.

**2.3** Without prior written approval of RUMC, Recipient shall not transfer or otherwise make available or accessible the Material, Confidential Information and/or Associated Personal Data to any third party or entity. As an exception to the foregoing, such prior approval shall not be required for service providers who may have access to Associated Personal Data in the context of the standard business operations of Recipient, such as parties who supply ICT infrastructure maintenance. Recipient will safeguard that any data processors who have access to the Associated Personal Data, are instructed by a binding agreement to process the personal data in accordance with the requirements stated in the GDPR.

[OPTION: Notwithstanding the restrictions on transfer given directly above, Recipient may transfer the Material and/or Associated Personal Data to academic third parties solely for the purpose of replication of the Recipient’s Research Project, in conformance with the data and replication policies of a journal that published the results of Recipient’s Research Project. Such transfers shall only be made by Recipient after the conclusion of a written agreement with terms at least as strict as the terms of this Agreement and without any further right of transfer.]

**2.4** Recipient agrees in its use of the Material, Confidential Information and Associated Personal Data to comply with all applicable laws, regulations and guidelines, including any public policy, statutory or common law, or governmental or international regulations.

**2.5** The Recipient shall not carry out any procedures with the Associated Personal Data, such as linking, comparison, processing, with which the identity of the Subject could be derived. Unless explicitly agreed under this Agreement as part of the Recipient’s Research Project description in Annex II, the Recipient shall not generate or perform analyses on genetic data. Genetic data for the purposes of this sub clause means: personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from genetic sequencing of a biological sample from the natural person in question.

**2.6** In case any of the Subjects makes it known that he/she withdraws his/her permission to perform scientific research with the Material or Associated Personal Data provided by him/her, RUMC will inform Recipient of that fact without delay. RUMC shall provide sufficient coded information to Recipient, so that Recipient may identify the relevant Material or Associated Personal Data. That Material or Associated Personal Data shall either be destroyed by Recipient without delay with written confirmation of such destruction to be sent to RUMC, or be returned to RUMC. Recipient shall not retain any copy of the Associated Data and shall not use Material and/or Associated Data for further research or any other purposes.

**2.7** The Original Material and Associated Data will be provided at no cost or with an optional transmittal fee solely to reimburse RUMC for the collection, storage, preparation and/or shipment. If a fee is requested, the amount will be indicated here: <…>. Recipient will pay the transmittal fee within forty five (45) days from the date of receipt of a valid invoice thereto. Payment will be made to a bank account in the name of the RUMC, as set out in the invoice.

**2.8** Recipient will report any Unsolicited Findings to RUMC

**Article 3. Unmodified Derivatives, Modifications, Improvements, Inventions and Patents.**

**3.1** Recipient shall be free to produce Unmodified Derivatives or develop Modifications only as part of, and only for the purposes of the Recipient’s Research Project specified in Annex II of this Agreement. The use of Derivatives and Modifications by Recipient shall be subject to the same terms and conditions as specified in Article 2 of this Agreement.

**3.2** Recipient shall inform RUMC forthwith of any Modifications created by Recipient, and shall give RUMC all relevant details concerning the said Modifications, which RUMC shall treat as Confidential Information.

**3.3** Recipient shall be the owner of the Modifications to the extent developed by Recipient but as stated above in Article 2.1, Recipient shall not obtain ownership rights on the Material that is contained in Modifications. Recipient shall not unreasonably refuse to make available to RUMC a quantity of any Modifications for research purposes upon request.

**3.4** Ownership of inventions shall follow inventorship. Where ownership of any inventions vests in Recipient, RUMC shall have a perpetual nonexclusive royalty free license to use such inventions for its internal research and teaching purposes. In case of joint inventions, Recipient and RUMC shall negotiate in good faith the terms of a separate agreement pertaining to the management of intellectual property and commercialization of such joint inventions. Until such agreement is effective, each Party shall be entitled to use the joint invention for research purposes, but neither Party shall be entitled to exploit, disclose, license or transfer its rights in connection with the joint invention.

**3.5** When any Dependent Inventions are made by Recipient, Recipient and RUMC shall in good faith negotiate the terms of a separate agreement pertaining to a reasonable share for RUMC of the revenues obtained by Recipient from the commercialization of such Dependent Inventions.

**Article 4. Confidentiality and the protection of Associated Personal Data.**

**4.1** Recipient shall treat al Confidential Information as confidential for the duration of this Agreement including any extension thereof and thereafter for a period of five (5) years following termination or expiry of this Agreement.

**4.2** Excluded from the obligation of confidentiality contained in 4.1 above, shall be any Confidential Information of which the Recipient can reasonably demonstrate that it (a) was previously known to Recipient, or (b) is, and/or becomes, publicly available through no fault of Recipient, or (c) is independently and lawfully developed by the Recipient, or (d) was published or otherwise disseminated in accordance with the publication procedure set out below in article 5. However, the foregoing exceptions shall not apply to: (a) Confidential Information contained within more general information that may fall within one or more of the exceptions, or (b) any combination of features or items of Confidential Information where one or more of the relevant individual features or items (but not the combination itself) may fall within one or more of the exceptions.

**4.3** The obligations of confidentiality contained in 4.1 above shall not apply to any disclosure required by law, provided that Recipient shall notify RUMC of any disclosure required by law in sufficient time so that RUMC may contest such requirement, if RUMC so chooses.

**4.4** Handling of Associated Personal Data

1. Associated Personal Data shall be provided by RUMC in a sufficiently secure manner and Parties shall handle all Associated Personal Data in accordance with the Applicable Data Protection Law and shall keep such Associated Personal Data confidential without any of the exclusions contained in Article 4.2 above.
2. With respect to the Associated Personal Data, Recipient shall be considered to be a separate data controller under the Applicable Data Protection Law for the processing of the Associated Personal Data for Recipient’s Research Project.
3. Recipient shall implement appropriate technical and organizational measures to meet the requirements for data controllers of the Applicable Data Protection Law.
4. If Recipient becomes aware of a personal data breach, Recipient shall promptly notify RUMC. In such a case Parties will fully cooperate with each other to remedy the personal data breach, fulfill the statutory notification obligations timely and cure any damages. The term ‘personal data breach’ refers to articles 33 and 34 of the GDPR.
5. In the event that a person from whom Associated Personal Data was obtained, withdraws his/her permission for the use thereof, Parties shall follow the procedures set out in 2.7 above.
6. Each Party’s shall add the contact details for inquiries regarding handling and protection of Associated Personal Data to Article 9.3 below.

**Article 5. Publication and acknowledgement.**

**5.1** Parties acknowledge the importance of disseminating the results of the Recipient’s Research Project. Therefore, Recipient shall endeavor to publish or otherwise publicly disclose information, any data, results or information generated using the Material and Associated Personal Data (“Disclosures”), after review by RUMC. The following shall apply to Disclosures:

1. Authorship of any publications shall follow the principles set out in the ICMJE recommendations ‘Defining the Role of Authors and Contributors’ as can be found on <http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>.
2. At least thirty (30) days before Recipient submits a paper or abstract for Disclosure, Recipient shall provide such paper or abstract to RUMC, who will have thirty (30) days to review proposed manuscripts and fifteen (15) days to review proposed paper or abstract to assure that its Confidential Information is protected. It is agreed that Recipient will fully comply with any reasonable written request by RUMC to omit specified Confidential Information of RUMC from such paper, abstract, press release or other disclosure prior to Disclosure.
3. In every disclosure by Recipient based upon results obtained from the research through the use of the Original Material, Associated Personal Data and/or other contributions provided by RUMC, Recipient shall acknowledge RUMC’s scientists as contributor of the Material and the Associated Personal Data and shall acknowledge and name the Radboud Biobank as source of the Material, if applicable in the Methods section and the Abstract. Reference will be made to the descriptive article Manders et al. (2018). The Radboud Biobank: A Central Facility for Disease-Based Biobanks to Optimise Use and Distribution of Biomaterial for Scientific Research in the Radboud University Medical Center, Nijmegen. Open Journal of Bioresources. 5, p.2. DOI: <http://doi.org/10.5334/ojb.36>.
4. Besides acknowledging the Radboud Biobank as the source of material/data reference must be made in every form of publication to the sub-biobank <…> from which the biomaterial and/or data was obtained.

**Article 6. Representations and Liability**

**6.1** Recipient acknowledges that any Original Material and Associated Personal Data delivered to it under this Agreement is experimental in nature. Other than those contained in this Agreement, RUMC makes no representations nor extends any warranties of any kind, with respect to its Material, Confidential Information and Associated Personal Data. There are no express or implied warranties of merchantability or fitness for a particular purpose, nor does RUMC represent that the Material, Confidential Information and Associated Personal Data and/or any use thereof will not infringe any patent, copyright, trade secret, trademark or other rights of third parties.

**6.2** Regarding the Original Material, RUMC warrants that a) it was collected from Subjects who were appropriately informed and who either explicitly consented to the use of their Material for scientific research or did not object, after having been given the opportunity to do so and b) that it shall be provided under approval from the relevant ethics committee –to the extent required-, all in accordance with locally applicable laws and regulations. Regarding the Associated Personal Data, RUMC warrants a) that it has verified that there is an appropriate legal ground for the provision of the Associated Personal Data to Recipient in accordance with the Applicable Data Protection Law, such as Article 6 and/or 5.1 sub b GDPR b) that there is a valid exception to the prohibition for processing personal health data (Article 9 GDPR) and c) that it shall be provided under approval from the relevant ethics committee -to the extent required-.

**6.3** The Recipient acknowledges that the Material is experimental in nature and may have hazardous properties and is supplied on an “as is” basis; to the extent allowed by law, Recipient assumes all liability for damages which may arise from use, storage, transport or disposal of the Material, except for damages that are caused by gross negligence or willful misconduct of RUMC

**6.4** In regards to the Associated Personal Data and personal data breaches, Recipient shall be responsible and liable for any damages, losses and fines resulting from its own actions or failures to adhere to the terms of this Agreement and Applicable Data Protection Law and Recipient shall indemnify and hold harmless RUMC for any of such damages. For the purposes of this sub clause, actions or omissions of data processors contracted by Recipient, shall be attributed to Recipient.

**Article 7. Duration and Termination**

**7.1** This Agreement shall become effective on the Effective Date and will terminate two years thereafter.

**7.2** If Recipient or RUMC wishes to extend the duration of this Agreement, they shall request the other Party in writing for such an extension.

**7.3** It is understood that any extension of the duration of this Agreement pursuant to Article 7.2 shall not be unreasonably withheld by one of the Parties, other than for reasons of non-performance of any part of this Agreement by the other Party; for reasons of non-use of the Material by the other Party; and/or for reasons involving commercial considerations, including but not limited to the granting by one of the Parties to any third party of any royalty-bearing exclusive license relating to the Materials and/or being under any patents, patent applications and/or other property rights covering the Material.

**7.4** Upon termination of this Agreement, Recipient shall immediately discontinue its use of the Material and any and all Modifications. Confidential Information provided by RUMC and Associated Personal Data; and shall also, upon the written request of RUMC, return to RUMC or destroy any remaining Material as well as any and all Modifications, any Confidential Information provided by RUMC and Associated Personal Data. [OPTION: However, Recipient may retain one copy of Material and any and all Modifications and Associated Personal Data solely to comply with transfer requests that third party academic institutions may make for replication of the Recipient’s research Project, as described in Article 2.3 above.] If any Material and/or Modifications, Confidential Information provided by RUMC or Associated Personal Data are destroyed by Recipient pursuant to this Article 7.4, Recipient shall, upon the written request of the other Party, provide RUMC with confirmation thereof in writing.

**Article 8. Survival**

**8.1** Articles 3.4, 3.5, 4, 5, 6, 7.4 and any such other provisions of this Agreement which shall be expected or intended by its nature to survive the termination or the expiration of this Agreement, shall survive the termination or the expiration of this Agreement.

**Article 9. Miscellaneous.**

**9.1.** This Agreement will be construed, governed, interpreted and enforced according to the laws of the Netherlands. Parties will first strive to settle any disputes amicably before taking legal action. All disputes arising out of or in relation to this Agreement that cannot be settled amicably will be brought before the competent court in Arnhem, the Netherlands .

**9.2** Except as expressly provided under this Agreement, no rights or licenses are granted or provided to Recipient with respect to the Material, with respect to any information pertaining to the Material, and/or under any patents, patent applications, trade secrets or other proprietary rights of RUMC.

**9.3** Any notice or communication required or permitted to be given by any Party hereunder will be deemed sufficiently given if mailed by certified mail, return receipt requested, and addressed to the party to whom notice is given as follows:

If to Recipient, to:

*Name:*

*Address:*

*Tel: +*

*Fax: +*

*e-mail:*

If to the RUMC, to:

*Name:*

*Address:*

*e-mail:*

with a copy to:

Technology Transfer Office

R903 DirVal

Radboud university medical center

P.O. Box 9101

6500 HB Nijmegen

The Netherlands

Secretariaat@val.umcn.nl

**9.4** This Agreement will be binding upon and inure to the benefit of the respective successors and assignees of the Parties hereto. However, Parties may not assign this Agreement in whole or in part without the prior written consent of the other Party.

**9.5** This Agreement may only be altered or amended by an instrument in writing signed by both of the Parties.

**9.6** If any portion of this Agreement is in violation of any applicable law, or is unenforceable or void for any reason whatsoever, such portion will be inoperative and the remainder of this Agreement will be binding upon the Parties

**9.7** If the lawful performance of any part of this Agreement by a Party is rendered impossible by or as a result of any cause beyond such Party's reasonable control, such Party will not be considered in breach hereof as a result of failing so to perform.

**IN WITNESS WHEREOF**, the parties have executed this Agreement, in duplicate originals or as a signed PDF, as of the Effective Date.

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| **For the** **Stichting Radboud universitair medisch centrum,**  **For the Department of …**  By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name:  Head of:  Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name:  Head of:  Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **READ AND ACKNOWLEDGED:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  RUMC’s Scientist  **Attachments:**   * **ANNEX I** * **ANNEX II** | **For Recipient**  By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name:  Title:  Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name:  Title:  Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **READ AND ACKNOWLEDGED:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Recipient’s Scientist |

**ANNEX I – Description of the Material and the Associated Personal Data**

**MATERIAL:**

<…>

**ASSOCIATED PERSONAL DATA:**

|  |  |
| --- | --- |
| **Data subjects** The personal data transferred concern the following categories of data subjects: |  |
| **Purpose of the transfer(s)** The transfer is made for the following purpose: | See Annex II |
| **Categories of data** The personal data transferred concern the following categories (types) of data: | NB: All health information qualifies as sensitive data as meant in the field below |
| **Sensitive data** (if appropriate) e.g.:  •racial or ethnic origin,  •political opinions,  •religious or philosophical beliefs,  •trade union membership,  •genetic data, biometric data,  •health data,  •sex life and sexual orientation |  |
| **Method of transfer**  e.g.: Soft- or hardware encrypted USB drive, database entry such as in Castor, etc. |  |
| **Method of data storage and security measures (e.g. method of encoding)** |  |
| **Authorized processors, if applicable, as indicated in clause 2.3 of the Agreement** |  |

**ANNEX II – Recipient’s Research Project**

<…>