Istituto Superiore di Sanità

MATERIAL TRANSFER AGREEMENT (MTA)

to non-profit recipients

Provider (The organisation providing the Original Material)	**Recipient** (The organisation receiving the Original Material)
Istituto Superiore di Sanità Viale Regina Elena, 299 00161 Rome, Italy	Name: Address:

Provider Scientist	**Recipient Scientist**
Name:Eleonora Aricò Position: Researcher Centre/Department: FaBioCell, Core Facilities	Name: Position: Centre/Department:

Original Material (Enter description of original material being transferred and amount requested)
…….

Purpose(s) of use of Original Material, hereinafter referred to as the "Studies", and duration
(Enter description of the study/studies to be conducted with the original material)
…….

Representations and undertakings of the RECIPIENT:

The RECIPIENT represents as follows and acknowledges that if PROVIDER agrees to supply the MATERIAL to the RECIPIENT, such representations shall become terms of the contract with the PROVIDER.

I. Definitions:

1. PROVIDER:
   Organisation providing the ORIGINAL MATERIAL. The name and address of this party is specified on the first page of the MTA.

2. PROVIDER SCIENTIST:
   The name and address of this party is specified on the first page of the MTA.

3. RECIPIENT:
   Organisation receiving the ORIGINAL MATERIAL. The name and address of this party is specified on the first page of the MTA.

4. RECIPIENT SCIENTIST:
   The name and address of this party is specified on the first page of the MTA.

5. ORIGINAL MATERIAL:
   The description of the material being transferred is specified on the first page of the MTA.

6. MATERIAL:
   ORIGINAL MATERIAL, PROGENY and UNMODIFIED DERIVATIVES. The MATERIAL shall not include: (a) MODIFICATIONS, or (b) other substances created by the RECIPIENT through the use of the MATERIAL which are not MODIFICATIONS, PROGENY, or UNMODIFIED DERIVATIVES.

7. PROGENY:
   Pure-bred descendants from the MATERIAL

8. UNMODIFIED DERIVATIVES:
   Substances created by the RECIPIENT which constitute an unmodified functional subunit or product expressed by the ORIGINAL MATERIAL. Examples include: cloned/subcloned Original MATERIAL, purified or fractionated subsets of the ORIGINAL MATERIAL, and proteins expressed from DNA/RNA supplied by the PROVIDER.

9. MODIFICATIONS:
   Substances created by the RECIPIENT which contain/incorporate the MATERIAL and which are not PROGENY or UNMODIFIED DERIVATIVES.

10. FOREGROUND:
    The tangible and intangible results which are generated within this agreement, including pieces of information, materials and knowledge.

11. BACKGROUND:
    Any data, know-how or information on MATERIAL whatever its form or nature, tangible or intangible held by the PROVIDER prior to the execution of this MTA.

12. COMMERCIAL PURPOSES:
    The sale, lease, license, or other transfer of the MATERIAL or MODIFICATIONS to a for-profit organisation. COMMERCIAL PURPOSES shall also include uses of the MATERIAL or MODIFICATIONS by any organisation, including RECIPIENT, to perform contract research, to screen compound libraries, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license, or transfer of the MATERIAL or

MODIFICATIONS to a for-profit organisation. However, industrially sponsored academic research shall not be considered a use of the MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSES per se, unless any of the above conditions of this definition are met.

13. NONPROFIT ORGANISATION(S):
    A university or other institution of higher education or an organisation exempt from taxation or any non-profit scientific or educational organisation qualified under a state nonprofit organisation statute. As used herein, the term also includes national, state, or local government agencies.

14. AFFILIATES:
    Any corporation or business entity controlled by, controlling or under common control with PROVIDER, control being the ownership of greater than 50% of the voting shares or interest of such corporation or business entity, or such other relationship as, in fact, constitutes actual control.

II. Terms and conditions of this Agreement:

1. Material ownership

1.1. The PROVIDER retains ownership of the MATERIAL, including any MATERIAL contained or incorporated in MODIFICATIONS.

1.2. The RECIPIENT retains ownership of:

(a) MODIFICATIONS (except that, the PROVIDER retains ownership rights to the MATERIAL included therein), and

(b) those substances created through the use of the MATERIAL or MODIFICATIONS, but which are not PROGENY, UNMODIFIED DERIVATIVES or MODIFICATIONS (i.e., do not contain the ORIGINAL MATERIAL, PROGENY, UNMODIFIED DERIVATIVES). If either 2(a) or 2(b) results from the collaborative effort, joint ownership may be negotiated.

2. Use of Material

2.1. The MATERIAL will be used in compliance with all applicable statutes and regulations, including guidelines and in accordance with ethical principles.

2.2. The MATERIAL is to be used solely for teaching and academic research purposes, and in particular for [fill in and specify: if investigations are in vitro or in laboratory animals in vivo, under which containment conditions…]

2.3. The MATERIAL will not be used, analyzed or modified other than necessary for the purpose of the Studies.

2.4. The MATERIAL will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects without the written consent of the PROVIDER;

2.5. The RECIPIENT shall not use the MATERIAL and any substance that is replicated or derived there from for any commercial or profit-generating purpose, or in the conduct of research that is subject to consulting, licensing or other similar legal or commercial obligations to another institution, corporation or business entity, unless PROVIDER provides its prior written consent.

2.6. The RECIPIENT has adequate training and facilities to study the MATERIAL and will directly supervise the Studies.

3. Transfer of Material

3.1. The RECIPIENT and the RECIPIENT SCIENTIST agree to refer to the PROVIDER any request for the MATERIAL from anyone other than those persons working under the RECIPIENT SCIENTIST's direct supervision.

3.2. The MATERIAL will not be transferred or made available to any individual not under the supervision and control of the Investigator without the prior consent in writing of the PROVIDER.

3.3. The RECIPIENT and/or the RECIPIENT SCIENTIST shall have the right, without restriction, to distribute substances created by the RECIPIENT through the use of the ORIGINAL MATERIAL only if those substances are not PROGENY, UNMODIFIED DERIVATIVES, or MODIFICATIONS.

3.4. To the extent supplies are available, the PROVIDER agrees to make the MATERIAL available, under a separate implementing letter to this Agreement or other agreement having terms consistent with the terms of this Agreement, to other scientists (at least those at NONPROFIT ORGANIZATION(S) who wish to replicate the RECIPIENT SCIENTIST's research; provided that such other scientists reimburse the PROVIDER for any costs relating to the preparation and distribution of the MATERIAL.

4. Results

4.1. All data obtained in the course of the Studies with the MATERIAL will be submitted to PROVIDER.

4.2. The RECIPIENT grants to PROVIDER and its AFFILIATES full access to any primary data relating to MATERIAL.

4.3. The data need only be accompanied by a further report to the extent necessary for their comprehension. Such a report shall be provided upon request of PROVIDER.

4.4. The RECIPIENT further grants the PROVIDER a perpetual and royalty-free license to use all data for commercial and non-commercial purposes.

5. Foreground and Background

5.1. Foreground:

5.1.1. The RECIPIENT shall immediately notify the PROVIDER of any Foreground made to the MATERIAL, including related technology.

5.1.2. Foreground not covered by section 5.1.3 of this Article 5 shall, whether patentable or not, be jointly owned by the Parties. The Parties shall jointly decide whether or not to pursue patent protection of such Foreground. Both Parties shall have the right to commercially Use any patentable and non-patentable Foreground covered by the section 5.1.3 without the prior written consent of the other Party.

5.1.3. Any Foreground that solely involves the use of the MATERIAL shall belong exclusively to the PROVIDER. The Parties therefore agree, that

5.1.3.1. all rights, interests and title to such Foreground shall belong exclusively to

the PROVIDER;

5.1.3.2. the RECIPIENT hereby assigns all of its actual and potential rights, interests and title to such Foreground to the PROVIDER;

5.1.3.3. the RECIPIENT shall, when any such Foreground occurs, execute all documents necessary to effect such assignment. The PROVIDER shall be fully responsible for all costs of obtaining subsequent patent protection.

5.2. Background:

This Article 5 does not in any way imply or grant a license or any other right or interest from PROVIDER to RECIPIENT to any of PROVIDER's Background, Material, intellectual property rights and/or Confidential Information existing prior to the effective date of execution of this MTA and/or developed independently hereof, and/or solely owned improvements.

6. Confidentiality

6.1. All unpublished information provided by PROVIDER with respect to the MATERIAL and/or concerning the PROVIDER or its AFFILIATES and/or all data, results and information resulting from the Studies ("Information") will be held strictly confidential and will not be used for any purpose other than for the Studies.

6.2. Information will not be disclosed to any third party, unless it needs to be disclosed by law or court order. In the latter case the PROVIDER will be informed prior to disclosure by the RECIPIENT in order to may seek a protective order or other remedy.

6.3. In the event publication is necessitated by law or court order, the RECIPIENT shall disclose only that portion of the Information that, in the opinion of its legal counsel, is legally required to be disclosed and will exercise reasonable efforts to ensure that any Information so disclosed will be accorded confidential treatment by the court or administrative agency through protective orders, filings under seal and other appropriate means.

6.4. However, Information shall not include any information of which can be shown by written evidence that:

6.4.1. at the time of first disclosure was already in the possession of the RECIPIENT or;

6.4.2. was in the public domain at the time of disclosure or;

6.4.3. has been received from a third party which did not acquire it directly or indirectly from the PROVIDER or any of its AFFILIATES.

7. Publications

This agreement shall not be interpreted to prevent or delay publication of research findings resulting from the use of the MATERIAL or the MODIFICATIONS. The RECIPIENT SCIENTIST agrees to provide appropriate acknowledgement of the source of the MATERIAL in all publications.

8. Liability

8.1. The Studies will be conducted under the RECIPIENT's exclusive responsibility and the PROVIDER will not be liable for any consequences thereof.

8.2. The MATERIAL has to be used and handled with caution and prudence in any experimental

work, since not all characteristics of the MATERIAL are necessarily known.

8.3. Except to the extent prohibited by law, the RECIPIENT assumes all liability for damages which may arise from its use, storage or disposal of the MATERIAL. 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 MATERIAL by the RECIPIENT, except to the extent permitted by law when caused by the gross negligence or wilful misconduct of the PROVIDER.

8.4. The RECIPIENT will indemnify, hold harmless and defend the PROVIDER, its AFFILIATES and their respective officers, directors, employees and agents against any and all claims, actions, demands, suits or causes of action for damages arising out of or relating to the RECPIENT's use, application, storage, destruction or disposal of the MATERIAL.

9. Warranty

9.1. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties.

9.2. The MATERIAL is being transferred to the RECIPIENT with no warranties, express or implied, of merchantability or fitness for a particular purpose or otherwise.

9.3. The PROVIDER makes no representations and extends no warranties concerning the fact that the use of the MATERIAL will not infringe or violate any patent or proprietary rights of third parties.

10. Termination of the Agreement

This Agreement will terminate on the earliest of the following dates: (a) on completion of the RECIPIENT's current research (referred to in page 1 of this agreement and in article 2.2 above) with the MATERIAL, or (b) on thirty (30) days written notice by either party to the other provided that:

(i) if termination should occur under 10(a) above, the RECIPIENT should inform the PROVIDER of the completion of the Studies and any unused MATERIAL thereof will, at the sole discretion of PROVIDER, either be returned to PROVIDER or disposed of under the RECIPIENT's supervision in accordance with the applicable laws and regulations, and the instructions of the PROVIDER, if any.

and

(ii) in the event the PROVIDER terminates this Agreement under 13(b) above 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. Upon the effective date of termination, or if requested, the deferred effective date of termination, any unused MATERIAL and derivatives thereof will, at the sole discretion of PROVIDER, either be returned to PROVIDER or disposed of under the RECIPIENT's supervision in accordance with the applicable laws and regulations, and the instructions of the PROVIDER, if any.

Paragraphs 2.5, 8 and 9 shall survive termination.

11. Applicable Law

Any and all disputes between the Parties concerning the existence, validity, interpretation, performance and termination of this Agreement shall be settled according to Italian Governing Law and Jurisdiction.

Agreement by Investigator:

_____
(Name)

_____
(Date)

Agreement by Applicant:

_____
(Authorized signatory of employing company or institution)

_____
(Date)

_____
(Name)

_____
(Title)

Acceptance by Provider

_____
Prof. Silvio Brusaferro
President

_____
(Date)

_____
Researcher Eleonora Aricò
Core Facilities Technical-Scientific Service

to acknowledgment

_____
Dr. Marco Crescenzi
Head of Core Facilities Technical-Scientific Service

_____
(Date)