MATERIAL AND DATA TRANSFER AGREEMENT FOR BIOLOGICAL SAMPLES

This Agreement is made between:

Istituto Don Calabria – IRCCS Ospedale Sacro Cuore Don Calabria (hereafter "IRCCS"), in particular DITM - Department of Infectious, Tropical and Microbiological Diseases, with registered office in Via San Zeno in Monte no. 23, 37129 Verona, Italy and operating office in Via Don A. Sempreboni no. 5, 37024 Negrar di Valpolicella, Verona, Italy C.F. and VAT no. 00280090234, represented by the CEO Dr. Claudio Cracco

and

_____ **(hereafter "Recipient")**
Director or legal representative
Researcher in charge of the study

Since:

- On 23/05/2018 by decree of the Ministry of Health the scientific character in the discipline "Infectious and tropical diseases" of the Hospital Classified Sacro Cuore - Don Calabria was recognised
- The Scientific Responsible of the Tropica Biobank project is Dr. Chiara Piubelli, Head of the Biomedical Research Unit
- The protocol of the research project involving human biological samples must be submitted to the competent Ethics Committee. Amendments to this Agreement shall only be made in advance, in writing, by a separate deed and with the agreement of both parties.

IRCCS and the Recipient, hereinafter collectively referred to as the "Parties", agreed the following:

IRCCS will provide the Recipient with biological samples (hereinafter indicated as "MATERIAL") and Associated Data, described in ATTACHMENT 1, for the sole purpose to conduct the experiments outlined in ATTACHMENT 2. The Recipient undertakes to use the MATERIAL only for the purpose provided for herein and specified in ATTACHMENT 2. The MATERIAL will be selected among the biological samples stored in Tropica Biobank. Both the Parties agree to the conditions detailed in the present document before the Recipient receives the MATERIAL.

1. Definitions

1.1. **"MATERIAL"** refers to the biological MATERIAL that is covered by this Agreement and shall mean Original MATERIAL, Progeny and Unmodified Derivatives, and any part thereof.

1.2. **"Modifications"** shall mean substances or materials (created or developed by the RECIPIENT) which contain or incorporate any form of the MATERIAL or parts of the MATERIAL.

1.3. **"Original MATERIAL"** shall mean all materials provided by the IRCCS, as defined in Attachment 1 as well as any medium in which the Original MATERIAL is provided, any parts of the Original MATERIAL (such as, but not limited to, any reproductive, genetic or other replicable parts).

1.4. **"Progeny"** shall mean all unmodified descendants from the Original MATERIAL, such as cell from cell, or organism from organism.

1.5. **"Unmodified Derivatives"** shall mean any substances created by Recipient which constitute an important unmodified functional sub-unit or product expressed by the Original MATERIAL.
1.6. **"Associated Data"** shall mean any data supplied with MATERIAL by the IRCCS.

2. Conditions of use of the MATERIAL for the Recipient are:

2.1. The non-re-identification of participants
2.2. The use of the MATERIAL and any Modifications shall be limited to the performance of the research indicated in this Agreement. The handling of the MATERIAL shall be carried out under the direct supervision of the responsible researcher identified by the Recipient herein.
2.3. The Recipient shall not isolate parts or sub-units of the MATERIAL to use them for other research purposes that are not expressly approved by the IRCCS.
2.4. The Recipient shall not transfer the MATERIAL, or any part thereof, or any modification or derivative thereof, or any information concerning the MATERIAL to a third party without written approval from IRCCS. The Recipient shall report any request concerning the MATERIAL to IRCCS.
2.5. The Recipient shall use the MATERIAL in accordance with the original informed consent and national and international laws (e.g. on the use of human material). The MATERIAL shall not be used in human subjects or clinical trials without written permission from IRCCS.
2.6. The research study involving the use of the MATERIAL must be submitted to the competent ethics committee.
2.7. This deed does not limit the right of the IRCCS to distribute the MATERIAL to other parties who request it.

3. Intellectual property rights

3.1. The IRCCS is the custodian of the MATERIAL and Associated Data. Nothing in this Agreement shall be deemed to grant Recipient any rights under any patent or patent application relating to the MATERIAL, nor any rights to use the MATERIAL or any parts thereof for commercial purposes, such as sale of the MATERIAL, use in manufacturing of products for sale, provision of a service to a third party in exchange for consideration or use in research or consulting for a for-profit entity under which that entity obtains rights to research results, without first negotiating and executing a license agreement with the IRCCS. Recipient recognizes that the IRCCS has no obligation to grant such a license. There are specific clauses depending on the individual case.
3.2. The Recipient has the obligation to inform the IRCCS about the results and the inventions directly relating to the MATERIAL or its use ("Results"). Parties agree that ownership of the Results will be negotiated and agreed between the Parties in good faith taking into account the Parties' respective contributions to the Results.
3.3. The Recipient agrees not to apply for any patent or any other industrial property title, which would claim the MATERIAL or Results, without informing the IRCCS.

4. Warranties – Liability

4.1. IRCCS does not warrant that the Recipient's research involving the use of the MATERIAL will not infringe any patent or other intellectual property of a third party. IRCCS is under no obligation to obtain or provide any licence required for the Recipient to use the MATERIAL.
4.2. The MATERIAL provided is experimental in nature and may have hazardous properties. IRCCS does not guarantee its merchantability or suitability for particular uses beyond those described in this Agreement.
4.3. The Recipient assumes all responsibility for damage that may result from the Recipient's use, storage or disposal of the MATERIAL.
4.4. IRCCS guarantees the correct packaging and coding of the MATERIAL for shipment. IRCCS cannot be held liable for any loss or damage whatsoever with regard to the MATERIAL incurred during the transport of the MATERIAL. IRCCS will not be obliged to resend MATERIAL. Shipping costs will be borne by the Recipient.

4.5. IRCCS as custodian of the samples and data has the right to unilaterally modify/terminate access agreements with the Recipient. IRCCS disclaims any liability for any illegitimate and/or unintended use of samples or data by Recipient under this Agreement.

5. Confidentiality – Publications

5.1. The IRCCS declares that the processing of biological samples and related information is conducted with the adoption of appropriate security measures and total confidentiality and protection of personal and sensitive data (D.Lgs. N. 196/03, as amended and GDPR EU 2016/679 art.13); data are associated to the samples, in a de-identified way, through a coding system and only the IRCCS can trace the key code that allows to re-identify the samples, as specified in the protocol regulating the use of Tropica Biobank, approved by the Ethical Committee for Clinical Trials of the Provinces of Verona and Rovigo.

5.2. Unless otherwise specified, any information made available by the IRCCS must be considered confidential and used exclusively for scientific research purposes.

5.3. The Recipient acknowledges that any confidential information is the property of IRCCS. Upon termination of this Agreement Recipient shall destroy the Confidential Information.

5.4. The supply of the MATERIAL does not in any way prevent the IRCCS from publishing any document relating to the MATERIAL itself.

5.5. For the publication and/or any dissemination of the results obtained through the use of the MATERIAL and/or Associated Data, the Recipient must provide a proposal for publication to the IRCCS so that it can verify compliance with data protection regulations and the possible safeguarding of intellectual property where there are references to data produced by the IRCCS itself.

5.6. The Recipient must always credit IRCCS and Tropica Biobank in case of publication and/or presentation, and indicate the correct nomenclature of the MATERIAL. IRCCS may be included as an author or in the acknowledgments, according to its scientific contribution per submitted work.

5.7. Any publication or dissemination of information resulting from research studies may not in any way disseminate subjects' data, except in a completely anonymous form (e.g. through statistical processing, in publications, at scientific conferences, etc.).

6. Duration – Termination procedure

6.1. This Agreement shall be valid from the date of signature by both Parties until the completion of the Research Project, as indicated in ATTACHMENT 2. Any termination prior to the completion of the Project may be effected by either Party upon written notice.

6.2. The IRCCS, as custodian of the samples and data, has the right to unilaterally modify or terminate access arrangements with the Recipient in the event that:

6.2.1. The Recipient breaches one or more of the requirements contained in this Agreement, or

6.2.2. One or more patients withdraw informed consent, or

6.2.3. The competent Ethics Committee requests for the terminations of the Project.

6.3. Upon termination of this Agreement, as set forth in Section 6.1, the Recipient shall destroy/return the unused MATERIAL and Associated Data. Any costs related to the return shall be borne by the Recipient.

7. Indemnity

7.1. The MATERIAL is provided at no cost. However, a reimbursement is provided to cover the costs of handling the request for samples.

8. Jurisdiction

8.1. All disputes that may arise between the Parties concerning the interpretation and/or execution of this Agreement, which cannot be amicably resolved, shall fall under the exclusive jurisdiction of the Court of Verona, Italy.

9. 231 Model

9.1. The Parties declare that they have adopted their own Organisational, Management and Control Model and Code of Conduct/Code of Ethics pursuant to Legislative Decree No. 231/2001, as updated from time to time, and published on their institutional website. Each Party declares that it

has read the aforesaid Organisational, Management and Control Model and the Code of Conduct/Code of Ethics of the other Party, acknowledging that failure to comply with the commitments provided therein shall be considered grounds for termination of the contract pursuant to Article 1456 of the Italian Civil Code with immediate effect.

10. Miscellaneous

10.1. This Agreement may not be modified, in whole or in part, except with the written consent of both Parties. If any provision of this Agreement is held to be unenforceable or invalid, the remaining provisions shall remain in force. The Parties certify that their respective organisations have accepted the terms and conditions of this Agreement and undertake to abide by its terms and conditions for the transfer described in this Agreement.

Accepted by:

Istituto Don Calabria – IRCCS Ospedale Sacro Cuore Don Calabria

Responsible of the Tropica Biobank
Dr. Chiara Piubelli

Place:
Date:

Chief Executive Officer
Dr. Claudio Cracco

Place:
Date:

Recipient

Legal/Authorised representative
Dr.

Place:
Date:

Investigator
Dr.

Place:
Date:

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ATTACHMENT 1

Description of the MATERIAL

Type of biological matrix requested (es. serum, plasma etc.):

Characteristics of the subjects/patients that would be analysed, based on the study purpose:

Number of requested samples per each biological matrix and volume/quantity (please note that the requested volume will be evaluated by the IRCCS, based on the available quantity in biobank):

Total number of requested Biological samples:

Description of the DATA

Type of needed associated data (please note that the requested data will be evaluated by the IRCCS, based on the availability and the compliance with the current regulations):

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ATTACHMENT 2

Brief description of the research study in which the material will be used

Title:

Principal Investigator:

Hypothesis:

Aims:

Methods:

Rational of the requested sample size.

Duration of the project:

(If applicable) Has the study already been submitted to the competent Ethics Committee? If so, indicate the protocol number.