

Consortium Agreement

Project 101056986 - BRAVEST

Building Resilience Against crisis: a
systematic and global approach to
adVancE organ Safety and supply in
Transplantation

Final Version – 18 July 2022

(Based on DESCA – Model Consortium Agreement for Horizon Europe, version 1, December 2021)

Table of Contents

1	Definitions	5
2	Purpose	6
3	Entry into force, duration and termination	6
4	Responsibilities of Parties.....	7
5	Liability towards each other	8
6	Governance structure	9
7	Financial provisions.....	18
8	Results.....	20
9	Access Rights.....	24
10	Non-disclosure of information	27
11	Miscellaneous	28
12	Signatures	30
	Attachment 1: Background included.....	40
	Attachment 2: Accession document	50
	Attachment 3: List of third parties for simplified transfer according to Section 8.3.2.....	51

Change Records

Version	Date	Changes
1.0	05 April 2022	First draft based on DESCA model
1.1	06 May 2022	Second draft taking into account the comments received from the Parties
1.2	18 July 2022	Third draft taking into account the requests for changes made by the Parties

CONSORTIUM AGREEMENT

THIS CONSORTIUM AGREEMENT is based upon Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014 laying down its rules for participation and dissemination (hereinafter referred to as "EU4Health Regulation"), and on the European Commission's General Model Grant Agreement for the Eu4health Programme and its Annexes, and is made on the Project start date or on the date of last signature of this Consortium Agreement whichever it is the earliest, hereinafter referred to as the Effective Date.

BETWEEN:

EUROPEAN SOCIETY FOR ORGAN TRANSPLANTATION, organised and existing under the laws of Netherlands, with its registered office at Westerdoksdijk 423, Amsterdam 1013 BX, Netherlands and VAT number NL820509498B01, represented by its President, Luciano Potena, hereinafter referred to as ESOT, the **Coordinator**;

ISTITUTO SUPERIORE DI SANITA', organised and existing under the laws of Italy, with its registered office at Viale Regina Elena 299, ROMA 00161, Italy and VAT number IT03657731000, represented by its President, Silvio Brusaferrò, hereinafter referred to as ISS - CNT;

ORGANIZACION NACIONAL DE TRASPLANTES, organised and existing under the laws of Spain, with its registered office at Calle Sinesio Delgado 8, Madrid 28029, Spain and VAT number ESQ2801335G, represented by its Director General, Beatriz Domínguez-Gil, hereinafter referred to as ONT;

ZAVOD REPUBLIKE SLOVENIJE ZA PRESADITVE ORGANOV IN TKIV SLOVENIJA TRANSPLANT, organised and existing under the laws of Slovenia, with its registered office at Zaloska Cesta 7, Ljubljana 1000, Slovenia and VAT number SI53164563, represented by its Director of the institute, Andrej Gadžijev, MD, hereinafter referred to as ST;

STICHTING EUROTRANSPLANT INTERNATIONAL FOUNDATION, organised and existing under the laws of Netherlands, with its registered office at Haagse Schouwweg 6, 2332 KG Leiden, the Netherlands and VAT number NL807217943B01, represented by its General Director, Peter Branger, hereinafter referred to as ET;

AGENCE DE LA BIOMEDECINE, organised and existing under the laws of France, with its registered office at Avenue du Stade de France 1, Saint Denis La Plaine CEDEX 93212, France, represented by its Director-General, Emmanuelle Cortot-Boucher, hereinafter referred to as ABM;

ORSZAGOS VERELLATO SZOLGALAT - OVSZ, organised and existing under the laws of Hungary, with its registered office at Karolina ut 19-21, Budapest 1113, Hungary and VAT number HU15329365, represented by its General Director, Andrea Bayerné Dr. Matusovits, hereinafter referred to as OVSZ;

INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE, organised and existing under the laws of France, with its registered office at Rue de Tolbiac 101, Paris 75654, France and VAT number FR31180036048, represented by its Délégué Régional INSERM DR Paris 5, François Chambelin, hereinafter referred to as INSERM;

EUROPEAN PUBLIC HEALTH ALLIANCE, organised and existing under the laws of Belgium, with its registered office at Rue de Treves 49-51, Bruxelles 1040, Belgium and VAT number BE0451133736, represented by its Director General, Dr Milka Sokolovic, hereinafter referred to as EPHA;

hereinafter, jointly or individually, referred to as "Parties" or "Party"

relating to the Action entitled

Building Resilience Against crisis: a systematic and global approach to adVancE organ Safety and supply in Transplantation

in short

BRAVEST

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 EU4Health Programme (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.

NOW, THEREFORE, IT IS HEREBY AGREED AS FOLLOWS:

1 Definitions

1.1

Definitions

Words beginning with a capital letter shall have the meaning defined either herein or in the EU4Health

1.2 Regulation or in the Grant Agreement including its Annexes.

Additional Definitions

"Background"

Background means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that is:

- a) held by the beneficiaries before they acceded to the Grant Agreement and
- b) needed to implement the Project or exploit the Results.

"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 identified to be in breach of this Consortium Agreement and/or the Grant Agreement as specified in Section 4.2 of this Consortium Agreement.

“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.

“Software”

Software means sequences of instructions to carry out a process in, or convertible into, a form executable by a computer and fixed in any tangible medium of expression.

2 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.

3.1

3 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.

- 3.2 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 Party, or
- the Grant Agreement is terminated, or
- a Party'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

- 3.3 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 Responsibilities of Parties

4.1

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 and promptly correct any error therein of which it is notified.

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.

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.

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. This agreement shall be in compliance with the terms of this Consortium Agreement.

5.1

5 Liability towards each other

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.

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.

- 5.2 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 the Consortium Plan of the Project.

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.

Damage caused to third parties

- 5.3 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.

Force Majeure

- 5.4 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.

6.1 6 Governance structure

General structure

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

- The **General Assembly** as the ultimate decision-making body of the consortium
- The **Management Board (MB)** as the supervisory body for the execution of the Project, which shall report to and be accountable to the General Assembly
- The **Coordinator** as the legal entity acting as the intermediary between the Parties and the Granting Authority will be ultimately responsible for the overall project coordination. 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. For doing this, it will avail itself of a person acting as **Project Coordinator** for strategic guidance of the Project and of a **Project Management Office** to manage both scientific and administrative issues.
- The **External Advisory Board (EAB)** provides suggestions and recommendations to the General Assembly and the Coordinator on a regular basis.

General operational procedures for all Consortium Bodies

6.2.1 Chairing and Representation in meetings

The meetings of each Consortium Body shall be chaired by the person acting as Project Coordinator.

6.2 Any Party which is appointed to take part in a Consortium Body shall designate one representative (hereinafter referred to as "Member").

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.

6.2.2 Preparation and organisation of meetings

6.2.2.1 Convening meetings:

The chairperson of a Consortium Body shall convene meetings of that Consortium Body.

	Ordinary meeting	Extraordinary meeting
General Assembly	At least once a year	At any time upon request of the Management Board or 1/3 of the Members of the General Assembly
Management Board	At least quarterly	At any time upon request of any Member of the Management Board

6.2.2.2 Notice of a meeting

The chairperson of a Consortium Body shall give written notice of a meeting to each Member of that Consortium Body as soon as possible and no later than the minimum number of days preceding the meeting as indicated below.

	Ordinary meeting	Extraordinary meeting
General Assembly	45 calendar days	15 calendar days
Management Board	14 calendar days	7 calendar days

6.2.2.3 Sending the agenda

The chairperson of a Consortium Body shall prepare and send each Member of that Consortium Body an agenda no later than the minimum number of days preceding the meeting as indicated below.

General Assembly	21 calendar days, 10 calendar days for an extraordinary meeting
Management Board	7 calendar days

6.2.2.4 Adding agenda items:

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

Any Member of a Consortium Body may add an item to the original agenda by written notice to all of the other Members of that Consortium Body up to the minimum number of days preceding the meeting as indicated below.

General Assembly	14 calendar days, 7 calendar days for an extraordinary meeting
Management Board	2 calendar days

6.2.2.5

During a meeting, the Members of a Consortium Body present or represented can unanimously agree to add a new item to the original agenda.

6.2.2.6

Meetings of each Consortium Body may also be held by tele- or videoconference, or other telecommunication means, as well as in hybrid forms.

Decisions may also be taken via online voting tools, provided the online vote duly observes the principles of fairness, transparency, proper documentation and confidentiality as required to ensure the same degree of reliability as a vote in a physical meeting. The Coordinator shall inform the Parties of the tool to be used for online voting in due time before the vote for each Party to make sure they have sufficient technical access and opportunity to cast their vote.

6.2.2.7

Decisions will only be binding once the relevant part of the minutes has been accepted according to Section 6.2.5.2.

6.2.2.8

Decisions without a meeting

Any decision may also be taken without a meeting if

- a) the Coordinator circulates to all Members of the General Assembly a written document illustrating the suggested decision with a deadline for responses of at least 10 calendar days after receipt by a Party and
- b) the decision is agreed by 51 % of all Parties.

Decisions may also be taken via online voting tools, provided the online vote duly observes the principles of fairness, transparency, proper documentation and confidentiality as required to ensure the same degree of reliability as a vote in a physical meeting. The Coordinator shall inform the Parties of the tool to be used for online voting in due time before the vote for each Party to make sure they have sufficient technical access and opportunity to cast their vote.

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

A veto according to Section 6.2.4 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.

6.2.3 Voting rules and quorum

6.2.3.1

Each Consortium Body shall not deliberate and decide validly in meetings unless two-thirds (2/3) of its Members are present or represented (quorum).

If the quorum is not reached, the chairperson of the Consortium Body 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.

6.2.3.2

Each Member of a Consortium Body present or represented in the meeting shall have one vote.

6.2.3.3

A Party which the General Assembly has declared according to Section 4.2 to be a Defaulting Party may not vote.

6.2.3.4

Decisions shall be taken by a majority of two-thirds (2/3) of the votes cast, except for the ones related to the evolution of the consortium to be taken by the General Assembly for which a unanimous vote is necessary instead.

6.2.4 Veto rights

6.2.4.1

A Party 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 a Consortium Body may exercise a veto with respect to the corresponding decision or relevant part of the decision.

6.2.4.2

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

6.2.4.3

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

A Party that is not appointed to participate to a particular Consortium Body may veto a decision within the same number of calendar days after receipt of the draft minutes of the meeting.

6.2.4.4

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

6.2.4.5

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

6.2.4.6

A Party 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.

6.2.4.7

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

6.2.5 Minutes of meetings

6.2.5.1

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

6.2.5.2

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

6.3 6.2.5.3

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

Specific operational procedures for the Consortium Bodies

6.3.1 General Assembly

In addition to the rules described in Section 6.2, the following rules apply:

6.3.1.1 Members

6.3.1.1.1

The General Assembly shall consist of one representative of each Party (hereinafter General Assembly Member). The Party shall ensure internally that the person acting at a meeting has the necessary authority or has obtained a mandate from the competent officer/s for the decisions to be taken.

6.3.1.1.2

Each General Assembly Member shall be deemed to be duly authorised to deliberate, negotiate and decide on all matters listed in Section 6.3.1.2. of this Consortium Agreement.

6.3.1.1.3

The Coordinator shall chair all meetings of the General Assembly, unless decided otherwise in a meeting of the General Assembly.

6.3.1.1.4

The Parties agree to abide by all decisions of the General Assembly. This does not prevent the Parties from exercising their veto rights, according to Section 6.2.4.1, or from submitting a dispute to resolution in accordance with the provisions of Settlement of disputes in Section 11.8.

6.3.1.2 Decisions

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.

In addition, all proposals made by the Management Board shall also be considered and decided upon by the General Assembly.

The following decisions shall be taken by the General Assembly:

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 8.3.2)
-

Evolution of the consortium

- Entry of a new Party to the Project and approval of the settlement on the conditions of the accession of such a new Party
- Withdrawal of a Party from the Project and the approval of the settlement on the conditions of the withdrawal
- 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
- 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

Appointments

On the basis of the Grant Agreement, the appointment if necessary of:

- Management Board Members
- External Advisory Board Members

6.3.2 Management Board (MB)

In addition to the rules in Section 6.2, the following rules shall apply:

6.3.2.1 Members

The Management Board shall consist of the Coordinator and the leaders of the different Work Packages appointed to it by the General Assembly.

The Coordinator shall chair all meetings of the Management Board, unless decided otherwise by a majority of two-thirds.

6.3.2.2 Minutes of meetings

Minutes of Management Board meetings, once accepted, shall be sent by the Coordinator to the General Assembly Members for information.

6.3.2.3 Tasks

6.3.2.3.1

The Management Board shall prepare the meetings, propose decisions and prepare the agenda of the General Assembly according to Section 6.3.1.2.

6.3.2.3.2

The Management Board shall seek a consensus among the Parties.

6.3.2.3.3

The Management Board shall be responsible for the proper execution and implementation of the decisions of the General Assembly.

6.3.2.3.4

The Management Board shall monitor the effective and efficient implementation of the Project. It will define the work of each Work Package from the beginning of the Project and it will agree upon the content and structure of deliverables. It will also evaluate the work done and future steps.

6.3.2.3.5

In addition, the Management Board shall collect information at least every 6 months on the progress of the Project, examine that information to assess the compliance of the Project with the Consortium Plan and, if necessary, propose modifications of the Consortium Plan to the General Assembly.

6.3.2.3.6

The Management Board shall support the Coordinator in preparing meetings with the Granting Authority and in preparing related data and deliverables.

6.3.2.3.7

In the case of abolished tasks as a result of a decision of the General Assembly, the Management Board shall advise the General Assembly on ways to rearrange tasks and budgets of the Parties concerned. Such rearrangement shall take into consideration any prior legitimate commitments which cannot be cancelled.

Coordinator

6.4 6.4.1

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

6.4.2

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 certifications) and specific requested documents to the Granting Authority
- transmitting documents and information connected with the Project to any other Parties concerned
- administering the financial contribution of the Granting Authority and fulfilling the financial tasks described in Section 7.2
- 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.

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.

6.4.3

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

6.4.4

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.

6.4.5

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

6.4.6

For strategic and scientific guidance of all Parties involved in the Project, the Coordinator has appointed a **Project Coordinator** who will also be responsible to identify key performance indicators for quality objectives.

To manage both scientific and administrative issues, the Coordinator will be supported in the day-to-day technical management by a **Project Manager (PM)**. On the administrative, financial, and legal side, the PC will be supported by the **Financial Assistance**. PM and Financial Assistance will be officially appointed at the kick-off meeting of the project. The Project Coordinator together with Project Manager and Financial Assistance will constitute the **Project Management Office**.

Specifically, the duties of the Project Management Office are:

- monitoring financial spending and integrate the needed information for official report submitted to the EC;
 - providing ICT tools to host ongoing project activities;
 - monitor the quality of online and in-presence technical meetings through devoted surveys among the participants whenever necessary;
 - providing support on organisation of events and workshops as well as material needed for dissemination;
- 6.5
- collecting input and integrating the content of the periodic reports.

External Advisory Board (EAB)

To strengthen the continuous communication and feed-back with key stakeholders, the General Assembly will be aided by an External Advisory Board (EAB). Candidate EAB members, with no link to any of the Parties, will be presented during the first General Assembly meeting, selected and then officially appointed by the General Assembly. The External Advisory Board (EAB) will include at least 5 members, with expertise in organ donation, kidney, liver, heart, lung transplantation, respectively.

The EAB is mainly in charge of:

- guide and give feedback to the GA on its ongoing activities, with a dedicated commission for the clinical issues;
- serving as the first contact point in communicating and applying the results of the project, strengthening the dissemination part of the project.

Members of the EAB will have access to all project documents and outputs upon signature of an NDA document, with terms not less stringent than those stipulated in this Consortium Agreement, including specific restrictions and rules for access to the Results, Background and Confidential Information, no later than 30 calendar days after their appointment or before any confidential information will be exchanged/disclosed, whichever date is earlier.

The External Advisory Board (EAB) will be steered by the Coordinator that shall write the minutes of the EAB meetings and submit them to the General Assembly. The EAB members shall be allowed to participate to plenary meetings and in General Assembly meetings upon invitation but have not any voting rights.

7 Financial provisions

General Principles

7.1.1 Distribution of Financial Contribution

7.1

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 7.2.

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

7.1.2 Justifying Costs

In accordance with its own usual accounting and management principles and practices, each Party shall be solely responsible for justifying its costs (and those of its Affiliated Entities, if any) 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.

7.1.3 Funding Principles

A Party that spends less than its allocated share of the budget as set out in the Consortium Plan or – in case of reimbursement via unit costs - implements less units than foreseen in the Consortium Plan will be funded in accordance with its units/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.

7.1.4 Excess payments

A Party has received excess payment

- a) if the payment received from the Coordinator exceeds the amount declared or
- b) 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.

7.1.5 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.

7.1.6 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 5.2 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.

7.2 Payments

7.2.1 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.

7.2.2

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 Authority Payment	Timing	Amount
Initial prefinancing (30% of the funding of costs included in the Consortium Plan)	Upon receipt of the initial prefinancing from the Funding Authority, without unjustified delay.	30% of the funding of costs included in the Consortium Plan for the Party concerned
Interim payment	Upon acceptance of M01-M18 Periodic report by the Funding Authority and receipt of the corresponding Interim payment issued by the Funding Authority to the Coordinator (around M24)	An amount equal to the funding for costs of the Party concerned that have been accepted by the Granting Authority, where this funding plus the prefinancing instalments received does not exceed the 90% of the funding of costs included in the Consortium Plan for the Party concerned.
Final payment	Upon acceptance of M19-M30 Periodic report by the Funding Authority and receipt of the corresponding Interim payment issued by the Funding Authority to the Coordinator (around M30+5)	The balance due to the Parties, in accordance with the following: - cumulative accepted EU contribution for the whole duration of the Project, - payments already received, - the conditions set out in Clause 7.1.3 above.

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 Beneficiary which has not yet signed this Consortium Agreement;
 - recover any payments already paid to a Defaulting Party except the costs already claimed by the Defaulting Party and accepted by the Granting Authority;
- 8.1
- withhold payments to a Party when this is suggested by or agreed with the Granting Authority.

8 Results

Ownership of Results

Results are owned by the Party that generates them.

Joint ownership

Two or more Parties own results jointly if:

1. they have jointly generated them and
- 8.2 2. it is not possible to:
 - establish the respective contribution of each Party, or
 - separate them for the purpose of applying for, obtaining or maintaining their protection.

The joint owners must agree—in writing—on the allocation and terms of exercise of their joint ownership ('joint ownership agreement'), to ensure compliance with their obligations under the Grant Agreement and this Consortium Agreement.

The joint ownership agreement shall be drawn up as soon as necessary and in any event before any industrial and/or commercial exploitation of the jointly owned Results.

The joint owners agree to endeavour the appointment among them of one joint owner in charge of the management and exploitation of the jointly owned Results in the name of all the other joint owners, notably for the granting of Access Rights to a requesting Party and for the negotiation of exploitation agreements with third parties (including exclusive license agreements). Unless otherwise agreed:

- each of the joint owners shall be entitled to use their jointly owned Results for non-commercial research and teaching activities on a royalty-free basis, and without requiring the prior consent of the other joint owner(s).
- each of the joint owners shall be entitled to otherwise Exploit the jointly owned Results and to grant non-exclusive licenses to third parties (without any right to sub-license) if the other joint owners are given: (a) at least 45 calendar days advance notice; and (b) fair and reasonable compensation.

The joint owners shall agree on all protection measures and the division of related cost in advance.

The joint owners may agree—in writing—to apply another regime than joint ownership.

- 8.3 If third parties (including employees and other personnel) may claim rights to the results, the beneficiary concerned must ensure that those rights can be exercised in a manner compatible with its obligations under the Grant Agreement and this Consortium Agreement.

Transfer of Results

8.3.1

The Parties may transfer ownership of their results, provided this does not affect compliance with their obligations under the Grant Agreement.

The beneficiaries must ensure that their obligations under the Agreement regarding their results are passed on to the new owner and that this new owner has the obligation to pass them on in any subsequent transfer.

Moreover, they must inform the other Parties with access rights of the transfer at least 45 days in advance (or less if agreed in writing), unless agreed otherwise in writing for specifically identified third

parties including affiliated entities or unless impossible under the applicable law. This notification must include sufficient information on the new owner to enable the Parties concerned to assess the effects on their access rights. The Parties may object within 30 days of receiving notification (or less if agreed in writing) if they can show that the transfer would adversely affect their access rights. In this case, the transfer may not take place until agreement has been reached between the Parties concerned.

8.3.2

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 Article 8.3.1 3rd paragraph of this Consortium Agreement.

8.3.3

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.

8.3.4

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.

8.3.5

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

8.4

Dissemination

Material to be disseminated shall be prepared in respect of the procedures of the Grant Agreement Article 17 and Annex 5 Section "Communication, Dissemination, and Visibility" and of Section 8 of this Consortium Agreement and then approved by the Project Coordinator together with the Parties involved in Work Package 2 - Communication, dissemination and exploitation.

8.4.1

For the avoidance of doubt, the confidentiality obligations set out in Section 10 apply to all dissemination activities described in this Section 8.4 as far as Confidential Information is involved.

8.4.2 Dissemination of own (including jointly owned) Results

8.4.2.1

During the Project and for a period of 1 year 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 Communication, Dissemination and Visibility, subject to the following provisions.

Prior notice of any planned publication shall be given to the other Parties at least 30 calendar days before the publication. Any objection to the planned publication 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 30 calendar days after receipt of the notice. If no objection is made within the time limit stated above, the publication is permitted.

8.4.2.2

An objection is justified if

- a) the protection of the objecting Party's Results or Background would be adversely affected, or
- b) the objecting Party's legitimate interests in relation to its Results or Background would be significantly harmed, or
- c) the proposed publication includes Confidential Information of the objecting Party.

The objection has to include a precise request for necessary modifications, it being specified that any such modifications shall not harm the scientific conclusions of the proposed publication or communication.

8.4.2.3

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

8.4.2.4

The objecting Party can request a publication delay of not more than 60 calendar days from the time it raises such an objection. After 60 calendar days the publication is permitted, provided that the objections of the objecting Party have been addressed.

8.4.3 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.

8.4.4 Cooperation obligations

The Parties undertake to cooperate to allow the timely submission, examination, publication and defense 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.

8.4.5 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.

9 Access Rights

Background included

9.1.1

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
9.1 restrictions or limits.

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

Each of the Parties retains full ownership or right of disposal on any data, know-how or information defined as its Background in Attachment 1.

9.1.2

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.

For avoidance of doubt, under no circumstances should the withdrawal of any Background impair the implementation of the Project.

9.2 General Principles

9.2.1

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.

9.2.2

Any Access Rights granted exclude any rights to sublicense unless expressly stated otherwise.

9.2.3

Access Rights Needed for the performance of the work of a Party under the Project shall be free of any administrative transfer costs.

9.2.4

Access Rights are granted on a non-exclusive basis.

9.2.5

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

9.2.6

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.

9.2.7

The requesting Party must show that the Access Rights are Needed.

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
9.3 Attachment 1.

Access Rights for Exploitation

9.4.1 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 to be agreed by the concerned Parties upon written separate agreement prior to any use of the Results by the requesting Party.

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

9.4.2

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

9.4.3

9.5 A request for Access Rights may be made up to twelve months after the end of the Project or, in the case of Section 9.7.2.1.2, after the termination of the requesting Party's participation in the Project.

Access Rights for entities under the same control

Access Rights for entities under the same control 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. Access Rights to an entity under the same control shall be granted on Fair and Reasonable conditions and upon written bilateral agreement prior to any use of the Background or Results by entity under the same control.

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.

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.

Access Rights for Parties entering or leaving the consortium

9.7.1 New Parties entering the consortium

9.7

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.

9.7.2 Parties leaving the consortium

9.7.2.1 Access Rights granted to a leaving Party

9.7.2.1.1 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.

9.7.2.1.2 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 9.4.3.

9.7.2.2 Access Rights to be granted by any leaving Party

9.8

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.

Specific Provisions for Access Rights to Software

For the avoidance of doubt, the general provisions for Access Rights provided for in this Section 9 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.

10 Non-disclosure of information

10.1 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".

10.2 The Recipients hereby undertake in addition and without prejudice to any commitment on non-disclosure under the Grant Agreement, for a period of 5 years after the end of the Project:

- 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 Recipients 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.

10.3

10.4 The Recipients shall be responsible for the fulfilment of the above obligations on the part of their 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.

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.

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

10.5

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.

10.6

10.7 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.

11 Miscellaneous

11.1

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 8.3.2).

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.

11.2 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.

No representation, partnership or agency

Except as otherwise provided in Section 6.4.4, 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.

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.

11.3 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 4.2, 9.7.2.1.1, and 11.4) 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.

Assignment and amendments

11.4 Except as set out in Section 8.3, 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 6.3.1.2 require a separate written agreement to be signed between all Parties.

11.5 Mandatory national law

Nothing in this Consortium Agreement shall be deemed to require a Party to breach any mandatory 11.6 statutory law under which the Party is operating.

Language

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

11.8 Applicable law

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

Settlement of disputes

The Parties shall endeavour to settle their disputes amicably.

All disputes arising out of or in connection with this Consortium Agreement, which cannot be solved amicably, shall be finally settled by the courts of Brussels.

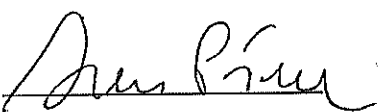
12 Signatures

AS WITNESS:

The Parties have caused this Consortium Agreement to be duly signed by the undersigned authorised representatives in 9 separate signature pages.

Each Party shall sign in original 1 copy and then send it to the Coordinator. The Coordinator shall gather all the signature pages signed in original by the Parties. Once received the last signature page signed in original, the Coordinator shall send a scan the complete signed version of this Consortium Agreement to the main contact person of each Party.

EUROPEAN SOCIETY FOR ORGAN TRANSPLANTATION (ESOT)

Signature 

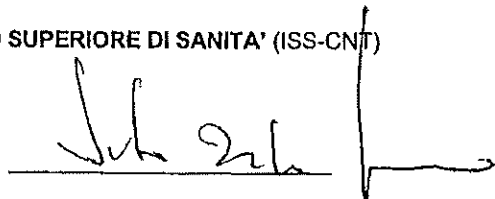
Name Luciano Potena

Title ESOT President

Date 18/09/2022

ISTITUTO SUPERIORE DI SANITA' (ISS-CNT)

Signature

A handwritten signature in black ink, appearing to read 'Silvio Brusaferrò', is written over a horizontal line. The signature is stylized and includes a vertical line extending upwards from the end of the horizontal line.

Name Silvio Brusaferrò

Title President of ISS

Date - 8 SET. 2022

ORGANIZACION NACIONAL DE TRASPLANTES (ONT)

DOMINGUEZ-GIL
GONZALEZ BEATRIZ
Signature - DNI 07965795K

Firmado digitalmente por
DOMINGUEZ-GIL GONZALEZ BEATRIZ
- DNI:07965795K
Fecha: 2022.09.23 15:02:51 +02:00'

Name Beatriz Domínguez-Gil

Title Director General

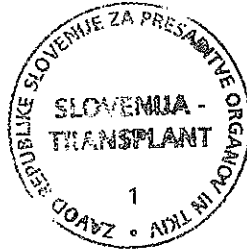
Date 23/09/2022



**ZAVOD REPUBLIKE SLOVENIJE ZA PRESADITVE ORGANOV IN TKIV SLOVENIJA TRANSPLANT
(ST)**

Signature Andrej Gadžijev

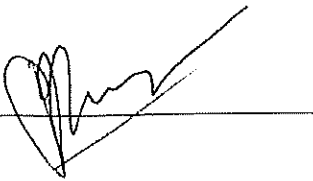
Name Andrej Gadžijev, MD



Title Director of the institute

Date 7. 9. 2022

STICHTING EUROTRANSPLANT INTERNATIONAL FOUNDATION (ET)

Signature 


Name Peter Branger

Title General Director

Date 08/09/22

EUROTRANSPLANT
Leiden
The Netherlands
Tel.+31 715795800
www.eurotransplant.org

AGENCE DE LA BIOMEDECINE (ABM)

Signature 
—

Name Emmanuelle CORTOT-BOUCHER

Title Director-General

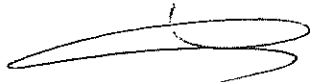
Date 07/09/2022

Jktbz.: OVbzK 1976-86/2022/1150

BRAVEST Consortium Agreement, final version, 18 July 2022

ORSZAGOS VERELLATO SZOLGALAT - OVSZ (OVSZ)

Signature _____




Name Andrea Bayerné Dr. Matusovits

Title General Director



Date 14 September 2022

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

Signature 

Name François Chambelin

Title Délégué Régional INSERM DR Paris IDF Centre Nord

Date 08.09.2022

EUROPEAN PUBLIC HEALTH ALLIANCE (EPHA)

Signature

Milka Sokolovic

European Public Health
Alliance (EPHA)
Rue de Trèves, 49 51
B-1040 Brussels - Belgium
BE 0451133736
www.ephia.org



Name Milka Sokolovic

Title Director General

Date 7 September 2022

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 - EUROPEAN SOCIETY FOR ORGAN TRANSPLANTATION (ESOT)

As to EUROPEAN SOCIETY FOR ORGAN TRANSPLANTATION, it is agreed between the Parties that, to the best of their knowledge, no data, know-how or information of EUROPEAN SOCIETY FOR ORGAN TRANSPLANTATION is Needed by another Party for implementation of the Project (Article 16.1 and its Annex 5 Grant Agreement, Section "**List of Background**") or Exploitation of that other Party's Results (Article 16.1 and its Annex 5 Grant Agreement, Section "**List of Background**").

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

PARTY 2 - ISTITUTO SUPERIORE DI SANITA' (ISS-CNT)

As to ISTITUTO SUPERIORE DI SANITA', 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 (Article 16.4 Grant Agreement and its Annex 5, Section "List of Background")	Specific restrictions and/or conditions for Exploitation (Article 16.4 Grant Agreement and its Annex 5, Section "List of Background")
Data on donation and transplantation activity in Italy as well as SARS-CoV-2 epidemiological data needed to support the work of WP3, as specified in the technical annex.	Access will be limited to the purposes described in the tasks of the BRAVEST Project.	Access will be limited to the purposes described in the tasks of the BRAVEST Project.

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

PARTY 3 - ORGANIZACION NACIONAL DE TRASPLANTES (ONT)

As to ORGANIZACION NACIONAL DE TRASPLANTES, 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 (Article 16.4 Grant Agreement and its Annex 5, Section "List of Background")	Specific restrictions and/or conditions for Exploitation (Article 16.4 Grant Agreement and its Annex 5, Section "List of Background")
<p>Data on donation and transplantation activity in Spain as well as SARS-CoV-2 epidemiological data needed to coordinate the WP3 (Analysis of COVID-19 pandemic impact on participating countries), as specified in the technical annex.</p>	<p>Access will be limited to the purposes described in the tasks of the BRAVEST Project.</p>	<p>Access will be limited to the purposes described in the tasks of the BRAVEST Project.</p>

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

PARTY 4 - ZAVOD REPUBLIKE SLOVENIJE ZA PRESADITVE ORGANOV IN TKIV SLOVENIJA TRANSPLANT (ST)

As to ZAVOD REPUBLIKE SLOVENIJE ZA PRESADITVE ORGANOV IN TKIV SLOVENIJA TRANSPLANT, it is agreed between the Parties that, to the best of their knowledge, No data, know-how or information of ZAVOD REPUBLIKE SLOVENIJE ZA PRESADITVE ORGANOV IN TKIV SLOVENIJA TRANSPLANT is Needed by another Party for implementation of the Project (Article 16.1 and its Annex 5 Grant Agreement, Section "**List of Background**") or Exploitation of that other Party's Results (Article 16.1 and its Annex 5 Grant Agreement, Section "**List of Background**").

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

PARTY 5 - STICHTING EUROTRANSPLANT INTERNATIONAL FOUNDATION (ET)

As to STICHTING EUROTRANSPLANT INTERNATIONAL FOUNDATION, 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 (Article 16.4 Grant Agreement and its Annex 5, Section "List of Background")	Specific restrictions and/or conditions for Exploitation (Article 16.4 Grant Agreement and its Annex 5, Section "List of Background")
Data on donation and transplantation activity in Eurotransplant countries as well as SARS-CoV-2 epidemiological data needed to support the work of WP3, as specified in the technical annex.	Access will be limited to the purposes described in the tasks of the BRAVEST Project.	Access will be limited to the purposes described in the tasks of the BRAVEST Project.

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

PARTY 6 - AGENCE DE LA BIOMEDECINE (ABM)

As to AGENCE DE LA BIOMEDECINE, 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 (Article 16.4 Grant Agreement and its Annex 5, Section "List of Background"	Specific restrictions and/or conditions for Exploitation (Article 16.4 Grant Agreement and its Annex 5, Section List of Background"
Data on donation and transplantation activity in France as well as SARS-CoV-2 epidemiological data needed to support the work of WP3, as specified in the technical annex.	Access will be limited to the purposes described in the tasks of the BRAVEST Project.	Access will be limited to the purposes described in the tasks of the BRAVEST Project.

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

PARTY 7 - ORSZAGOS VERELLATO SZOLGALAT – OVSZ (OVSZ)

As to ORSZAGOS VERELLATO SZOLGALAT - OVSZ, 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 (Article 16.4 Grant Agreement and its Annex 5, Section “List of Background”)	Specific restrictions and/or conditions for Exploitation (Article 16.4 Grant Agreement and its Annex 5, Section “List of Background”)
Data on donation and transplantation activity in Hungary as well as SARS-CoV-2 epidemiological data needed to support the work of WP3, as specified in the technical annex.	No limitation.	No limitation.

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

PARTY 8 - INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM)

As to INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE, it is agreed between the Parties that, to the best of their knowledge,, No data, know-how or information of **INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE** is Needed by another Party for implementation of the Project (Article 16.1 and its Annex 5 Grant Agreement, Section "**List of Background**") or Exploitation of that other Party's Results (Article 16.1 and its Annex 5 Grant Agreement, Section "**List of Background**").

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

PARTY 9 - EUROPEAN PUBLIC HEALTH ALLIANCE (EPAH)

As to EUROPEAN PUBLIC HEALTH ALLIANCE, it is agreed between the Parties that, to the best of their knowledge, No data, know-how or information of EUROPEAN PUBLIC HEALTH ALLIANCE is Needed by another Party for implementation of the Project (Article 16.1 and its Annex 5 Grant Agreement, Section "**List of Background**") or Exploitation of that other Party's Results (Article 16.1 and its Annex 5 Grant Agreement, Section "**List of Background**").

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.

INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM):
Université Paris Cité

