Collaboration and Material Transfer Agreement for the project "ALS human muscle RNA"

DECRETO DEL DIRETTORE GENERALE - N. 4215 del 22/10/2026 - Allegato Utente 1 (A01)

between

Universitair Medisch Centrum Utrecht (UMC Utrecht) Universitair Medisch Centrum Utrecht, a legal person under public law, stablished at Heidelberglaan 100, 3584 CX Utrecht, The Netherlands ("UMC Utrecht"), for the purposes of this Agreement legally represented by prof. dr. J.J. van Os, Medical Scientific Manager and drs. A. Rietveld, Division Manager, and with VAT number NL004205315B01, (hereinafter referred as the "**Company**")
hereinafter referred to also **"Company"** or "**Recipient".**

and

Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, with its registered offices in via Francesco Sforza, 28 - 20122 Milan, Italy, VAT number and tax code 04724150968, in the person of the Chief Scientific Officer, (hereinafter referred to also as '**Policlinico'** or **Provider.**

hereinafter also referred individually as '**Party**' and jointly as '**Parties**'.

Whereas**:**

- **UMC Utrecht The University Medical Center Utrecht (UMC Utrecht) is** one of the largest public healthcare and academic institutions in the Netherlands and focuses on its multidisciplinary research and clinical expertise on six strategic programs, including brain research. The UMC Utrecht's mission is committed to accessibility, innovation, and sustainability and places patient autonomy and collaborative healthcare at
- the heart of its operations.
- **Policlinico is** a public research hospital strongly committed, according to standards of excellence, in scientific, clinical and translational research, in the biomedical field as well as in the patient's health care;
- **Policlinico is** a member of The *Telethon Network of Genetic Biobanks* (TNGB) that stores more than 120,000 human biological samples representing approximately 1,000 distinct rare genetic diseases;
- given their respective missions and research plans, the **Parties** view the pursuit of collaborative research activities as a common interest and have therefore agreed to proceed with signing this collaboration and Material transfer agreement (the "Agreement") to conduct the research project entitled **"ALS human muscle RNA".** For the sake of clarity,

nothing in this Agreement shall prevent either Party from implementing at any time other collaborations with third parties whether private or public.

All that stated and considered, which forms an integral and essential part of this Agreement, **Company and Policlinico** agree as follows.

Art. 1 – Definitions

1.1. Description of Samples. '**Samples**' consist in six RNA samples: 3 RNAs from ALS patients and 3 RNAs from control patients, that have been collected by **Policlinico** in the its **Bank of muscle tissue, peripheral nerve, DNA and cell culture**;
1.2. Description of the Research activities. '**Research activities**' are the activities put in place by the **Parties** to carry out the Project as described in art. 3.
1.3. Description of Data. '**Data**' include "common" personal data (*i.e.*, personal data other than those encompassed within the special categories as per art. 9 of the GDPR), data concerning health such as anamnestic, clinical, laboratory information collected by **Policlinico** and related to the Samples.
1.4. Definition of Personal Data, Data Concerning Health and Genetic Data. '**Personal data**' means any information relating to an identified or identifiable natural person ('Data Subject') who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person; "**Data Concerning Health**" means Personal Data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status.
1.5. Foreground. '**Foreground**' or '**Results**' means the output of the activities established in the present Agreement, including investigation, research and computational analysis following the processing and analysis of the Samples, information, materials and knowledge, whether or not jointly generated.
1.6. Background. '**Background**' means the pre-existing material and intellectual property that each of the Parties shall make available to the other as necessary to perform the activities under this Agreement.
1.7 Sideground. "**Sideground**" means and data, information, know-how, results and intellectual property that each Party may generate, conceive, after the signing of the collaboration agreement, but outside of the Study, even in the same research field, and without the Background or the Confidential Information of the other Party.
1.8. Confidential Information. '**Confidential Information**' means all the information of any kind that is not public or publicly available, referring to the activities of the **Parties**, both written and verbal, which has been identified as confidential upon disclosure from one **Party** to the other within the framework of this Agreement, provided that such information:

- is not publicly known or available from other sources who are not under a confidentiality obligation to the source of information;
- has not been made available by its owners to others without a confidentiality obligation;
- is not independently developed by the receiving **Party**.

Any **Background** subject to general data protection regulation and intellectual property rigSponsors pertaining to a **Party** shall be considered **Confidential Information**. The same shall apply to the **Foreground** where the owners have agreed on applying for a patent or if it is pending the period to evaluate such application.

Art. 2 – Scope of the Agreement

2.1 This Agreement provides for the general terms and conditions for the Research activities between the Parties, for the realisation of which the Parties encourage and rely on their synergistic collaboration based on the exchange of complementary know-how and resources, as detailed in the Agreement itself and its annexes. The scope of the Agreement is to regulate the transfer of the Samples.

The Results of the Project will be published in aggregate and statistical forms, in ways that do not infringe obligations of confidentiality nor personal data protection provisions.

Art. 3 – Description of the Research activities and responsibilities of the Parties

3.1. Policlinico, which shall act as Autonomous controller of Personal Data according to Article 7.3 below, shall be responsible for the following activities:

(i) collection and appropriate processing of Samples;

(iii) supplying to the Recipient Samples as well as Data in pseudonymised form, for the purpose of the Research activities under this Agreement;

3.2. The Recipient will conduct the research described below:

Confirming RNA sequencing hits from IPSC-derived 3D skeletal muscle in RNA from human muscle biopsies.

Art. 4 – Background, Sideground, Foreground and publications

4.1. The Parties agree that any Background information shall remain the exclusive and absolute property of the Party owning the Background. Each Party undertakes to grant non-exclusive time-limited licences to their Background to the other Party to the extent necessary and solely for the purpose of carrying out the activities under this Agreement. The Sideground shall remain the exclusive and absolute property of the Party that have generated it. If the use of Sideground it is necessary to carried out the collaboration, each party may ask to the other the access to the Sideground. The terms and conditions of the access will be the same as those established for the Background.

4.2. All intellectual property rights on the Foreground belong to the Parties in an equal percentage of ownership that will manage their respective rights in good faith through separate agreements on

the basis of the general principles stated in art. 6; authorship is attributable to researchers from both Parties (as well as from their eventual collaborating partner institution(s) which contributed to the research activities, if any) who participated in the research in accordance with widely accepted international authorship criteria and guidelines, such as the recommendations of the International Committee of Medical Journal editors (http://www.icmje.org).

4.3. To this end, all publications made by researchers of both Parties involved in the Research activities must report all institutional affiliations, using the standard nomenclature adopted by the Parties.

4.4. The Parties shall agree on the procedures for the approval of publications and their relevant timing. No Party shall have the rights to publish or publicly disclose the Results or information acquired while performing the Research activities or subsequently without the written consent of the other Party. The Parties agree on the timing of the publication case by case in order to ensure that the publication - or parts of it - will not compromise the novelty of any invention resulting from the Research activities before the patent application relating to the invention is duly filed. No publication may contain any Confidential Information or other, which could prevent the patentability of any invention.

The Recipient shall send all pre-publication documents for review to Policlinico at least fifteen (15) days before the agreed submission date of the manuscript. Policlinico shall give feedback within fifteen 15) days of receipt of these documents. In the absence of feedback from Policlinico, the Recipient shall assume that the Policlinico has no objection to the proposed publication.

Art. 6 – Management of Intellectual Property

6.1 The Recipient shall inform the other Party in case the Foreground - or parts of it - is patentable/copyrightable. Within 30 days from the communication of said patentable/copyrightable Foreground, the Parties shall mutually declare their intent to file a patent/ copyrightable and shall agree case by case on the form of protection of the invention/work. If all Parties are interested in protecting the patentable/ copyrightable Foreground, the Parties shall file a joint patent/ copyrightable application. The Parties shall stipulate specific agreements to manage joint ownership, to the extent necessary. The inventors/authors are entitled to moral rights, which are not alienable.

Art. 7 – Confidentiality and protection of Personal Data

7.1 The Parties agree that they will preserve the confidentiality of the Confidential Information and undertake to adopt all necessary measures to maintain the utmost secrecy and privacy of the abovementioned information and to prevent unauthorised use, undue internal or external disclosure.

Parties shall maintain the property of their own Confidential Information which they might exchange during the course of the programs of activity. The confidentiality provisions will remain in

force for the whole duration of the Agreement, and they will end after five years from the termination of said Agreement.

7.2 The Parties undertake to process the personal data, which will be disclosed in the context of this Agreement, for the purposes foreseen within this Agreement, the Privacy Policy, as well as for the fulfilment of the relating legal obligations, in full compliance with the applicable law on the protection of personal data,

7.3 With reference to the processing activities of data related to the Samples, the Parties shall both comply with their respective obligations set out in the Study Protocol and applicable law.

Among the other obligations set out in the abovementioned documents,

a. Policlinico shall:

- pseudonymize the Samples and Data collected, removing all the identifying information which could disclose the identity of the Data Subject and assign them an ID Code (alphanumeric code, without data subjects' identifiers or parts of the latter) and a barcode, before transferring them to the Recipient;
- store the re-identification keys in a separate archive, which shall be accessible only to authorized subjects, and adopt or implement the appropriate safeguard measures;
- should it become necessary on the basis of what is set forth in the relevant information notice on data processing or in the case of a request from the Recipient, proceed to re-contact the Data Subjects, without disclosing their identity to the Recipient;
- should it become necessary or appropriate for the Recipient to proceed with the identification of a Data Subject, according to the abovementioned information notice on data processing, support and cooperate with the Recipient;

b. the Recipient shall:

- process the Data and Samples received from Policlinico only for the scientific research purposes described in Project and in the abovementioned information notice on data processing;
- notify Policlinico whenever a possible Data Subjects submits a request under the provisions of GDPR directly to the Recpient or it is necessary to disclose the identity of one of the Data Subjects in order to answer to a Supervising Authorithy's request;
- not make attempts to re-identify or contact the Data Subject.

7.4 The Samples and the Personal Data provided by Policlinico to the Recipient will be subjected to pseudonymisation and shall only be identified by a barcode, and in no case, it will be possible for the Recipient to have access to the identifying information of the Subjects. The Recipient will process such Data and Samples only for scientific research purpose and in no case, it will proceed to reversal of pseudonymisation (reidentification).

Art. 8 - Access Charge

8.1 The shipment of the samples shall be arranged and paid for by the recipient through the Central Diagnostic Laboratory (CDL), which is responsible for coordinating the collection and international shipment of biological materials.

Art. 9 – Liability

9.1 Recipient acknowledges and agrees that the legal custodianship of the Sample is transferred to the Recipient.
9.2 Recipient understands that the Samples delivered hereby is experimental in nature and should be used with prudence and appropriate caution since not all of its characteristics are known.
9.3 Recipient assumes all liability for damages, which may arise from the use, storage, handling or disposal of the Samples or its derivatives, except to the extent caused by Provider's gross negligence or wilful misconduct.
9.4 Provider makes no representations and extends no warranties of any kind, either expressed or implied with respect to the Samples. Provider and its directors, officers, employees, or agents assume no liability and make no representations in connection with the Samples or the derivatives or the information or their use by Recipient or its investigators.
9.5 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 Samples, derivatives or information. There are no expressed or implied warranties of merchantability or fitness for a particular purpose, or that the use of the Samples and related information will not infringe any third parties' patent, copyright, trademark or other rights.

Art. 10 – Term and termination

10.1 Term. This Agreement will remain in effect for the entire duration of the Project estimated in 5 years unless terminated sooner or extended in writing through a specific agreement, duly signed by the Parties.
The Parties hereby agree to meet two months prior to the expiry date of the present Agreement to negotiate in good faith its extension and/or amendments of any of the clauses contained therein.
10.2 Termination. Each Party reserves the right to terminate this Agreement in the event of breach by the other Party of any of the obligations under this Agreement, by registered letter with return receipt of which the other Party must be notified with advance notice of 30 (thirty) days, unless the Party in breach resolves its non-compliance status during that notice period.
10.3 Survival. The provisions of Articles 6 (Management of Intellectual Property) and 7 (Confidentiality and Protection of Personal Data) will survive any expiration or termination of this Agreement.

Art. 11 – Governing law and Jurisdiction

11.1 Any dispute arising between the Parties under the Agreement shall be resolved amicably.

In case the Parties do not achieve an agreement after this attempt of amicable settlement, the Court of Milan shall have exclusive jurisdiction to deal with any dispute that may arise out of or in connection with this Agreement.

Art. 12 – Administrative communications

12.1 Any request and communication concerning the provisions of this Agreement shall be addressed to the following addresses:

- if to **UMC Utrecht Nederland**: Domino Schlegel
  Email: d.k.schlegel@umcutrecht.nl

- if to **Policlinico**: Direzione Scientifica
  Email: direzionescinetifica@policlinico.mi.it

Art. 13– Miscellaneous

13.1 This Agreement shall be registered only in the event of use. All expenses relating to its potential registration will be exclusively borne by the Party requesting registration.

Art. 14– Annexes

14.1 The following documents shall be deemed as attached to and an integral and substantial part of the present Agreement:

Annex 1 - Conditions for transfer of Samples
In witness whereof, both Parties this Agreement shall be digitally signed by both Parties.

Netherlands,		Milan,
UMC Utrecht	**UMC Utrecht**	**Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico**
Division Manager drs. A. Rietveld	**Medical Scientific Manager** prof. dr. J.J. van Os	Chief Scientific Officer Prof. Fabio Blandini
ValidSigned door Arnoud Rietveld op 29-09-2026 _____	ValidSigned door Jim van Os op 29-09-2026 _____	_____

Annex 1 – Conditions for transfer of Samples

1. SUBJECT MATTER

1.1 Supply of Samples. Policlinico undertakes to transfer to the Recipient the possession of the Samples in pseudonymised form.
1.2 Permitted use. Samples shall be used for the purpose of conducting the Research activities.
2. USE OF THE SAMPLES
2.1 Research. The Recipient must use the Samples for the purpose of carrying out the research activities of the PROJECT.
2.2 Tracking. The Recipient shall track the use of the Samples in order to be able, at any time, to provide detailed information to Policlinico about their location and current use, upon Policlinico's request.
2.3 Laboratories. The Recipient must keep the Samples in its laboratories adopting all the necessary measures to avoid their loss or access by unauthorized third parties.
2.4 Prohibition of use on human subjects. The Recipient shall not use the Samples on human subjects, in clinical trials involving human subjects or for diagnosis purposes involving human subjects, without prior written consent of Policlinico.
2.6 The Recipient personnel. Employees, collaborators and students, who work under the responsibility of the Recipient are authorized to use the Samples, but the Recipient states and warrants that they will be bound by the same obligations of the Recipient regarding the use of the Samples and undertakes to be responsible in case of any violation.
2.7 Prohibition to commercialize. The Recipient shall not commercialize the Samples.