Versione 2, 25 settembre 2023

DATA TRANSFER AGREEMENT

This Data Transfer Agreement (DTA) is concluded by and between

IRCCS Istituto Giannina Gaslini, BIT-Gaslini Biobank,

Via G. Gaslini, 5, 16147, Genova, Italy

and

Name of recipient organization

Address of Recipient Organization

1. The **PROVIDER** IRCCS Istituto Giannina Gaslini, BIT-Gaslini, a biobank established with the aim to facilitate research on its collection of human biological data, agrees to provide the **RECIPIENT** …… with ……. data for use in the Laboratory of …… (Name of recipient Scientist, e-mail:) for the purpose of ……..
2. This Agreement governs the transfer and use of human **DATA** that is made available by the **PROVIDER** to the entity that wishes to use this research **DATA** for its own research purposes (**RECIPIENT**).
3. This Agreement is effective as of the date of last signature ("Effective Date") The **PROVIDER** provides to the **RECIPIENT** the following data: … [fill in precisely or point to an attachment where the provision is described].

4. The **RECIPIENT** acknowledges that the **DATA** are provided on an "as is" basis without any warranty of satisfactory quality or fitness for a particular purpose or use or any other warranty, express or implied.

1. DEFINITIONS

1.1. **PROVIDER**: Istituto Giannina Gaslini, Biobank-BIT 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, katiamazzocco@gaslini.org

1.3. **RECIPIENT:** ….(Name and address of RECIPIENT Institute)

1.4. **RECIPIENT SCIENTIST:** ….. (name and e-mail address of RECIPIENT scientist)

1.5. **DATA:** data that is to be delivered by Provider to Recipient. Any **DATA** derived from the original **DATA** will be considered as the original **DATA** and subjected to this agreement, even if said **DATA** has been modified to have other special properties.

1.6. **COMMERCIAL PURPOSES:** the sale, lease, license, or other transfer of the **DATA** to a for-profit organization. **COMMERCIAL PURPOSES** shall also include uses of the **DATA** by any organization, including **RECIPIENT**, to perform contract research, or to conduct research activities that resulting any sale, lease, license or transfer of the **DATA** to a for-profit organization. However, industrially sponsored academic research shall not be considered a use of the **DATA** for **COMMERICAL PURPOSES** per se, unless any of the above conditions of this definition are met.

1.7. **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.

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

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

1.10. **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**.

1.11. **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.

2. TERMS AND CONDITIONS OF THIS AGREEMENT:

2.1. The **PROVIDER** confirms that for the purposes of this **DTA** it is entitled to supply the **DATA** to the **RECIPIENT** and that consent covering the intended use has been obtained from the relevant donors/data subjects.

2.2. The **RECIPIENT** confirms that all work using the **DATA** will be carried out in compliance with all applicable laws, regulations, guidelines and approvals (EU Regulation 2016/679UE 679/2016 (GDPR).

2.3. The **RECIPIENT** will retain the **DATA** in a secure network system at such standard as would be reasonably expected for the storage of valuable and proprietary for sensitive/confidential **DATA**. The **RECIPIENT** shall refrain from tracing or identifying the identity of any donors who provided the **DATA**. Recipient agrees to preserve, at all times, the confidentiality of information pertaining to identifiable donors. The Recipient agrees not to give access to **DATA**, in whole or part, or any identifiable **DATA** derived from the **DATA**, to any third party. The **RECIPIENT** shall limit access to and processing of the **DATA** to those employees or other authorized representatives of **RECIPIENT** who: (i) need to process such **DATA** in order to conduct their work in connection with the **DATA** and the Protocol and (ii) have signed agreements with the **RECIPIENT** obligating them to maintain the confidentiality of the **DATA** and any information to be derived thereof or disclosed to them.

2.4. The **RECIPIENT** and the **RECIPIENT SCIENTIST** agree :

2.4.1. that the **DATA** will not be transferred to anyone else within the **RECIPIENT** organization without the prior written consent of the **PROVIDER**;

2.4.2. that the **DATA** will not be transferred to anyone else without the prior written consent of the **PROVIDER**

2.4.3. to refer to the **PROVIDER** any request for the **DATA** from anyone other than those persons (**STAFF**) working under the **RECIPIENT SCIENTIST'S** direct supervision.

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

2.4.5. that the **RECIPIENT** and/or the **RECIPIENT SCIENTIST** may NOT provide the **DATA** for **COMMERCIAL PURPOSES**.

2.5. The **RECIPIENT** shall not attempt to contact any **DATA** subject.

2.6. **RECIPIENT** shall take reasonable steps to delete **DATA** for a given subject when the **PROVIDER** deems that subject to have withdrawn his or her consent. The **RECIPIENT** confirms that it will deal

promptly and appropriately with any withdrawals by donors/data subjects which the **PROVIDER** notify to the **RECIPIENT**.

2.7. On the Completion of the Research Project or on the termination of this agreement, the **RECIPIENT** will delete the **DATA** and confirm to the **PROVIDER** (in writing) that this has taken place.

2.8. Any provisions of this agreement intended to protect the rights of human donors/data subjects shall survive the expiry or termination of this agreement.

2.9. The **PROVIDER** retains ownership of the **DATA** and the **DATA** are made available to the **RECIPIENT** as a service to the research community.

2.10. This Agreement shall not be interpreted to prevent or delay publication of research findings resulting from the use of the **DATA**.

2.11. The **RECIPIENT SCIENTIST** shall periodically inform the **PROVIDER SCIENTIST** of research results related to the **DATA** and will provide the **PROVIDER SCIENTIST** with a copy of any on-line report, meeting abstract, or manuscript describing the results of such research before the manuscript is submitted for publication.

2.12. **RECIPIENT** shall mention by name in any publication the BIT-Gaslini as **PROVIDER** and the BIT-Gaslini responsible member(s) as co-author(s).

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 donors/**DATA** subjects, 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.

3. GENERAL

3.1. This Agreement will terminate on the earliest following dates:

3.1.1. On completion of the **RECIPIENT**'s current research with the **DATA** or

3.1.2. On thirty (30) days written notice by either party to the other, or

3.1.3. Three (3) years from the date this Agreement is signed.

3.2. This **DTA** governs the relationship between the parties to the exclusion of any other terms and conditions and, together with any other document referred to in this Agreement, constitutes the whole agreement between the parties in relation to the subject matter hereof.

3.3. All variations to this **DTA** must be agreed, set out in writing and signed on behalf of the parties before they take effect.

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

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

Versione 2, 25 settembre 2023

PROVIDER INFORMATION and AUTHORIZED SIGNATURE:

PROVIDER Scientist: Katia Mazzocco, UOC Laboratory Anatomy, IRCCS Istituto Giannina Gaslini, Via G. Gaslini 5, 16147, Genova, Italy, katiamazzocco@gaslini.org.

_____ _____

Signature of PROVIDER Scientist Date

PROVIDER : IRCCS Istituto Giannina Gaslini, Via G. Gaslini 5, 16147 Genova, Italy
Name of Authorized Official: Dr. Renato Botti
Title of Authorized Official: General Director

_____ _____

Signature of Authorized Official Date:

RECIPIENT INFORMATION and AUTHORIZED SIGNATURE:

RECIPIENT Scientist:

RECIPIENT:

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 **DATA**.

_____ _____

Versione 2, 25 settembre 2023

Signature of RECIPIENT Scientist Date