Data Transfer Agreement
non-commercial studies (applications [DAC] [OR] [RDR])
(Recipient is data controller)

**Provider’s ref: S[…] [AND/OR] RDR ref. …**

This data transfer agreement is effective as of [DD Month YYYY] (“**Effective Date**”) and is entered into by and between:

**UZ Leuven**, with offices at Herestraat 49 3000 Leuven, Belgium, enterprise number: 0419.052.173 and represented by its legal representative, Prof. Dr. Paul Herijgers, hereinafter referred to as “**UZ Leuven**” or “**Provider**”;

and

**[Name institution]**, with offices at [address] and represented by its legal representative(s), [Name(s) legal representative(s)], hereinafter referred to as “**Recipient**”;

The Provider and the Recipient are hereinafter referred to individually as a “**Party**” and jointly as the “**Parties**”.

WHEREAS the Recipient is conducting the Study, and has now requested the Provider to provide the Recipient with the Data for use in the Study;

**WHEREAS** the Provider is willing to provide the Data to the Recipient (in particular to the Recipient’s Investigator) in accordance with the terms and conditions of this Agreement.

1. **Definitions**

**Agreement**: This data transfer agreement together with all of its appendices and amendments.

**Authorised Personnel**: The Recipient’s Investigator (as identified in Appendix B) and any individuals employed at, affiliated with or enrolled at the Recipient and acting under the direction and supervision of the Recipient’s Investigator to whom the Provider grants access to the Data.

**Commercial Purposes**: The sale, lease, license, or other transfer of the Data to a for-profit organization. Commercial Purposes will also include uses of the Data by any organization, including the Recipient, to perform contract research, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license, or transfer of the Data to a for-profit organization. However, industrially sponsored academic research will not be considered a use of the Data for Commercial Purposes per se, unless any of the above conditions of this definition are met.

**Data**: The data being transferred under this Agreement by the Provider to the Recipient (details of which are set out in Appendix A) for the performance of the Study and any individual-level data derived from the Data.

**Data Protection Legislation**: Applicable legislation regarding data protection and privacy, such as, as applicable, the GDPR.

**GDPR**: 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, and repealing Directive 95/46/EC (General Data Protection Regulation) as amended, replaced or superseded from time to time. If used, the terms “**Controller**”, “**Data Subject**”, “**Personal Data Breach**”, “**Processing**”, “**Processor**” and “**Supervisory Authority**” will have the same meaning as in the GDPR, and their cognate terms will be construed accordingly.

**Results**: The inventions, know-how and other results conceived or generated by the Recipient (whether patentable or not) and related to the Data or their use, or developed using the Data.

**Study**: The research project (a description of which is set out in Appendix B) for which the Recipient requests access to the Data.

1. **Terms and Conditions**
	* 1. The Data is made available as a service to the research community pursuant to the terms and conditions of this Agreement.
		2. In its use of the Data, Recipient agrees to comply with the Data Protection Legislation and the obligations set forth under Appendix C.
		3. The Recipient agrees that the Data:
			1. is to be used only for the purpose of the performance of the Study by Authorised Personnel and within the limitations set out in Appendix A (if any). The Recipient will notify the Provider prior to any significant changes to the Study;
			2. will not be used for Commercial Purposes; and
			3. will not be transferred to a third party, even if such third party is involved in the conduct of the Study. The Recipient will refer any request for the Data to the Provider. Access to the Data by a third party will always be subject to the conclusion of a separate data transfer agreement by that third party with the Provider.
		4. The Recipient will restrict disclosure of the Data solely to the Authorised Personnel who require the Data for the performance of the Study. The Recipient will require the Authorised Personnel to comply with the obligations as set forth in this Agreement and remains responsible for their compliance with the provisions of this Agreement.
		5. The Parties are sole and separate controllers as they will not jointly determine the purposes and the means of the processing of the Data under this Agreement. Provider will transfer the Data to the Recipient who agrees to receive the Data from the Provider for further processing of the Data in accordance with this Agreement for the purpose of the Study as determined by the Recipient.
		6. The Recipient agrees not to make intellectual property claims on the Data and not to use intellectual property protection in ways that would prevent or block access to, or use of, any element of the Data, or conclusion drawn directly from the Data.
		7. Subject to Article 6 and 9, the Recipient will be the sole owner of, and will be entitled to use and exploit, at its sole discretion, any and all Results.
		8. The Recipient will provide a report specifying the Results to the Provider on a confidential basis upon the Provider’s first request.
		9. The Provider will have the irrevocable, non-exclusive, royalty-free right to use the Results for its internal non-commercial research and teaching purposes.
		10. Except as provided in this Agreement, no express or implied licenses or other rights are provided to the Recipient hereunder. Nothing in this Agreement will be deemed to grant the Recipient any rights under any patent or patent application, nor any direct or indirect rights or license to use, or permit the use of, any products or processes containing, or using, or derived from the Data for Commercial Purposes.
		11. The Recipient agrees to preserve, at all times, the confidentiality of the Data. In particular, it undertakes not to use, or attempt to use the Data to compromise or otherwise infringe the confidentiality of information on a Data Subject. The Recipient agrees not to link the Data to or combine the Data with other information or archived data available in a way that could re-identify a Data Subject, even if access to that data has been formally granted to the Recipient or is freely available without restriction. Without prejudice to the generality of the foregoing, the Recipient agrees to have in place at least the security measures set out in Appendix C to protect the Data.
		12. The Recipient will have the right to publish and disclose the Results. The Recipient agrees to acknowledge the Provider as the source of the Data in any publications reporting use of it as is customary in the scientific community and the acknowledgment will include [the EGA dataset ID] **[OR]** [the dataset’s persistent identifier] (as specified in Appendix A) (to the specific version of the dataset(s) analyzed). The Recipient agrees to cite the Provider’s publication (to the extent specified in Appendix A) in any publication reporting use of the Data. The Recipient agrees to protect the confidentiality of Data Subjects in any publications that they prepare by taking all reasonable care to limit the possibility of both direct and indirect identification.
		13. The Recipient will notify the Provider as soon as it becomes aware of a breach of the terms or conditions of this Agreement.
		14. The Data is provided at no cost.
		15. This Agreement will become effective on the Effective Date and, unless terminated earlier, will terminate at: (a) the completion of the Study; or (b) three (3) years after the Effective Date; whichever is earlier. Either Party can terminate this Agreement upon one (1) month prior written notice. If the Recipient fails to fully comply with the obligations arising from this Agreement and, in the case of a breach capable of remedy, fails to remedy the shortcoming within fourteen (14) days after the occurrence of the shortcoming, the Provider, without prejudice to other termination possibilities as provided for in this Agreement, may terminate this Agreement immediately without judicial intervention and the Provider will also be entitled to suspend the fulfilment of its obligations under this Agreement. Any clauses that will be expected or intended by its nature to survive the termination of this Agreement, will survive the termination of this Agreement. Upon termination of this Agreement, any further transfer of Data will automatically end. Upon termination of this Agreement or once the use of the Data is no longer necessary for the performance of the Study, whichever is earlier, the Recipient will irrevocably erase the Data held, including copies and backup copies. The Recipient will provide the Provider, at its first request, written confirmation thereof, provided that Recipient may retain in its confidential files one (1) copy of the Data for purposes of verifying compliance with this Agreement. Until the Data is deleted, the Recipient will continue to ensure compliance with its obligations arising from this Agreement.
		16. The Recipient agrees that the Provider, and all other parties involved in the creation, funding or protection of the Data: (a) make no warranty or representation, express or implied as to the accuracy, quality or comprehensiveness of the Data or that the use of the Data will not infringe any patent, copyright, trademark, or other proprietary rights; (b) exclude to the fullest extent permitted by law all liability for actions, claims, proceedings, demands, losses (including but not limited to loss of profit), costs, awards, damages and payments made by the Recipient that may arise (whether directly or indirectly) in any way whatsoever from the Recipient’s use of the Data or from the unavailability of, or break in access to, the Data for whatever reason; and (c) bear no responsibility for the further analysis or interpretation of the Data.
		17. This Agreement will be construed, governed, interpreted and enforced according to the laws of Belgium, excluding its conflict of law provisions. All disputes arising out of or in relation to this Agreement will be brought before the competent courts of Leuven, Belgium.
		18. This Agreement sets forth the entire agreement between the Parties as to the subject matter hereof, and supersedes and replaces all previous understandings, agreements, statements, documents, representations, negotiations, whether written or oral, between the Parties relating to its subject matter. No modifications hereof will be binding unless executed in writing by the authorised signatories of the Parties hereto.
		19. If any portion of this Agreement is in violation of any applicable regulation, or is unenforceable or void for any reason whatsoever, such portion will be considered inoperative without prejudice to the validity of the rest of this Agreement.

**IN WITNESS WHEREOF**, the Parties hereto have caused this Agreement to be executed by their duly authorised signatories.

|  |  |
| --- | --- |
| For PROVIDER | Read and acknowledged by the PROVIDER’s INVESTIGATOR |
| Signature:Name: Prof Dr Paul HerijgersTitle: Chief Executive OfficerDate: ……………………. | Signature:Name: Prof […]Title: ……………………………………...Date: ……………………. |
| For RECIPIENT | [Read and acknowledged by the] RECIPIENT’s INVESTIGATOR |
| Signature:Name: ……………………………………Title: ……………………………………Date: ……………………. | Signature:Name: ……………………………………Title: ……………………………………...Date: ……………………. |

# **DATA**

[**EGA Dataset ID] [OR] [Persistent Identifier]**: […]

**Dataset details**: The dataset is pseudonymised. [Specify further dataset details, if applicable]

**[Name and reference number of study in the framework of which the dataset was created**: [Study name] (S[…])]

**Provider’s Investigator(s)**: […]

**Publication of the dataset to be cited by the Recipient**: […]

**Names of other data producers/collaborators**: […]

**Specific limitations on areas of research**: […]

# **STUDY**

**Brief abstract of the Study in which the Data will be used (500 words max)**: […]

**Recipient’s Investigator**: […]

**Recipient’s processing operations**:

[ ]  Receiving data, including collection, accessing, retrieval, recording, and data entry

[ ]  Holding data, including storage, organisation and structuring

[ ]  Using data, including analysing, consultation, testing, automated decision making and profiling

[ ]  Updating data, including correcting, adaptation, alteration, alignment and combination

[ ]  Protecting data, including restricting, encrypting, and security testing

[ ]  Sharing data, including disclosure, dissemination, allowing access or otherwise making available

[ ]  Returning data to the data provider or data subject

[ ]  Erasing data, including destruction and deletion

[ ]  Other (please provide details of other types of processing): […]

**Description of the technical and organisational measures implemented by the Recipient (including any relevant certifications) to ensure an appropriate level of security, taking into account the nature, scope, context and purpose of the processing, and the risks for the rights and freedoms of natural persons**:

[…]

# **DATA PROTECTION APPENDIX**

1. **Description of the Transfer**

The details of the transfer, and in particular the categories of personal data that are transferred and the purpose(s) for which they are transferred, are specified in Schedule 1.

1. **Obligations of each party**

Each Party agrees to comply with the Data Protection Legislation and the arrangements provided in this Appendix C in relation to its processing of the Data.

Each Party has the duty to ensure that it has a legal basis for its processing of the Data and that the Data are not further processed in a manner that is incompatible with the purposes for which they were originally collected by the Provider.

The Recipient and, during transmission, also the Provider undertakes to put in place appropriate technical and organisational measures to ensure the security of the Data, including protection against a personal data breach. The Parties will in particular pseudonymise the Data and will consider having recourse to encryption, including during transmission, where the purpose of processing can be fulfilled in that manner.

Each Party will designate a data protection officer (DPO) if the conditions of Article 37(1) GDPR are met. Each Party will inform the other Party in writing of the contact details, and any changes thereto, of its DPO (if applicable) and its point(s) of contact with respect to compliance of a Party with the Data Protection Legislation and the processing of the Data (see Schedule 2).

1. **TRANSPARENCY**

In order to enable data subjects to effectively exercise their rights pursuant to Article 4, the Recipient will inform them in accordance with Article 14 of the GDPR. Where providing the information directly to the data subject proves impossible or would involve a disproportionate effort for the Recipient, the Recipient will, to the extent possible, make the information publicly available.

1. **Rights of data subjects**

The Recipient will deal with any enquiries and requests it receives from a data subject relating to the processing of the Data and the exercise of his/her rights in accordance with the Data Protection Legislation. However, in accordance with Article 11 of the GDPR, the Recipient cannot be compelled to acquire or process additional information in order to identify the data subjects for the sole purpose of complying with their rights.

1. **Personal data breach**

In the event of a personal data breach concerning the Data processed by the Recipient hereunder, the Recipient will take appropriate measures to address the personal data breach, including measures to mitigate its possible adverse effects. Where a personal data breach is likely to result in a risk to the rights and freedoms of natural persons, the Recipient will without undue delay notify both the Provider and the competent supervisory authority in accordance with Article 33 of the GDPR. Schedule 3 may be used for such notification to the Provider, but if not used, the content of the notification to the Provider must be equivalent to the content of Schedule 3. Where a personal data breach is likely to result in a high risk to the rights and freedoms of natural persons, the Recipient will also notify without undue delay the data subjects affected in accordance with Article 34 of the GDPR.

**Schedules**

Schedule 1 (*Description of transfer*)

Schedule 2 (*Data Protection Officer or other contact(s) responsible for data protection at a Party*)

Schedule 3 (*Sample form for reporting personal data breaches*)

Schedule 4 (*European’s Commission Standard Contractual Clauses*)

1. **Description of transfer**

|  |  |
| --- | --- |
| **Description of the Provider’s processing activity under which the Data was initially collected and processed** | See Appendix A |
| **Purpose of the transfer and further processing of the personal data** | See Appendix B |
| **Categories of personal data transferred to the Recipient** | **[EGA dataset:** Genetic and health data (see Appendix A)]**[OR]****[RDR dataset:** **Regular personal data:**[ ]  Personal details, including any information that identiﬁes the data subject and their personal characteristics, including: name, address, contact details, age, date of birth, sex, and physical description[ ]  Personal details issued as an identifier by a public authority, including passport details, national insurance numbers, identity card numbers, driving licence details[ ]  Family, lifestyle and social circumstances, including any information relating to the family of the data subject and the data subject’s lifestyle and social circumstances, including current marriage and partnerships, marital history, details of family and other household members, habits, housing, travel details, leisure activities, and membership of charitable or voluntary organisations[ ]  Education and training details, including information which relates to the education and any professional training of the data subject, including academic records, qualiﬁcations, skills, training records, professional expertise, student and pupil records[ ]  Employment details, including information relating to the employment of the data subject, including employment and career history, recruitment and termination details, attendance records, health and safety records, performance appraisals, training records, and security records[ ]  Financial details, including information relating to the ﬁnancial affairs of the data subject, including income, salary, assets and investments, payments, creditworthiness, loans, beneﬁts, grants, insurance details, and pension information[ ]  Goods or services provided and related information, including details of the goods or services supplied, licences issued, and contracts[ ]  Personal data relating to criminal convictions and offences[ ]  Other: […][ ]  **Special categories of personal data, being personal data which is on, which reveals, or which concerns:**[ ]  racial or ethnic origin[ ]  political opinions[ ]  religious or philosophical beliefs[ ]  trade union membership[ ]  genetic data[ ]  biometric data (if used to uniquely identify a natural person)[ ]  health[ ]  sex life or sexual orientation[ ]  criminal convictions and offences] |
| **Sensitive data transferred? If so, description of applied restrictions and safeguards** | **[EGA dataset:** Yes. Strict purpose limitation, access restrictions, restrictions for onward transfers and pseudonymisation.]**[OR]****[RDR dataset:** *Yes/No. If so, please describe the applied restrictions or safeguards that fully take into consideration the nature of the data and the risks involved, such as for instance strict purpose limitation, access restrictions (including access only for staff having followed specialised training), keeping a record of access to the data, restrictions for onward transfers or additional security measures.*] |
| **Categories of data subjects whose personal data is transferred** | [x]  Patients[x]  Healthy volunteers[ ]  Staff including volunteers, agents, temporary and casual workers☐ Customers and clients (including their staff)☐ Suppliers (including their staff)☐ Members or supporters☐ Shareholders☐ Relatives, guardians and associates of the data subject☐ Students and pupils[ ]  Other: […] |
| **Recipient’s processing operations** | See Appendix B |
| **Frequency of the transfer** | One-off |
| **Format of the transfer** | **[EGA dataset:** Via the European Genome-phenome Archive’s (EGA) secure distribution under controlled access**[OR]****[RDR dataset:** *E.g. encrypted on memory stick; remote access*] |
| **The period for which the personal data will be retained by the Recipient, or, if that is not possible, the criteria used to determine that period and appropriate technical or organisational measures to ensure compliance with this obligation** | The Recipient will retain the personal data for no longer than necessary for the purpose(s) for which it is processed (see Article 15 and Appendix B). It will put in place appropriate technical or organisational measures to ensure compliance with this obligation, including erasure or anonymisation of the data and all back-ups at the end of the retention period. |
| **Security measures** | See Appendix B |

1. **Data Protection Officer or other contact(s) responsible for data protection at a Party**

Each Party will nominate one or more point(s) of contact (POC) within their organisation who can be contacted in respect of queries, requests or complaints regarding the processing of the Personal Data under this Appendix C or regarding compliance with Data Protection Laws or in case of personal data breaches. Please specify the Study concerned by mentioning the title as well as the names of the researchers involved:

|  |  |  |  |
| --- | --- | --- | --- |
| **Party** | **Name** | **Position** | **Email address** |
| Provider | First POC:[Insert name Provider’s Investigators] | Provider’s Investigators | [insert email] |
| Secondary POC:Data Protection Officer | DPO | Gdpr.research@uzleuven.be  |
| Recipient | [insert name / position] | [insert position] | [insert email] |

1. **Sample form for reporting personal data breaches**

|  |
| --- |
| **Date:** |
|  |
| **Party name:** |
| **Address:** |
| **ZIP code:** |
|  |
| **Who identified the breach?** |
| Name (optional): |
| Job Title: |
| **When was the breach identified?** |
| Date: |
| Time: |
|  |
| Describe the security incident that led to the breach of personal data security: |
| **When did the breach occur?** |
| 1. On (date + time)
 |
| 1. Between (date + time) and (date + time)
 |
| 1. Not yet determined
 |
|  |
| **Establish context of the data involved in the breach:**  |
| **Classification of the data:** |
| 1. None, the data cannot be traced back to an individual
 |
| 1. Name and address information
 |
| 1. Telephone numbers
 |
| 1. E-mail addresses, Facebook IDs, Twitter IDs, etc.
 |
| 1. Usernames, passwords or other login details, customer numbers
 |
| 1. Financial information: account numbers, credit card numbers
 |
| 1. National registration number
 |
| 1. Copies of proofs of identity
 |
| 1. Gender, date of birth and/or age
 |
| 1. Data concerning someone's religious or personal beliefs, race, political views or trade unions membership
 |
| 1. Data concerning someone's health or sexual orientation
 |
| 1. Personal data relating to criminal justice or unlawful or disturbing behaviour in respect of an injunction arising from that behaviour
 |
| 1. Data concerning someone's financial or economic situation, information on debts, salary or payment details
 |
| 1. Derived financial data (income category, home ownership, car ownership)
 |
| 1. Lifestyle characteristics (including family composition, living situation, interests), demographic characteristics (age, gender, nationality, occupation, education)
 |
| 1. Data obtained from (public) social media profiles (Facebook, LinkedIn and Twitter accounts, etc.)
 |
| 1. Other, namely:
 |
| **Classification of the context involved in the breach:** |
| **How many people's personal data are involved in the breach?** |
| 1. None, the data cannot be traced back to an individual
 |
| 1. Not yet determined
 |
| 1. At least …………………………………… (number), but not more than ………………………….. (number) involved
 |
| **Describe the group of people whose personal data was involved in the breach:** |
|  |
| **Circumstances of the data breach (multiple answers possible):** |
| 1. Reading (an unauthorised third party was able to gain sight of (confidential) data. Data is still in possession of the Recipient.) - Confidentiality is at risk
 |
| 1. Copying (an unauthorised third party was able to copy data. Again, data is still in possession of the Recipient.) - Confidentiality is at risk
 |
| 1. Altering (an unauthorised third party altered data, or was in a position to, in the Recipient’s system) - Integrity is at risk
 |
| 1. Removal or destruction (an unauthorised third party has removed data from the Recipient’s system or destroyed it.) - Availability is at risk
 |
| 1. Theft - Availability is at risk
 |
| 1. Not yet known
 |
|  |
| **Has the personal data been rendered incomprehensible or inaccessible for unauthorised third parties, for example through encryption or hashing?** |
| Yes |
| No |
| Partly, namely |
|  |
| **If so, in what manner has the personal data been encrypted:** |
|  |
| **Does the breach concern individuals from other EU countries?** |
| Yes |
| No |
| If so, which EU countries and indicate how many: |
|  |
| **What security measures (technical and organisational) have been taken to deal with the breach and to prevent re-occurrence?** |
|  |
| **Who can be approached for more information on the breach?** |
| Name of the Recipient’s contact person: |
| E-mail: |
| Telephone number: |

1. **EU Commission's Standard Contractual Clauses for the transfer of Personal Data to third countries**

[**OPTION 1: SCCs NEEDED:** The transfer of data from the Provider to the Recipient will be in accordance with the latest version of the EU Commission's Standard Contractual Clauses (**MODULE ONE: Transfer controller to controller**)[[1]](#footnote-1) for the transfer of Personal Data to third countries, which are incorporated herein by reference and form an integral part of the present Agreement.

The following options and specifications are chosen:

* Clause 7 – Docking clause is not added;
* The option in Clause 11 – Redress is not added;
* In Clause 17 – Governing law and Clause 18 – Choice of forum and jurisdiction Belgium is specified as Member State.

Completion of annexes:

* ANNEX I:
	+ A. LIST OF PARTIES:
		- The Provider is the data exporter and the Recipient is the data importer;
		- The name and address of the Provider and the Recipient is available in the introduction to the Parties’ section in the Agreement;
		- Each Party’s contact person’s name, position and contact details is set out in Schedule 2 to Appendix C.
		- The activities relevant to the data transferred under these Clauses are described in the Agreement;
		- The GDPR roles of the Parties are described in Article 5 of the Agreement (separate controllers).
	+ B. DESCRIPTION OF THE TRANSFER: the requested information is available in Schedule 1 to Appendix C.
	+ C. COMPETENT SUPERVISORY AUTHORITY: Belgian Data Protection Authority, https://www.dataprotectionauthority.be.
* ANNEX II: the requested information is available in Appendix B.

**[OR]**

[**OPTION 2: NO SCCs NEEDED:** mention “Not applicable, intentionally left blank” **[AND]** [**OPTION 2.1: ADEQUACY DECISION**: make reference to the appropriate adequacy decision of the European Commission[[2]](#footnote-2)] **[OR]** [**OPTION 2.2: NO INTERNATIONAL TRANSFER:** state that there is no transfer outside EEA or to an international organisation within the meaning of the GDPR.]]

1. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021D0914&qid=1739373280163>. For more information, please consult <https://commission.europa.eu/law/law-topic/data-protection/international-dimension-data-protection/standard-contractual-clauses-scc_en>. [↑](#footnote-ref-1)
2. <https://commission.europa.eu/law/law-topic/data-protection/international-dimension-data-protection/adequacy-decisions_en>. [↑](#footnote-ref-2)