MATERIAL TRANSFER AGREEMENT FOR HUMAN BIOLOGICAL SAMPLES

This Agreement is made between

[• Host Institution], having its principal offices **[• Host Institution's address]**, duly represented by **[• Name of Biobank's Director]**, **[• Title of Biobank's Director]** (hereinafter "**Provider**")

and

[• Recipient Institute's name] whose registered office is situated at **[• Recipient Institute's address]**, duly represented by **[• Name]**, **[• Title]** (hereinafter "**Recipient**").

Recipient and Provider are hereinafter also individually called "**Party**" and collectively as the "**Parties**".

WHEREAS:

- Fondazione Telethon Network of Genetic Biobanks (hereinafter "**TNGB**") financially supported by Fondazione Telethon (Italy), is an Italian network of biological biobanks which provides human biospecimens (DNAs, cells, tissues, etc…) as a service to the scientific community conducting research on genetic diseases;
- Provider has constituted the **[• Biobank]**, which has no juridical personality and which, as a member of the TNGB, has adhered to the TNGB Charter (http://biobanknetwork.telethon.it/Pages/View/TheCharter);
- Recipient is a **[• To be completed: non-profit organisation, company, etc.]** whose principal object is to research and develop in the field of genetic diseases and specifically in the field of **[• To be completed]**;
- Recipient acknowledges that the mission of TNGB is to encourage scientific collaboration and exchange of data and material in the field of genetic diseases.

IT IS HEREBY AGREED AS FOLLOWS:

Pursuant to Recipient's request **[• ID#]** that certain research material be made available for research and/or testing purposes, Provider agrees to provide to Recipient biological material under the following terms and conditions.

Supply of samples and information

1. This agreement will enter into effect on the date of the last signature by the Parties ("**Effective Date**").
2. The research material covered by this agreement, hereinafter "**Biological Material**", consists of the aliquot(s) of the material identified in the Sample Request Form tangibly transferred by Provider to

Recipient (*Annex A*) and includes unmodified derivatives and functional subunits or products that Recipient obtains by means of the supplied samples.

3. Provider shall provide Recipient with samples (as detailed in the *Annex A*) of the Biological Material, in good condition along with associated information and data developed by Provider as appropriate, provided that the Total Cost, as reported in *Annex A*, if applied, has been paid by Recipient according to Article 18.

4. The responsibility for the Biological Material will pass to Recipient and Principal Investigator (as identified in the Annex A) from the time of delivery of the sample to the Recipient's site. Recipient and Principal Investigator will then be responsible for the use, storage and disposal of the Biological Material in accordance with the terms and conditions provided by this Agreement. Recipient and Principal Investigator agree not to take or send the Biological Material to any other location or to any third party without previous written approval of Provider. In addition, Recipient and Principal Investigator will be responsible for the management of any leftover sample(s); unused aliquot must be destroyed once the project is completed. Alternatively, Principal Investigator has to submit a new request for its/their reuse.

5. The Project shall be carried out under the direct supervision and responsibility of Principal Investigator. Recipient hereby declares that the Project (as defined under following Article 6) was approved by the Ethics Committee **[• Specify the Committee]** on **[• Date of approval]** (if not applicable please add: N.A.).

6. Recipient hereby agrees to use the Biological Material for the sole purpose of conducting the experimental research described in *Annex A*, hereinafter the "**Project**". The Biological Material will be used by Recipient for research purposes only. The Recipient will not manufacture, sell or transfer upon a commercial basis the Biological Material.

7. Recipient shall use the Biological Material in compliance with all applicable laws and government regulations. Under no condition will the Biological Material be used on human subjects.

8. The Biological Material has been collected and processed by Provider in compliance with Italian applicable laws, rules, regulations and other requirements of the applicable governmental authority, including without limitation those applicable to patient informed consent (http://biobanknetwork.telethon.it/Pages/View/Documents). Provider confirms that the patients involved have been informed about potential uses of the results derived from the use by Recipient of the Biological Materials according to the policies in place at the time such Biological Materials have been collected. Provider also confirms that patients have been informed that no potential economic gain or rights deriving from such results will return to them and/or to the Biobank. For the sake of clarity, protection and treatment of confidentiality is governed under European General Data Protection Regulation (GDPR) n.679/2016 and Italian Legislative Decree no. 196/2003 "Personal data protection code" and no. 101/2018 for national implementation of GDPR, and subsequent amendments.

9. Recipient acknowledges and agrees that the legal custodianship of the Biological Material is transferred to the Recipient.

10. Prior to the transfer of the Biological Material to Recipient, Provider will ensure that the samples are coded, so that under no circumstance will Recipient be supplied with the identity of the patient,

or any basic clinical information that in Provider's opinion could identify the patient. Recipient undertakes not to perform any activities aimed at patients' identification.

11. 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 wilful misconduct.

12. Provider makes no representations and extends no warranties of any kind, either expressed or implied with respect to the Biological Material. Provider and its directors, officers, employees, or agents assume no liability and make no representations in connection with the Biological Material or the derivatives or the information or their use by Recipient or its investigators. To the widest extent allowed by the laws under which Recipient is established, Recipient will defend, indemnify and hold harmless Provider, its directors, officers, employees, and agents from any damages, claims, or other liabilities which may arise from or in connection with Recipient's use, handling, storage, or disposition of the Biological Material, derivatives or information. There are no expressed or implied warranties of merchantability or fitness for a particular purpose, or that the use of the Biological Material and related information will not infringe any third parties' patent, copyright, trademark or other rights.

Research results/publication/acknowledgement of contribution

13. Recipient shall keep complete and accurate records of the results of the Project and shall make them available in confidence to Provider in a final report to the extent that such results are relevant to the health of patients, (e.g. incidental findings). Recipient undertakes also to send a copy of any publication reporting the use of the Biological Material, promptly after it is published, to Provider and to Fondazione Telethon at the following e-mail addresses: biobanknetwork@telethon.it and papers@telethon.it.

14. If any modified derivatives of the Biological Material are generated, Recipient shall communicate it to Provider and Provider, if interested, will request Recipient to send an aliquot of such modified derivatives to the Provider. Provider, at its own complete discretion, will decide to include them in the TNGB catalogue and provide such modified derivatives to any third party which so requires.

15. In accordance with scientific customs, the contributions of those who have made the Biological Material available will be reflected expressly in all written or oral public disclosures concerning the Project using the Biological Material, by acknowledgment or co-authorship, as appropriate. The origin of the Biological Material must be included in such disclosures, as follows: "The **[• Biobank]**, member of the Fondazione Telethon Network of Genetic Biobanks (project no. GTB12001), funded by Fondazione Telethon Italy, **[• and of the EuroBioBank network]**, provided us with specimens".

Publicity

16. Neither Recipient nor Provider shall use the logo and/or name of the other Party or any contraction or derivative thereof or the name(s) of the other Party's faculty members, employees, contractors or students, as applicable, in any advertising, promotional, sales literature, or fund-raising documents without prior written consent from the other Party.

Confidentiality

17. Each of Recipient and Provider undertakes to retain in confidence and not disclose to any third party any confidential information received from the other Party. Such information may, however, be disclosed insofar as such disclosure is necessary to allow a Party, or its employees to defend against litigation, to file and prosecute patent applications, or to comply with governmental regulations. Such obligation of confidentiality shall be waived as to information which (i) is in the public domain; (ii) comes into the public domain through no fault of the receiving party; (iii) was known to receiving Party prior to its disclosure by the disclosing Party, as evidenced by written records at the time of disclosure; (iv) is disclosed to the receiving Party by a third party having a lawful right to make such disclosure; (v) is independently developed by the receiving Party without use of confidential information; or (vi) the receiving Party has obtained written permission by disclosing Party. Such obligations of confidentiality shall continue for five (5) years from the completion or termination of the Project. The present Agreement, *Annex A* and the Access Charges shall be considered confidential information.

Access Charge

18. Shipping costs will be charged to Recipient, who is requested to detail in the relevant section of the Sample Request Form (*Annex A*) the name and the account number of the courier to be used for the shipment. Recipient also agrees to contribute to a cost recovery mechanism (if applied by Provider) which is based on the payment of an Access Charge, which differs according to the legal status of the Recipient. The applicable Access Charge due by Recipient to Provider for providing the Biological Material covered by this Agreement is reported in *Annex A*. In addition, VAT (if applicable) will also be charged to Recipient.
    Provider will send the invoice to the Recipient to the following address:
    Attention of: **[• To be completed]**
    [• Address where sending the invoice]
    Payment will be made by bank transfer within **[•]** days from the date of the invoice. Invoice shall mention the Sample Request number **[• ID#]**, as well as the references of the banking account to which the payments must be made.

Term and Termination

19. This agreement will terminate on the earliest of the following dates: (a) on completion of the Recipient's Project with the Biological Material, i.e. **[•]** months from the effective date, or (b) on thirty (30) days written notice by either Party to the other. In the event Provider terminates this Agreement under 19(b) other than for breach of this Agreement or for cause such as an imminent health risk or patent infringement, the Provider will defer the effective date of termination for a period of up to one year, upon request from the Recipient, to permit completion of research in progress.
20. On termination for any reason or upon written request of Provider, Recipient agrees to promptly inform Provider of any unused Biological Material and to destroy it or to submit a new request for it, or, alternatively, return it in accordance with the Provider's directions.

21. The provisions under Articles 11, 12, 13, 14, 15, 16 and 17 shall survive expiration or early termination of this Agreement for any reason whatsoever.

Miscellaneous

22. This Agreement constitutes the complete and exclusive agreement between Provider and Recipient with respect to the subject matter hereof, and supersedes all prior oral or written understandings, communications or agreements not specifically incorporated herein. This Agreement may not be modified. If any provision of this Agreement is held to be unenforceable for any reason, such provision shall be reformed only to the extent necessary to make it enforceable, and such decision shall not affect the enforceability (i) of such provision under other circumstances, or (ii) of the remaining provisions hereof under all circumstances.

Laws and Jurisdiction

23. This agreement shall be interpreted and governed under the Laws of Italy. Any dispute arising from or in connection with this agreement shall be under the exclusive jurisdiction of the Milan Court.

[SIGNATURES ON NEXT PAGE]

In witness whereof, Recipient and Provider have executed this agreement as of the date below.

PROVIDER

By:

Name:

Title:

Date:

RECIPIENT

By:

Name:

Title:

Date:

Read and understood
PRINCIPAL INVESTIGATOR

By:

Name:

Title:

Date:

Documents attached:
Annex A: Ordering Form

Recipient expressly accepts the clauses set out under Articles 11, 12, 14, 19 and 23.

RECIPIENT

By:

Name:

Title:

Date:

ANNEX A: ORDERING FORM
REQUEST ID #

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

Name of the Biobank Director and of the Institution

Address	Biobank Address		
Fax	Biobank fax number	**e-mail**	Biobank e-mail address

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			

SAMPLE(S) AND SERVICE(S) DETAILS

Sample(s) Code	Sample(s) Type	Service Code to be filled in by the Biobank	Total Cost to be filled in by the Biobank

The Principal Investigator agrees to the following conditions:

- Not to use samples for commercial purposes;
- Not to perform activities aimed at patient's identification;
- Not to distribute Samples to other investigators without written permission of the Biobank;
- Either to destroy any leftover sample(s) once the project is completed or to submit a new request for its (their) reuse;
- To make results of the Project available in confidence to Provider in a final report to the extent that such results are relevant to the health of the patients, (e.g. incidental findings);
- In the case of publication of the results obtained using the samples, to include in the acknowledgements, the following: "The **[• Biobank]**, member of the Fondazione Telethon Network of Genetic Biobanks (project no. GTB12001), funded by Fondazione Telethon Italy, **[• and of the EuroBioBank network]**, provided us with specimens";
- To send a paper reprint to the Biobank;
- To pay for shipping and service charges.

Place, Date **Signature of Investigator**