



MATERIAL AND DATA TRANSFER AGREEMENT

This agreement (hereinafter referred to as the “*Agreement*”) is made and entered into by and between

IRCCS Istituto Centro San Giovanni di Dio Fatebenefratelli, belonging to the “Provincia Lombardo Veneta dell’Ordine Ospedaliero di San Giovanni di Dio – Fatebenefratelli (IRCCS Fatebenefratelli), whose principal place of business is at Via Pilastroni 4, 25125, Brescia, Italy, hereby legally represented by the general director Dr. Renzo Baldo (hereinafter referred to as “**PROVIDER**”)

and

[**NAME OF RECIPIENT ORGANIZATION**] (“**RECIPIENT**”)

[Address of Recipient Organization]

Hereinafter jointly referred to as the “*Parties*” and individually as a “*Party*”.

PROVIDER AND RECIPIENT AGREE AS FOLLOWS:

PREAMBLE

RECIPIENT wishes to conduct RESEARCH with ORIGINAL MATERIAL and DATA. PROVIDER is willing to provide ORIGINAL MATERIAL and DATA to RECIPIENT under the terms and conditions as follows hereafter.

The effective date of this Agreement is the date of the last required signature obtained.

The biological material and data as described in Annex A will be delivered by PROVIDER to RECIPIENT under the terms of this Agreement.

DEFINITIONS

ORIGINAL MATERIAL: Biological material that is to be delivered by PROVIDER to RECIPIENT as described in Annex A.

PROGENY: unmodified descendant material from the original material, such as virus from virus, cell from cell, or organism from organism.

DATA: data provided by PROVIDER to RECIPIENT related to ORIGINAL MATERIAL as described in Annex A.

UNMODIFIED DERIVATIVES: substances created by the RECIPIENT which constitute an unmodified functional subunit or product deriving from the ORIGINAL MATERIAL, e.g. sub-clones of unmodified cell lines, purified or fractionated subsets of the ORIGINAL MATERIAL, proteins expressed by DNA/RNA.

MODIFICATIONS: substances created by the RECIPIENT which contain/incorporate the ORIGINAL MATERIAL, e.g. homologous recombination products, cassette exchange products, germ line transmission products, crosses, new varieties, cell fusions, etc.

RESEARCH, RESEARCH PROJECT: Research project and experiments with the MATERIAL to be performed by RECIPIENT, as specified in Annex B. Any use will be only for the described research purpose.

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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.

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.

PURPOSE

PROVIDER will provide RECIPIENT with MATERIAL under the conditions as set forth in this Agreement.

The MATERIAL may not itself be commercialized and is to be used solely by RECIPIENT. The RESEARCH to be conducted by RECIPIENT is restricted to the RESEARCH PROJECT described in Annex B.

MATERIAL and MODIFICATIONS will be stored in a secure location and will only be used in laboratory animals or in vitro experiments.

The RECIPIENT will ensure that RECIPIENT's scientists do not transfer the MATERIAL or MODIFICATIONS to anyone who does not work under his or her direct supervision and responsibility.

[*Se pertinente:* The Recipients will use the MATERIALS solely for its internal noncommercial biomedical research purposes in connection with the Project and must not use them for any products or for the generation of other products or processes for profit-making or commercial purposes.]

COMPLIANCE WITH LAW, RULES AND REGULATIONS

The MATERIAL and DATA have been collected and processed by PROVIDER in compliance with GDPR and all applicable laws, at national and European level. The MATERIAL and DATA have been collected and processed by PROVIDER in compliance with the IRCCS FBF Biobank Regulation (Annex C) and the Fatebenefratelli Ethical Code for the use of biological material for research or experimental purpose (Annex D).

RECIPIENT agrees to comply with IRCCS FBF Biobank Regulation (Annex C) and the Fatebenefratelli Ethical Code for the use of biological material for research or experimental purpose (Annex D) and with all laws applicable to the research, the handling of biological material and data.

RECIPIENT confirms that the RESEARCH PROJECT has been subject to review and approved by the [Name of Ethical Committee (approval number)] as further described in Annex B and attach the EC Opinion.

The MATERIAL shall be used only (i) under the conditions specified by PROVIDER (Annex D: Fatebenefratelli Ethical code for the use of biological material for research or experimental purposes), including any conditions specified at the time of collection, as set forth in Annex A and (ii) as provided for by law.

PROVIDER confirms that a written consent covering the intended use has been signed by the relevant person providing the MATERIAL or by their legal representative.

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RECIPIENT agrees to protect MATERIAL against misuse through appropriate organizational and technical measures. Secure MATERIAL access and security shall be guaranteed at all stages of the process.

RECIPIENT understands that the Biological Material delivered hereby is experimental in nature and should be used with prudence and appropriate caution since not all of its characteristics are known. RECIPIENT assumes all liability for damages, which may arise from the use, storage, handling or disposal of the Biological Material or its derivatives, except to the extent caused by PROVIDER's gross negligence or willful misconduct.

RIGHTS & GUARANTEES

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, 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.

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.

FEES AND SHIPPING COSTS

The RECIPIENT undertakes to meet shipping costs, including any applicable taxes.

The Original Materials shall be transferred by the PROVIDER and at the RECIPIENT's expense, who shall reimburse the Provider for any costs incurred.

INTELLECTUAL PROPERTY RIGHTS

The MATERIAL sent, all related information and all associated patent rights and other property rights are the property of the SUPPLIER and are made available as part of the Project. No right or license is granted on the MATERIAL or any related information. In the event that the use of the MATERIAL sent by the Provider has been decisive for the achievement of the results achieved with the Research Project, the Parties must define the percentages of ownership for the economic exploitation of a possible patent. The RECIPIENT undertakes to quote the PROVIDER in any publication that mentions the study carried out with the MATERIALS provided with this contract.

PUBLICATIONS *(Paragrafo da adattare al singolo caso)*

The purpose of biological resources' use is scientific research and RECIPIENT shall publish its RESULTS related to the MATERIAL or MODIFICATIONS. RECIPIENT agrees to acknowledge PROVIDER as

- or coauthors of the publication in case of PROVIDER's proactive involvement as well as significant for the same research;
- or cite as the source of the MATERIAL in all written publications, posters or oral presentations.

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This applies to any publication on MATERIAL or MODIFICATIONS that discloses or relates in any way to RECIPIENT's use of the MATERIAL, unless otherwise agreed in writing by PROVIDER.

RECIPIENT will acknowledge the name of the biobank and/or individual(s) who have collected the MATERIAL.

RECIPIENT agrees to submit written publications to PROVIDER in confidence for review and comment no later than thirty (30) days prior to submission for publication. If no objection is made within thirty days stated above, the publication is permitted.

RESEARCH RESULTS (*Paragrafo da adattare al singolo caso*)

RECIPIENT agrees, in accordance with its established practice, to keep complete and accurate accounts, notes, data and records of the RESEARCH.

If the RESEARCH PROJECT does not lead to any publication before the expiration of this contract, RECIPIENT provides PROVIDER with a summary of any RESULTS obtained.

Upon completion of the RESEARCH or on PROVIDER's 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.

APPLICABLE COURT AND COMPETENT FORUM

This Agreement shall be governed by the laws of Italy and UE. Any claim or controversy arising out of or related to this Agreement shall be submitted to the competent courts of ... [Name of Region - City], Italy.

LIABILITY

The RECIPIENT declares to be aware that the MATERIAL delivered under this contract must be considered experimental in nature and, therefore, potentially dangerous if not used with due precautions. The MATERIAL is sent as it is. The SUPPLIER, therefore, does not issue any guarantee or any declaration on the suitability of the material for a particular purpose or that its use may violate patents, copyrights or other property rights over it.

In the event of termination of this contract, for any reason whatsoever, the RECIPIENT shall immediately return all remaining MATERIAL in compliance with the Fatebenefratelli Ethical Code for the use of biological material for research or experimental purpose (Annex D).

CONFIDENTIALITY

All confidential information regarding the material received and that becomes known incidentally during the performance of any activity pertaining to this Agreement, must be considered confidential and may not be disclosed or transferred to third parties without the express authorization of the sending Party. The receiving Party undertakes not to disclose the information learned with the receipt and use of the

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material without written authorization from the Party that provided it, except as required by law or an order of an administrative or judicial authority.

Confidential information shall mean any information, documentation and knowledge, even partial or incomplete, of an economic, technical or scientific nature owned by the sending Party, relating to inventions, discoveries, developments, technical information, know-how, methods, techniques, formulas, data, findings, procedures, projects and other ideas that may or may not be subject to patent or copyright rights, as well as any results of any and all research work and consequent elaborations however derived therefrom.

DURATION, WITHDRAWAL AND TERMINATION

The remaining material shall be returned to PROVIDER upon termination.

Signatures

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ANNEXES

Annex A:

Description of the ORIGINAL MATERIAL and related DATA to be delivered by PROVIDER to RECIPIENT

Please, fill in and sign the form, then send it back to:

IRCCS Istituto Centro San Giovanni di Dio Fatebenefratelli Biobank (Biobank FBF)

IRCCS Centro San Giovanni Di Dio Fatebenefratelli

Via Pilastroni n.4, Brescia (BS) 25030

biobanca.irccs@fatebenefratelli.eu

+39 0303501328

PROJECT DETAILS

Principal investigator:

Project title:

Grant sponsor:

Project no:

Institute:

Phone:

Fax:

E-mail:

Project description:

(Please describe the data you hope to gather through the requested sample)

SHIPPING DETAILS

Shipping address:

Courier name:

Courier account number:

INVOICE DETAILS

Organisation Full Name:

Complete Address:

VAT Code (EU States):

Contact Person:

Phone:

Fax:

E-mail:

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ORDINE OSPEDALIERO DI SAN GIOVANNI DI DIO
FATEBENEFRAPELLI
PROVINCIA LOMBARDO VENETA
*I.R.C.C.S. – Centro San Giovanni di Dio
Fatebenefratelli*

Annex B:

Research project (protocol) and experiments to be performed with the MATERIAL by RECIPIENT.

Annex C:

Biobank Regulation

Annex D:

Fatebenefratelli Ethical code for the use of biological material for research or experimental purposes

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Via Cavour, 22 Tel 02/92761-Telefax 02/9276-781
www.fatebenefratelli.it

Sistema Sanitario  Regione
Lombardia



Sede Legale: 25125 BRESCIA - Via Pilastroni, 4
Iscrizione Prefettura di Brescia n 513 Registro PG
C.F. e P.IVA 01647730157