#

# <Title Study and Study Code>

# DATA SHARING AGREEMENT

# *Isala Supplier*

**THE UNDERSIGNED**:

1. **Isala Zwolle**, with principal place of business at Dokter van Heesweg 2, 8025 AB Zwolle, lawfully represented by Mw. H.H. Kuper in her function of Member of the Board of Directors**,** hereafter referred to as the “**Supplier”**

and

2. **<NAME>**, having its office at <**ADDRESS>,** lawfully represented by **<NAME>,** **<TITLE>,**  hereinafter referred to as the **“Recipient”**

The foregoing entities are solely referred to as “**Party**” and collectively referred to as “**Parties**”.

**WHEREAS**:

- The Supplier owns the rights to certain clinical data derived from patient care and/or research, and is willing to provide the Recipient, and in particular Recipient’s researcher **[Name]** with such data for the study **“<TITLE STUDY>”** (hereinafter: the **“Research”**) as set forth in **Annex 1**.

- The Recipient will also collect such clinical trial/cohort data from other parties. The full dataset in which all subdatasets are included will be used for the Research.

* The Research shall be conducted by [the Recipient/the Supplier and Recipient jointly/ the Supplier and Recipient jointly with the other parties referred to above], in accordance with **Annex 1**.

- The Parties now desire to enter into this Data Sharing Agreement (hereinafter: “**Agreement**”) to confirm the terms and conditions upon which the Recipient agrees to conduct the Research (defined below) and upon which the Supplier agrees to transfer the clinical trial/cohort data.

* Since the Recipient is located outside the Union, in a country that is not subject to an adequacy decision of the European Commission, the Parties shall enter into a Standard Model Contract (EU Controller to Non-EU Controller), which is attached to this Agreement as **Annex 4.**

Now, therefore, in consideration of their mutual promises to each other, hereinafter stated, the Parties agree as follows:

**Definitions**

1. “**Data**” means the data as identified in **Annex 1** which the Supplier will transfer to the Recipient. The Data will contain personal data - which will be pseudonymized - as described in **Annex 2**.
2. “**Confidential Information**” means any proprietary information, know-how, data, or procedure related to the Data and disclosed by the Supplier to the Recipient pursuant to its rights or obligation under this Agreement.
3. “**Controller**”, “**Data subject**”, “**Personal data**”, “**Processing**”, “**Processor**” and “**Supervisory authority/authority**” shall have the meaning as in the General Data Protection Regulation (EU) 2016/679 (hereinafter: “**GDPR**”).
4. “**Pseudonymised data**” means Personal data which can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the Personal Data are not attributed to an identified or identifiable natural person.

**Clause 1. The processing of Personal Data**

* 1. The Supplier will provide the Recipient with the Data in accordance with the terms of this Agreement. With respect to the Data, the Supplier and Recipient are both considered controllers for the processing of the Personal data and will both act in accordance with the GDPR and additional data protection laws in the Netherlands Both Supplier and Recipient shall implement appropriate technical and organizational measures to meet the requirements of the GDPR.
	2. The Supplier warrants and undertakes that:
1. the Personal data that are part of the Data have been collected, processed and transferred in accordance with the GDPR and additional data protection laws in the Netherlands.
2. that the Data will only contain Pseudonymised data and no directly identifing Personal data. By way of example, but not limitation, Provider shall remove names, and other data elements which could identify individuals from study records, identify records only with arbitrary study codes, and will carefully safeguard the key to the Pseudonymized Personal data;
3. it has obtained any regulatory or ethics approvals necessary to collect the Data and transfer the Data to the Recipient;
4. it has full authority to transfer the Data to the Recipient;
5. in accordance with 458 of the Dutch Medical Treatment Act (WGBO), informed consent of the Data subjects is not required. Data will be collected on opt-out basis.

1.3 The Recipient warrants and undertakes that:

1. the Personal data will be processed in accordance with the laws applicable to the Recipient and in accordance with the GDPR and any (additional) applicable national law;
2. the Data will be used for the sole purpose of the Research in accordance with the permitted uses of the Data specified in the opt-out form of the Data subjects from whom the Data was collected;
3. appropriate technical and organisational measures are in place 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;
4. all Personal data will be treated strictly confidential and that Recipient shall have in place procedures so that any third party it authorises to have access to the Personal data, including employees and (sub)Processors, will respect and maintain the confidentiality and security of the Personal data. Any person or organisation acting under the authority of the Recipient, including a (sub)Processor, shall be obligated to process the Personal data only on instructions from the Recipient and in accordance with the permitted use under this Agreement. This provision does not apply to persons authorised or required by law or regulation to have access to the Personal data;
5. all employees, agents, and contractors with access to the Data comply with the terms of this Agreement, as well as the GDPR and any (additional) applicable national law, and that only those of its employees, agents, and contractors directly concerned with the Research have access to the Data and that they shall be bound by confidentiality and user undertakings and limitations substantially similar and no less stringent than those provided for in this Agreement;
6. in the event a Data subject objects to the use of the Data, Recipient will – at the instruction of Supplier – immediately return or destroy the Data from that particular Data subject;
7. it will not perform any act which would lead to the re-identification of the Data subjects concerned.

1.4 If either Party becomes aware of a Personal data breach in connection with the Data, that Party shall promptly notify the other Party. In such a case Parties will fully cooperate with each other to remedy the Personal data breach, fulfil the (statutory) notification obligations timely and cure the damages. A Personal data breach refers to a Personal data breach as meant in articles 33 and 34 of the European General Data Protection Regulation.

##### **Clause 2. Confidentiality**

2.1 Confidential Information is the sole property of the Supplier and shall be used by the Recipient solely for the purpose of the Research. The Recipient agrees not to disclose Confidential Information to third parties without the consent of the Supplier and under an agreement by the third party to be bound by the obligations of this Clause 2. The Recipient shall safeguard Confidential Information with the same standard of care that is used with Recipient’s own confidential information, but in no event less than reasonable care. The Data is not considered to be Confidential Information for the purpose of this Agreement.

* 1. The obligations under this Clause 2 shall not extend to any information:
* which is or becomes publicly available through no breach of this Agreement;
* which Recipient can demonstrate that it possessed free of any obligation of confidence prior to, or developed independently from, disclosure under this Agreement;
* which Recipient receives from a third party which is not legally prohibited from disclosing such information; or
* which Recipient is required by law to disclose.

2.3 The obligations of this Clause 2 shall survive this Agreement for a period of five (5) years after termination or expiration of this Agreement. Upon the request of the Supplier, the Recipient agrees to return the Confidential Information to the Supplier or destroy, at the option of the Supplier, all copies of Confidential Information; provided, however, that Recipient shall be entitled to retain one copy of Confidential Information solely to ensure compliance with its rights and obligations hereunder.

**Clause 3. Intellectual Property Rights**

3.1 Recipient acknowledges that, as between Supplier and Recipient, all Data received by Recipient from Supplier in connection with this Agreement shall be and remain the sole property of Supplier. Supplier hereby grants Recipient a non-exclusive, non-transferable, worldwide, perpetual, fully paid-up and royalty-free right and license, only to receive, analyze, utilize, copy, store, commingle and process the Data solely for the purpose of the Research.

3.2 All discoveries, developments, databases, inventions (whether patentable or not), methods, reports, know-how, or trade secrets which are made by the Recipient as a result of the conduct of the Research (hereinafter: “Results”) shall be the sole property of the Recipient.

3.3 Provider shall have the right to use the Results for its internal hospital and/or non-commercial research and/or educational activities, such research or educational activities whether or not in collaboration with other non-commercial institutions.

##### **Clause 4. Publication**

4.1 The Results of the Research shall be published in accordance with the publication procedure included in **Annex 3.**

4.2 Recipient agrees to acknowledge the source of the Data in any publications reporting on Recipient's use of it.

##### **Clause 5. Representations and warranties**

5.1 Other than the warranties set out in section 1.2, the Data is provided by the Supplier to the Recipient without any warranties whatsoever, express or implied, including any warranties for merchantability or fitness for a particular purpose.

5.2 Nothing in this Agreement shall be construed as granting to Recipient, either expressly or by implication, any right or licence to the Data, under any patent, patent application, trade secret, know how, confidential information, trade or service mark, copyright, or other intellectual and/or industrial property rights Supplier possesses or may possess, nor any option to any such right or license, other than as expressly set forth in this Agreement.

##### **Clause 6. Liabilities and indemnification**

6.1 The Recipient assumes the risk of any damage, loss, or expense associated with or resulting from the conduct of the Research or Recipient’s use of the Data, unless such damage or loss is caused by the gross negligence or wilful misconduct of the Supplier.

6.2 The Recipient will indemnify and hold the Supplier, its directors or employees harmless against all claims of any kind whatsoever that may arise or result from the use of the Data.

6.3 The Supplier shall not be liable toward the Recipient for any claims, costs or damages that may result, directly or indirectly, out of Recipient’s use of the Data and/or Results, unless and to the extent that damage is caused by gross negligence and/or due to wilful misconduct by the Supplier.

6.4 The Parties shall in no case be liable for any indirect, incidental or consequential damages (including without limitation, lost business or profits, or loss of use of equipment) suffered by another Party.

##### **Clause 7. Duration and termination of the Agreement**

7.1 This Agreement shall enter into force on the date of signing, and the duration of this Agreement shall be identical to the duration mentioned in Annex 1, including any extensions thereof.

7.2 This Agreement can be terminated earlier by either Party with immediate effect by receipt of written notice:

a. Upon a material breach of this Agreement by the other Party, if it is not cured within thirty (30) days after the breaching Party has received written notice of such material breach.

b. in the event the other Party is in state of bankruptcy or suspension of payment or a petition to that effect is filed by or against that Party;

c. in the event the business of the other Party will be winded up or closed down;

d. in case of force majeure - as determined in clause 12 below - if the force majeure situation will last over ninety (90) days.

7.3 The Recipient agrees, on termination of this Agreement (whether as a result of its breach or otherwise) to cease all use of the Data and shall within fifteen (15) days return all Data to Supplier or destroy all Data at the sole discretion of Supplier, or to deal immediately with the Data in accordance with Supplier’s written instructions.

7.4 The Recipient shall have an exit plan for the fulfilment of any obligations arising from this Agreement, in the event that the Agreement is terminated prematurely. The Recipient shall furnish the Supplier with a copy of the aforementioned plan upon first request.

7.5 Clauses 1-6, 8, 9 and 14 shall survive expiration or early termination of this Agreement, as well as any terms that by their nature would be expected to survive expiration or early termination of this Agreement.

##### **Clause 8. Retention period, restoration and destruction of Personal Details**

8.1 The Recipient shall not retain the Data longer than strictly necessary, which includes the statutory retention period or any retention period agreed between the Parties, as laid down in Annex 1. Under no circumstances shall the Recipient retain the Data after the termination of this Agreement. It is up to the Supplier to decide if the data are to be retained, and if so, for how long.

8.2 When this Agreement is terminated, or, where applicable, at the end of the agreed retention period, or upon the written request of the Supplier, the Recipient shall irrevocably destroy or cause to be destroyed the Data. At the request of the Supplier, the Recipient shall submit evidence of the irrevocable destruction or removal of the data. If the data are to be restored, such shall be done electronically, in a commonly used, well-structured and documented data format. If an irrevocable destruction or removal of the Data is impossible, the Recipient shall notify the Supplier of this fact at once. In such cases, the Recipient shall guarantee that it shall treat the data confidentially and that it shall cease processing them.

##### **Clause 9. Publicity**

Neither Party will use the logo or name of the other Party or the name of an employee of the other Party, for promotional purposes, in any publicity, advertising or news release, without prior written approval of the Party whose name is to be used.

##### **Clause 10. Modifications**

Modifications, changes and extensions to this Agreement are only binding after these have been agreed upon in writing between the Parties.

##### **Clause 11. Assignment**

 The rights and obligations as determined in the Agreement may not be assigned by a Party without the prior written consent of the other Party, which consent shall not be unreasonably with­held or delayed.

##### **Clause 12. Force Majeure**

In case of force majeure the concerning Party is entitled to suspend the obligations for the duration and extent of the force majeure, provided that the other Party has been notified in writing of the force majeure. Force majeure situations will concern those situations which prevent the execution of the Agreement and which are not imputable to the concerning Party pursuant to law, Agreement or according to generally accepted standards and as a result will not be attributable to that Party.

##### **Clause 13. Severability**

 The invalidity or unenforceability of any particular provision of this Agreement shall not affect any other provisions therein. The Agreement shall be construed in all respects as if such invalid or unen­forceable provision were omitted.

##### **Clause 14. Governing law**

 13.1 This Agreement will be governed by Dutch law.

 13.2 In the event a dispute may arise from the Agreement, or from the execution of the Agreement, Parties will first try to settle such dispute amicably. If the dispute cannot be settled amicably, it will be submitted to the Court of Overijssel, the Netherlands.

##### **Clause 15. General Terms and conditions**

 No general conditions of either Party will apply to this Agreement.

**IN WITNESS WHEREOF**, the Parties hereto have by their authorized represen­tative duly caused this

Agreement to be executed as of the date hereinafter written.

**Supplier Recipient**

……………………………………… ………………………………………

Date: Date:

Name: Mw. H.H. Kuper Name:

Title: Board member Title:

Annexes:

1. Protocol
2. Description of Data Transfer
3. Privacy Matrix
4. Model contract (EU Controller to Non-EU Controller)

**Annex 1: Protocol**

The entire protocol is added as an attachment.

**Annex 2: Description of the transfer and Privacy Matrix**

**Data subjects**

**Purposes of the transfer(s)**
The transfer is made for the following purposes:

Clinical research as described in Annex 1.

 **Categories of data**
The personal data transferred concern the following categories of data:

*

**Sensitive data** (if appropriate)
The personal data transferred concern the following categories of sensitive data:

* data concerning health.

**Additional information** (storage limits, security measures and other relevant information)

**Pseudonymization techniques used**

 **Contact points for data protection enquiries**

**FB Isala**

**Supplier:**  **Recipient:**

**PRIVACY APPENDIX TO THE DATA SHARING AGREEMENT BETWEEN <name> and Isala Zwolle (hereinafter: “main agreement”)**

|  |
| --- |
| **Privacy arrangements****<name> and Isala Medical Center (Isala) are joint controllers with regard to the Personal Data that will be processed by virtue of the main agreement. In this context Parties determine and agree on- in accordance with article 26 of the GDPR- their respective obligations with regard to compliance with the GDPR.** |
| **Privacy obligation** *(please mention below the applicable privacy obligations).* | *Please mention below with regard to each obligation: the name of the responsible Party, the personal data and processing activities involved and if necessary the arrangement(s) about how to fulfill the obligation.*  |
| 1. **Provide information on the processing of the Personal Data to data subjects in accordance with article 13, 14 GDPR, The Medical Treatment Contracts Act (WGBO) and article 12 of the Medical Research Involving Human Subjects Act (WMO).**
 | Supplier; done by opt-out letter. |
| 1. **Safeguarding that informed consent for the processing of the personal data is obtained or that another legitimate basis for the processing of the personal data is in place (article 6 GDPR).**
 | Supplier; done by opt-out letter |
| 1. **Safeguarding that the data subjects can exercise their right of access, to rectification, erasure, restriction of processing and to object to the processing (articles 15 to 18 and article 21 GDPR).**
 | Supplier shall comply with requests. |
| 1. **Safeguarding that the data subjects can exercise their right to data portability (article 20 GDPR),**
 | Not applicable. |
| 1. **Safeguarding the security of the Personal Data in accordance with article 32 GDPR and in accordance with other arrangements in this Agreement.**
 |   |
| 1. **Comply with data breach obligations (articles 33 and 34 GDPR).**
 | Both parties – as set out in the Data Sharing Agreement. |
| 1. **Safeguarding that employees who have access to Personal Data are instructed by a binding agreement in accordance with Article 32 lid 4 GDPR, to process the Personal Data in conformity with the instructions of the Controllers to the Personal Data, including observing the duty of confidentiality with regard to the Personal Data.**
 | Both parties have employees bound to confidentiality agreements |
| 1. **Safeguarding that engaged (sub) processors who have access to Personal Data are instructed by a binding agreement (data processor agreement) to process the Personal Data in accordance with the requirements stated in article 28 of the GDPR, including among others the documented instruction of the Controllers to the Personal Data and all other GDPR requirements applicable to the processor.**
 | Not applicable, only the study coordinator will process the Personal Data. |
| 1. **Safeguarding that: (1) regular monitoring takes place in order to assess if the processing of the Personal Data by the (sub) processor is in compliance with the data processor agreement entered into with the (sub) processor; and (2) that breach of the data processor agreement is addressed by appropriate measures.**
 | Not applicable, only the study coordinator will process the Personal Data. |
| 1. **Safeguarding that the transfer of Personal Data takes place in accordance with the transfer requirements of the GDPR.**
 | Not applicable – no transfer outside EEA  |
| 1. **Safeguarding the compliance with the requirements regarding retention periods, destruction, return and/or migration of the Personal Data.**
 | Mention agreed retention periods, arrangements regarding destruction, return and/or migration and the responsible party.Each Party to comply with Article 8 Data Sharing Agreement.  |
| 1. **Safeguarding that a Privacy Impact Assessment (PIA) is executed prior to the collection, including obtaining and further processing of the Personal Data (Article 35 AVG).**
 | PIA has been executed in . |
| 1. **Further agreements regarding privacy responsibilities.**
 | None. |

**Annex 3: Publication Procedure**

**Annex 4: Standard Model Contract (EU Controller to Non-EU Controller)**

**Standard contractual clauses for the transfer of personal data from the Community to third countries (controller to controller transfers) in accordance with Decision 2001/497/EC.**

**Data transfer agreement**

Between

**<name Supplier>**, having its office at <address>, legally represented by <name, function>,

hereinafter “**data exporter**”

and

**<name Recipient>**, having its registered office and principal place of business at <address>, legally represented by <name, function>, hereinafter “**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

|  |  |
| --- | --- |
|  | the data processing principles set forth in the Data Sharing Agreement and Annex A. |

 |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| (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 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.

**Data Exporter Data Importer**

……………………………………… ………………………………………

Date: Date:

Name: Name:

Title: Title:

**Annex A To the Standard Contractual Clauses – Data Processing Principles**

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 necessaryto

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 To the Standard Contractual Clauses - description of the transfer**

For the description of the transfer Annex 2 of the Data Sharing Agreement is included herein by reference.