

## Material and Data Transfer Agreement Biobank Princess Máxima Center

### 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, hereafter referred to as “Provider”;  
and
2. **NAME INSTITUTION**, having its office at **ADDRESS**, legally represented by **TITLE, NAME**, hereinafter referred to as “Recipient”;

The foregoing (legal) entities are solely referred to as “Party” and collectively referred to as “Parties”.

### WHEREAS:

- The Provider has human biological material available, which has been obtained on the basis of informed consent and the use of the material is restricted to non-commercial scientific research purposes only;
- The Recipient is interested in conducting research with this Material. The Provider is willing to provide Material to the Recipient, under the conditions set out in this agreement;

### ARTICLE 1. DEFINITIONS

- 1.1 Provider: Organization providing the original material: **NAME/ADDRESS**
- 1.1 Provider Scientist: **NAME, TITLE, DEPARTMENT**
- 1.2 Recipient: Organization receiving the original material: **NAME ADDRESS**
- 1.3 Recipient Scientist: **NAME, TITLE, DEPARTMENT**
- 1.4 Original Material: Description of the Material as provided by Provider and specified in Annex 1.
- 1.5 Material: Original Material, Progeny and Unmodified Derivatives. The Material shall not include a) Modifications or b) other substances created by the Recipient through use of the Material which are not Modifications, Progeny or Unmodified Derivatives.
- 1.6 Coded Subject Information: coded information concerning a Subject (Subject is a patient or other person) from whom the Material was taken. The information provided does not allow direct identification of the Subject.
- 1.7 Data: clinical and pathological characterization of the Subject who provided the human material transferred in a coded form from Provider to Recipient under this Agreement, specified in Annex 1.

- 1.8 Progeny: Unmodified descendant from the Material, such as virus from virus, cell from cell, or organism from organism
- 1.9 Unmodified Derivatives: Substances created by the Recipient which constitute an unmodified functional subunit or product expressed by the Material. Some examples include: subclones of unmodified cell lines, purified or fractionated subsets of the Material, proteins expressed by DNA/RNA supplied by the Provider.
- 1.10 Modifications: Substances created by the Recipient which contain/incorporate the Material which are not Unmodified Derivatives.
- 1.11 Non-commercial Purposes: The sale, lease, license, or other transfer of the Material or Modifications and/or Data to a non-profit organization for internal research purposes only. Non-commercial Purposes shall also include uses of the Material and/or Data by any other profit or non-profit organization, including Recipient, to screen or analyse the Material and/or Data or to jointly conduct scientific research activities of which the results are made public.
- 1.12 Research: Recipient's research project in which the Material and Data will be used, as described in Annex 1.
- 1.13 Results: the results from the Research.

## **ARTICLE 2. OWNERSHIP**

Provider is willing to provide Recipient with the Material and the Data. As the Material is human material and the Data is human data, these are not owned by either Party, although Provider is custodian of the Material and the Data. Neither Recipient nor the scientists employed by the Recipient, nor any other third party shall have rights in the Material and/or Data other than as provided for in this Agreement.

## **ARTICLE 3. USE**

- 3.1 The Recipient agrees that:
  - (a) the Material and Data is to be used solely for Non –Commercial purposes
  - (b) the Material and Data is to be used solely for the Research described in Annex 1;
  - (c) the Material and Data will not be used in human subjects, in clinical trials, contract research or for diagnostic purposes involving human subjects;
  - (d) the Material and Data is to be stored and used only at the Recipient's organization and only in the Recipient Scientist's laboratory under the direction of the Recipient Scientist or others working under his/her direct supervision;
  - (e) the Material and Data will not be transferred to anyone else within or outside the Recipient organization;
  - (f) The Material and Data will be stored and used in compliance with the Research Protocol, other internal regulations from Provider applicable to providing material and all applicable statutes and regulations.
- 3.2 Without prior written consent from the Provider, the Recipient is not allowed to use the Material and/or Data in any other way than as stated under clause 3.1 a-f.
- 3.3 As an exception to article 3.1 under (d), Recipient is entitled to transfer Material and/or Data to collaborators as described in Annex 1 to screen or analyse the Material and/or Data or to jointly conduct scientific research activities.

In such an event, Recipient will ensure and warrant to Provider that it will conclude an agreement with such collaborator in which they agree to the same terms and condition of this original MTA and as such the collaborator will use the Material solely for the purpose of the Research and under the direction of the Recipient and not to use that Material for any other purpose without the express written consent of Provider. In all cases, Recipient and Recipient scientist remain responsible for the Material and will ensure that any remaining material is transferred back to Recipient or destroyed. In the event Recipient wishes to transfer the material to other collaborators than described in Annex 1, Recipient requires the prior written consent of Provider.

- 3.4 If Recipient wishes to use the Material and Data for a certain Research other than described in annex 1, Recipient will refer such request to the Provider in order to request the Biobank Ethical Review Committee of Provider to decide after receiving such request. If the evaluation is positive, Material and or Data may be used by Recipient under the terms of this Agreement.

#### **ARTICLE 4. RESULTS**

- 4.1 The ownership of any Result shall be determined by applicable law and shall recognize the respective contributions and technical knowledge made thereto by each party.
- 4.2 Where ownership of any Results vests in Recipient, Provider shall have a perpetual nonexclusive royalty free license to use such Results for the sole purpose of its internal research and teaching.
- 4.3 In case Results are jointly owned between Recipient and Provider, the parties agree to enter into a joint ownership agreement for fair and equitable sharing of patent costs, income, and invention management responsibilities based on each party's contribution to the respective Results.

#### **ARTICLE 5 REPRESENTATIONS, WARRANTIES and LIABILITIES**

- 5.1 Any Material delivered pursuant to this Agreement is supplied “as is” and is understood to be experimental in nature and may have hazardous properties. The Provider makes no representations and extends no warranties of any kind, either expressed or implied with regard to the Material or Data. There are no express or implied warranties or fitness for a particular purpose, or that the use of the Material and/or Data will not infringe any patent, copyright, trademark or other proprietary rights. The Provider agrees to promptly inform Recipient in writing if Provider obtains knowledge of any patent or property rights of third being infringed by the use of the Material.
- 5.2 Provider or, to the extent applicable, the legal owner of the Material and/or Data referred to in Article 2.1, may grant exclusive or non-exclusive, non-commercial or commercial licenses with regard to the Material or Data to any third party(ies), or sell or assign all or part of the rights in the Material or Data to any third party(ies). In any such event, this contract remains unaffected.
- 5.3 Except to the extent prohibited by law, the Recipient assumes all liability for damages which may arise from its use, storage or disposal of the Material and Data, unless caused by gross negligence or willful misconduct of Provider. The Provider will not be liable to the Recipient for any loss, claim or demand made by the Recipient, or made against the Recipient by any other party, due to or arising from the use of the Material or Data by the Recipient, except to the extent prescribed by law when caused by the gross negligence or willful misconduct of the Provider.

## ARTICLE 6. PUBLICATION

- 6.1 Due to the collaborative nature of this Agreement, it is anticipated that some manuscripts arising from the research hereunder will be joint publications. In all cases, the standards of authorship shall be defined by the Uniform Requirements for Manuscripts Submitted to Biomedical Journals established by the International Committee of Medical Journal Editors (see [www.icmje.org](http://www.icmje.org)) with authorship determined by usual academic standards.
- 6.2 Both parties shall be free to use the results of their own research hereunder for their own internal teaching, research, educational, clinical and publication purposes without the payment of royalties or other fees to the other party. Notwithstanding the foregoing, in the event that one party elects to publish the results of the research performed at its site, the publishing party shall provide a copy of the proposed publication or presentation to the non-publishing party for review at least thirty (30) days prior to submission to a publisher thereof. If the non-publishing party requests the removal of Confidential Information, the non-publishing party agrees to allow the use of sufficient information regarding the identity and properties of the Material to enable the complete and accurate publication of the research results. If the non-publishing party determines that the proposed publication or presentation contains subject matter requiring patent protection, the publishing party shall delay publication or presentation for up to an additional sixty (60) days for the filing of patent applications. Such publication or presentation shall contain appropriate acknowledgement of the role, contribution and/or financial and material support of the non-publishing party in the Research.

## ARTICLE 7. CONFIDENTIALITY AND DATA PROTECTION

- 7.1 Recipient agrees to keep confidential any proprietary information, know-how, data, or procedure related to the Materials and Data disclosed by Provider to Recipient under this Agreement (“Confidential Information”). Recipient agrees not to disclose Confidential Information to third parties. 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. These confidentiality obligations shall survive this Agreement for a period of five (5) years after termination or expiration of this Agreement. Any personal patient data or data suitable for identity disclosure contained in or related to the Material and Data have to be kept confidential by Recipient indefinitely.
- 7.2 The Parties acknowledge that the Data consists of coded data and that the Material is coded material of Subjects. Both are collected and maintained in accordance with the provided informed consent (ICF) and the applicable rules and legislation including but not limited to protection of privacy aspects of the medical and personal data and material of the persons.
- 7.3 In particular Parties agree that Data and Material have been and will be collected, processed and transferred in accordance with the General Data Protection Regulation 95/46/EC (“GDPR”), which includes but shall not be limited to:
- a) adopting appropriate technical and organizational measures to prevent any unauthorized or accidental use, access or processing of personal data (Security Breach).

- b) informing the other Party of any Security Breaches in a timely manner to enable the other Party to comply with its reporting obligations under Applicable Law.

- 7.4 If either Party becomes aware of a personal data breach, that Party shall immediately without delay 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. All data breach notifications shall be detailed and include a clear reference to this Agreement and the Provider and Recipient Scientists name.
- 7.5 The Data and Material are considered personal data under Applicable Law. According to Article 26 of the GDPR, it is assumed that the Parties are considered as joint controllers and consequently are to determine their respective responsibilities according to the GDPR in a transparent manner.
- 7.6 Each Party shall indemnify the other Party and compensate the other Party for any claims, actions or rights by third parties and any fines imposed by a Data Protection Authority, which arise directly from breaching its obligations under this Article 3.
- 7.7 The capitalized terms in this Article 7 shall have the meaning as defined in the GDPR.
- 7.8 Provider warrants that the Material was legally acquired, and that the transfer to Recipient for the intended scientific research is legally allowed. Provider is not aware of any defects in the Material or of any other circumstances that would limit the intended use and value of the Material to Recipient under this Agreement. The Material will be coded and supplied when appropriate with basic Subject information. Under no circumstances shall the Provider supply personal information which could identify the Subject. The Recipient shall not carry out any procedures with the coded Data (linking, comparison, processing) with which the identity of the Subject could be derived. Unless explicitly agreed, The Recipient shall not perform analyses on genetic data. Genetic data means personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question.
- 7.9 In case of theft or loss of the material, Provider must be informed within 24 hours. In case of a data breach of data suitable for identity disclosure, Provider must be informed also within 24 hours.

## **ARTICLE 8. MISCELLANEOUS**

- 8.1 The parties acknowledge that the abovementioned Subject(s) or its representatives shall at all times have the right to request to destroy their Material. In the event a Subject files such a request with Provider, the Recipient shall, if reasonably possible, promptly return the Material to Provider upon Provider's first written request or shall destroy the Material. A written confirmation of the destruction of the Material needs to be send to Provider. The Results already obtained through Research can be kept.
- 8.2 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 from which the Material was derived or its family) Provider shall be informed in accordance with the research Protocol and other applicable protocols.

- 8.3 Recipient will comply in all material aspects with all applicable laws and regulations such as, for example, those relating to research involving the use of patient material and/or data .

#### **ARTICLE 9. EFFECTIVE DATE AND TERMINATION**

- 9.1 This Agreement will become effective on [date] and shall terminate as described in article 3.2.
- 9.2 This Agreement will terminate on the earliest of the following dates: (a) on completion of the Research or (b) after three (3) years from the Effective Date.
- 9.3 Provider may terminate this agreement with immediate effect:
- if Recipient is in breach of this Agreement (including its Annexes) and, in case a remedy is possible, fails to remedy such breach within a reasonable time after receipt of request by Provider to remedy such breach;
  - in the event Recipient is in state of bankruptcy or suspension of payment or a petition to that effect is filed by or against that Recipient;
  - in the event the business of the other Party will be winded up or closed down;
  - in the event the control of the business of Recipient will be transferred to a third party;
  - in the event the behavior of Recipient or its employees endangers the integrity of Provider in any way.
- 9.4. At all times Provider retains the right to recall the Material and/or Data on the following grounds:
- The Recipient or scientists employed by the Recipient fail to comply with the conditions of this Agreement and – in cases where remedy is possible, having been notified by Provider of this failure to comply - have not remedied such failure within a reasonable time after receipt of notification from Provider;
  - the Subject or the Subject's representative withdraw its consent to or objects to the use of the Material and/or Data in research.
- 9.5 Upon the effective date of termination or expiry, Recipient will discontinue its use of the Material and/or Data and will, upon clear instructions from Provider, return or destroy, any remaining Material and Data (including Progeny, Unmodified Derivatives and any Modifications of the Material). A written confirmation of the action taken is required.
- 9.6. If one Party is in breach of this agreement, this Party will be liable for any costs that may result from this breach.
- 9.7 The rights and obligations under this Agreement that by their nature would be expected to survive termination of this Agreement shall survive termination.

#### **ARTICLE 10. GOVERNING LAW AND COMPETENT COURT**

- 10.1 This agreement shall be interpreted, governed and enforced exclusively in accordance with the laws of the Netherlands.

10.2 All disputes between the Parties related to this Agreement, are to be instituted by the competent court of Midden-Nederland, location Utrecht, the Netherlands.

**ARTICLE 11. DETAILS PROVIDER AND RECIPIENT AND PROVISION OF DATA AND MATERIAL**

- 11.1 The Material and Data is provided against the Costs Estimation as specified in Annex 2 which includes, if applicable, reconstruction costs and/or a handling and transmittal fee to reimburse the Provider for its preparation and distribution costs.
- 11.2 The Recipient will receive an invoice of the costs involved and will transfer the amount specified within 30 days of receiving the invoice to the provider if so agreed upon.
- 11.3 The transporter states that he has all the applicable licenses and required permits to transport human material in and outside the Netherlands. Provider cannot be held liable for any costs, damages or fines that may incur because of the absence of necessary licenses and/or permits.
- 11.4 The Provider will not be accountable or responsible for (change in) the quality of the human material during transportation.

Agreed and signed in duplicate,

**Provider**

**Recipient**

\_\_\_\_\_  
Name: dr. B.J. Tops  
Title: Head of Diagnostic Laboratory  
Date:

\_\_\_\_\_  
Name:  
Title:  
Date:

READ AND ACKNOWLEDGED

READ AND ACKNOWLEDGED

**Provider Scientist**

**Recipient Scientist**

\_\_\_\_\_  
Name:  
Date:

\_\_\_\_\_  
Name:  
Date:

## **Annex 1 – Research Protocol (description of the Research)**

Biobank-number



## **Annex 2 – Costs Estimation**