MATERIAL TRANSFER AGREEMENT

between

Prinses Máxima Centrum voor Kinderoncologie B.V.

and

[• name external research institute]

[• date] 2017

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, the Netherlands, listed in the Commercial Register of the Chamber of Commerce under number 54327946 and duly represented in this matter by the chair of the 'Biobank and Data access committee' ("**MÁXIMA**");

In the presence of:

A Principal Investigator of the **PRINSES MÁXIMA CENTRUM VOOR KINDERONCOLOGIE B.V.** assigned by the 'Biobank and Data access committee' to serve as primary contact person;

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]** and duly represented in this matter by **[• name(s) authorized representative(s)]** (the "**[• Recipient]**");

And / in the presence of:

III. A Principal Investigator employed by the Recipient.

MÁXIMA (and its Principal Investigator), and the Recipient (and its Principal Investigator) will hereinafter be referred to collectively as "**Parties**", and each individually as "**Party**";

WHEREAS:

A. MÁXIMA is engaged in the promotion of optimum forms of diagnostics testing, treatment and care of children and adolescents suffering from cancer or precursors thereof, with the objective of curing every child and adolescent and offering them the best possible quality of life, and that, against this background, MÁXIMA also conducts scientific research into all types of pediatric cancer, performing both prospective and retrospective (cohort) studies;

B. the Recipient engages in and has as its objective **[• further description of activities / objective];**

C. MÁXIMA, in the treatment of its paediatric oncology patients, (the "**Research Participant**"), from time to time (i) extracts human biological material that is stored in its biobank (the "**Biobank**") and (ii) collects data that are recorded in the patient records and of which the 'clinical data' are also stored in the Biobank. The biological material and its associated clinical data is collectively referred to as the "**Material**".

D. the Recipient is currently engaged in medical scientific research into **[• further description of the type of research]**, and the Recipient requires the Material in this context. A more detailed description of this medical scientific research and

the analyses and research activities to be performed in the context thereof (the "**Research**") can be found in the research plan (the "**Research Plan**"), which has been attached to this agreement (the "**Agreement**") as Annex **[I]**);

E. the Parties have entered into consultations with one another about MÁXIMA making the Material available to the Recipient, and MÁXIMA is willing, under conditions to be further specified in the Agreement, to make the Material available to the Recipient (i) in pseudonymized form and (ii) on a non-commercial basis, so that the Recipient can use the Material only for the purposes of the Research. The Parties would therefore like to record the mutual rights and obligations involved in writing in this Agreement.

THE PARTIES HAVE AGREED THE FOLLOWING:

ARTICLE 1. DEFENITIONS

1.1 Authorized Investigators: Individuals at the Recipient [listed in [Annex I], to whom Máxima grants access to the Material. This includes the Recipient's Principal Investigator, and any other individuals for whom access to the Material is required for the Research.
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 clinical/medical data associated the Material with and may be comprised by the supply of the Material.
1.4 Material: the material to which the Recipient has requested access. The Material may include Data ((clinical) data closely associated with the Material).
1.5 Publications: includes, without limitation, articles published in print journals, electronic journals, reviews, books, posters and other written and verbal presentations of research.
1.6 Research Participant: an individual whose (pseudonymized) data is part of the Data and used in the Research.
1.7 Principal Investigator (PI): the person responsible for the structure and execution of the Research for which access to the Material is requested.
1.8 Pseudonymization: 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.
1.9 Recipient: the institution that has requested access to the Material and is party under this agreement.
1.10 Research: the research project for which the Recipient has requested access to Material. A description of the Research and the primarily responsible PI 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 Material available to the Recipient in pseudonymized form during the Term (as defined below in Clause **[11.1]** of the Agreement) – exclusively within the context of the Research.

2.2 The arties start from the explicit assumption that the Agreement will only be executed in accordance with applicable laws and regulations, including in any event the Dutch Medical Research (Human Subjects) Act (*Wet medisch wetenschappelijk onderzoek met mensen*), Dutch Medical Treatment Contracts Act (*Wet inzake de Geneeskundige Behandelingsovereenkomst*), EU General Data Protection Regulation and subsequent local regulation, if applicable.

ARTICLE 3. THE RELEASE OF MATERIAL

3.1 The Parties agree that, during the Term, MÁXIMA will make the Material available to the Recipient once in the context of the Research. MÁXIMA will retain ownership of the Material that will be made available to the Recipient.

3.2 The transport of the Material will be for the account and risk of the Recipient.

ARTICLE 4. REQUIRED CONSENT AND INFORMATION PROVISION

4.1 MÁXIMA will only make Material available to the Recipient if the Research Participant, or his/her legal representative, has given prior consent for the use of said Material for the purposes of scientific research by MÁXIMA or other research institutes/collaborating partners, or, in case of anonymous Material, such consent is not required under applicable laws. In case such consent is required, MÁXIMA uses a consent form to obtain the abovementioned consent.

ARTICLE 5. PERMITTED USE

5.1 The Recipient hereby declares that it will only use the Material in the context of the Research, as further specified in [**Annex I**]. The Recipient is not entitled to use the Material for any other research, and in no event for any commercial purposes. If the Recipient wishes to use the Material for other purposes, it will consult MÁXIMA in this respect and will require MÁXIMA's prior written permission.

5.2 Without the prior written permission of MÁXIMA, the Recipient will not make any Material available to third parties in any way, shape or form.

5.3 If the Recipient has not used or no longer needs parts of the Material for the Research, or when the Research is completed (whichever is first), the Recipient will immediately inform MÁXIMA thereof. In respect to this remaining material (the "**Remaining Material**"), MÁXIMA will then indicate to the Recipient in writing whether MÁXIMA would like the Recipient to either return the Remaining Material to MÁXIMA or to destroy the Remaining Material. If the Remaining Material will be returned to MÁXIMA, this will be done within **[eight (8)]** weeks after the said notification by MÁXIMA. The Recipient will arrange and be responsible for the transportation thereof to MÁXIMA, in such way that the Remaining Material will be preserved and will not be damaged. Any costs connected thereto will be for the account of the Recipient. The destruction of the Remaining Material by the Recipient will be carried out by consensus in accordance with all applicable laws and regulations.

ARTICLE 6. PRIVACY, SAFETY AND PROTECTION

6.1 The Recipient will take adequate technical and organizational measures to prevent unauthorized third parties, not being authorized employees and representatives of the Recipient, from having or being able to obtain access to the Material and being able to process the Material. This means that storage/processing of Material shall only take place in manners supported, approved or organized by the Recipient.

6.2 The Recipient will ensure that only its employees or any representatives that are involved

in the Research will have access to the Material and will be entitled to process the Material. The Recipient will take internal measures to ensure that the persons involved in the Research will be bound by the confidentiality as laid down in Clause **[8]** of the Agreement.

6.3 The Recipient will also ensure that the safety, integrity and quality of the Material is safeguarded at all times.

ARTICLE 7. INTELLECTUAL PROPERTY RIGHTS

7.1 The Recipient agrees not to make intellectual property claims on the Material or data derived thereof and not to use intellectual property protection in ways that would prevent or block access to, or use of, any elements of the Material or data derived thereof, or conclusions drawn directly from studies using the Material.

7.2 The Recipient can elect to perform further research that would add intellectual and resource capital to the Material of data derived thereof 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. CONFIDENTIALITY

8.1 The Parties will observe confidentiality in respect of the contents of the Agreement, all information and data that they receive from one another in the context of the Agreement and that has been classified as confidential or of which the confidential nature is or should reasonable be known to the receiving Party (the "**Confidential Information**").

8.2 The Parties will only use the Confidential Information for the execution of the Agreement. The Parties will not copy the Confidential Information, will not make it available to third parties and will not disclose it in any other way.

8.3 The Parties are entitled to make the Confidential Information available to their personnel and advisers who necessarily have to receive the Confidential Information in the context of the execution of the Agreement. The making available of such information has to occur under the obligation to impose the duty of confidentiality that arises from the Agreement on these persons as well by means of a written agreement.

8.4 The duty of confidentiality does not apply to information and data:

a. that is/are known publicly;
b. that has/have been released pursuant to a statutory obligation;
c. that is/are known pursuant to a court decision with force of *res judicata* in respect of which written discharge has been granted; or
d. insofar as the disclosure thereof is necessary for the enforcement of the rights of the Party in question.

In all of the above cases, the disclosure is limited to the extent strictly necessary. In case of disclosure, the other Party will be informed in advance of the intention to disclose the information.

8.5 The provisions in this Clause **[8]** will apply with retroactive effect as from the time the first contact was laid between the Parties, or their respective representatives or advisers, in the context of the formation of the Agreement, insofar as the duties of confidentiality

do not already follow from confidentiality statements agreed between the Parties at an earlier stage.

ARTICLE 9. REPORTS, NOTIFICATIONS AND PUBLICATIONS

9.1 Within thirty (30) days, to be calculated from the moment the Research has been completed, has ended or has been prematurely terminated, the Recipient will provide MÁXIMA with a final report that includes all current Research results.

9.2 The Recipient will inform MÁXIMA in writing if and as soon as developments or events unfold that might have an adverse effect on the progress of the Research.

9.3 Unexpected, relevant discoveries in the Material by the Recipient during the Research that could have considerable consequences for the health and/or well-being of the Research Participant and/or his/her blood relatives will be reported to MÁXIMA by the Recipient within **[eight (8) weeks]** after the discovery thereof.

9.4 The Parties hereby agree and establish that, with respect to the Material, MÁXIMA will be stated as the source in any (scientific) publication and/or any other disclosure by the Recipient with regard to this Material. Authorship shall be determined in accordance with the generally accepted guidelines for authorship on scientific and scholarly publications

9.5 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.

ARTICLE 10. LIABILITY

10.1 Any liability 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 The Recipient is fully liable for direct damage, indirect damage and/or consequential damage, by any virtue whatsoever, including breach of contract, if MÁXIMA can demonstrate that the damage is the direct or indirect consequence of an attributable failure on the part of the Recipient.

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. TERMS AND TERMINATION

11.1 The Agreement is entered into for a period of **[XX]** years, to be calculated from **[• commencement date]** (the "**Term**"). On expiry of the Term, the Agreement will be extended for an indefinite period of time, such with due observance of the other provisions in this clause of the Agreement.

11.2 Either Party can terminate the Agreement at any time with due observance of a notice period of **[three (3)]** months. Such termination must be given at the end of a calendar

month by means of a registered letter.

11.3 The Agreement will end prematurely by operation of law:
- if the Research has been fully completed;
- 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 return the unused Material and any Remaining Material still in its possession to MÁXIMA within **[eight (8)]** weeks after the relevant termination [**• or destroy such by consensus in accordance with all relevant laws and regulations]**.

11.5 Obligations that, by their nature, are intended to continue even after termination of the Agreement, including in any event the provisions of Clauses **[7]**, **[8]** and **[10]** of the Agreement will remain in full force between the Parties after the termination of the Agreement.

ARTICLE 12. EXPENSE ALLOWANCES

12.1 Depending of the type of Material requested, direct handling costs may apply. These costs will be passed on to the Recipient. The Parties will **[not]** charge one another other expense allowances in connection with the execution of the Agreement.

ARTICLE 13. MISCELLANEOUS PROVISIONS

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

13.2 The Agreement constitutes the entire final agreement between the Parties in respect of the matters covered therein and supersedes any and all earlier agreements and understandings either verbally or in writing.

13.3 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 that deviates as little as possible from the null and void or non-binding provision of the Agreement.

13.4 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.

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

ARTICLE 14. APPLICABLE LAW AND DISPUTES

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

14.2 Any disputes that may arise in relation to the Agreement will only be submitted in the first instance to the competent court at the Midden-Nederland District Court, location Utrecht.

As agreed, drawn up in duplicate and signed by:

*** Signatures on the next page ***

SIGNATURE PAGE

PRINSES MÁXIMA CENTRUM VOOR KINDERONCOLOGIE B.V.	**PRINSES MÁXIMA CENTRUM VOOR KINDERONCOLOGIE B.V.**
_____	_____
By: Position: Chair of the 'Biobank and Data access committee' Date:	By: Position: Principal Investigator Date:
[• NAME EXTERNAL RESEARCH INSTITUTE]	**[• NAME EXTERNAL RESEARCH INSTITUTE]**
_____	_____
By: **[• Mr/Ms] [• name]** Position: director under the articles of association Date:	By: **[• Mr/Ms] [• name]** Position: Principal Investigator Date:

ANNEX I RESEARCH PLAN [• NAME EXTERNAL RESEARCH INSTITUTE]