#

# DATA SHARING AGREEMENT

# *LUMC as Recipient*

**THE UNDERSIGNED**:

1. [**Hier eigen instelling invullen]**,having its registered office and principal place of business at **[adres eigen instelling]**, in **[Plaats eigen instelling]**, legally represented by **[Lokale onderzoeker]** hereafter referred to as the **“Supplier”**

and

2. **Leids Universitair Medisch Centrum (LUMC),** having its registered office and principal place of business at Albinusdreef 2, 2333 ZA Leiden, the Netherlands, hereinafter referred to as the **“Recipient”**

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

**WHEREAS**:

1. The Supplier owns the rights to certain data and is willing to provide the Recipient with such data for the purpose of executing the Research ’Clinical features of COVID-19 in children’ (COPP study) (hereinafter: the **“Research”**) as set forth in **Annex 1**.
2. The Recipient will also collect such data from other parties . The full dataset in which all sub-datasets are included will be used for the Research.
3. That both Parties collaborate in the framework of the Research as set forth in **Annex 1**.
4. With this agreement, the Parties aim to determine the terms and conditions upon which the Recipient agrees to conduct the Research and upon which the Supplier agrees to transfer the data.

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 pseudonymised - 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. This additional information will be stored by the Supplier, to whom te Recipient will not have acces.

**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, both the Supplier and the Recipient are jointly considered as controller with regard to the Personal Data that will processed by virtue of the present agreement, in accordance for the processing of the personal data and will act in accordance with the GDPR and additional data protection laws in the Netherlands.
	2. The Recipient shall implement appropriate technical and organizational measures to meet the requirements of the GDPR, with respect to the use of Data, and shall manage and use the Databases in accordance with the guidelines established by European data protection regulations.
	3. The Supplier warrants and undertakes that:
1. the Personal 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 Pseudonymisied data and no directly identifing 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 457 of the Dutch Medical Treatment Act (WGBO), informed consent of the Data subjects is obtained by the Supplier;

1.4 The Recipient warrants and undertakes that:

1. the Personal data will be processed in accordance with the laws applicable to the Recipient and 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 informed consent form of the Data subjects from whom the Data was collected and guarantee the use of information supplied by Recipient solely and exclusively within the framework of the Research;.
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 confidentially and 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. in the event a Data subject whitdraws it consent or 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.

1.5 If either Party becomes aware of a personal data breach, that Party shall promptly notify the other Party/ies. 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: 1) a personal data breach according to applicable law in the territory where the Data are treated, and 2) 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.

* 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. Results**

3.1 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 jointly owned by Supplier and Recipient.

3.2 The Supplier shall be entitled to submit an application to a steering committee (‘taskforce COVID registratie kinderen’) established by Recipient to use the Results for its own research proposal(s).

**Clause 4. Publication**

4.1 Parties will jointly publish the Results in one or more articles in peer reviewed journals, which publication shall be coordinated by the Recipient. Parties will not publish the Results independently.

4.2. Supplier will not publish its Results independently, unless such intended publication is submitted for review to the steering committee (‘taskforce COVID registratie kinderen’) established by the Recipient. Submission for review must occur at least 30 days prior to the intended publication.

**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.

**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 Analyses 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 become effective on the date of the last Party’s signature below, and shall remain in force for the period of the Research, unless terminated earlier in accordance with section 7.2. The Parties agree that the term may be extended by mutual written agreement.

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 11 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 Clauses 1-6, 8 and sections 7.4 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 shall survive such expiration or early termination.

##### **Clause 8. 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 9. Modifications**

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

**Clause 10. 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 11. 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 12. 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 13. Governing law**

 This Agreement shall be interpreted and governed by the laws of The Netherlands in any action. Any dispute relating to the interpretation or implementation of this Agreement which the Parties hereto have failed to settle amicably shall be exclusively referred to the competent courts of The Netherlands for settlement.

 **Clause 14. General Terms and conditions**

 No general conditions 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.

**Leids Universitair Medisch Centrum XXXXXXXX**

……………………………………… ………………………………………

Date: Date:

Name: Name:

Title: Title:

**Annex 1: Protocol**

(inserted by reference)

**Annex 2: Privacy Matrix**

**PRIVACY APPENDIX TO THE DATA SHARING AGREEMENT BETWEEN LUMC (Recipient) and [lokale centrum] XXXX (Supplier) (hereinafter: “main agreement”)**

**PART I. Description of the data transfer**

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| **Data subjects**The personal data transferred concern the following categories of data subjects: | Subjects participating in the COPP study; Clinical features of COVID-19 in pediatric patients. |
| **Purposes of the transfer(s)**The transfer is made for the following purposes: | To analyze data and answer the research question: to describe clinical features of COVID-19 in children  |
| **Categories of data**The personal data transferred concern the following categories of data: | Coded information of study subjects. Patient characterisitics, clinical features, course and treatment of disease. Summarized this data will contain:* Patient characteristics and risk factors: age, gender, height, weight, exposure to
* known COVID-19 cases, prior medical history, medication.
* Clinical features at presentation: symptoms, vital signs, physical examination, imaging results, laboratory results.
* Course of illness: clinical symptoms, vital signs, physical examination, imaging results,
* laboratory result, the need for respiratory support, the need for IC treatment, medication, aerosol treatment, co-morbidity and outcome.

Scarce patient material (i.e. blood samples). |
| **Sensitive data** (if appropriate)The personal data transferred concern the following categories of sensitive data: | Date of birth, date of hospital visit, first two numbers of postal code.  |
|  **Method of transfer** | By means of Castor database. |
| **Method of data storage and security measures (e.g. method of encoding)** | Encoding by study number. Storage in Castor database.  |
| **Authorized sub-processors** | Castor |

**Part II. Arrangement on data protection responsibilities**

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|  **LUMC and Supplier 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).**
 | Data Supplier shall inform the data subjects on the processing of their data through the informed consent procedure as stated below. |
| 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).**
 | Data Supplier has obtained informed consent from subjects for providing the Personal Data to Recipient under this Agreement.  |
| 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).**
 | If a subject exercises any of its rights mentioned in the GDPR, the first addressed Party shall discuss with the other Party on the manner to safeguard the subject’s rights in accordance with the GDPR and the Dutch GDPR Implementation Act.N.B. the right of access, rectification and restriction of processing is exempted in Article 44 of the Dutch GDPR Implementation Act:*“Where processing is carried out by institutions or services for purposes of scientific research or statistics, and the necessary steps have been taken to ensure that the personal data can be used solely for statistical or scientific purposes, the controller may refrain from applying Articles 15, 16 and 18 of the Regulation.”* |
| 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.**
 | Supplier shall safeguard a safe transfer of the Data to Recipient as described in Part I.After receiving the Data, Recipient shall safeguard the safe storage and use of the Personal Data as described in Part I.Both Parties shall have in place appropriate technical and organizational measures to protect the Personal Data against accidental or unlawful destruction or accidental loss, alteration, unauthorized disclosure or access, which provide a level of security appropriate to the risk represented by the processing and the nature of the data to be protected.  |
| 1. **Comply with data breach obligations (articles 33 and 34 GDPR).**
 | Recipient and Supplier will comply with data breach obligations according to articles 33 and 34 GDPR.If a Party becomes aware of a data breach in respect of data received from the other Party, it shall immediately without delay within 24 hours notify the Principal Investigator in writing and also by other appropriate and quick manners such as by calling. Such Party shall assist the other Party by appropriate technical and organizational measures, insofar as this is possible, for the fulfilment of the other Party’s obligation to respond to requests for exercising the data subject’s rights laid down in Chapter III of the GDPR and assist the other Party in ensuring compliance with the obligations pursuant to Articles 32 to 36 of the GDPR taking into account the nature of the processing and the information available. In case of a (potential) breach the Parties will fully cooperate with each other to remedy the personal data breach, fulfil the (statutory) notification obligations timely and cure the damages.LUMC data protection officer: E-mail: infoavg@lumc.nl Recipient data protection officer to contact: [lokaal centrum]Data Protection Officer Email: [lokaal centrum] |
| 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 de Controllers to the Personal Data, including observing the duty of confidentiality with regard to the Personal Data.**
 | Both Recipient and Supplier will safeguard that employees who have access to personal data are instructed by a binding agreement in accordance with Article 32 paragraph 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. |
| 1. **Safeguarding that, in the event that one of the Parties sub-contracts someone, 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.**
 | Both Recipient and Supplier will safeguard that engaged data processors (if applicable) 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.Each Party shall be liable to the other party for any breaches of its processors. |
| 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.**
 | All parties will safeguard that: (1) regular monitoring takes place in order to assess if the processing of the personal data by the processor is in compliance with the data processor agreement entered into with the processor; and (2) that breach of the data processor agreement is addressed by appropriate measures. |
| 1. **Safeguarding that the transfer of Personal Data takes place in accordance with the transfer requirements of the GDPR.**
 | No transfer outside the European Economic Area is allowed. Recipient shall be liable to Supplier for any breaches of its affiliates and indemnify Supplier for any damages or penalties that result from such breach. |
| 1. **Safeguarding the compliance with the requirements regarding retention periods, destruction, return and/or migration of the Personal Data.**
 | Recipient may store the Personal Data in for the term of this Agreement and shall delete all Personal Data from its servers after expiration or earlier termination of the 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).**
 | Each of the Parties is separately responsible for compliance with the DPIA obligation, for its part of the processing. |
| 1. **Further agreements regarding privacy responsibilities.**
 | If the arrangements in this matrix appear to be incomplete or incorrect, the parties shall amend this matrix so as to be compliant with the GDPR. |