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**data sharing AGREEMENT**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

between

**Princess Máxima Center for Pediatric Oncology B.V.**

and

**[****• name external research institute]**

**[****• date dd-MMM-yyyy]**

**THE UNDERSIGNED:**

1. **Princess Máxima Center for Pediatric Oncology B.V.**, located at Heidelberglaan 25, 3584 CS Utrecht, the Netherlands and its successors and assigns, hereinafter referred to as “the Máxima”;

and

1. **NAME INSTITUTION**, having its office at ADDRESS, legally represented by TITLE, NAME, hereinafter referred to as the “Recipient”;

The Máxima and the Recipient will hereinafter be referred to collectively as “**Parties**” and each individually as “**Party**”.

The Máxima owns certain data as described in Annex I attached hereto (“**Data**”) and Recipient would like to use the Data to conduct non-commercial scientific research as described in Annex I (“**Research**”). The Parties now desire to enter into this agreement to confirm the terms and conditions upon which the Máxima agrees to disclose or make available to Recipient the Data and upon which Recipient will use the Data for the Research.

**THE PARTIES HAVE AGREED THE FOLLOWING:**

1. **Object and principles**
   1. Subject to the terms and conditions of this agreement, the Máxima will disclose to Recipient the Data and Recipient agrees to use the Data solely to conduct the Research and to publish the results of the Research as further specified in Annex 1 (the “**Permitted Purpose**”) and for no other purpose.
   2. The Parties start from the explicit assumption that this agreement will only be executed in accordance with applicable laws and regulations, the EU General Data Protection Regulation 2016/679 (GDPR) and subsequent local regulation, and the Data is to be used only in accordance with Rules of Procedure of the Biobank and Data Access Committee Princess Máxima Center for Pediatric Oncology.
2. **data Privacy**
   1. The Máxima shall only provide such Data as necessary for the conduct of the Research. To the extent the data cannot be fully anonymized (for instance by aggregating the Data), the Máxima shall only provide Data which is de-identified to the fullest extent possible to ensure as much as possible that, without access to the master identifier file, all records are unidentifiable.
   2. Parties recognize that any Data disclosed hereunder may constitute personal data as defined in the GDPR (“Personal Data”), including personal data concerning health. Recipient will comply with all applicable laws, standards and regulations in using the Data. For the avoidance of doubt, Recipient will not perform any act which would lead to the re-identification of the individuals concerned, including by linking different sets of data, comparing and processing data. If Recipient wishes to obtain supplementary information in the course of the Research concerning the individuals whose Data have been used, the relevant Data will be provided again in such a manner that Recipient cannot use the supplementary Data to re-identify the individuals concerned. Upon the Máxima’s first request, Recipient undertakes to no longer use Data for future research of individuals who have notified the Máxima that they no longer wish for their Personal Data to be processed or who have requested for erasure of their data and, to the extent legally required, Recipient will erase the Data concerned.
   3. The Recipient shall treat all Personal Data strictly confidential and shall have in place procedures so that any third party it authorises to have access to the Personal Data, including (sub)processors as defined in the GDPR, will respect and maintain the confidentiality and security of the Personal Data. Any person or organisation acting under the authority of Recipient, including such (sub)processor, shall be obligated by the Recipient to process the Personal Data only on instructions from Recipient. This provision does not apply to persons authorised or required by law or regulation to have access to the Personal Data.
3. **REQUIRED CONSENT** 
   1. The Máxima will only make Data available to the Recipient if the Research Participant, or his/her legal representative, has given prior consent for the use of said Data for the purposes of scientific research by the Máxima or other research institutes.

**3.2** If required by applicable laws and regulations, the Máxima will ensure that records of informed consent forms are maintained, documented and retained.

1. **data SECurity**
   1. The Recipient shall only use the Data for the Permitted Purpose. The Recipient is not entitled to use the Data for any other research and in no event for any commercial purposes. If the Recipient wishes to use the Data for other purposes, it will consult the Máxima in this respect and will require the Máxima’s prior written permission.
   2. Recipient shall use appropriate safeguards to prevent use or disclosure of the Data other than as permitted under this agreement or applicable laws and regulations, including by transmitting the Data via a secure transfer.
   3. Recipient shall ensure that only those of its employees directly concerned with the Permitted Purpose have access to the Data. The Recipient shall ensure that all employees, agents, and contractors with access to the Data comply with the terms of this agreement, as well as any applicable data privacy and security laws and regulations and are bound to confidentiality.
   4. Recipient may only disclose non-individually identifiable information regarding the Data in a summary form that aggregates more than one individual’s clinical information for scientific journal publication, in all events to the extent permitted under applicable laws and regulations.
   5. Recipient shall promptly notify the Máxima about requests of disclosure of Data and any accidental or unauthorized access, removal, damage, loss or any other unlawful act of processing of the Data.
   6. Without prior written permission of the Máxima, the Recipient will not make any Data available to third parties in any way, shape or form.
   7. The Recipient agrees to destroy or discard the Data held, once it is no longer used for the Research, unless obliged to retain the Data for archival purposes in conformity with audit or legal requirements.
   8. The Parties further acknowledge that in case of a finding (an unsought and unsuspected result of the Research which is considered of immediate importance for the future health of an individual subject or its family) Provider shall be informed in accordance with the Research protocol and/or other applicable protocols.
2. **Intellectual property rightS**
   1. Recipient acknowledges that all Data received by Recipient from the Máxima in connection with this agreement is and shall remain the sole property of the Máxima, subject to the rights of use granted to Recipient hereunder.
   2. The Máxima hereby grants Recipient a non-exclusive, non-transferable, royalty-free right and license to receive, analyze, utilize, copy, store, commingle and process the Data solely for the Permitted Purpose and only in the European Economic Area.
   3. Recipient shall be entitled to any results to the extent that these result from Recipient's own independent use of the Data (“Results”). Recipient shall notify the Máxima regarding any patentable finding concerning its use of the Data. Recipient shall grant the Máxima a worldwide, non-exclusive, fully paid up, irrevocable research license with respect to the Results. To the extent that Recipient and the Máxima have each intellectually contributed to an invention with respect to the use of the Data, Recipient and the Máxima shall jointly own any rights to such Results.
3. **publications**
   1. Publications will be in accordance with international recognized scientific and ethical standards concerning publications and authorship, including the Uniform Requirements for Manuscripts Submitted to Biomedical Journals, established by the International Committee of Medical Journal Editors. Copyrights concerning publications of the Research remain with the authors of the publication, regardless of any other provisions regarding intellectual property rights.
   2. Recipient agrees to acknowledge the source of the Data in any publications reporting on the Recipient's use of it.
   3. The Recipient hereby agrees that in any publication based on the Data, the Recipient will describe how the Data can be accessed, including the name of the public database and its accession numbers.
   4. The Recipient hereby agrees that, with respect to the Data, the Máxima will be stated as the source in any (scientific) publication and/or any other disclosure by the Recipient with regard to the Data.
   5. The Parties mutually agree not to include one another’s name, trademark and/or logo in any (scientific) publication, press release or any other communication with regard to the Research without the prior written permission of the other Party.
   6. Recipient agrees to submit a report to the Máxima on completion of the agreed Permitted Purpose. Recipient further agrees to provide a copy of any publications arising from the use of the Data to the Máxima within thirty (30) days of its publication.

1. **LIABILITY**
   1. Any liability, to the fullest extent permitted by law, of the Máxima towards the Recipient for direct damage, indirect damage and/or consequential damage, by any virtue whatsoever, including breach of contract, is excluded, unless this damage was caused by intent or gross negligence on the part of the Máxima.
   2. The Máxima makes no warranty or representation, express or implied as to the accuracy, quality or comprehensiveness of the Data and bears no responsibility for the further analysis or interpretation of the Data.

* 1. The Recipient indemnifies the Máxima, its employees, and any third parties engaged in the context of the performance of the Máxima’s obligations under the agreement, against all third-party claims resulting from its use, storage and/or handling insofar as these were caused by the Recipient’s failure to perform the obligations under the agreement.

1. **termination**
   1. The agreement is entered into for the duration of the Research as described in [**Annex I**]. If necessary, the duration of the Research can be extended in accordance with clause 9.1.
   2. Either Party can terminate the agreement at any time with due observance of a notice period of thirty days. Such termination must be given by means of a registered letter, or by means of an email using confirm receipt option sent to: For the Máxima: *biobank@prinsesmaximacentrum.nl* and for Recipient: the email addresses mentioned in Annex 1.
   3. The agreement will end prematurely by operation of law:

* if the Research is ended prematurely
* if the Research is re-located to new premises;
* if one of the Parties is granted a suspension of payments or goes bankrupt;
* if one of the Parties ceases its business operations or liquidates its business in full or in part, or passes a resolution in that respect; or
* by mutual consent between the Parties.
  1. Upon termination of this agreement or completion of the Permitted Purpose, Recipient shall discontinue its use of, and shall, at the sole discretion of the Máxima, return or destroy the Data. The Recipient shall not retain any copies of the Data, except to the extent any portion of the Data (i) is incorporated in any publications or draft publications or any other derivative works generated by or for the Recipient, or (ii) is necessary to comply with all applicable laws and regulations as well as the Recipient’s internal document retention policies aimed at legal, corporate governance or regulatory compliance. Any retained Data shall remain subject to the disclosure and use restrictions set forth in this agreement.
  2. Obligations that, by their nature, are intended to continue even after termination of the agreement, including in any event the provisions of Clause 4, 5, 6,7 and 10 of the agreement will remain in full force between the Parties after the termination of the agreement.

1. **miscellaneous provisions**
   1. The agreement can only be amended or supplemented through a document signed by all Parties.
   2. Should any of the provisions of these terms and conditions be or be declared null and void or non-binding, the remaining provisions of the agreement will remain in full force and effect in all other respects insofar as, in view of the object and purpose of the agreement, these remaining provisions are not inextricably connected to the null and void or non-binding provisions. In such a case, the Parties will do their utmost to reach agreement on a new provision that, in view of the object and scope of the agreement, deviates as little as possible from the null and void or non-binding provision of the agreement.
   3. Neither Party is authorized to assign its rights and/or obligations under the agreement in full or in part to a third party without the prior written permission of the other Party.
   4. The agreement can be signed in multiple original copies, whereby the agreement has been concluded once all Parties have duly signed the agreement. This agreement may be delivered in or by facsimile, Adobe® Portable Document Format, Docusign and/or other legible electronic format, and when so delivered will have the same force and effect as delivery of an original signature.
2. **Applicable law and disputes**
   1. The agreement is governed by the laws of the Netherlands.
   2. Any disputes that may arise in relation to the agreement and which cannot be settled amicably between Parties, will only be submitted in the first instance to the competent court at the Midden-Nederland District Court, location Utrecht.

**Agreed for Princess Máxima Center for Pediatric Oncology B.V.:**

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| **Signature:** |  |
| **Name:** |  |
| **Title:** |  |
| **Date:** |  |

**Agreed for Recipient:**

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| --- | --- |
| **Signature:** |  |
| **Name authorized representative of Recipient:** |  |
| **Title:** |  |
| **Name organization:** |  |
| **Date:** |  |

**Acknowledgment by Principal Investigator of Recipient requesting the Data:**

**I confirm that I have read and understood this Agreement.**

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| --- | --- |
| **Signature:** |  |
| **Name:** |  |
| **Title:** |  |
| **Name organization** |  |
| **Date:** |  |

**ANNEX 1:   
- Data description/reference  
- Research description and permitted purpose**

**ANNEX I DATASET AND RESEARCH PROJECT DETAILS**

**Biobank and Data Access Committee   
Number of approved request: PMCLAB20XX.YYY**

**EGA dataset(s) reference:**

**Dataset reference, other:**

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| **Brief abstract of the Research in which the Data will be used (500 words max): *(copy or summary from the approved Biobank Request Form)*** |

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| **Data subjects The personal data transferred concern the following categories of data subjects:**  **Pediatric oncology patients of the Máxima**  **Underage <16 years  Young adults > 16 years** |

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| **Purposes of the transfer(s): *The transfer is made to perform the project as described in the abstract. The transferred data will solely be used for health, medical or biomedical research.  The data can never be used to perform germline analyses.***  **Additional remarks:** |

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| **Categories of sensitive data**  **The personal data transferred concern the following categories of data:**  **Clinical data**  **Genetic data**  **Biometrical data** |

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| **Security measures:**  *File access*  *Receiver of the Data guarantees the below restrictions on file access:*   * *Data is preferably stored on institutional storage and server systems with proper security measures in place, including Unix user group read/write access for one or more appropriate groups but not Unix world read/write access behind a secure firewall. Portable drives and laptops are discouraged, but in case these are used, data must be encrypted and laptops holding these data should have password protected logins and screenlocks enabled (set to lock after 5 minutes of inactivity).* * *Data is not transferrable to third parties. If a third party should be granted access to the Data, the third party should apply through the formal DAC procedure (see below: ‘Process of acquiring access to dataset’).* * *If Receiver of the Data is leaving the institute where he/she acquired the Data, Data should be removed from all systems.* |

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| **Additional useful information (storage limits and other relevant information):** |

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| **Contact points for data protection incident:**  [*fg@prinsesmaximacentrum.nl*](mailto:fg@prinsesmaximacentrum.nl) *and biobank@prinsesmaximacentrum.nl*  *An incident is an investigation of confiscation of the Data by government officials of a suspicion that such may occur at some point in the future, a violation of the Data within the meaning of Article 4.12 of the General Data Protection Regulation or any unauthorized access, removal, damage, loss or any other unlawful act of processing of the Data.*  *When an incident occurs, has occurred or may be about to occur, the Recipient is required to notify the Máxima at once and to provide any relevant information on:*   1. *the nature of the incident;* 2. *in case of a violation of the Data: the contact information of the party reporting;* 3. *the Data that (may) have been affected;* 4. *information on developments with regard to the Incident;* 5. *what has been observed and the presumable consequences of the incident or data breach; and* 6. *the measures which have been or will be taken to resolve the incident or to minimize the consequences or damage to the maximum extent possible.* |