**DATA SHARING AGREEMENT**

**(for academic organization established outside the EAA)**

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

**University Medical Center Groningen**, established by virtue of the Higher Education and Research Act (Wet hoger onderwijs en wetenschappelijk onderzoek), having its principal office at Hanzeplein 1, 9713 GZ Groningen, the Netherlands, represented by a member of the Board of Directors, on behalf of its Department of Genetics, hereinafter referred to as the “data exporter”,

and

**[party's legal name]**, having its principal office at [address], legally represented by [name authorised representative], hereinafter referred to as the “data importer”.

The data exporter and the data importer can also be referred to hereinafter individually as “party” and jointly as “parties”.

WHEREAS

1. The data exporter has obtained and/ or generated the Data as further defined below;
2. The data importer, through [the data importer's employee name] (hereinafter the “data importer scientist”), has requested the data exporter, through Monique van der Wijst (hereinafter the “data exporter’s scientist”), to provide the data importer with the Data for use by the data importer’s scientist for the purpose of its the data importer’s Research Plan;
3. The purpose and means the data importer’s Research Plan have been determined by the data importer;
4. The data exporter is willing, subject to the terms and conditions of this Agreement, to provide the Data to the data importer.

## Definitions

| “Applicable Data Protection Law”: | means 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 or GDPR) and any additional local personal data protection legislation applicable to the data exporter. |
| --- | --- |
| “Confidential Information”: | means all any scientific, technical and non-technical information, including know-how, grant applications, methods of work, techniques, Research Plan and expertise of any of the Parties supplied in any form (in writing or orally) by a party to the party under this Agreement. |
| “Data”: | means the data being transferred under this Agreement, as specified in Annex B to this Agreement, provided without directly identifying personal information. |
| “Effective Date”: | means the date of last signature of this Agreement. |
| “Invention”: | means any invention, discovery, improvement, material, signal, process, formula, know-how or other innovation related to or arising from the use of the Data and/or Confidential Information, whether patentable or not and obtained as a result of the performance the data importer’s Research Plan. |
| ”Research Plan”: | means the data importer’s research plan as specified in EXHIBIT I of this Agreement. |
| “Personal Data Breach”: | means an accidental or unlawful use, processing destruction, loss, alteration, unauthorised disclosure of, or access to the Data transferred under this Agreement, whether or not that is the result of a breach of the technical and organisatorial measures implemented by any of the parties to provide an appropriate level of security to the personal data processing activities envisaged under this Agreement. |
| “Subject(s)”: | means an identified or identifiable natural person from whom the Data was obtained. |
| “SCC”: | means the Standard Contractual Clauses and their annexes as attached in EXHIBIT II of this Agreement. |

## Research objective

1. The Data and any other information provided hereunder is made available as a service to the research community and no ownership rights in the Data and any other information shall be obtained by the data importer under this Agreement.

## Data processing and protection

1. With regards to Data processing and protection, the parties have agreed to incorporate the SCC in this Agreement, in their entirety and without modification, as provided for in EXHIBIT II.
2. The parties agree that all Data processing activities will be in accordance with the SCC.
3. With regards to Data processing and protection, in the event of a conflict between a provision – whether in whole or in part - of this Agreement and a provision of the SCC, the provision of the SCC will prevail, leaving that provision and/or this Agreement in all other aspects unaffected.
4. The data importer warrants that the Data requested from the data exporter is adequate, relevant and limited to what is necessary for the Research Plan, in accordance with Annex A of the SCC.
5. The data importer shall maintain the confidentiality and security of the Data and will not carry out any procedures with the Data, such as linking, comparison, processing, with the purpose of deriving the identity of any Subject. The exclusions to the obligations of confidentiality mentioned in Article 18 shall not apply to Data.
6. The data importer and the data importer’s scientist agree that the Data: (a) is to be used only for academic purposes as described in the data importer’s Research Plan and (b) will not be used for any other purpose, including commercial purposes. Furthermore, in carrying out the data importer’s Research Plan, the data importer shall not allow third parties that are not expressly mentioned in ANNEX B of the SCC to access or otherwise process the Data without prior written approval of the data exporter.
7. The parties agree that the Data provided by the data exporter to the data importer will be provided without directly identifying personal information. Coding or pseudonimyzation will be in accordance with the Applicable Data Protection Law. Under no circumstances shall the code or pseudonym, which allows the re-identification of Subjects be transferred or otherwise made known to the data importer or the data importer’s Scientist. Such code shall remain at all times at the data exporter’s location and shall be kept separate from the Data.
8. In addition to what is stated under clauses I d. and II e. of the SCC, the parties agree that they will inform each other promptly of any inquiries concerning the Data they receive from a Subject or the competent data protection authority in the territory in which the data exporter is established.
9. In the event that a Subject withdraws his/her consent for the processing of his/ her personal data for the use contemplated in this Agreement, the data exporter shall inform the data importer. The data importer shall immediately cease all use of the relevant Data and, if requested by the data exporter on behalf of the Subject, delete all copies of the Subject’s Data . Upon request from the data exporter, the data importer shall confirm the deletion of the Subject’s Data in writing.
10. If any of the parties becomes aware of any possible Personal Data Breach, they shall promptly notify the other party and agree to fully cooperate with each other in order to investigate and cure any Personal Data Breach. The data importer understands that the data exporter must comply with statutory notification obligations under the Applicable Data Protection Law. Upon request of the data exporter, the data importer agrees to promptly provide the data exporter with all information and documentation that the data exporter needs to fulfil its statutory obligations. The information and documentation mentioned above concerns the processing activities conducted by the data importer with the Data and the technical and organisatorial measures implemented by the data importer to safeguard the Data.
11. Each party shall perform its obligations under this Agreement at its own cost.
12. The parties’ contact details for inquiries regarding this Agreement are as follows:

| For the data exporter, | For the data importer, |
| --- | --- |
| Regarding scientific matters:  University Medical Center Groningen  Attn. Monique van der Wijst  Hanzeplein 1, 9713 GZ Groningen  The Netherlands  e-mail: m.g.p.van.der.wijst@umcg.nl | Regarding scientific matters:  [contact details] |
| Regarding personal data and Personal Data Breaches :  University Medical Center Groningen  Attn. PWO, LB41  Hanzeplein 1, 9713 GZ Groningen, The Netherlands  E-mail: privacy@umcg.nl  Tel: +31(0)50-3616161.  With a copy to the data exporter’s scientist and loket\_contract\_research@umcg.nl with reference to: 2017N0883 | Regarding personal data and Personal Data Breaches:  [contact details] |
| Regarding this Agreement:  University Medical Center Groningen  Attn. Board of Directors, LA10  Hanzeplein 1, 9713 GZ Groningen, The Netherlands  E-mail: loket\_contract\_research@umcg.nl  with reference to: 2017N0883  With a copy to the data exporter’s Scientist. | Regarding this Agreement:  [contact details] |

## Results

1. Upon request, the data importer’s scientist shall keep the data exporter’s scientist informed of the results arising from the data importer’s Research Plan.
2. The data importer will report any Inventions to the data exporter and the data exporter’s scientist. The data importer shall promptly provide the data exporter with a detailed written description of any Invention and indicate the role, if any, of any the data importer’s employees in creating the Invention. Ownership of Inventions will follow inventorship. Where ownership of any Invention vests in the data importer, the data exporter shall have a perpetual non-exclusive royalty free license to use such Invention for its internal research and teaching purposes. In the event an Invention is a joint Invention, both parties shall make appropriate mutual arrangements concerning the protection and exploitation of such joint Invention. Until such agreement is effective, each party shall be entitled to use the joint Inventions for research purposes, but neither party shall be entitled to exploit, disclose, license or transfer its rights in connection with the joint Invention without the written permission of the other party.
3. Except as provided for in this Agreement, no express or implied license or other right is provided to the data importer under any Intellectual Property (IP) rights of the data exporter.

## Delivery

1. The Data will be provided at no cost.
2. Data will be provided to the data importer by the data exporter in a sufficiently secure manner and in a format to be agreed upon by the data importer’s scientist and the data exporter’s scientist.

## Warranties, Liability and Indemnification

1. The data importer warrants that Data will only be processed for the Research Plan and that all Data processing will be in compliance with the SCC and the data processing principles set forth in Annex A of the SCC.
2. Except as provided for in the SCC under clause I (a) and (b), it is expressly understood that the data exporter does not make any warranties of any kind regarding the Data. The data exporter does not warrant or guarantee that the Data is accurate, merchantable or useful for any particular purpose, including for the Research Plan. As such, the data exporter cannot and shall not be held liable for any claims or damages by the data importer or any third party, in connection with or as a result of any use of Data by the data importer. Unless and to the extent caused by the data exporter’s gross negligence or wilful misconduct, the data importer undertakes to indemnify and hold harmless the data exporter at all times against any and all such damages, claims and expenses, including any legal expenses incurred.
3. In addition, the data importer shall indemnify and hold harmless the data exporter for any and all damages, losses or fines imposed by the competent data protection authority in the territory in which the data exporter is established and any expenses, including legal expenses, which result directly or indirectly from the data importer’s breach of this Agreement and/or of any clause of the SCC, including any clauses Subject’s third party rights established under the SCC. For the purposes of this article, actions or omissions of data processors contracted by the data importer, shall be attributed to the data importer.

## Confidentiality

1. Each party shall treat all 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. Information shall not be considered Confidential Information and subject to the confidentiality obligations hereunder if the receiving party can establish that the information: (a) was previously known to the receiving party, or (b) is, and/or becomes, publicly available through no fault of the receiving party, or (c) is independently and lawfully developed by the receiving party, or (d) was published or otherwise disseminated in accordance with the publication procedure set out below in article 25.
2. The obligation of confidentiality shall not apply to any disclosure required by law regulation or court order provided that the receiving party takes reasonable steps to limit the scope of such disclosure, discloses the minimum required Confidential Information and notifies the providing party of any disclosure required by law or court order within reasonable time to allow the providing party to contest such requirement, if the providing party so chooses.

## Publication

1. The parties acknowledge the importance of disseminating the results of the data importer’s Research Plan. Therefore, the data importer shall endeavour to publish or otherwise publicly disclose information, any data, results or information generated using the Data (“Disclosure(s)”), after review by the data exporter. The following shall apply to Disclosures:
2. 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> .
3. At least thirty (30) days before the data importer submits a paper or abstract for Disclosure, the data importer shall provide such paper or abstract to the data exporter, who will have thirty (30) days to review proposed manuscripts and fifteen (15) days to review proposed abstracts to assure that the data exporter’s Confidential Information is protected. It is agreed that the data importer will fully comply with any reasonable written request by the data exporter to omit specific Confidential Information of the data exporter, Data, personally identifiable information and joint Inventions from such paper, abstract, press release or other disclosure prior to Disclosure.
4. The data importer shall appropriately acknowledge the data exporter and the data exporter’s scientist as contributor of the Data in every Disclosure of results of the Research Plan for which the Data was used.

## Term & termination

1. This Agreement enters into force on the Effective Date and shall continue in force until the earlier of either 2 years after the Effective Date or completion of the Research Plan.
2. In the event that the data importer is in breach of its obligations under the SCC or this Agreement, the data importer will, upon written notice of the data exporter, stop any and all use of the Data and the Confidential Information with immediate effect. The data importer agrees that, if so requested by the data exporter, it will allow the data exporter, or agent selected by the data exporter and not reasonably objected to by the data importer, access to its premises to verify that this has been done, with reasonable notice and during business hours.
3. The data exporter may terminate this Agreement upon written notice to the data importer, with immediate effect, if a) the data importer is in breach of its obligations under the SCC and/or this Agreement, and the breach, if capable of a remedy, is not remedied within one month; and b) in the events listed in VI (b) of the SCC.
4. In case the SCC is terminated by either party in accordance with VI (c) of the SCC, the parties will renegotiate the terms of this Agreement. If the parties cannot come to an agreement, within a reasonable period of time, this Agreement will be terminated.
5. In addition to clause VI (d) of the SCC, any clauses of this Agreement which are expected or intended by its nature to survive the termination or the expiration of this Agreement, will remain in force after the expiration of this Agreement.
6. Upon expiration or termination of this Agreement, the right to use the Data and Confidential Information will automatically end.
7. Upon expiration or termination of this Agreement, the data importer shall return all Confidential Information and Data and all copies of the Data to the data exporter or, at the data exporter’s choice, destroy all copies of the same and certify to the data exporter that it has done so, unless the data importer is prevented by its national law or local regulator from destroying or returning all or part of the Data, in which case, the Data will be kept confidential and will not be actively processed for any purpose. The data importer agrees that, if so requested by the data exporter, it will allow the data exporter, or an agent selected by the data exporter and not reasonably objected to by the data importer, access to its premises to verify that this has been done, with reasonable notice and during business hours.

## Miscellaneous

1. This Agreement and the SCC are construed, interpreted and enforced and governed by the law of the country in which the data exporter is established. With regards to the processing of the Data by, and only in this regard, clause II (h) of the SCC shall prevail.
2. The parties will first strive to settle any disputes related with this Agreement amicably before taking legal action. All disputes arising out of or in connection with this Agreement that cannot be settled amicably will be brought before the competent court in the district of the Northern Netherlands.
3. The data importer may not assign this Agreement in whole or in part without the prior written consent of the data exporter.
4. This Agreement may only be altered or amended by an instrument in writing signed by all of the parties. If the Standard Contractual Clauses for data transfers from data controllers in the EU to data controllers established outside the EU or European Economic Area (EEA), adopted by the European Commission’s decision 2004/915/EC of 27 December 2004 are replaced by the European Commission, the parties will incorporate the new Standard Contractual Clauses into this Agreement.
5. If any portion of this Agreement is in violation of any applicable law or regulation, 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.
6. Both parties acknowledge that the signatories to this Agreement are authorized representatives of each of the parties and legally authorized to sign this Agreement.
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, in electronic form through a validated electronic signing software or as a signed PDF, as of the Effective Date.

| For the **University Medical Center Groningen**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name: [name of authorised person]  Title  Date: | For the **[party's legal name]**,    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name: [name of authorised person]  Title  Date: |
| --- | --- |
| Read and acknowledged:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name: Monique van der Wijst  Date: | Read and acknowledged:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name: [name of the data importer's scientist]  Date: |

**EXHIBIT I**

**The data importer’s Research Plan**

**EXHIBIT II**

**Standard contractual clauses for the transfer of personal data from the Community to third countries (controller to controller transfers)**

**Data transfer agreement**

between

the data exporter

and

the data importer

each a “party”; together “the parties”.

**Definitions**

For the purposes of the clauses:

| (a) | “personal data”, “special categories of data/sensitive data”, “process/processing”, “controller”, “processor”, “data subject” and “supervisory authority/authority” shall have the same meaning as in Directive 95/46/EC of 24 October 1995 (whereby “the authority” shall mean the competent data protection authority in the territory in which the data exporter is established); |
| --- | --- |

| (b) | “the data exporter” shall mean the controller who transfers the personal data; |
| --- | --- |

| (c) | “the data importer” shall mean the controller who agrees to receive from the data exporter personal data for further processing in accordance with the terms of these clauses and who is not subject to a third country’s system ensuring adequate protection; |
| --- | --- |

| (d) | “clauses” shall mean these contractual clauses, which are a free-standing document that does not incorporate commercial business terms established by the parties under separate commercial arrangements. |
| --- | --- |

The details of the transfer (as well as the personal data covered) are specified in Annex B, which forms an integral part of the clauses.

**I. Obligations of the data exporter**

The data exporter warrants and undertakes that:

| (a) | The personal data have been collected, processed and transferred in accordance with the laws applicable to the data exporter. |
| --- | --- |

| (b) | It has used reasonable efforts to determine that the data importer is able to satisfy its legal obligations under these clauses. |
| --- | --- |

| (c) | It will provide the data importer, when so requested, with copies of relevant data protection laws or references to them (where relevant, and not including legal advice) of the country in which the data exporter is established. |
| --- | --- |

| (d) | It will respond to enquiries from data subjects and the authority concerning processing of the personal data by the data importer, unless the parties have agreed that the data importer will so respond, in which case the data exporter will still respond to the extent reasonably possible and with the information reasonably available to it if the data importer is unwilling or unable to respond. Responses will be made within a reasonable time. |
| --- | --- |

| (e) | It will make available, upon request, a copy of the clauses to data subjects who are third party beneficiaries under clause III, unless the clauses contain confidential information, in which case it may remove such information. Where information is removed, the data exporter shall inform data subjects in writing of the reason for removal and of their right to draw the removal to the attention of the authority. However, the data exporter shall abide by a decision of the authority regarding access to the full text of the clauses by data subjects, as long as data subjects have agreed to respect the confidentiality of the confidential information removed. The data exporter shall also provide a copy of the clauses to the authority where required. |
| --- | --- |

**II. Obligations of the data importer**

The data importer warrants and undertakes that:

| (a) | It will have in place appropriate technical and organisational measures to protect the personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access, and which provide a level of security appropriate to the risk represented by the processing and the nature of the data to be protected. |
| --- | --- |

| (b) | It will have in place procedures so that any third party it authorises to have access to the personal data, including processors, will respect and maintain the confidentiality and security of the personal data. Any person acting under the authority of the data importer, including a data processor, shall be obligated to process the personal data only on instructions from the data importer. This provision does not apply to persons authorised or required by law or regulation to have access to the personal data. |
| --- | --- |

| (c) | It has no reason to believe, at the time of entering into these clauses, in the existence of any local laws that would have a substantial adverse effect on the guarantees provided for under these clauses, and it will inform the data exporter (which will pass such notification on to the authority where required) if it becomes aware of any such laws. |
| --- | --- |

| (d) | It will process the personal data for purposes described in Annex B, and has the legal authority to give the warranties and fulfil the undertakings set out in these clauses. |
| --- | --- |

| (e) | It will identify to the data exporter a contact point within its organisation authorised to respond to enquiries concerning processing of the personal data, and will cooperate in good faith with the data exporter, the data subject and the authority concerning all such enquiries within a reasonable time. In case of legal dissolution of the data exporter, or if the parties have so agreed, the data importer will assume responsibility for compliance with the provisions of clause I(e). |
| --- | --- |

| (f) | At the request of the data exporter, it will provide the data exporter with evidence of financial resources sufficient to fulfil its responsibilities under clause III (which may include insurance coverage). |
| --- | --- |

| (g) | Upon reasonable request of the data exporter, it will submit its data processing facilities, data files and documentation needed for processing to reviewing, auditing and/or certifying by the data exporter (or any independent or impartial inspection agents or auditors, selected by the data exporter and not reasonably objected to by the data importer) to ascertain compliance with the warranties and undertakings in these clauses, with reasonable notice and during regular business hours. The request will be subject to any necessary consent or approval from a regulatory or supervisory authority within the country of the data importer, which consent or approval the data importer will attempt to obtain in a timely fashion. |
| --- | --- |

| (h) | It will process the personal data, at its option, in accordance with:   | (i) | the data protection laws of the country in which the data exporter is established, or | | --- | --- |  | (ii) | the relevant provisions[(1)](https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32004D0915&from=NL#ntr1-L_2004385EN.01007702-E0001) of any Commission decision pursuant to Article 25(6) of Directive 95/46/EC, where the data importer complies with the relevant provisions of such an authorisation or decision and is based in a country to which such an authorisation or decision pertains, but is not covered by such authorisation or decision for the purposes of the transfer(s) of the personal data[(2)](https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32004D0915&from=NL#ntr2-L_2004385EN.01007702-E0002), or | | --- | --- |  | (iii) | the data processing principles set forth in Annex A.  The data importer to indicate which option it selects:  Initials of the data importer:\_; | | --- | --- | |
| --- | --- | --- | --- | --- | --- | --- | --- |

| (i) | It will not disclose or transfer the personal data to a third party data controller located outside the European Economic Area (EEA) unless it notifies the data exporter about the transfer and   | (i) | the third party data controller processes the personal data in accordance with a Commission decision finding that a third country provides adequate protection, or | | --- | --- |  | (ii) | the third party data controller becomes a signatory to these clauses or another data transfer agreement approved by a competent authority in the EU, or | | --- | --- |  | (iii) | data subjects have been given the opportunity to object, after having been informed of the purposes of the transfer, the categories of recipients and the fact that the countries to which data is exported may have different data protection standards, or | | --- | --- |  | (iv) | with regard to onward transfers of sensitive data, data subjects have given their unambiguous consent to the onward transfer. | | --- | --- | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |

**III. Liability and third party rights**

| (a) | Each party shall be liable to the other parties for damages it causes by any breach of these clauses. Liability as between the parties is limited to actual damage suffered. Punitive damages (i.e. Damages intended to punish a party for its outrageous conduct) are specifically excluded. Each party shall be liable to data subjects for damages it causes by any breach of third party rights under these clauses. This does not affect the liability of the data exporter under its data protection law. |
| --- | --- |

| (b) | The parties agree that a data subject shall have the right to enforce as a third party beneficiary this clause and clauses I(b), I(d), I(e), II(a), II(c), II(d), II(e), II(h), II(i), III(a), V, VI(d) and VII against the data importer or the data exporter, for their respective breach of their contractual obligations, with regard to his personal data, and accept jurisdiction for this purpose in the data exporter’s country of establishment. In cases involving allegations of breach by the data importer, the data subject must first request the data exporter to take appropriate action to enforce his rights against the data importer; if the data exporter does not take such action within a reasonable period (which under normal circumstances would be one month), the data subject may then enforce his rights against the data importer directly. A data subject is entitled to proceed directly against a the data exporter that has failed to use reasonable efforts to determine that the data importer is able to satisfy its legal obligations under these clauses (the data exporter shall have the burden to prove that it took reasonable efforts). |
| --- | --- |

**IV. Law applicable to the clauses**

These clauses shall be governed by the law of the country in which the data exporter is established, with the exception of the laws and regulations relating to processing of the personal data by the data importer under clause II(h), which shall apply only if so selected by the data importer under that clause.

**V. Resolution of disputes with data subjects or the authority**

| (a) | In the event of a dispute or claim brought by a data subject or the authority concerning the processing of the personal data against either or both of the parties, the parties will inform each other about any such disputes or claims, and will cooperate with a view to settling them amicably in a timely fashion. |
| --- | --- |

| (b) | The parties agree to respond to any generally available non-binding mediation procedure initiated by a data subject or by the authority. If they do participate in the proceedings, the parties may elect to do so remotely (such as by telephone or other electronic means). The parties also agree to consider participating in any other arbitration, mediation or other dispute resolution proceedings developed for data protection disputes. |
| --- | --- |

| (c) | Each party shall abide by a decision of a competent court of the data exporter’s country of establishment or of the authority which is final and against which no further appeal is possible. |
| --- | --- |

**VI. Termination**

| (a) | In the event that the data importer is in breach of its obligations under these clauses, then the data exporter may temporarily suspend the transfer of personal data to the data importer until the breach is repaired or the contract is terminated. |
| --- | --- |

| (b) | In the event that:   | (i) | the transfer of personal data to the data importer has been temporarily suspended by the data exporter for longer than one month pursuant to paragraph (a); | | --- | --- |  | (ii) | compliance by the data importer with these clauses would put it in breach of its legal or regulatory obligations in the country of import; | | --- | --- |  | (iii) | the data importer is in substantial or persistent breach of any warranties or undertakings given by it under these clauses; | | --- | --- |  | (iv) | a final decision against which no further appeal is possible of a competent court of the data exporter’s country of establishment or of the authority rules that there has been a breach of the clauses by the data importer or the data exporter; or | | --- | --- |  | (v) | a petition is presented for the administration or winding up of the data importer, whether in its personal or business capacity, which petition is not dismissed within the applicable period for such dismissal under applicable law; a winding up order is made; a receiver is appointed over any of its assets; a trustee in bankruptcy is appointed, if the data importer is an individual; a company voluntary arrangement is commenced by it; or any equivalent event in any jurisdiction occurs | | --- | --- |   then the data exporter, without prejudice to any other rights which it may have against the data importer, shall be entitled to terminate these clauses, in which case the authority shall be informed where required. In cases covered by (i), (ii), or (iv) above the data importer may also terminate these clauses. |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |

| (c) | Either party may terminate these clauses if (i) any Commission positive adequacy decision under Article 25(6) of Directive 95/46/EC (or any superseding text) is issued in relation to the country (or a sector thereof) to which the data is transferred and processed by the data importer, or (ii) Directive 95/46/EC (or any superseding text) becomes directly applicable in such country. |
| --- | --- |

| (d) | The parties agree that the termination of these clauses at any time, in any circumstances and for whatever reason (except for termination under clause VI(c)) does not exempt them from the obligations and/or conditions under the clauses as regards the processing of the personal data transferred. |
| --- | --- |

**VII. Variation of these clauses**

The parties may not modify these clauses except to update any information in Annex B, in which case they will inform the authority where required. This does not preclude the parties from adding additional commercial clauses where required.

**VIII. Description of the Transfer**

The details of the transfer and of the personal data are specified in Annex B. The parties agree that Annex B may contain confidential business information which they will not disclose to third parties, except as required by law or in response to a competent regulatory or government agency, or as required under clause I(e). The parties may execute additional annexes to cover additional transfers, which will be submitted to the authority where required. Annex B may, in the alternative, be drafted to cover multiple transfers.

Signed and agreed:

| FOR The data importer  Name:  Title:  Date: | FOR The data exporter  Name:  Title:  Date: |
| --- | --- |

**ANNEX A**

**Data PROCESSING PRINCIPLES**

| 1. | Purpose limitation: Personal data may be processed and subsequently used or further communicated only for purposes described in Annex B or subsequently authorised by the data subject. |
| --- | --- |

| 2. | Data quality and proportionality: Personal data must be accurate and, where necessary, kept up to date. The personal data must be adequate, relevant and not excessive in relation to the purposes for which they are transferred and further processed. |
| --- | --- |
| 3. | Transparency: Data subjects must be provided with information necessary to ensure fair processing (such as information about the purposes of processing and about the transfer), unless such information has already been given by the data exporter. |
| 4. | Security and confidentiality: Technical and organisational security measures must be taken by the data controller that are appropriate to the risks, such as against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access, presented by the processing. Any person acting under the authority of the data controller, including a processor, must not process the data except on instructions from the data controller. |
| 5. | Rights of access, rectification, deletion and objection: As provided in Article 12 of Directive 95/46/EC, data subjects must, whether directly or via a third party, be provided with the personal information about them that an organisation holds, except for requests which are manifestly abusive, based on unreasonable intervals or their number or repetitive or systematic nature, or for which access need not be granted under the law of the country of the data exporter. Provided that the authority has given its prior approval, access need also not be granted when doing so would be likely to seriously harm the interests of the data importer or other organisations dealing with the data importer and such interests are not overridden by the interests for fundamental rights and freedoms of the data subject. The sources of the personal data need not be identified when this is not possible by reasonable efforts, or where the rights of persons other than the individual would be violated. Data subjects must be able to have the personal information about them rectified, amended, or deleted where it is inaccurate or processed against these principles. If there are compelling grounds to doubt the legitimacy of the request, the organisation may require further justifications before proceeding to rectification, amendment or deletion. Notification of any rectification, amendment or deletion to third parties to whom the data have been disclosed need not be made when this involves a disproportionate effort. A data subject must also be able to object to the processing of the personal data relating to him if there are compelling legitimate grounds relating to his particular situation. The burden of proof for any refusal rests on the data importer, and the data subject may always challenge a refusal before the authority. |
| 6. | Sensitive data: The data importer shall take such additional measures (e.g. relating to security) as are necessary to protect such sensitive data in accordance with its obligations under clause II. |
| 7. | Data used for marketing purposes: Where data are processed for the purposes of direct marketing, effective procedures should exist allowing the data subject at any time to “opt-out” from having his data used for such purposes. |
| 8. | Automated decisions: For purposes hereof “automated decision” shall mean a decision by the data exporter or the data importer which produces legal effects concerning a data subject or significantly affects a data subject and which is based solely on automated processing of personal data intended to evaluate certain personal aspects relating to him, such as his performance at work, creditworthiness, reliability, conduct, etc. The data importer shall not make any automated decisions concerning data subjects, except when:   | (a) | | (i) | such decisions are made by the data importer in entering into or performing a contract with the data subject, and | | --- | --- | | (ii) | (the data subject is given an opportunity to discuss the results of a relevant automated decision with a representative of the parties making such decision or otherwise to make representations to that parties. | | | --- | --- | --- | --- | --- | --- |   or   | (b) | where otherwise provided by the law of the data exporter. | | --- | --- | |

**ANNEX B**

**DESCRIPTION OF THE TRANSFER**

| **Description of the data** | This Project includes single cell RNA-sequencing (scRNA-seq) data from ~1M PBMCs from 165 Lifelines DEEP participants from the general population of the northern part of the Netherlands (Tigchelaar, E. F. *et al*. Cohort profile: LifeLines DEEP, a prospective, general population cohort study in the northern Netherlands: study design and baseline characteristics. *BMJ Open* **5**, e006772-2014-006772 (2015)). The cohort comprised predominantly Dutch participants; 93.7% had both parents born in the Netherlands. The available data consists of 2 separate scRNA-seq datasets. The first dataset, containing 45 individuals (van der Wijst et al. Nature Genetics, 2018), consists of on average ~550 PBMCs of each individual. These were analyzed using scRNA-sequencing on a HiSeq4000, resulting in about 511 Gb of data (239 Gb BAM-files and 272 Gb fastq-files). An additional text file is included in which the Demuxlet method was used to couple each cell barcode to an individual/sample-id (using genotype data). The second dataset, containing 120 individuals (unpublished), consists of on average ~1170 PBMCs per condition per individual. This dataset contains 7 different conditions per person: unstimulated, 3h and 24h Candida Albicans, Pseudomonas Aeruginosa and Mycobacterium Tuberculosis stimulations of the PBMCs. These PBMCs were analyzed using scRNA-sequencing on a NovoSeq6000, resulting in about 13.2 TB of data (6.2 TB BAM-files and 7 TB fastq-files). An additional text file is included in which the Souporcell method (Heaton et al., BiorXiv 2019) was used to couple each cell barcode to an individual/sample-id (using genotype data).  A vcf-file containing previously generated (Tigchelaar E.F. et al. 2015) genotype data (HumanCytoSNP-12 BeadChip, Dolmans G.H., et al. 2011) imputed with the HRC-reference panel (McCarthy S. et al. 2016) is available for all 165 samples. Access to data is available by application to the LLDEEP DAG2+ Data Access Committee. Access to data will be granted to qualified investigators for appropriate use. |
| --- | --- |
| **Purpose of the transfer(s)** The transfer is made for the following purpose: | See EXHIBIT I |
| **Recipients**  The personal data transferred may be disclosed only to the following recipients or categories of recipients: | [the data importer's employee name] |
| **Sensitive data** (if appropriate) the personal data transferred concern the following categories of sensitive data:  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 | Genetic data, biometric data |
| **Method of transfer**  The following method of transfer is used: | Access through EGA (raw data) or UMCG HPC. |
| Method of data storage and security measures (e.g. method of encoding) | All the EGA data has to be processed in a secure environment that no one can access except the applicant. The pseudoanonymized genetic data has to be processed in a secure environment and it is not allowed to be transferred from the UMCG HPC. |
| **Contact points for data protection enquiries:** | |
| The data importer  [contact details] | The data exporter  University Medical Center Groningen  Attn. PWO, LB41  Hanzeplein 1, 9713 GZ Groningen, The Netherlands  E-mail: privacy@umcg.nl  Tel: +31(0)50-3616161. |