

MATERIAL TRANSFER AGREEMENT

This Material Transfer Agreement (MTA) is concluded by and between

BIT-Gaslini Biobank

IRCCS Istituto Giannina Gaslini, Via G. Gaslini, 5, 16147, Genova, Italy

and

Name of recipient organization

Address of Recipient Organization

- The PROVIDER BIT Gaslini Biobank, (IRCCS Istituto Giannina Gaslini, Via G. Gaslini, 5, 16147, Genova, Italy), agrees to provide the RECIPIENT ...(Name and address of RECIPIENT Institute) with about and with any data for use in the Laboratory of (Name of recipient Scientist, e-mail)... for the purpose of conducting scientific work in the topic of (SPECIFICATION OF EXPERIMENTS) under the following conditions:
- The MATERIAL and DATA will be delivered and will be used under the terms and conditions as follows hereafter and under the terms of this Agreement.

1. Definitions:

1.1 **PROVIDER:** -Gaslini Biobank, IRCCS Istituto Giannina Gaslini, Via G. Gaslini, 5, 16147, Italy

1.2 **PROVIDER SCIENTIST:** Katia Mazzocco, UOC Laboratory Anatomy, IRCCS Istituto Giannina Gaslini, Via G. Gaslini 5, 16147, Genova, Italy, katiamazocco@gaslini.org

1.3 **PROVIDER ORGANIZATION:** Istituto Giannina Gaslini, Via G. Gaslini, 5, 16147 Genova

1.4 **RECIPIENT SCIENTIST:** (Name and e-mail address of RECIPIENT scientist)

1.5 **RECIPIENT ORGANIZATION:**(Name and e-mail address of RECIPIENT organization)

1.6 **MATERIAL:** Biological material that is to be delivered by Provider to Recipient. Any **MATERIAL** derived from the original **MATERIAL** will be considered as the original **MATERIAL** and subjected to this agreement, even if said **MATERIAL** (f.e. cell lines) has been modified to have other special properties.

1.7 **DATA:** Preanalytical data related to **MATERIAL** provided by **PROVIDER** to **RECIPIENT**.

1.8 **COMMERCIAL PURPOSES:** the sale, lease, license, or other transfer of the **MATERIAL** to a for-profit organization. **COMMERCIAL PURPOSES** shall also include uses of the **MATERIAL** by any organization, including **RECIPIENT**, to perform contract research, to screen compound libraries, to produce or manufacture products for general sale, or to conduct research activities resulting in any sale, lease, license or transfer of the **MATERIAL** to a for-profit organization. However, industrially sponsored academic research shall not be considered a use of the **MATERIAL** for **COMMERCIAL PURPOSES** per se, unless any of the above conditions of this definition are met.

1.9 **NONPROFIT ORGANIZATION(S):** A university or other institution of higher education or an organization or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute. As used herein, the term also includes government

agencies.

1.10 **STAFF:** the Researcher/s and those individuals under the direct supervision of the researcher/s

1.11 **RESEARCH, RESEARCH PROJECT:** Research project and experiments with the **DATA** to be performed by **RECIPIENT**. Any use will be only for research purpose.

1.12 **RESULTS:** Any output of the **RESEARCH**, which are not **PROGENY** or **UNMODIFIED DERIVATIVES**, such as invention, data, software, algorithms, knowledge, know-how or information that is generated in the **RESEARCH**, whatever its form or nature, whether it can be protected, as well as any rights attached to it, including **INTELLECTUAL PROPERTY RIGHTS**.

1.13 **INTELLECTUAL PROPERTY RIGHTS:** all intellectual property rights throughout the world, whether existing under statute, at common law or equity, registered or unregistered, now or hereafter in force or recognized including trade secrets and know-how.

1.14 .

2. Terms and Conditions of this Agreement:

2.1 The **PROVIDER** retains ownership of the **MATERIAL** including any derived **MATERIAL** or cell lines carrying the biological genetic or genomic characteristics expressed by the original **MATERIAL**.

2.2 The **RECIPIENT ORGNIZATION** and the **RECIPIENT SCIENTIST** agree that the **MATERIAL**:

2.2.1 is to be used solely for its internal non-commercial biomedical research purposes and must not be used for any products or for the generation of other products or processes for profit-making or commercial purposes;

2.2.2 will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects without the written consent of the **PROVIDER**

2.2.3 is to be used only at the **RECIPIENT ORGANIZATION** and only in the **RECIPIENT SCIENTIST'S** laboratory under the direction of the **RECIPIENT SCIENTIST** or **STAFF** working under his/her direct supervision;

2.2.4 will not be transferred to anyone else without the prior written consent of the **PROVIDER**;

2.3 The **RECIPIENT ORGANIZATION** and the **RECIPIENT SCIENTIST** agree to refer to the **PROVIDER** any request for the **MATERIAL** from anyone other than those persons (**STAFF**) working under the **RECIPIENT SCIENTIST'S** direct supervision.

2.4 The **RECIPIENT ORGANIZATION** and/or the **RECIPIENT SCIENTIST** shall have the right, without restrictions, to distribute substances created by the **RECIPIENT** through the use of the **MATERIAL** only if those substances are not the **MATERIAL**.

2.5 Under a separate Agreement (or an Agreement at least as protective of the **PROVIDER'S** rights), the **RECIPIENT** may distribute the **MATERIAL** to **NONPROFIT ORGANIZATION(S)** for research and teaching purposes only.

2.6 The **RECIPIENT ORGANIZATION** and/or the **RECIPIENT SCIENTIST** may NOT provide the **MATERIAL** for **COMMERCIAL PURPOSES**.

2.7 The **RECIPIENT** acknowledges that the **MATERIAL** is or may be the subject of a patent application. Except as provided in this Agreement, no express or implied licenses or other rights are provided to the **RECIPIENT** under any patents, patent applications, trade secrets or other proprietary rights of the **PROVIDER**, including any altered form of the **MATERIAL** made by the **PROVIDER**. In particular, no express or implied licenses or other rights are provided to use the **MATERIAL** or any related patents of the **PROVIDER** for **COMMERCIAL PURPOSES**.

- 2.8 Any **MATERIAL** delivered pursuant to this Agreement 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. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE **MATERIAL** WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.
- 2.9 The **RECIPIENT** agrees to be responsible for all claims and damages that directly result from the negligent acts or omissions of the **RECIPIENT**, its employees or agents. 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** by the **RECIPIENT**, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the **PROVIDER**.
- 2.10 The **MATERIAL** has been collected and processed by **PROVIDER** in compliance with RGPD and all applicable laws, at National and European level.
- 2.11 The **PROVIDER** confirms that a written consent covering the intended use has been signed by the relevant person providing the **MATERIAL** or by his/her legal representative.
- 2.12 The **RECIPIENT** agrees to use the **MATERIAL** in compliance with all applicable statutes and regulations, relating to research involving the use of human tissues or genomic **MATERIAL**.
- 2.13 **PROVIDER** and **RECIPIENT** ensure to each other that they will protect, in their respective areas of responsibility under applicable law and the present Agreement, the fundamental rights of the person providing the **MATERIAL**, and in particular (i) the protection of privacy, (ii) the right to autonomy and informational self determination, (iii) the right of access, (iv) the right of portability, and (v) the right of withdrawal.
- 2.14 In case of full or partial withdrawal of consent, the provider must inform the **RECIPIENT** of this revocation without delay. A written notification shall be sent to the **PROVIDER** upon receipt and after completion of the request.
- 2.15 The **RECIPIENT** undertakes to meet shipping costs, including any applicable taxes.
- 2.16 This Agreement shall not be interpreted to prevent or delay publication of research findings resulting from the use of the **MATERIAL**. The **RECIPIENT SCIENTIST** shall periodically inform the **PROVIDER SCIENTIST** of research results related to the **MATERIAL**.
- 2.17 **RECIPIENT** agrees to provide in confidence the **PROVIDER SCIENTIST** with a copy of any manuscript describing the results of such research for review and comments. no later than thirty (30) days prior to submission of the manuscript for publication. If no objection is made within thirty days stated above, the publication is permitted.
- 2.18 **RECIPIENT** agrees, in accordance with its established practice, to keep complete and accurate accounts, notes, data, and records of the RESEARCH.
- 2.19 If the research project does not lead to any publication before the expiration of this contract, **RECIPIENT** provides **PROVIDER** with a summary of ant results obtained.
- 2.20 **RECIPIENT** agrees to acknowledge the name of the Biobank as the source of the **MATERIAL** and individual(s) who have collected and characterized the **MATERIAL** as co-authors in all written publications, posters or oral presentations.
- 2.21 Upon completion of the research or on **PROVIDER** request, **RECIPIENT** will disclose to

PROVIDER all results obtained from conducting the research, which relate to the use of the **MATERIAL** or modifications. **PROVIDER** agrees to keep these **RESULTS** confidential until they are published

- 2.22 **RECIPIENT** shall retain exclusive ownership of all research results arising from its use of the **MATERIAL** under this Agreement including, but not limited to, any data, know-how, technology, biological **MATERIALS** (except those considered a **MATERIAL** under Paragraph 1.6), discoveries, and inventions. No express or implied license is granted to **PROVIDER** for the use of any Research Results. **RECIPIENT** shall be free to publish, for any purpose, any Research Results.
- 2.23 The **RECIPIENT** agrees to use the **MATERIAL** in compliance with all applicable statuses and regulations, relating to research involving the use of human tissues or genomic **MATERIAL**.
- 2.24 This Agreement will terminate on the earliest following dates:
- 2.24.1 On completion of the recipient's current research with the **MATERIAL** or
 - 2.24.2 On thirty (30) days written notice by either party to the other, or
 - 2.24.3 Three (3) years from the date this Agreement is signed.
- 2.25 This wording contains the entire Agreement between the parties; any changes of the Agreement have to be made in writing.

The parties executing this Agreement certify that their respective organizations agree to be bound by its terms, for the transfer specified above.

The **PROVIDER Organization**, **PROVIDER Scientist**, **RECIPIENT Organization**, and **RECIPIENT SCIENTIST** must sign both copies of this letter and return one signed copy to the **PROVIDER**. The **PROVIDER** will then send the **MATERIAL**.

PROVIDER INFORMATION and AUTHORIZED SIGNATURE:

PROVIDER Scientist: Katia Mazzocchi, Laboratorio di Anatomia Patologica, IRCCS Istituto Giannina Gaslini

Signature of PROVIDER Scientist

Date

PROVIDER Organization: IRCCS Istituto Giannina Gaslini, Via G. Gaslini 5, 16147 Genova, Italy

Name of Authorized Official: Renato Botti

Title of Authorized Official: General Director

Signature of Authorized Official

Date:

RECIPIENT INFORMATION and AUTHORIZED SIGNATURE:

RECIPIENT Scientist:

RECIPIENT Organization:

Name of Authorized Official:

Title of Authorized Official:

Signature of Authorized Official

Date:

Certification of **RECIPIENT Scientist**: I have read and understood the conditions outlined in this agreement, and I understand that I must abide by them to receive and use the **MATERIAL**.

Signature of RECIPIENT Scientist

Date