Consortium Agreement



**TREM2MEDS**

Version [2] – [18.07.2024]

(Based on DESCA – Model Consortium Agreement for Horizon Europe, version 1.1, November 2022)

Table of Contents

[1 Definitions 4](#_Toc119507112)

[2 Purpose 5](#_Toc119507113)

[3 Entry into force, duration and termination 5](#_Toc119507114)

4 - Transfer of Material

[5 Responsibilities of Parties 6](#_Toc119507115)

[6 Liability towards each other 7](#_Toc119507116)

[7 Governance structure 8](#_Toc119507117)

[8 Financial provisions 14](#_Toc119507118)

[9 Results 17](#_Toc119507119)

[10 Access Rights 19](#_Toc119507120)

[11 Non-disclosure of information 22](#_Toc119507121)

[12 Miscellaneous 24](#_Toc119507122)

[13 Signatures 26](#_Toc119507123)

[Attachment 1: Background included 31](#_Toc119507124)

[Attachment 2: Accession document 35](#_Toc119507125)

[Attachment 3: List of third parties for simplified transfer according to Section 8.3.2. 36](#_Toc119507126)

[Attachment 4: Identified entities under the same control according to Section 9.5 37](#_Toc119507127)

[Attachment 5: NDA for Clinical Advisory Board agreed under Section 6 38](#_Toc119507128)

Attachment 6 : Material Transfer Agreement

**CONSORTIUM AGREEMENT**

THIS CONSORTIUM AGREEMENT is based upon Regulation (EU) No 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation (2021-2027), laying down its rules for participation and dissemination (hereinafter referred to as “Horizon Europe Regulation”), and on the European Commission’s General Model Grant Agreement and its Annexes, and is made on 01.04.2024, hereinafter referred to as the Effective Date

**BETWEEN:**

**UNIVERSITÀ DEGLI STUDI DI PADOVA (UNIPD)**, established at Via VIII Febbraio 2, 35122, Padua, Italy, the Coordinator

**USTAV MOLEKULARNI GENETIKY AKADEMIE VED CESKE REPUBLIKY VEREJNA VYZKUMNA INSTITUCE (IMG)**, established at Videnska 1083, 142 20, Praha 4, Czechia

**INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM)**, established at Rue de Tolbiac 101, 75654, Paris, France

hereinafter, jointly or individually, referred to as ”Beneficiaries” or ”Beneficiary”

**UNISMART – FONDAZIONE UNIVERSITÀ DEGLI STUDI DI PADOVA (UNISMART)**, established at Via VIII Febbraio 2, 35122, Padua, Italy

hereinafter referred to as Affiliated Entity,

hereinafter Beneficiaries and Affiliated Entity, jointly or individually, referred to as “Parties” or ”Party”relating to the Action entitled

**Towards the clinical implementation of TREM2 Microglia Engineering for treating DementiaS**

in short

**TREM2MEDS**

hereinafter referred to as “Project”

**WHEREAS:**

The Parties, having considerable experience in the field concerned, have submitted a proposal for the Project to the Granting Authority as part of Horizon Europe – the Framework Programme for Research and Innovation (2021-2027).

The Parties wish to specify or supplement binding commitments among themselves in addition to the provisions of the specific Grant Agreement to be signed by the Parties and the Granting Authority (hereinafter “Grant Agreement”).

The Parties are aware that this Consortium Agreement is based upon the [DESCA model consortium agreement](http://www.desca-agreement.eu).

NOW, THEREFORE, IT IS HEREBY AGREED AS FOLLOWS:

# Definitions

## Definitions

Words beginning with a capital letter shall have the meaning defined either herein or in the Horizon Europe Regulation or in the Grant Agreement including its Annexes.

## Additional Definitions

**“Consortium Body”**

Consortium Body means any management body described in Section 6 (Governance Structure) of this Consortium Agreement.

**“Consortium Plan”**

Consortium Plan means the description of the Action and the related agreed budget as first defined in the Grant Agreement and which may be updated by the General Assembly.

**“Granting Authority”**

means the body awarding the grant for the Project.

**“Defaulting Party”**

Defaulting Party means a Party which the General Assembly has declared to be in breach of this Consortium Agreement and/or the Grant Agreement as specified in Section 5.2 of this Consortium Agreement.

**“Affiliated Entity”**

Affiliated Entity means entities directly involved in the Action which are listed in Article 8 of the Grant Agreement and which have a legal or capital link to a Beneficiary (which is neither limited to the Action nor established for the solo purpose of its implementation), which implement part of the Action and which are allowed to charge costs directly to the EC. For the purpose of this Agreement, Unismart – Fondazione Università degli Studi di Padova has been identified as Affiliated Entity.

**“Needed”**

means:

*For the implementation of the Project:*

Access Rights are Needed if, without the grant of such Access Rights, carrying out the tasks assigned to the recipient Party would be technically or legally impossible, significantly delayed, or require significant additional financial or human resources.

*For Exploitation of own Results:*

Access Rights are Needed if, without the grant of such Access Rights, the Exploitation of own Results would be technically or legally impossible.

**“Biological Material”**

Biological Material means any Material collected on human or non-human subjects used in accordance with the scientific project. Biological Material remains under the sole control, management and responsibility of the Party providing the Biological Material.

# Purpose

The purpose of this Consortium Agreement is to specify with respect to the Project the relationship among the Parties, in particular concerning the organisation of the work between the Parties, the management of the Project and the rights and obligations of the Parties concerning inter alia liability, Access Rights and dispute resolution.

# Entry into force, duration and termination

## Entry into force

An entity becomes a Party to this Consortium Agreement upon signature of this Consortium Agreement by a duly authorised representative.

This Consortium Agreement shall have effect from the Effective Date identified at the beginning of this Consortium Agreement.

An entity becomes a new Party to the Consortium Agreement upon signature of the accession document (Attachment 2) by the new Party and the Coordinator. Such accession shall have effect from the date identified in the accession document.

## Duration and termination

This Consortium Agreement shall continue in full force and effect until complete fulfilment of all obligations undertaken by the Parties under the Grant Agreement and under this Consortium Agreement.

However, this Consortium Agreement or the participation of one or more Parties to it may be terminated in accordance with the terms of this Consortium Agreement.

If

* the Grant Agreement is not signed by the Granting Authority or a Beneficiary, or
* the Grant Agreement is terminated, or
* a Beneficiary's participation in the Grant Agreement is terminated,

this Consortium Agreement shall automatically terminate in respect of the affected Party/ies, subject to the provisions surviving the expiration or termination under Section 3.3 of this Consortium Agreement.

## Survival of rights and obligations

The provisions relating to Access Rights, Dissemination and confidentiality, for the time period mentioned therein, as well as for liability, applicable law and settlement of disputes shall survive the expiration or termination of this Consortium Agreement.

Termination shall not affect any rights or obligations of a Party leaving the Project incurred prior to the date of termination, unless otherwise agreed between the General Assembly and the leaving Party. This includes the obligation to provide all necessary input, deliverables and documents for the period of its participation.

## 4 - Transfer of Material

When a Party (the “Provider”) sends Biological Material to another Party (the “Recipient”) in respect of the Project, a bilateral material transfer agreement (MTA) shall be concluded between such Parties, a template of which is included in Attachment 6, to specify the conditions applying to the transfer of such material.

Each Party shall ensure that the terms of such MTA shall be completed correctly, adapted to the relevant situation and that it complies with this Consortium Agreement and all applicable rules, laws or regulations.

Any Party which is aware of, or becomes aware of, a health safety risk, which originates from any of the Biological Material and/or Materials transferred, shall inform the other Parties without delay and provide them with all the information in its possession or at its disposal concerning risks of this kind.

The Recipient agree that the Material:

1. Unless otherwise agreed, is to be used solely for the purpose of executing the Recipient’s work plan and only for as long as it is necessary for this purpose, to the exclusion of any other application, in particular for commercial purposes.
2. no express or implied licenses or other rights are provided to the Recipient under any patents, patent applications, trade secrets or other proprietary rights of the Provider, other than the right to use the Material and/or Data for conducting the Project;
3. will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects;
4. is to be used only at the Recipient organization and only in the Recipient Scientist's laboratory under the direction of the Recipient Scientist or others working under his/her direct supervision;
5. will not be disclosed, distributed, transferred or licensed to anyone else without prior written authorization from the Provider and in accordance with the authorization necessary for the transfer. In any case, the Material shall not be transferred to another Party or to a subcontractor or to any third party before any identifiable information has been removed by coding or by rendering it anonymous in accordance with all applicable laws and regulations;
6. will be used and stored in accordance with the applicable legal and regulatory provisions, notably the provisions relating to the protection of the personal Data and to medical secrecy. In particular, the Recipient ensures that it has obtained any necessary authorizations and/or opinions and taken appropriate measures for the storage and use of the concerned Material.
7. Will be returned to the Provider, or destroyed at the discretion of the Provider, in the event of the withdrawal of the consent or the exercise of the opposition right of the person which would be communicated by the Provider to the Recipient;
8. Unless otherwise agreed, will no longer be used and will be returned to the Provider (or destroyed, at the Provider’s discretion) upon request and/or in the event of the termination of this Consortium Agreement and/or upon the expiry thereof and without any copy being made thereof; and
9. Will be used and stored exclusively on the premises of the Recipient within the performance of the Project and by scientists working on the premises of the Recipient or under its direct responsibility and with the same degree of security that it applies to its own Material.

Any Material delivered pursuant to this Agreement is supplied “as is” and is understood to be experimental in nature and may have hazardous properties. The Recipient acknowledges that the Material is or may be the subject of a patent application. Provider makes no representations and extends no warranties of any kind, either expressed or implied, in relation to the Material, the uses to which it may be put or its suitability for any particular purpose. There are no express or implied warranties that the use of the Material will not infringe any patent, copyright, trademark, or other rights of any third party. Recipient hereby acknowledges that is has satisfied itself in relation to the foregoing matters.

Recipient recognizes the existence of potential biological risks related to the preservation, use and manipulation of the Material transferred and guarantees that it will adopt the appropriate measures when it implements these activities, in order to reduce the health risks that may result from them, as far as possible.

Recipient recognizes that the Material transferred has not been tested by the Provider and may contain infectious and/or potentially hazardous agents.

Except to the extent prohibited by law, the Recipient assumes all liability for any damages which may arise from its use, storage or disposal of the Material or any Modification and further agrees to indemnify and hold harmless the Provider, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the Provider.

Any Party which is aware of, or becomes aware of, a health safety risk, which originates from any of the Materials transferred, shall inform the other Parties without delay and provide them with all the information in its possession or at its disposal concerning risks of this kind.

Recipient undertakes that only staff with specific competencies in the manipulation of human biological elements shall receive and manipulate these Materials transferred. The Recipient undertakes to inform such staff of the dangers inherent in the preservation, use and manipulation of the Materials transferred and to train them in the procedures allowing for safe manipulation of such Materials.

Provider recognizes that it is authorized to transfer the Material to the Recipient, and in particular for the purpose of the Project, and that the Material were collected in compliance with the applicable laws and regulatory provisions, and notably with the Regulation 2016/679 REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) . Provider will communicate to the Recipient all the information at its disposal relating to the preservation and use of the Materials.

Any transfer and/or access to Material shall be evidenced by the execution of a material transfer agreement, a template of which is included in Attachment 5, and which may be completed by concerned Parties (notably with regard to the reimbursement and shipping costs) in accordance with the Consortium Agreement.

Each Party using the template is responsible for ensuring that the transmission sheet is completed correctly, adapted to the relevant situation and that it complies with all applicable rules, laws or regulations, and with the Consortium Agreement from the Effective Date, especially concerning the human biological samples importation and exportation and Data protection.

All the aforementioned obligations shall be complied with due consideration of a Party’s obligations according to applicable laws or regulations regarding access to public documents and keeping, archiving or storing a copy or other mandatory obligations.

# 5 Responsibilities of Parties

## 5.1 General principles

Each Party undertakes to take part in the efficient implementation of the Project, and to cooperate, perform and fulfil, promptly and on time, all of its obligations under the Grant Agreement and this Consortium Agreement as may be reasonably required from it and in a manner of good faith as prescribed by Belgian law.

Each Party undertakes to notify promptly the Granting Authority and the other Parties, in accordance with the governance structure of the Project, of any significant information, fact, problem or delay likely to affect the Project.

Each Party shall promptly provide all information reasonably required by a Consortium Body or by the Coordinator to carry out its tasks and shall responsibly manage the access of its employees to the EU Funding & Tenders Portal.

Each Party shall take reasonable measures to ensure the accuracy of any information or materials it supplies to the other Parties.

## 5.2 Breach

In the event that the General Assembly identifies a breach by a Party of its obligations under this Consortium Agreement or the Grant Agreement (e.g. improper implementation of the Project), the Coordinator or, if the Coordinator is in breach of its obligations, the Party appointed by the General Assembly, will give formal notice to such Party requiring that such breach will be remedied within 30 calendar days from the date of receipt of the written notice by the Party.

If such breach is substantial and is not remedied within that period or is not capable of remedy, the General Assembly may decide to declare the Party to be a Defaulting Party and to decide on the consequences thereof which may include termination of its participation.

## 5.3 Involvement of third parties

A Party that enters into a subcontract or otherwise involves third parties (including but not limited to Affiliated Entities or other Participants) in the Project remains responsible for carrying out its relevant part of the Project and for such third party’s compliance with the provisions of this Consortium Agreement and of the Grant Agreement. Such Party has to ensure that the involvement of third parties does not affect the rights and obligations of the other Parties under this Consortium Agreement and the Grant Agreement.

## 5. 4 Specific responsibilities regarding data protection

Where necessary, the Parties shall cooperate in order to enable one another to fulfil legal obligations arising under applicable data protection laws (the *Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data* and relevant national data protection law applicable to said Party) within the scope of the performance and administration of the Project and of this Consortium Agreement.

In particular, the Parties shall, where necessary, conclude a separate data processing, data sharing and/or joint controller agreement before any data processing or data sharing takes place.

## 5.5 Specific responsibilities for Affiliated Entities

Unismart – Fondazione Università degli Studi di Padova (UNISMART) has been identified as Affiliated Entity to Università degli Studi di Padova (UNIPD).

For the avoidance of doubt, the Affiliated Entity does not sign the Grant Agreement, still receives funding from the Granting Authority and therefore has the right to charge costs or claim contributions from the Granting Authority. However, certain terms and conditions of the Grant Agreement and its Annexes are applicable to the Affiliated Entity.

The Affiliated Entity hereby commits to implement the Project tasks attributed to it in Annex 1 of the Grant Agreement. In addition, the Affiliated Entity hereby commits especially to the following articles of the Grant Agreement and related regulations of Annex 5:

* Proper implementation of the action (Article 11)
* Conflicts of interest (Article 12)
* Confidentiality and security (Article 13)
* Ethics and values (Article 14)
* Visibility (Article 17.2)
* Specific rules for carrying out the action (Article 18)
* Information obligations (Article 19)
* Record-keeping (Article 20)

The Affiliated Entity supports the Beneficiaries regarding their exploitation, dissemination and Open Science obligations and commits to contribute to the technical and continuous reporting during and after the implementation of the Project.

Furthermore, the Affiliated Entity hereby explicitly agrees to cooperate with and grants access to bodies according to Article 25 of the Grant Agreement (the Granting Authority, the European Anti-Fraud Office (OLAF), the European Public Prosecutor’s Office (EPPO), the European Court of Auditors (ECA)), so that these bodies can carry out checks, reviews, audits and investigations also towards the Affiliated Entity.

In case of termination or being declared a Defaulting Party, the Affiliated Entity shall, within the limits specified in section 6.2 of this Consortium Agreement, bear any reasonable and justifiable costs occurring to the other Parties for performing its tasks and the costs for additional efforts necessary to implement the Project.

Moreover, the Affiliated Entity is obliged to indemnify the other Parties for any claim of the Granting Authority against them, caused by its actions or omissions during Grant Agreement preparation, Project implementation or after Project end. Regarding such claims the Associated Partner´s special liability is limited to once the amount of its total budget as indicated in Annex 1 of the Grant Agreement.

# 6 Liability towards each other

## 6.1 No warranties

In respect of any information or materials (incl. Results and Background) supplied by one Party to another under the Project, no warranty or representation of any kind is made, given or implied as to the sufficiency or fitness for purpose nor as to the absence of any infringement of any proprietary rights of third parties.

Therefore,

* the recipient Party shall in all cases be entirely and solely liable for the use to which it puts such information and materials, and
* no Party granting Access Rights shall be liable in case of infringement of proprietary rights of a third party resulting from any other Party (or its entities under the same control) exercising its Access Rights.

## 6.2 Limitations of contractual liability

No Party shall be responsible to any other Party for any indirect or consequential loss or similar damage such as, but not limited to, loss of profit, loss of revenue or loss of contracts, except in case of breach of confidentiality.

A Party’s aggregate liability towards the other Parties collectively shall be limited to once the Party’s share of the total costs of the Project as identified in Annex 2 of the Grant Agreement.

A Party’s liability shall not be limited under either of the two foregoing paragraphs to the extent such damage was caused by a wilful act or gross negligence or to the extent that such limitation is not permitted by law.

## 6.3 Damage caused to third parties

Each Party shall be solely liable for any loss, damage or injury to third parties resulting from the performance of the said Party’s obligations by it or on its behalf under this Consortium Agreement or from its use of Results or Background.

## 6.4 Force Majeure

No Party shall be considered to be in breach of this Consortium Agreement if it is prevented from fulfilling its obligations under the Consortium Agreement by Force Majeure.

Each Party will notify the General Assembly of any Force Majeure without undue delay. If the consequences of Force Majeure for the Project are not overcome within 6 weeks after such notice, the transfer of tasks - if any - shall be decided by the General Assembly.

# 7 Governance structure

## 7.1 General structure

The organisational structure of the consortium shall comprise the following Consortium Bodies:

The **General Assembly** is the decision-making body of the consortium.

The **Coordinator** is the legal entity acting as the intermediary between the Parties and the Granting Authority. The Coordinator shall, in addition to its responsibilities as a Party, perform the tasks assigned to it as described in the Grant Agreement and this Consortium Agreement.

The Project Coordinator and Primary Contact for the Coordinator is Prof. Alessandra Biffi.

Furthermore, the following roles will be appointed:

Data Protection Officer (DPO), responsible for proper data management and data protection;

Exploitation Manager (EM), responsible for exploitation and IPR management.

## 7.2 Members

The General Assembly shall consist of one representative of each Beneficiary Party (hereinafter referred to as “Member”).

Each Member shall be deemed to be duly authorised to deliberate, negotiate and decide on all matters listed in Section 7.3.7 of this Consortium Agreement.

The Coordinator shall chair all meetings of the General Assembly, unless decided otherwise by the General Assembly.

The Beneficiaries agree to abide by all decisions of the General Assembly.

This does not prevent the Beneficiaries from exercising their veto rights, according to Section 7.3.5, or from submitting a dispute for resolution in accordance with the provisions of settlement of disputes in Section 12.8 of this Consortium Agreement.

## 7.3 Operational procedures for the General Assembly:

### 7.3.1 Representation in meetings

Any Member:

* should be present or represented at any meeting;
* may appoint a substitute or a proxy to attend and vote at any meeting;
* and shall participate in a cooperative manner in the meetings.

A representative of the Affiliated Entity may participate to the General Assembly meetings without the right to vote.

### 7.3.2 Preparation and organisation of meetings

#### 7.3.2.1 Convening meetings:

The chairperson shall convene ordinary meetings of the General Assembly at least once every six months and shall also convene extraordinary meetings at any time upon written request of any Member.

#### 7.3.2.2 Notice of a meeting

The chairperson shall give written notice of a meeting to each Member as soon as possible and no later than 14 calendar days preceding an ordinary meeting and 7 calendar days preceding an extraordinary meeting.

#### 7.3.2.3 Sending the agenda:

The chairperson shall prepare and send each Member an agenda no later than 14 calendar days preceding the meeting, or 7 calendar days before an extraordinary meeting.

#### 7.3.2.4 Adding agenda items:

Any agenda item requiring a decision by the Members must be identified as such on the agenda.

Any Member may add an item to the original agenda by written notice to all of the other Members no later than 7 calendar days preceding the meeting and 2 days preceding an extraordinary meeting.

#### 7.3.2.5

During a meeting of the General Assembly the Members present or represented can unanimously agree to add a new item to the original agenda.

#### 7.3.2.6

Meetings of the General Assembly may also be held by tele- or videoconference or other telecommunication means.

#### 7.3.2.7

Decisions will only be binding once the relevant part of the minutes has been accepted according to Section 7.3.6.2.

### 7.3.3 Decisions without a meeting

Any decision may also be taken without a meeting if

1. the Coordinator circulates to all Members of the General Assembly a suggested decision with a deadline for responses of at least 10 calendar days after receipt by a Beneficiary and
2. the decision is agreed by the majority of all Beneficiaries.

The Coordinator shall inform all the Members of the outcome of the vote.

A veto according to Section 7.3.5 may be submitted up to 15 calendar days after receipt of this information.

The decision will be binding after the Coordinator sends a notification to all Members. The Coordinator will keep records of the votes and make them available to the Parties on request.

### 7.3.4 Voting rules and quorum

#### 7.3.4.1

The General Assembly shall not deliberate and decide validly in meetings unless all of its Members are present or represented (quorum).

If the quorum is not reached, the chairperson of the General Assembly shall convene another ordinary meeting within 15 calendar days. If in this meeting the quorum is not reached once more, the chairperson shall convene an extraordinary meeting which shall be entitled to decide even if less than the quorum of Members is present or represented.

#### 7.3.4.2

Each Member present or represented in the meeting shall have one vote.

#### 7.3.4.3

A Party which the General Assembly has declared according to Section 5.2 to be a Defaulting Party may not vote.

#### 7.3.4.4

Decisions shall be taken by the majority of the votes cast.

### 7.3.5 Veto rights

#### 7.3.5.1

A Beneficiary which can show that its own work, time for performance, costs, liabilities, intellectual property rights or other legitimate interests would be severely affected by a decision of the General Assembly may exercise a veto with respect to the corresponding decision or relevant part of the decision.

#### 7.3.5.2

When the decision is foreseen on the original agenda, a Beneficiary may only veto such a decision during the meeting.

#### 7.3.5.3

When a decision has been taken on a new item added to the agenda before or during the meeting, a Beneficiary may veto such decision during the meeting or within 15 calendar days after receipt of the draft minutes of the meeting.

#### 7.3.5.4

When a decision has been taken without a meeting a Party may veto such decision within 15 calendar days after receipt of the written notice by the chairperson of the outcome of the vote.

#### 7.3.5.5

In case of exercise of veto, the Beneficiaries shall make every effort to resolve the matter which occasioned the veto to the general satisfaction of all Parties.

#### 7.3.5.6

A Beneficiary may neither veto decisions relating to its identification to be in breach of its obligations nor to its identification as a Defaulting Party. The Defaulting Party may not veto decisions relating to its participation and termination in the consortium or the consequences of them.

#### 7.3.5.7

A Beneficiary requesting to leave the consortium may not veto decisions relating thereto.

### 7.3.6 Minutes of meetings

#### 7.3.6.1

The chairperson shall produce minutes of each meeting which shall be the formal record of all decisions taken. He/she shall send draft minutes to all Members within 10 calendar days of the meeting.

#### 7.3.6.2

The minutes shall be considered as accepted if, within 15 calendar days from receipt, no Beneficiary has sent an objection to the chairperson with respect to the accuracy of the draft minutes by written notice.

#### 7.3.6.3

The chairperson shall send the accepted minutes to all the Members, and to the Coordinator, who shall retain copies of them.

### 7.3.7 Decisions of the General Assembly

The General Assembly, shall be free to act on its own initiative to formulate proposals and take decisions in accordance with the procedures set out herein.

The following decisions shall be taken by the General Assembly:

1. Content, finances and intellectual property rights
* Proposals for changes to Annexes 1 and 2 of the Grant Agreement to be agreed by the Granting Authority
* Changes to the Consortium Plan
* Modifications or withdrawal of Background in Attachment 1 (Background Included)
* Additions to Attachment 3 (List of Third Parties for simplified transfer according to Section 9.3.2)
* Additions to Attachment 4 (Identified entities under the same control)
1. Evolution of the consortium
* Entry of a new Beneficiary to the Project and approval of the settlement on the conditions of the accession of such a new Beneficiary
* Withdrawal of a Beneficiary from the Project and the approval of the settlement on the conditions of the withdrawal
* Proposal to the Granting Authority for a change of the Coordinator
* Proposal to the Granting Authority for suspension of all or part of the Project
* Proposal to the Granting Authority for termination of the Project and the Consortium Agreement
1. Breach, defaulting party status and litigation
* Identification of a breach by a Party of its obligations under this Consortium Agreement or the Grant Agreement
* Declaration of a Party to be a Defaulting Party
* Remedies to be performed by a Defaulting Party
* Termination of a Defaulting Party’s participation in the consortium and measures relating thereto
* Steps to be taken for litigation purposes and the coverage of litigation costs in case of joint claims of the parties of the consortium against a Party (Section 8.1.4)
1. Appointments
2. On the basis of the Grant Agreement, the appointment of the Clinical Advisory Board Members.

In the case of abolished tasks as a result of a decision of the General Assembly, Members shall rearrange the tasks of the Parties concerned. Such rearrangement shall take into consideration any prior legitimate commitments which cannot be cancelled.

## 7.4 Coordinator

### 7.4.1

The Coordinator shall be the intermediary between the Beneficiaries and the Granting Authority and shall perform all tasks assigned to it as described in the Grant Agreement and in this Consortium Agreement.

### 7.4.2

In particular, the Coordinator shall be responsible for:

* monitoring compliance by the Parties with their obligations under this Consortium Agreement and the Grant Agreement
* keeping the address list of Members and other contact persons updated and available
* collecting, reviewing to verify consistency and submitting reports, other deliverables (including financial statements and related certification) and specific requested documents to the Granting Authority
* preparing the meetings, proposing decisions and preparing the agenda of General Assembly meetings, chairing the meetings, preparing the minutes of the meetings and monitoring the implementation of decisions taken at meetings
* transmitting promptly documents and information connected with the Project to any other Party concerned
* administering the financial contribution of the Granting Authority and fulfilling the financial tasks described in Section 8.2
* providing, upon request, the Parties with official copies or originals of documents that are in the sole possession of the Coordinator when such copies or originals are necessary for the Parties to present claims
* appointing the Data Protection Officer (DPO)
* appointing the Exploitation Manager (EM)

If one or more of the Parties is late in submission of any Project deliverable, the Coordinator may nevertheless submit the other Parties’ Project deliverables and all other documents required by the Grant Agreement to the Granting Authority in time.

### 7.4.3

If the Coordinator fails in its coordination tasks, the General Assembly may propose to the Granting Authority to change the Coordinator.

### 7.4.4

The Coordinator shall not be entitled to act or to make legally binding declarations on behalf of any other Party or of the consortium, unless explicitly stated otherwise in the Grant Agreement or this Consortium Agreement.

### 7.4.5

The Coordinator shall not enlarge its role beyond the tasks specified in this Consortium Agreement and in the Grant Agreement.

## 7.5 Clinical Advisory Board (CAB)

A Clinical Advisory Board (CAB) of a maximum of 5 members will be appointed, based on the proposal of the Coordinator, and steered by the General Assembly. The CAB shall assist and facilitate the General Assembly in defining the first-in-human treatment protocol, including inclusion criteria and end points.

The Coordinator will ensure that a non-disclosure agreement is executed between all Beneficiaries and each CAB member.

Its terms shall be not less stringent than those stipulated in this Consortium Agreement, and it shall be concluded no later than 30 days after their nomination or before any confidential information will be exchanged/disclosed, whichever date is earlier.

By way of exception to Section 7.4.4 above, the Beneficiaries hereby mandate the Coordinator to execute, in their name and on their behalf, a non-disclosure agreement (hereafter “NDA”) with each member of the CAB, in order to protect Confidential Information disclosed by any of the Beneficiaries to any member of the CAB. The NDA for the CAB members is enclosed in Attachment 5. The mandate of the Coordinator comprises solely the execution of the NDA in Attachment 5.

The Coordinator shall write the minutes of the CAB meetings and submit them to the General Assembly. The CAB members shall be allowed to participate in General Assembly meetings upon invitation but have not any voting rights.

# 8 Financial provisions

## 8.1 General Principles

### 8.1.1 Distribution of Financial Contribution

The financial contribution of the Granting Authority to the Project shall be distributed by the Coordinator according to:

* the Consortium Plan
* the approval of reports by the Granting Authority, and
* the provisions of payment in Section 8.2.

A Party shall be funded only for its tasks carried out in accordance with the Consortium Plan.

### 8.1.2 Justifying Costs

In accordance with its own usual accounting and management principles and practices, each Party shall be solely responsible for justifying its costs with respect to the Project towards the Granting Authority. Neither the Coordinator nor any of the other Parties shall be in any way liable or responsible for such justification of costs towards the Granting Authority.

### 8.1.3 Funding Principles

A Party that spends less than its allocated share of the budget as set out in the Consortium Plan will be funded in accordance with its actual duly justified eligible costs only.

A Party that spends more than its allocated share of the budget as set out in the Consortium Plan will be funded only in respect of duly justified eligible costs up to an amount not exceeding that share.

### 8.1.4 Excess payments

A Party has received excess payment

1. if the payment received from the Coordinator exceeds the amount declared or
2. if a Party has received payments but, within the last year of the Project, its real Project costs fall significantly behind the costs it would be entitled to according to the Consortium Plan.

In case a Party has received excess payment, the Party has to inform the Coordinator and return the relevant amount to the Coordinator without undue delay. In case no refund takes place within 30 days upon request for return of excess payment from the Coordinator, the Party is in substantial breach of the Consortium Agreement.

Amounts which are not refunded by a breaching Party and which are not due to the Granting Authority, shall be apportioned by the Coordinator to the remaining Parties pro rata according to their share of total costs of the Project as identified in the Consortium Budget, until recovery from the breaching Party is possible. The General Assembly decides on any legal actions to be taken against the breaching Party according to Section 6.3.7.

### 8.1.5 Revenue

In case a Party earns any revenue that is deductible from the total funding as set out in the Consortium Plan, the deduction is only directed toward the Party earning such revenue. The other Parties’ financial share of the budget shall not be affected by one Party’s revenue. In case the relevant revenue is more than the allocated share of the Party as set out in the Consortium Plan, the Party shall reimburse the funding reduction suffered by other Parties.

### 8.1.6 Financial Consequences of the termination of the participation of a Party

A Party leaving the consortium shall refund to the Coordinator any payments it has received except the amount of contribution accepted by the Granting Authority or another contributor.

In addition, a Defaulting Party shall, within the limits specified in Section 6.2 of this Consortium Agreement, bear any reasonable and justifiable additional costs occurring to the other Parties in order to perform the leaving Party´s task and necessary additional efforts to fulfil them as a consequence of the Party leaving the consortium. The General Assembly should agree on a procedure regarding additional costs which are not covered by the Defaulting Party or the Mutual Insurance Mechanism.

## 8.2 Payments

### 8.2.1 Payments to Parties are the exclusive task of the Coordinator

In particular, the Coordinator shall:

notify the Party concerned promptly of the date and composition of the amount transferred to its bank account, giving the relevant references

perform diligently its tasks in the proper administration of any funds and in maintaining financial accounts

undertake to keep the Granting Authority’s financial contribution to the Project separated from its normal business accounts, its own assets and property, except if the Coordinator is a Public Body or is not entitled to do so due to statutory legislation.

With reference to Article 22 of the Grant Agreement, no Party shall before the end of the Project receive more than its allocated share of the maximum grant amount less the amounts retained by the Granting Authority for the Mutual Insurance Mechanism and for the final payment.

### 8.2.2

The transfer of the initial pre-financing, the additional pre-financings (if any) and interim payments to Parties will be handled in accordance with Article 22.1. and Article 7 of the Grant Agreement following this payment schedule:

 Funding of costs included in the Consortium Plan will be paid by the Coordinator to the Parties after receipt of payments from the Granting Authority without undue delay and in conformity with the provisions of the Grant Agreement. Costs accepted by the Granting Authority will be paid to the Party concerned.

The Coordinator is entitled to withhold any payments due to a Party identified by the General Assembly to be in breach of its obligations under this Consortium Agreement or the Grant Agreement or to a Party which has not yet signed this Consortium Agreement.

The Coordinator is entitled to recover any payments already paid to a Defaulting Party except the costs already claimed by the Defaulting Party and accepted by the Granting Authority. The Coordinator is equally entitled to withhold payments to a Party when this is suggested by or agreed with the Granting Authority.

## 8.3 Allocation of Overheads cost category

The Coordinator will retain from the pre-financing a percentage of the total overheads of each Party in order to cover the consultancy costs incurred in the pre-award phase.

The total amount to be retained corresponds to € 161.027,80. The amount to be retrieved from the pre-financing for each Party is calculated accordingly to the Party’s share of the total costs of the Project.

In order to define the amount due by each Party, the following Consortium Plan Budget shall apply.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Consortium Plan Budget** | **Overheads** | **Total Costs** | **Total costs Party’s share** | **Amount to be retrieved for each Party from the Pre-financing** | **Total Costs minus amount retrieved** |
| **UNIPD** | € 313.626,25 | € 1.623.131,25 | 65% | € 104.559,36 | € 1.679.599,69 |
| **UNISMART** | € 20.000 | € 109.000 | 4% | € 7.021,59 | € 101.978,41 |
| **IMG** | € 99.883 | € 499.415 | 20% | € 32.171,47 | € 467.243,53 |
| **INSERM** | € 53.635 | € 268.175 | 11% | € 17.275,38 | € 250.899,62 |
| **TOTAL** | **€ 487.144,25** | **€ 2.499.721,25** | **100%** | **€ 161.027,80** | **€** 2.499.721,25 |

# 9 Results

## 9.1 Ownership of Results

Results are owned by the Party that generates them.

## 9.2 Joint ownership

**9.2.1**

Joint ownership is governed by Grant Agreement Article 16.4 and its Annex 5, Section Ownership of results, with the following additions:

In the case of joint patentable Results in respect of which two or more Parties have expressed an interest in patenting, a jointly owned patent application shall be filed. The share of ownership due to each Party will be established with a separate joint ownership agreement (JOA) that the Parties involved undertake to define as soon as possible, in proportion to the inventive activity carried out by each of the Parties. The agreement will also define the methods for filing and continuing the patent application (or other form of protection) and the division of the related expenses, the sharing of revenues or profits as well as the management and Exploitation of the rights over the project Results.

**9.2.2**

The Parties agree that:

* each of the joint owners shall be entitled to use their jointly owned Results for internal non-commercial research and non-commercial teaching activities on a royalty-free basis, according to the procedure provided for in Art.9.4 of this CA
* neither Party may otherwise Exploit the joint Results before the JOA is signed
* the spinoff to be set up under the project will have a priority right to a licence or to a transfer of ownership on the project Results, under conditions to be negotiated.

## 9.3 Transfer of Results

### 9.3.1

Each Party may transfer ownership of its own Results, including its share in jointly owned Results, following the procedures of the Grant Agreement Article 16.4 and its Annex 5, Section Transfer and licensing of results, sub-section “Transfer of ownership”, and subject to art. 9.2.2 of this CA.

### 9.3.2

Each Party may identify specific third parties it intends to transfer the ownership of its Results to in Attachment (3) of this Consortium Agreement. The other Parties hereby waive their right to prior notice and their right to object to such a transfer to listed third parties according to the Grant Agreement Article 16.4 and its Annex 5, Section Transfer of licensing of results, sub-section “Transfer of ownership”, 3rd paragraph.

### 9.3.3

The transferring Party shall, however, at the time of the transfer, inform the other Parties of such transfer and shall ensure that the rights of the other Parties under the Consortium Agreement and the Grant Agreement will not be affected by such transfer. Any addition to Attachment (3) after signature of this Consortium Agreement requires a decision of the General Assembly.

### 9.3.4

The Parties recognise that in the framework of a merger or an acquisition of an important part of its assets, it may be impossible under applicable EU and national laws on mergers and acquisitions for a Party to give at least 45 calendar days prior notice for the transfer as foreseen in the Grant Agreement.

### 9.3.5

The obligations above apply only for as long as other Parties still have - or still may request - Access Rights to the Results.

## 9.4 Dissemination

### 9.4.1

For the avoidance of doubt, the confidentiality obligations set out in Section 11 apply to all dissemination activities described in this Section 9.4 as far as Confidential Information is involved.

### 9.4.2 Dissemination of own (including jointly owned) Results

#### 9.4.2.1

During the Project and for a period of 5 years after the end of the Project, the dissemination of own Results by one or several Parties including but not restricted to publications and presentations, shall be governed by the procedure of Article 17.4 of the Grant Agreement and its Annex 5, Section Dissemination, subject to the following provisions.

Prior notice of any planned dissemination activity shall be given in writing to the other Parties at least 60 calendar days before the dissemination. Any objection to the planned dissemination shall be made in accordance with the Grant Agreement by written notice to the Coordinator and to the Party or Parties proposing the dissemination within 45 calendar days after receipt of the notice. If no objection is made within the time limit stated above, the publication is permitted.

#### 9.4.2.2

An objection is justified if

1. the protection of the objecting Party's Results or jointly owned Results or Background would be adversely affected, or
2. the objecting Party's legitimate interests, including interests in Exploitation, in relation to its Results or jointly owned Results or Background would be significantly harmed, or
3. the proposed publication/dissemination includes Confidential Information of the objecting Party.

The objection has to include a request for necessary modifications.

 If an objection has been raised the involved Parties shall discuss how to overcome the justified grounds for the objection (for example by amendment to the planned dissemination and/or by protecting information before dissemination) and the objecting Party shall not unreasonably continue the opposition if appropriate measures are taken following the discussion.

#### 9.4.2.3

The objecting Party can request a delay of the dissemination of not more than 6 months from the time it raises such an objection. After this deadline the publication/dissemination is permitted, provided that the objections of the objecting Party have been addressed. In the event of disagreement between the Parties on the measures to be taken to overcome the objection, in particular when it may be appropriate not to disseminate the Results or other information, the opinion of the General Assembly will be sought. In this case the six-month deadline will be suspended to allow the General Assembly to give its opinion on a timely basis.

### 9.4.3 Dissemination of another Party’s unpublished Results or Background

A Party shall not include in any dissemination activity another Party's Results or Background without obtaining the owning Party's prior written approval, unless they are already published.

### 9.4.4 Cooperation obligations

The Parties undertake to cooperate to allow the timely submission, examination, publication and defence of any dissertation or thesis for a degree that includes their Results or Background subject to the confidentiality and publication provisions agreed in this Consortium Agreement.

### 9.4.5 Use of names, logos or trademarks

Nothing in this Consortium Agreement shall be construed as conferring rights to use in advertising, publicity or otherwise the name of the Parties or any of their logos or trademarks without their prior written approval.

# 10 Access Rights

## 10.1 Background included

### 10.1.1

In Attachment 1, the Parties have identified and agreed on the Background for the Project and have also, where relevant, informed each other that Access to specific Background is subject to legal restrictions or limits.

Anything not identified in Attachment 1 shall not be the object of Access Right obligations regarding Background.

### 10.1.2

Any Party may add additional Background to Attachment 1 during the Project provided they give written notice to the other Parties. However, approval of the General Assembly is needed should a Party wish to modify or withdraw its Background in Attachment 1.

## 10.2 General Principles

### 10.2.1

Each Party shall implement its tasks in accordance with the Consortium Plan and shall bear sole responsibility for ensuring that its acts within the Project do not knowingly infringe third party property rights.

### 10.2.2

Any Access Rights granted exclude any rights to sublicense unless expressly stated otherwise. The authorisation to sublicense must not be unreasonably refused.

### 10.2.3

Access Rights shall be free of any administrative transfer costs.

### 10.2.4

Access Rights are granted on a non-exclusive basis.

### 10.2.5

Results and Background shall be used only for the purposes for which Access Rights to it have been granted.

### 10.2.6

All requests for Access Rights shall be made in writing. The granting of Access Rights may be made conditional on the acceptance of specific conditions aimed at ensuring that these rights will be used only for the intended purpose and that appropriate confidentiality obligations are in place.

### 10.2.7

The requesting Party must show that the Access Rights are Needed. In case of disagreement, the requesting Party can better substantiate its request and the opinion of the General Assembly will be sought.

## 10.3 Access Rights for implementation

Access Rights to Results and Background Needed for the performance of the own work of a Party under the Project shall be granted on a royalty-free basis, unless otherwise agreed for Background in Attachment 1.

## 10.4 Access Rights for Exploitation

### 10.4.1 Access Rights to Results

Access Rights to Results if Needed for Exploitation of a Party's own Results shall be granted on Fair and Reasonable conditions.

Access rights to Results for internal non-commercial research and for non-commercial teaching activities shall be granted on a royalty-free basis.

### 10.4.2

Access Rights to Background if Needed for Exploitation of a Party’s own Results, shall be granted on Fair and Reasonable conditions.

### 10.4.3

A request for Access Rights, under the conditions defined above, may be made up to 36 months after the end of the Project or, in the case of Section 10.7.2.1.2, after the termination of the requesting Party’s participation in the Project.

## 10.5 Access Rights for entities under the same control

Entities under the same control have Access Rights under the conditions of the Grant Agreement Article 16.4 and its Annex 5, Section "Access rights to results and background”, sub-section “Access rights for entities under the same control” if they are identified in Attachment 4 (Identified entities under the same control) to this Consortium Agreement.

Such Access Rights must be requested by the entity under the same control from the Party that holds the Background or Results. Alternatively, the Party granting the Access Rights may individually agree with the Party requesting the Access Rights to have the Access Rights include the right to sublicense to the latter's entity under the same control [listed in Attachment 4]. Access Rights to an entity under the same control shall be granted on Fair and Reasonable conditions and upon written bilateral agreement.

Entities under the same control which obtain Access Rights in return fulfil all confidentiality obligations accepted by the Parties under the Grant Agreement or this Consortium Agreement as if such entities were Parties.

Access Rights may be refused to entities under the same control if such granting is contrary to the legitimate interests of the Party which owns the Background or the Results.

Access Rights granted to any entity under the same control are subject to the continuation of the Access Rights of the Party with whom it is under the same control, and shall automatically terminate upon termination of the Access Rights granted to such Party.

Upon cessation of the status as an entity under the same control, any Access Rights granted to such former entity under the same control shall lapse.

Further arrangements with entities under the same control may be negotiated in separate agreements.

## 10.6 Additional Access Rights

For the avoidance of doubt any grant of Access Rights not covered by the Grant Agreement or this Consortium Agreement shall be at the absolute discretion of the owning Party and subject to such terms and conditions as may be agreed between the owning and receiving Parties.

## 10.7 Access Rights for Parties entering or leaving the consortium

### 10.7.1 New Parties entering the consortium

As regards Results developed before the accession of the new Party, the new Party will be granted Access Rights on the conditions applying for Access Rights to Background.

### 10.7.2 Parties leaving the consortium

#### 10.7.2.1 Access Rights granted to a leaving Party

##### 10.7.2.1.1 Defaulting Party

Access Rights granted to a Defaulting Party and such Party's right to request Access Rights shall cease immediately upon receipt by the Defaulting Party of the formal notice of the decision of the General Assembly to terminate its participation in the consortium.

##### 10.7.2.1.2 Non-defaulting Party

A non-defaulting Party leaving voluntarily and with the other Parties' consent shall have Access Rights to the Results developed until the date of the termination of its participation.

It may request Access Rights within the period of time specified in Section 10.4.3.

#### 10.7.2.2 Access Rights to be granted by any leaving Party

Any Party leaving the Project shall continue to grant Access Rights pursuant to the Grant Agreement and this Consortium Agreement as if it had remained a Party for the whole duration of the Project.

## 10.8 Specific Provisions for Access Rights to Software

For the avoidance of doubt, the general provisions for Access Rights provided for in this Section 10 are applicable also to Software.

Parties’ Access Rights to Software do not include any right to receive source code or object code ported to a certain hardware platform or any right to receive respective Software documentation in any particular form or detail, but only as available from the Party granting the Access Rights.

# 11 Non-disclosure of information

## 11.1

All information in whatever form or mode of communication, which is disclosed by a Party (the “Disclosing Party”) to any other Party (the “Recipient”) in connection with the Project during its implementation and which has been explicitly marked as “confidential” at the time of disclosure, or when disclosed orally has been identified as confidential at the time of disclosure and has been confirmed and designated in writing within 15 calendar days from oral disclosure at the latest as confidential information by the Disclosing Party, is “Confidential Information”.

## 11.2

The Recipient hereby undertakes in addition and without prejudice to any commitment on non-disclosure under the Grant Agreement:

* not to use Confidential Information otherwise than for the purpose for which it was disclosed;
* not to disclose Confidential Information without the prior written consent by the Disclosing Party;
* to ensure that internal distribution of Confidential Information by a Recipient shall take place on a strict need-to-know basis; and
* to return to the Disclosing Party, or destroy, on request all Confidential Information that has been disclosed to the Recipients including all copies thereof and to delete all information stored in a machine-readable form to the extent practically possible. The Recipient may keep a copy to the extent it is required to keep, archive or store such Confidential Information because of compliance with applicable laws and regulations or for the proof of on-going obligations provided that the Recipient complies with the confidentiality obligations herein contained with respect to such copy.

## 11.3

The Recipient shall be responsible for the fulfilment of the above obligations on the part of its employees or third parties involved in the Project and shall ensure that they remain so obliged, as far as legally possible, during and after the end of the Project and/or after the termination of the contractual relationship with the employee or third party.

## 11.4

The above shall not apply for disclosure or use of Confidential Information, if and in so far as the Recipient can show that:

* the Confidential Information has become or becomes publicly available by means other than a breach of the Recipient’s confidentiality obligations;
* the Disclosing Party subsequently informs the Recipient that the Confidential Information is no longer confidential;
* the Confidential Information is communicated to the Recipient without any obligation of confidentiality by a third party who is to the best knowledge of the Recipient in lawful possession thereof and under no obligation of confidentiality to the Disclosing Party;
* the disclosure or communication of the Confidential Information is foreseen by provisions of the Grant Agreement;
* the Confidential Information, at any time, was developed by the Recipient completely independently of any such disclosure by the Disclosing Party;
* the Confidential Information was already known to the Recipient prior to disclosure, or
* the Recipient is required to disclose the Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order, subject to the provision Section 10.7 hereunder.

## 11.5

The Recipient shall apply the same degree of care with regard to the Confidential Information disclosed within the scope of the Project as with its own confidential and/or proprietary information, but in no case less than reasonable care

## 11.6

Each Recipient shall promptly inform the relevant Disclosing Party by written notice of any unauthorised disclosure, misappropriation or misuse of Confidential Information after it becomes aware of such unauthorised disclosure, misappropriation or misuse.

## 11.7

If any Recipient becomes aware that it will be required, or is likely to be required, to disclose Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order, it shall, to the extent it is lawfully able to do so, prior to any such disclosure

* notify the Disclosing Party, and
* comply with the Disclosing Party’s reasonable instructions to protect the confidentiality of the information.

# 12 Miscellaneous

## 12.1 Attachments, inconsistencies and severability

This Consortium Agreement consists of this core text and:

* Attachment 1 (Background included)
* Attachment 2 (Accession document)
* Attachment 3 (List of third parties for simplified transfer according to Section 9.3.2)
* Attachment 4 (Identified entities under the same control )
* Attachment 5 (NDA for External Expert Advisory Board agreed under Section 7)
* Attachment 6 – Material Transfer Agreement (MTA)

In case the terms of this Consortium Agreement are in conflict with the terms of the Grant Agreement, the terms of the latter shall prevail. In case of conflicts between the attachments and the core text of this Consortium Agreement, the latter shall prevail.

Should any provision of this Consortium Agreement become invalid, illegal or unenforceable, it shall not affect the validity of the remaining provisions of this Consortium Agreement. In such a case, the Parties concerned shall be entitled to request that a valid and practicable provision be negotiated that fulfils the purpose of the original provision.

## 12.2 No representation, partnership or agency

Except as otherwise provided in Section 7.4.4, no Party shall be entitled to act or to make legally binding declarations on behalf of any other Party or of the consortium. Nothing in this Consortium Agreement shall be deemed to constitute a joint venture, agency, partnership, interest grouping or any other kind of formal business grouping or entity between the Parties.

## 12.3 Formal and written notices

Any notice to be given under this Consortium Agreement shall be addressed to the recipients as listed in the most current address list kept by the Coordinator.

Any change of persons or contact details shall be immediately communicated to the Coordinator by written notice. The address list shall be accessible to all Parties.

Formal notices:

If it is required in this Consortium Agreement (Sections 5.2, 10.7.2.1.1, and 12.4) that a formal notice, consent or approval shall be given, such notice shall be signed by an authorised representative of a Party and shall either be served personally or sent by mail with recorded delivery with acknowledgement of receipt.

Written notice:

Where written notice is required by this Consortium Agreement, this is fulfilled also by other means of communication such as e-mail.

## 12.4 Assignment and amendments

Except as set out in Section 9.3, no rights or obligations of the Parties arising from this Consortium Agreement may be assigned or transferred, in whole or in part, to any third party without the other Parties’ prior formal approval.

Amendments and modifications to the text of this Consortium Agreement not explicitly listed in Section 6.3.7 require a separate written agreement to be signed between all Parties.

## 12.5 Mandatory national law

Nothing in this Consortium Agreement shall be deemed to require a Party to breach any mandatory statutory law under which the Party is operating. In particular, any transfer of Biological Material shall comply with the applicable mandatory statutory law.

## 12.6 Language

This Consortium Agreement is drawn up in English, which language shall govern all documents, notices, meetings, arbitral proceedings and processes relative thereto.

## 12.7 Applicable law

This Consortium Agreement shall be construed in accordance with and governed by the laws of Belgium excluding its conflict of law provisions.

## 12.8 Settlement of disputes

The Parties shall endeavour to settle their disputes amicably. Any dispute, controversy or claim arising under, out of or relating to this contract and any subsequent amendments of this contract, including, without limitation, its formation, validity, binding effect, interpretation, performance, breach or termination, as well as non-contractual claims, which cannot be solved amicably within six months, shall be submitted and referred to and finally determined by arbitration in accordance with the WIPO Expedited Arbitration Rules by one single arbitrator. The place of arbitration shall be Brussels unless otherwise agreed upon. The language to be used in the proceedings shall be English unless otherwise agreed upon. Nothing in this Consortium Agreement shall limit the Parties' right to seek injunctive relief in any applicable competent court.

# 13 Signatures

**AS WITNESS:**

The Parties have caused this Consortium Agreement to be duly signed by the undersigned authorised representatives in separate signature pages the day and year first above written. The signature of a Party via a qualified electronic signature in accordance with the EU eIDAS regulation, shall have the same force and effect as an original handwritten signature for the purposes of validity, enforceability and admissibility. Scan or a digitized image of handwritten signature are not accepted. Each Party receives a fully executed copy of the Consortium Agreement. If the signatures are wet-ink, each Party receives one original hard copy (in total 4 originals of this Consortium Agreement shall be signed), if the signatures are electronic, each party receives the originally signed electronic copy.

**UNIVERSITÀ DEGLI STUDI DI PADOVA (UNIPD)**

Signature:

Name: xxx

Title: Head of the Department of Women and Children Health

Date:

Signature:

Name: xxx

Title: Project Coordinator and Primary Contact

Date:

**UNISMART – FONDAZIONE UNIVERSITÀ DEGLI STUDI DI PADOVA (UNISMART)**

Signature:

Name: xxx

Title: General Manager

Date:

**USTAV MOLEKULARNI GENETIKY AKADEMIE VED CESKE REPUBLIKY VEREJNA VYZKUMNA INSTITUCE (IMG)**

Signature:

Name: RNDr. Petr Dráber, DRSc.

Title: Director

Date:

Signature:

Name:

Role: Lead Investigator

Date:

**INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM)**

Signature:

Name: xxx

Title: Regional Delegate Inserm Paris idF Sud

Date:

Signature:

Name: xxx

Role: Lead Investigator

Date:

Attachment 1: Background included

According to the Grant Agreement (Article 16.1) Background is defined as “data, know-how or information (…) that is (…) needed to implement the Action or exploit the results”. Because of this need, Access Rights have to be granted in principle, but Parties must identify and agree amongst them on the Background for the Project. This is the purpose of this attachment.

**PARTY 1**

As to **UNIVERSITÀ DEGLI STUDI DI PADOVA (UNIPD)**, it is agreed between the Parties that, to the best of their knowledge, the following Background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

|  |  |  |
| --- | --- | --- |
| **Describe Background** | **Specific restrictions and/or conditions for implementation**  | **Specific restrictions and/or conditions for Exploitation** |
| Data package: proof of efficacy of HSC gene therapy with TREM2 LV in 5XFAD mouse model | Consultation only | IP protected |
| hPGK\_hTREM2 3rd generation SIN LV transfer plasmid | Available for implementing the action to INSERM | IP protected |
| hHLA\_DRA\_hTREM2 3rd generation SIN LV transfer plasmid | Available for implementing the action to INSERM | IP protected |

This represents the status at the time of signature of this Consortium Agreement.

**PARTY 2**

As to **UNISMART – FONDAZIONE UNIVERSITÀ DEGLI STUDI DI PADOVA (UNISMART)**, it is agreed between the Parties that, to the best of their knowledge, no data, know-how or information of **UNISMART – FONDAZIONE UNIVERSITÀ DEGLI STUDI DI PADOVA (UNISMART)** is Needed by another Party for implementation of the Project (Article 16.1 and its Annex 5 Grant Agreement, Section “Access rights to results and background”, sub-section “Access rights to background and results for implementing the action”) or Exploitation of that other Party’s Results (Article 16.1 and its Annex 5 Grant Agreement, Section “Access rights to results and background”, sub-section “Access rights for exploiting the results”).

This represents the status at the time of signature of this Consortium Agreement.

**PARTY 3**

As to **USTAV MOLEKULARNI GENETIKY AKADEMIE VED CESKE REPUBLIKY VEREJNA VYZKUMNA INSTITUCE (IMG)**, it is agreed between the Parties that, to the best of their knowledge, no data, know-how or information of **USTAV MOLEKULARNI GENETIKY AKADEMIE VED CESKE REPUBLIKY VEREJNA VYZKUMNA INSTITUCE (IMG)** is Needed by another Party for implementation of the Project (Article 16.1 and its Annex 5 Grant Agreement, Section “Access rights to results and background”, sub-section “Access rights to background and results for implementing the action”) or Exploitation of that other Party’s Results (Article 16.1 and its Annex 5 Grant Agreement, Section “Access rights to results and background”, sub-section “Access rights for exploiting the results”).

This represents the status at the time of signature of this Consortium Agreement.

**PARTY 4**

As to **INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM)**, it is agreed between the Parties that, to the best of their knowledge, the following Background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

|  |  |  |
| --- | --- | --- |
| **Describe Background** | **Specific restrictions and/or conditions for implementation**  | **Specific restrictions and/or conditions for Exploitation** |
| Production of lentiviral gene transfer vectors in preclinical grade at 8L scale  | Inserm will need to obtain the transfer plasmids from UNIPDInserm will use its own helper plasmids and the producer cells to produce batches of vectors for preclinical studies Implementation of the vector production will be done in R&D conditions suitable for preclinical studies (traceable in the quality system in place) but is non GMP | Exploitation for commercial use is subjected to eventual third party rights on the plasmids and producer cells. Exploitation of the vector production process for industrial manufacture by a CDMO is subjected to an agreement with Inserm. |
| Lentiviral insertion site analysis using the VISPA pipeline adapted at Inserm | Implementation of the insertion site analysis in R&D conditions (non GMP) | Exploitation for commercial use is subjected to a licensing agreement with Inserm. |

This represents the status at the time of signature of this Consortium Agreement.

Attachment 2: Accession document

ACCESSION

**of a new Party to**

**[Acronym of the Project] Consortium Agreement, version […, YYYY-MM-DD]**

[OFFICIAL NAME OF THE NEW PARTY AS IDENTIFIED IN THE Grant Agreement]

hereby consents to become a Party to the Consortium Agreement identified above and accepts all the rights and obligations of a Party starting [date].

[OFFICIAL NAME OF THE COORDINATOR AS IDENTIFIED IN THE Grant Agreement]

hereby certifies that the consortium has accepted in the meeting held on [date] the accession of [the name of the new Party] to the consortium starting [date].

This Accession document has been done in 2 originals to be duly signed by the undersigned authorised representatives.

[Date and Place]

[INSERT NAME OF THE NEW PARTY]

Signature(s)

Name(s)

Title(s)

[Date and Place]

[INSERT NAME OF THE COORDINATOR]

Signature(s)

Name(s)

Title(s)

Attachment 3: List of third parties for simplified transfer according to Section 8.3.2.

Attachment 4: Identified entities
under the same control according to Section 9.5

Attachment 5: NDA for Clinical Advisory Board
agreed under Section 6

**BETWEEN:** Università degli Studi di Padova (the “Coordinator”) acting as Coordinator in the names and on behalf of the Parties of the TREM2MEDS Consortium (Università degli Studi di Padova, Unismart - Fondazione Università degli studi di Padova, Ustav Molekularni Genetiky Akademie Ved Ceske Republiky Verejna Vyzkumna Instituce, Institut National de la Sante et de la Recherche Medicale)

hereinafter collectively referred to as the “Consortium” and individually as “Consortium Member(s)”,

**AND:** xxx, residing at xxx, xxx (job title), (the “CLINICAL ADVISOR”),

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

**WHEREAS:**

The Consortium is undertaking a project entitled “*Towards the clinical implementation of TREM2 Microglia Engineering for treating DementiaS*”, in short TREM2MEDS (the “Project”), funded by the European Commission under Grant Agreement nº 101159096 (the “Grant Agreement”) as part of the European Union Horizon Europe Framework Programme for Research and Innovation and the Associated Partner’s national funding;

The Clinical Advisor (CA) is an international Alzheimer’s Disease (AD) and/or hematopoietic cell transplant expert, with knowledge, experience and expertise in the field and has accepted the appointment as CA; the role of the CA is to advise on the first-in human treatment protocol, including inclusion criteria and end points, by offering recommendations to the General Assembly.

In accordance with Article 6.5 of the Consortium Agreement for the Project, the Coordinator has to ensure that a Non-Disclosure Agreement is executed between the CA and the Coordinator acting in the name and on behalf of the Consortium.

In order to enable the CA to act as an independent expert and to fulfill the role as described above, the Consortium Members will make available certain sensitive information to the CA.

The Parties wish to set forth the terms and conditions, pursuant to which the CA shall be entitled to receive, use and protect such information;

**THE PARTIES HEREBY AGREE AS FOLLOWS:**

1. The CA shall treat as confidential any type of information, and/or data disclosed and/or made accessible by the Consortium or the Consortium Members to the CA, as well as any information and/or data that the CA has access to, notably during meetings, conferences and/or visits. This information and/or data shall be regarded as “Confidential Information”, whether it is disclosed orally or in writing, regardless of the medium it takes and regardless of its nature, whether technical, financial, commercial, legal or of any other nature. Confidential Information includes, without limitation, any sample, prototype, product, chart, plan, data and/or process, whether protected by any intellectual property right or title, and/or patentable or not.

2. The CA shall use the Confidential Information solely for advising the ethics issues associated with the Project, by offering recommendations to the General Assembly. Any other use of the Confidential Information shall therefore be subject to a specific written agreement between the Parties.

3. The CA shall apply the same degree of care with regard to the Confidential Information as with his/her own confidential and/or proprietary information, but in no case less than reasonable care. In this respect, the CA undertakes to take all necessary precautions to deny third parties access to the Confidential Information he/she receives. In particular, the CA undertakes not to disclose the Confidential Information to any third party. In the event that, in spite of these precautions, a third party has access to all or to a piece of Confidential Information, the CA undertakes to immediately inform the disclosing Consortium Member, by any means, immediately after its discovery.

4. Any Confidential Information is made available by the Consortium on an “as-is” basis, without any warranty, express or implied, as to the accuracy, fitness for the Purpose or any other qualities of the Confidential Information.

5. The CA acknowledges and agrees that all property, including intellectual property, in the Confidential Information shall remain with and be vested in the Consortium Members. This Agreement does not grant the CA any license or right other than expressly stated herein.

6. Notwithstanding the foregoing Articles, the CA is under no obligation and is subject to no restriction regarding any Confidential Information, if and in so far as the CA can show that:

a) the Confidential Information becomes publicly available by means other than a breach of the CA’s confidentiality obligations;

b) the Confidential Information was disclosed with the written permission of the disclosing Consortium Member from which it originated;

c) the Confidential Information is communicated to the CA without any obligation of confidentiality by a third party who is to the best knowledge of the CA in lawful possession thereof and under no obligation of confidentiality to the Consortium;

d) the Confidential Information was already known to the CA prior to disclosure and is not subject to any confidentiality undertaking; or

e) the CA is required to disclose the Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order.

7. This Agreement shall enter into force on DD/MM/YYYY, for a duration of three (3) years.

Notwithstanding the termination or the expiration of this Agreement for any reason, the CA remains bound by the confidentiality obligations until the Confidential Information is made available to the public without any infringement of the Agreement.

8. Upon request, as well as following the end of the Agreement, the CA shall within ten (10) days of receiving such a request:

- at the discretion of the disclosing Consortium Member, return or destroy all original copies of documents, equipment, electronic or other medium containing the Confidential Information or their summaries in its possession;

- issue a formal written statement certifying that it has not retained any Confidential Information and/or copies of the said Confidential Information on any medium whatsoever, with the exception of a single copy that it may retain in its statutory archives with a view to monitoring its commitments under the Agreement.

9. The provisions of this Agreement shall be interpreted in accordance with their true meaning and effect and independent of national and local law. If this Consortium Agreement is silent on a matter or any of its provisions are ambiguous or unclear, then in those circumstances only and not in respect of the Agreement as a whole, reference shall be made to Belgian substantive law, excluding its conflict of law provisions.

10. The Parties shall endeavour to settle their disputes amicably. Any dispute, controversy or claim arising under, out of or relating to this contract and any subsequent amendments of this contract, including, without limitation, its formation, validity, binding effect, interpretation, performance, breach or termination, as well as non-contractual claims, shall be submitted and referred to and finally determined by the competent Belgian Court of Brussels. The language to be used in the proceedings shall be English unless otherwise agreed upon.

11. Any amendment to this Agreement shall be made in writing and signed by the Parties.

|  |  |
| --- | --- |
| **Università degli Studi di Padova**  | **The Clinical Advisor** |
| Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Name :Title: | Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Name :Title: |

# Attachment 5: Material Transfer Agreement

**MATERIAL TRANSFER AGREEMENT**

|  |  |
| --- | --- |
| **Date**  | [Please fill day month, year] (‘**Effective Date**’) |
| **Provider** | [Official legal name of the institution], with tax number [insert number], having its registered offices at [street, post code, city, country], represented by [name], with [identification document/passport] number, in his/her role as [position] of [legal short name]. |
| **Recipient** | [Official legal name of the institution], with tax number [insert number], having its registered offices at [street, post code, city, country], represented by [name], with [identification document/passport] number, in his/her role as [position] of [legal short name]. |
| **Material** | The original materials specified in Schedule A hereto, as well as their Progeny and Unmodified derivatives. |
| **Project** | TREN2MEDS |

In consideration of the mutual covenants set out in this Agreement and for other good and valuable consideration the receipt and sufficiency of which is hereby acknowledged by each of the Parties, the Parties agree as follows:

**WHEREAS**:

1. Provider is in possession of a certain material as defined in Schedule A, hereinafter referred to as the “**Material**”;
2. Recipient is interested in the use of the Material for the purpose of the Project.
3. Provider is willing to provide Recipient with the Material, on the following terms:

Therefore, it is agreed as follows:

1. **Agreement** means the present Material Transfer Agreement including Schedule A being the descriptions of the Material and of the Project, and including Schedule B being the “Terms and Conditions” of the Agreement, which shall be complied with due consideration of a Party’s obligations according to applicable laws or regulations regarding access to public documents and keeping, archiving or storing a copy or other mandatory obligations.
2. **Material**

Material has the meaning attributed to it in Schedule A. In short, this means: [please briefly explain].

1. **Provider Scientist**:

[Name of Principal Investigator]

[Contact details]

1. **Recipient Scientist**:

[Name of Principal Investigator]

[Contact details]

1. **Consideration and Delivery of Material**

***[Option 1: If Material is provided free of cost by Provider]***

The Material is provided free of charge. Each party shall be responsible for funding their portions of research on their own premises.

*[Note: Cost of shipment (sending and/or returning or cost of destroying) needs to be agreed by the Parties. See clause 3.7 of the Terms &Conditions for further information]*

***[Option 2: If Material provided is subject to a fee]***

The Material is provided at cost [please detail] in order to reimburse Provider for the preparation and maintenance of the Material. Payment to the Provider shall be made within thirty (30) days after the invoice date.

*[Note: Cost of shipment (sending and/or returning or cost of destroying) needs to be agreed by the Parties. See clause 3.7 of the Terms &Conditions for further information]*

The Material will be supplied within [please detail term in days or weeks] after the execution of this Agreement.

**IN WITNESS WHEREOF** the duly authorized signatories of the Parties signed this Agreement, including Schedules, in two (2) originals, both in the English language, both having the same validity, for and on behalf of

|  |  |  |
| --- | --- | --- |
| **Provider** |  | **Recipient** |
|  |  |  |
| [Name of legal Representative][title]  |  | [Name of legal Representative][title] |

**For acknowledgement:**

I have read and understood this Agreement, including Schedules, and agree to act in accordance with all the terms and conditions of the Agreement. I further agree to ensure that all participants working under my supervision or otherwise involved in working with the Material are aware of and abide by the terms of this Agreement.

|  |  |  |
| --- | --- | --- |
|  |  |  |
|  |  |  |
| [Name of Principal Investigator] Principal Investigator - Provider |  | [Name of Principal Investigator] Principal Investigator – Recipient |

**Schedule A**

**Description of the Material and of the PROJECT**

1. **Material**

Materials means any biological human or non-human material which is either owned/stored by a Party before the commencement of the Project or collected/generated by a Party during the Project which may be transferred between the Parties for the performance of the Project.

Material means, *[Please briefly explain]*

1. **Project**

*[Please briefly explain]*

**Schedule B**

**Terms and Conditions:**