DATA ACCESS AGREEMENT

between

Prinses Máxima Centrum voor Kinderoncologie B.V.

and

[• name external research institute]

[• date]
THE UNDERSIGNED:

I. PRINSES MÁXIMA CENTRUM VOOR KINDERONCOLOGIE B.V., a private limited liability company under Dutch law, with its official seat in Utrecht and its principal place of business at Heidelberglaan 25 (3584 CS) in Utrecht, listed in the Commercial Register of the Chamber of Commerce under number 54327946 ("Máxima");

and

II. [NAME EXTERNAL RESEARCH INSTITUTE], a type of legal entity under public law, with its official seat in the Municipality of [city] and its principal place of business at [address + (postal code)] in [city], listed in the Commercial Register of the Chamber of Commerce under number [number](the "Recipient");

Máxima and the Recipient will hereinafter be referred to collectively as “Parties”, and each individually as “Party”;

This agreement contains the terms and conditions under which Máxima will give the Recipient managed access to Data (details of which are set out in Annex I)) to which the Recipient has requested access. The Recipient agrees to be bound by these terms and conditions.

THE PARTIES HAVE AGREED THE FOLLOWING:

ARTICLE 1. DEFINITIONS

1.1 Authorized Personnel: Individuals at the Recipient listed in Annex I, to whom Máxima grants access to the Data. This includes the Principal Investigator, and any other individuals for whom the Recipient subsequently requests access to the Data. Details of the initial Authorised Personnel are set out in Annex I.

1.2 Commercial party: the Recipient is considered to be a Commercial party if it has the aim to make profit with the (in-)direct results of the Research.

1.3 Data: the managed access datasets to which the Recipient has requested access.

1.4 Publications: includes, without limitation, articles published in print journals, electronic journals, reviews, books, posters and other written and verbal presentations of research.

1.5 Research Participant: an individual whose (pseudonomized) data is part of the Data and used in the Research.

1.6 Principal Investigator (PI): the person at Recipient who is responsible for the structure and execution of the Research for which access to the Data is requested.

1.7 Pseudonimization: the procedure by which the most identifying fields within a data record are replaced by one or more artificial identifiers or pseudonyms. Pseudonymization occurs through a trusted third party (TTP) who maintains the key.

1.8 Recipient: the institution that has requested access to the Data and is party under this agreement.

1.9 Research: the research project for which the Recipient has requested access to Data. A description of the Research is set out in Annex I.
ARTICLE 2. OBJECT AND PRINCIPLES

2.1 The aim of the Parties under the Agreement is that Máxima will make the Data available to the Recipient in pseudonymized form for the duration of the Research and exclusively within the context of the Research as described in [Annex I].

2.2 The Recipient agrees to only use the Data for the purpose of the Research as described in [Annex I].

2.3 The Parties start from the explicit assumption that the Agreement will only be executed in accordance with applicable laws and regulations, including in any event (but not exclusively) the Dutch Medical Research (Human Subjects) Act (Wet medisch wetenschappelijk onderzoek met mensen), Dutch Medical Treatment Contracts Act (Wet inzake de Geneeskundige Behandelingsovereenkomst) and the EU General Data Protection Regulation and subsequent local regulation.

ARTICLE 3. ACCESS TO THE DATA

3.1 The Parties agree that, during the duration of the Research, Máxima gives the Recipient access to the Data. Máxima will retain ownership of the Data that will be made available to the Recipient.

ARTICLE 4. REQUIRED CONSENT

4.1 Máxima will only make pseudonymized 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 Máxima or other research institutes. Máxima uses a dedicated consent form to obtain the abovementioned consent.

ARTICLE 5. PERMITTED USE, DESTROY/DISCARD REMAINING DATA

5.1 The Recipient hereby declares that it will only use the Data in the context of the Research, such as further specified in [Annex I]. 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 Máxima in this respect and will require Máxima’s prior written permission.

5.2 The Recipient agrees not to link or combine the Data to other information or archived data available in a way that could re-identify the Research Participants, even if access to that data has been formally granted to the Recipient or is freely available without restriction.

5.3 The Recipient agrees only to transfer or disclose the Data, in whole or part, or any information derived from the Data, to the Authorised Personnel named in [Annex I], and only in manners supported, approved or organized by the Recipient. This means that Recipient shall ensure use or storage of Data is located at the Recipient’s facilities, and
not on Authorized Personnel’s privately owned data storage carrier, medium or device.

5.4 If the Recipient wishes to share the Data with any third party, this third party must complete a separate application for access to the Data. Without prior written permission of Máxima, the Recipient will not make any Data available to third parties in any way, shape or form.

5.5 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.

ARTICLE 6. PRIVACY, SAFETY AND PROTECTION

6.1 The Recipient will take adequate technical and organizational measures to prevent unauthorized third parties, not being Authorised Personnel of the Recipient, from having or being able to obtain access to the Data and being able to process the Data.

6.2 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 the Research Participants.

6.3 The Recipient agrees to protect the confidentiality of Research Participants in any Publications that they prepare by taking all reasonable care to limit the possibility of identification.

6.4 The Recipient will ensure that only its Authorised Personnel will have access to the Data and will be entitled to process the Data. The Recipient will take internal measures to ensure that these persons involved in the Research will comply with the provisions in this Agreement.

6.5 If requested, the Recipient will allow data security and management documentation to be inspected by Máxima to verify that it is complying with the terms of this agreement.

ARTICLE 7. INTELLECTUAL PROPERTY RIGHTS

7.1 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 elements of the Data, or conclusion drawn directly from the Data.

7.2 The Recipient can elect to perform further research that would add intellectual and resource capital to the Data and decide to obtain intellectual property rights on these downstream discoveries. In this case, the Recipient agrees to implement licensing policies that will not obstruct further research.

ARTICLE 8. PUBLICATIONS
The Recipient agrees to follow the Fort Lauderdale Guidelines (https://www.genome.gov/pages/research/wellcomereport0303.pdf) and The Toronto Statement (Nature. 2009; 461(7261):168-70). This includes but is not limited to recognizing the contribution of the Data producers and including a proper acknowledgement in all reports or Publications resulting from the use of the Data.

Máxima intends to publish the results of their analysis of the Data and do not consider its deposition into public databases to be the equivalent of such Publications. Máxima anticipates that the Data could be useful to other qualified researchers for a variety of purposes. In some cases this Data can be subject to a publication moratorium. The Recipient will respect the moratorium period for Máxima to publish the first peer-reviewed report describing and analysing the Data. The publication moratorium covers any Publications that describe the use of the Data. The submission of any publication should not occur until six months after the Data were first made available on the public database, unless Máxima has provided written consent for earlier submission.

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.

The Recipient hereby agrees that, with respect to the Data, Máxima will be stated as the source in any (scientific) publication and/or any other disclosure by the Recipient with regard to the Data.

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.

ARTICLE 9. NOTIFICATIONS

Unexpected, relevant discoveries in the Data by the Recipient during the Research that could have considerable consequences for the health and/or well-being of the Research Participants and/or his/her blood relatives will be reported to Máxima by the Recipient within 30 days after the discovery thereof.

The Recipient will notify Máxima prior to any significant changes to the Research Protocol.

The Recipient will notify Máxima within 30 days of any changes or departures of Authorised Personnel which occur during the Research period.

The Recipient will notify Máxima as soon as it becomes aware of a breach of the terms of conditions of this agreement.

ARTICLE 10. LIABILITY

Any liability, to the fullest extent permitted by law, of Máxima toward 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 Máxima.

10.2 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.

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

ARTICLE 11. TERMINATION

11.1 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 article 12.1.

11.2 Either Party can terminate the Agreement at any time with due observance of a notice period of thirty days. Such termination must be given at the end of a calendar month by means of a registered letter, or by means of an email using confirm receipt option sent to: For Máxima: biobank@prinesmaximacentrum.nl and for Recipient: the email addresses mentioned in Annex 1, Authorized Personnel.

11.3 The Agreement will end prematurely by operation of law:
• if the Research is ended prematurely;
• 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.

11.4 If and as soon as the Agreements ends for whatever reason, the Recipient will destroy any Data or discard any access to the Data within thirty days after the relevant termination. This includes copies and backup copies of the Data. This clause does not prevent the Recipient from retaining the Data as stated in [5.5].

11.5 Obligations that, by their nature, are intended to continue even after termination of the Agreement, including in any event the provisions of Article 5, through Article 13 of the Agreement will remain in full force between the Parties after the termination of the Agreement.

ARTICLE 12. MISCELLANEOUS PROVISIONS

12.1 The Agreement can only be amended or supplemented through a document signed by all Parties.

12.2 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.

12.3 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.

12.4 The Agreement can be signed in multiple original copies, whereby the Agreement has been concluded once all Parties have duly signed the Agreement.

ARTICLE 13. APPLICABLE LAW AND DISPUTES

13.1 The Agreement is governed by the laws of the Netherlands.

13.2 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 Maxima Center for pediatric oncology

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Agreed for Recipient: *Please insert name Organization*

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Acknowledgment by Principal Investigator of Recipient requesting access to the Data

I confirm that I have read and understood this Agreement.

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ANNEX 1:
- Data description/reference
- Research description
- List of expected Authorized Personnel of Recipient with access to the Data

ANNEX 1  DATASET AND RESEARCH PROJECT DETAILS
Dataset reference

Brief abstract of the Research in which the Data will be used (500 words max)

All Authorized Personnel at the Recipient to be named as registered users (including Principal Investigator)

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<tr>
<th>Name of Registered Users of Recipient</th>
<th>Email (professional email addresses)</th>
<th>Job Title (PhD/Post-doc, scientific field etc.)</th>
<th>Supervisor</th>
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