CONSORTIUM AGREEMENT

PROJECT TITLE

PRE-CLINICAL DEVELOPMENT OF AN ACYLCERAMIDE NANOSTRUCTURED DELIVERY SYSTEM TO RESCUE THE SKIN BARRIER IN PATIENTS WITH ICHTHYOSIS

PROJECT ACRONYM

LIPARCI

Table of Content

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 April 1st, 2022, hereinafter referred to as the Effective Date.

BETWEEN:

INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE,
A public scientific and technological institute having its registered office at 101 rue de Tolbiac, 75013 Paris, FRANCE, represented by its Chairman and Chief Executive Officer Dr. Gilles BLOCH, who has delegated signing authority for this Agreement to the Regional Delegate of Inserm Occitanie Pyrénées delegation, Mr Jacques CAVAILLE,

Inserm acting as a supervisor of the following joint research unit:

- « INFINITy : Toulouse Institute for Infectious and Inflammatory Diseases », Inserm joint research Unit 1291/ Université Toulouse 3 – Paul Sabatier / CNRS.

referred to as « **Inserm** » or « **Coordinator** »,

AGENCIA ESTATAL CONSEJO SUPERIOR DE INVESTIGACIONES CIENTÍFICAS, M.P., represented by Dr. Ángeles Gómez Borrego, its Vice-president for International Affairs,

referred to as « **CSIC** »,

FUNDACION PARA LA INVESTIGACION BIOMEDICA DEL HOSPITAL INFANTIL UNIVERSITARIO NINO JESUS,
represented by Emma Méndez Calleja as director of the FUNDACION PARA LA INVESTIGACION BIOMEDICA DEL HOSPITAL INFANTIL NINO JESUS, Avda. Menéndez Pelayo, 65 288009 Madrid, represented by,

referred to as « **FIBHNJS** »,

CHARLES UNIVERSITY – FACULTY OF PHARMACY IN HRADEC KRALOVE,
Akademika Heyrovského 1203, 50005 Hradec Králové, Czech Republic, represented by the dean of the faculty prof. PharmDr. Jaroslav Roh, Ph.D.

referred to as « **Charles University** »,

BEZMIALEM VAKIF UNIVERSITY - FACULTY OF PHARMACY
Topkapı Mahallesi Adnan Menderes Vatan Bulvarı 34093 Fatih/İstanbul, represented by the dean of the faculty Prof. Dr. Gülaçtı Topçu.

referred to as « **Bezmialem Vakif University** »,

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

relating to the project entitled

Pre-clinical development of an acylceramide nanostructured delivery system to rescue the skin barrier in patients with ichthyosis

in short

LIPARCI

hereinafter referred to as “Project”

WHEREAS:
The Parties, having considerable experience in the field concerned, have submitted a project proposal in response to the EuroNanomed 3 joint transnational call for proposals (2021) for “European innovative research & technological development projects in nanomedicine”.

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

NOW, THEREFORE, IT IS HEREBY AGREED AS FOLLOWS:

Section 1: Definitions

1.1 Definitions

Words beginning with a capital letter, in singular or plural, shall have the meaning defined herein.

1.2 Additional Definitions

“**Access Rights”**
Access Rights means rights to use Results or Background under the terms and conditions laid down in this Agreement.

“Affiliated Entity or Affiliate”
Affiliated Entity means any legal entity that is:
- under the direct or indirect control of a participant, or
- under the same direct or indirect control as the participant, or
- directly or indirectly controlling a participant.

‘Control’ may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.
However, the following relationships between legal entities shall not in themselves constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

Affiliates at the date of signature are listed in Attachment 4.

“Agreement” or “Consortium Agreement”
Agreement or Consortium Agreement means this body text, its attachments and its possible further amendments.

“Authorization”
Authorization means (1) all notices and authorizations granted by the Competent Authority prior to the completion of a part of the Project or the Project and necessary to execute the part of the Project or the Project, and (2) the declarations as well as all the formalities to be carried out before the implementation of the part of the Project or the Project.

“Background”
Background means all information which is held by a Party prior to the conclusion of this Agreement or prior to the Project, or generated outside the scope of this Agreement and/or the Project, including but not limited to reports, inventions, data, ideas, methods, solutions, devices, materials, prototypes, know-how, etc. irrespective of whether they are or can be protected by intellectual property rights such as copyright, patent or confidentiality, and which is needed for implementing the Project or exploiting the Results.

“Competent Authority”
Competent Authority refers to, without limitation, all the agencies, services, departments, structures from which formalities must be completed prior to the implementation of the Project in accordance with the laws and regulations in force in order to obtain an Authorization according to the legal qualification of the Project.

“Data”
Data means any data which is part of a Party’s Background included in the Project or which is generated under the Project, including, as the case may be, Personal Data as defined and protected under the European or national applicable legislation(s), and notably with the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 (General Data Protection Regulation).

- Personal Data: means any information relating to an identified or identifiable natural person, an identifiable person being one who can be identified , directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his/her physical, physiological, genetic, mental, economic, cultural or social identity.

“Defaulting Party”
Defaulting Party means a Party which the Steering Committee has identified to be in breach of this Consortium Agreement

“Force Majeure”
Force Majeure shall mean any unforeseeable and exceptional event affecting the fulfilment of any obligation under this Consortium Agreement by the Parties, which is beyond their control and cannot be overcome despite their reasonable endeavours. Any default of a product or service or delays in making them available for the purpose of performing the Project and affecting such performance, including, for instance, anomalies in the functioning or performance of such product or service, labour disputes, strikes or financial difficulties do not constitute Force Majeure.

"Funding Authority"
Funding Authority means the respective national bodies awarding the grant for the Project to the Parties:
- France: Agence Nationale de la Recherche (ANR);
- Spain: Instituto de Salud Carlos III (ISCIII);
- Czech Republic: (Technology Agency of the Czech Republic (TACR);
- Turkey: The Scientific and Technological Research Council of Turkey (TUBITAK).

“Material”
Material means any human or non-human material (including Samples and Data) which is either owned/stored by a Party before the commencement of the Project or collected/generated by a Party during the Project and which may be the subject of a transfer between this Party and another Party for the performance of the Project.

“Needed”
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.

“Results”
Results means any (tangible or intangible) output of the Project such as data, knowledge, technical or other information which is not in the public domain - whatever its form or nature, whether it can be protected or not, that is generated in the Project, as well as any rights attached to it, including intellectual property rights. Results can be Joints Results or Own Results:

- **“Joint Results”**: means Results developed jointly be several Parties to the Project.
- **“Own Results”**: means the Results developed by a single Party pursuant to the Project, without any contribution from another Party.

“Samples”
Samples means any human tissue or material or any derivatives of such human biological material such as stem cells or cell lines and any human biological product, which is necessary for the implementation of the Project.

“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.

Section 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.

Section 3: Entry into force and duration

3.1 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 enter into force at the Effective Date.

A new entity becomes a Party to the Consortium Agreement upon signature of the accession document (Attachment 3) by the new Party and the Coordinator. Such accession shall have effect from the date identified in the accession document.

3.2 Duration

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

3.3 Survival of rights and obligations

The provisions relating to Access Rights, Dissemination and Confidentiality, for the time period mentioned therein, as well as for Background and results, 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 Consortium incurred prior to the date of termination according to article 11.2, unless otherwise agreed between the Steering Committee and the leaving Party. This includes the obligation to provide all Results, deliverables (such as financial statements and related certifications) and documents for the period of its participation.

Section 4: Responsibilities of the 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 financial agreement concluded with the Funding Authority and this Consortium Agreement as may be reasonably required from it and in a manner of good faith.

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

Each Party shall promptly provide all information reasonably required by the Steering Committee or by the Coordinator to carry out its tasks relating to the Project.

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

4.2 Breach

In the event that the Steering Committee identifies a breach by a Party (hereafter “Defaulting Party”) of its obligations under this Consortium 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 Steering Committee, 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 Steering Committee 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 in the consortium under the terms of this Consortium Agreement.

4.3 Involvement of third parties

A Party that enters into a subcontract or otherwise involves third parties (including but not limited to Affiliated Entities) 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 for the consequences arising from such third party’s non compliance according to the terms of this Consortium Agreement. It has to ensure that the involvement of third parties does not affect the rights and obligations of the other Parties under this Consortium Agreement.

Each Party undertakes in particular to take all steps to acquire the intellectual property rights for the Results obtained by such third party within the scope of the Project, so as not to limit the rights granted to the other Parties within the scope of the Consortium Agreement. Such third party may not claim any intellectual property right or right of use of the Results it generates or Background of any of the Parties.

4.4 Transfer of Material

The Parties recognise that for the good governance of the Project, for good Intellectual Property management, and to facilitate compliance with legal and ethical standards, it is desirable to record any transfer of Material between the Parties for the performance of the Project.

In the event that one Party (the "Supplier") transfers Material to another Party (the "Recipient"), the Recipient Party undertakes that all or part of such Material:

(a) will only be used for the sole purposes of conducting the Project and only for as long as it is necessary for this purpose, to the exclusion of any other application, in particular for commercial purposes. No express or implied licenses or other rights or intellectual property rights are provided to the Recipient under any patents, patent applications, trade secrets or other proprietary rights of the Supplier, other than the right to use the Material for conducting the Project;

(b) will not be disclosed, distributed, transferred or licensed to a third party, for any purpose whatsoever, without prior written authorization from the Supplier and in accordance with the Authorization necessary for the transfer;

(c) will not be used on human subjects, particularly for clinical trials or diagnostic purposes, except as defined in the Project description and necessary for the implementation of the Project;

(d) will be used and stored in accordance with the applicable legal and regulatory provisions, notably the provisions relating to the privacy and protection of the Personal Data and to medical confidentiality. In particular, the Recipient ensures that it has obtained any necessary Authorizations and taken appropriate measures for the storage and use of the concerned Material;

(e) will be returned to the Supplier or delete in the event of the withdrawal of the consent or the exercise of the opposition right of the patient which would be communicated by the Supplier to the Recipient;

(f) will no longer be used and will be returned to the Supplier (or destroy, at the Supplier'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

(g) will be used and stored exclusively on the premises of the Recipient within the performance of the Project and by scientists working within the performance of the Project on the premises of the Recipient or under its direct responsibility and with the same degree of confidentiality and security that it applies to its own Material.

Except as specifically agreed otherwise among the relevant Parties in respect of a particular transfer of Material, the Recipient acknowledges that the Material is a research tool supplied "as is", without any guarantee of any kind, whether express or implied, particularly as regards the preservation, use or manipulation of the Material, the fitness and sufficiency or the possibility of using them for a given purpose, or infringement of third party's rights. In particular, the Material is supplied without any guarantee of any kind, whether express or implied, particularly as regards the possibility of using it for a given purpose.

The 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.

Without any legal obligation of analysis and testing being borne by the Supplier, the Recipient recognizes that the Material transferred has not been tested by the Supplier and may contain infectious and/or potentially hazardous agents and, accordingly, the Supplier, subject to article 5.5, may not be

held liable for any damage that may result from the preservation, use or manipulation of the Material, unless such damage is due to a breach by the Supplier of its obligation to provide information based on this Consortium Agreement.

Any Party which is aware of, or becomes aware of, a health safety risk, which originates from any of the Material 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 undertakes that only staff with specific competencies in the manipulation of human biological elements shall receive and manipulate the Samples transferred. The Recipient undertakes to inform such staff of the dangers inherent in the preservation, use and manipulation of the Samples transferred and to train them in the procedures allowing for safe manipulation of such Samples.

The Supplier 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 under patients' consent (where such consent is necessary) in compliance with the applicable laws and regulatory provisions, and notably with the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 (General Data Protection Regulation). The Supplier will communicate to the Recipient all the information at its disposal relating to the preservation and use of the Material.

In any case, the Material shall not be transferred to another Party, except the Supplier, or to a subcontractor or to any third party before any Personal Data has been removed by coding and by rendering it anonymous in accordance with all applicable laws and regulations.

Any transfer and/or access to Material shall be evidenced by the execution of a transmission sheet, the model of which is given in attachment 5, which may be completed by the concerned Parties (notably with regard to the reimbursement and shipping costs) in accordance with the Consortium Agreement.

Each Party concluding a Material Transfer Agreement is responsible that it complies with all applicable rules, laws or regulations, and with the Consortium Agreement, especially concerning the human biological Samples importation and exportation and Data protection.

4.5 Ethical and Regulatory Approvals

The Sponsor shall be responsible for securing all necessary Authorizations, ethical and regulatory approvals from the relevant Competent Authority(ies) and committee(s) before undertaking any part of the Project requiring such Authorization and/or approval and the Sponsor and/or the other concerned Parties, where applicable, shall, if required, obtain properly signed informed consent and acknowledgement forms from any human subjects or their legal guardians who they will involve in the Project. Where any part of the Project takes place in a hospital, the Sponsor shall ensure that the Party involved shall first obtain all necessary approvals and agreements from that hospital.

4.6 Compliance

Each Party shall ensure that its work on the Project complies fully with all applicable Host Country(ies), local, government and international laws, regulations and guidelines which are effective during the period of the Consortium Agreement, including those governing health and safety, data protection, and where relevant, the use of human subjects and good clinical practice such as defined by the International HSR Standards and those adopted by the Council for International Organizations of Medical Sciences and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human use (including national legislation implementing the Parliament's Directive 2001/20/EC on good clinical practice). In this regard, each Party shall maintain the confidentiality, in accordance with section 10 of this Consortium Agreement, of all Samples and Data, which is created or used in the course of the Project.

More specifically, the Sponsor ensures that each local principal investigator identified as such in the Project description as set out in Attachment 1 will implement and monitor the conduct of the Project according to the trial protocol and proceduress validated by the Steering Committee and undertaken in this regard to respect the Project description in Attachment 1 and its annexes.

The Parties will respect all and any Host Country(ies) and international laws, regulations and technical instructions regarding the use, transfer and storage and of Pharmaceutical Products.

4.7 Visiting employee

The presence of employees of one of the Parties on the premises of another Party for the purposes of execution of the Project ("Visiting Employees"), will comply with the following provisions:
The presence of Visiting Employees shall be subject to the prior written agreement of the Party receiving them, it being specified that this agreement will only be given depending on the availability dates at the receiving site and that all the costs relating to their trip will be borne by the employer of the Visiting Employee.
Such Visiting Employees must comply with the internal rules and regulations and all general rules and specific instructions with regard to health, safety and authorization of access applicable on the site receiving them and the directives notified to them by the scientific manager of the Party receiving them.
In any case, the Visiting Employees will remain under the hierarchical authority of their employer.

4.8 Social cover for staff

Notwithstanding the provisions of section 5.5, each of the Parties shall be responsible for providing cover for their staff in accordance with applicable legislation in the field of social security, accidents at work and occupational diseases which applies to them and shall carry out the formalities that they are required to accomplish, even when such staff carries out its allocated work on the premises of another Party.

Section 5: Liability towards each other and Insurance

5.1 No warranties

In respect of any information (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
- 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 Affiliated Entities) exercising its Access Rights.

5.2 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, provided such damage was not caused by a wilful act.

Notwithstanding the provisions of section 5.5 "Insurance" below, 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 provided such damage was not caused by a wilful act or gross negligence of that Party.

The terms of this Consortium Agreement shall not be construed to amend or limit any Party's statutory and regulatory liability.

Without prejudice to any Party's right to take any action against the other, neither Party will bring an action against the employees, students, agents, or appointees of the other except in relation to fraud, negligence or wilful misconduct. Each Party to this Agreement shall be liable for the actions or inactions of its own employees, students, agents or appointees who contribute to the Project.

The rights, duties, obligations and liabilities of the Parties hereto shall not be joint and several.

5.3 Damage caused to third parties

Notwithstanding the provisions of section 5.5 "Insurance" below, 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.

5.4 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 Steering Committee of any Force Majeure without undue delay. If the consequences of Force Majeure for the Project are not overcome within 6 weeks after such notification, the transfer of tasks - if any - shall be decided by the Steering Committee.

5.5 Insurance

Each Party, shall as necessary take out and maintain valid insurance policies necessary to cover potential damage to property or persons that may arise within the scope of performance of the Agreeement. Unless there is any statutory obligation to the contrary, public institutes of the government act as their own insurers.

Section 6: Governance structure

6.1 General structure

The organisational structure of the Project shall comprise the following consortium body:

- The Coordinator
- The Steering Committee as the ultimate decision-making body of the consortium

6.2 Coordinator

6.2.1 Role of the Coordinator

The Parties convened that the position of Coordinator shall be taken over by Inserm appointing Pr Nathalie JONCA as project coordinator (hereinafter "Project Coordinator") of the Project.

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

In particular, the Coordinator shall be responsible for:

- monitoring compliance by the Parties with their obligations;
- 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 Parties upon request by the Funding Authority;
- preparing the meetings, proposing decisions and preparing the agenda of the Steering Committee meetings, chairing the meetings, preparing the minutes of the meetings and monitoring the implementation of decisions taken at meetings;
- transmitting documents and information connected with the Project to any Party concerned ;
- 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.

Each Party is responsible to timely submit any technical or financial reports to the Funding Authority, if applicable.

If the Project Coordinator fails in its coordination tasks, the Steering Committee may propose to change the Project Coordinator.

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

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

In the event that an impediment prevents the Project Coordinator from performing his duties, the Coordinator will designate another person to assume such duties.

If for any reason whatsoever, the Coordinator is no longer in a position to assume such role, the Parties will endeavor to find a replacement solution by mutual agreement. If no solution is found within sixty (60) days, this agreement will be terminated under the conditions provided in section 11.

6.2.2 Obligations of the Parties with regard to the Coordinator
Each Party undertakes to provide the Coordinator, within the alloatted deadlines, with the following documents relating to the Project:

- the interim report for transmission to the Funding Authority if requested,
- the necessary information for preparation of the final report for the Funding Authority,
- the information making it possible to respond to potential resquests by the Funding Authority,
- every individual financial statements for itself in due time and, if required, certificates on the financial statements,
- ethics committee opinions and notifications or authorisations for activities raising ethical issues,
- any other documents or information required by the EuroNanoMed 3 Joint Call Secretariat under the Agreement, unless a Party is required to submit the document or information directly to the EuroNanoMed 3 Joint Call Secretariat.

Furthermore, each Party shall inform the Coordinator immediately of any changes related to its name, address, legal representatives, legal form and organisation types and to its legal, financial, technical, organisational or ownership situation and inform the Coordinator of any difficulty in its execution of its part of the Project.

6.3 Steering Committee
6.3.1 Members
The Steering Committee shall consist of one representative of each 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 6.3.2 of this Consortium Agreement.

A Member may be assisted, if necessary, by the persons and/or experts from its institution whose presence will be necessary according to the agenda. The attendance of any third-party participant will be accepted on the prior condition that each Party has been previously informed and that such participant signs a conflict of interest declaration and a confidentiality agreement in compliance with the terms and conditions of this Consortium Agreement.

The presence of a third-party participant can be denied if a Party can show that its legitimate interests would be severely affected by the presence of such participant.

One of the leading independent experts shall chair all meetings of the Steering Committee.

The Parties agree to abide by all decisions of the Steering Committee.
This does not prevent the Parties from submitting a dispute for resolution in accordance with the provisions of settlement of disputes in section 12.8 of this Consortium Agreement.

6.3.2. Role of the Steering Committee
The Steering Committee is the decisional body of the project. It makes sure that the project is implemented properly acording to the initial Project Plan, not only scientifically but also clinically and ethically, and taking into account the required adjustments when need be.

It ensures the correct implementation of the Project and compliance with the protocol and the Standard Operational Procedures of the Sponsor. It identifies strategic opportunities in a timeline shaping the scientificside of the Project.

The Steering Committee 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 Steering Committee:
- Changes to Attachments 1 and 2 to be agreed by the Funding Authority if needed;
- Modifications to Attachment 4;
- Entry of a new Party to the consortium and approval of the settlement on the conditions of the accession of such a new Party;
- Withdrawal of a Party from the consortium 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;
- 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;
- Creation of ad hoc committees and approval of the settlement on the conditions of the functioning rules;
- Suspension for of all or part of the Project in accordance with the Funding Authority;
- Termination of the Project and the Consortium Agreement in accordance with the Funding Authority.

In the case of abolished tasks as a result of a decision of the Steering Committee, Members shall rearrange the tasks of the Parties concerned. Such rearrangement shall take into consideration the legitimate commitments taken prior to the decisions, which cannot be cancelled.

6.3.3 Operational procedures for the Steering Committee

6.3.3.1 Representation in meetings
Any Member:
- should be present;
- shall participate in a cooperative manner in the meetings; and

- if not present, may appoint a substitute or a proxy who is a member of the Steering Committee to vote at the meeting.

6.3.3.2 Preparation and organisation of meetings

6.3.3.2.1 Convening meetings
The chairperson shall convene meetings of the Steering Committee at least once a year and shall also convene extraordinary meetings at any time upon written request of any Member.

6.3.3.2.2 Notice of a meeting
The chairperson assisted by the Project Coordinator shall give notice in writing of a meeting to each Member as soon as possible and no later than 20 calendar days preceding an ordinary meeting and 7 calendar days preceding an extraordinary meeting.

6.3.3.2.3 Sending the agenda
The chairperson assisted by the Project Coordinator shall prepare and send each Member a written original agenda no later than 14 calendar days preceding the meeting or 7 calendar days before an extraordinary meeting. All relevant and supporting documentation for the meeting shall also be sent accompanying the agenda.

6.3.3.2.4 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 notification to all of the other Members no later than 14 calendar days preceding the meeting or 7 calendar days before an extraordinary meeting.

6.3.3.2.5 During a meeting of the Steering Committee the Members can unanimously agree to add a new item to the original agenda.

6.3.3.2.6 Any decision may also be taken without a meeting if the chairperson circulates to all Members a written document, which is then agreed by the defined majority (see Section 6.3.2.3). Such document shall include the deadline for responses.

6.3.3.2.7 Meetings of the Steering Committee may also be held by teleconference or other telecommunication means.

6.3.3.2.8 Decisions will only be binding once the relevant part of the minutes has been accepted according to section 6.5.3.5 of this Consortium Agreement.

Decisions taken without a meeting shall be considered as accepted if, within the period set out in section 6.3.3.4, no Member (and/or Party) has sent an objection in writing to the chairperson. The decisions will be binding after the chairperson sends to all Members of the Consortium Body and to the Coordinator a written notification of this acceptance.

6.3.3.3 Voting rules and quorum

The Steering Committee shall not deliberate and decide validly unless two-thirds (2/3) of its Members are present or appointed (quorum). If the quorum is not reached, the chairperson shall convene an extraordinary meeting within no more than fifteen (15) days from this date. This extraordinary meeting shall be entitled to decide even if less than the quorum of Members are present or appointed and then all decisions shall be taken by a majority of four-fifth (4/5) of the votes unless otherwise provided on this Agreement.

Each Member present shall have one (1) single vote and receives only one mandate.

Defaulting Parties may not vote.

Decisions shall be taken by unanimity. If unanimity is not reached, the chairperson shall proceed to another vote where decisions will be taken by a majority of two-thirds (2/3) of the votes cast.

In case of written consultations, the letter of the chairperson shall specifiy the imparted deadline for response. Failure to respond within this deadline shall be deemed as a non-vote for the application of the quorum and majority vote requirements.

6.3.3.4 Veto rights

A Member 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 Steering Committee may exercise a veto with respect to the corresponding decision or relevant part of the decision.

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

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

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

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

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

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

6.3.3.5 Minutes of meetings

The chairperson shall produce written minutes of each meeting which shall be the formal record of all decisions taken. S/he shall send the draft minutes to all Members within 15 calendar days of the meeting for validation/modifications.

The minutes shall be considered as accepted if, within 15 calendar days from sending, no Member (and/or Party) has sent an objection in writing to the chairperson with respect to the accuracy of the draft of the minutes.

The chairperson shall send the signed and accepted minutes to all the Members of the Steering Committee and to the Coordinator, who shall safeguard them. If requested the Coordinator shall provide authenticated duplicates to Parties.

Section 7: Financial provisions

7.1. Distribution of financial contribution

The financial contribution of the Funding Authority to the Project shall be distributed by the respective Funding Authorities according to the Grant Agreement.

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

7.2 Justifying costs
In accordance with its own usual accounting and management principles and practices and the conditions set out in the Grant Agreement, each Party shall be solely responsible for justifying its costs with respect to the Project towards the Funding 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 Funding Authority.

7.3 Financial consequences of the termination of the participation of a Party
A Party leaving the consortium according to the provisions of article 11 below shall refund all payments it has received except the amount of contribution accepted by the Funding Authority or another contributor.

Section 8: Background and Results

8.1 Ownership of 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 2. Background is Confidential Information within the meaning of section 10.1 of this Consortium Agreement.

8.2 Ownership and transfer of Results

8.2.1 Own Results
Own Results are owned by the Party that generates them.

A Party will decide alone on the protection measures to be taken for its Own Results and initiate them in its own name at its expense. Any new patents that may arise there from will be filed in its name only, at its expense and on its sole initiative.

8.2.2 Joint Results
Where several Parties have jointly carried out work generating Results and where their respective share of the work cannot be ascertained, they shall have joint ownership of such Results.

The joint owners must agree in writing on the allocation and terms of exercise of their joint ownership in a separate written agreement (i.e joint ownership agreement) to ensure compliance with their obligations under this Consortium Agreement. This agreement shall be drawn up as soon as necessary and in any event before any industrialand/or commercial exploitation of the Joint Results.

The joint owners agree to endeavour the appointment among them of one joint owner in charge of the management and exploitation of the Joint 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.

Unless otherwise agreed in the joint ownership agreement:
(i) each joint owners shall be entitled to use their jointly owned Results for non-commercial research and/or humanitarian activities on a royalty-free basis, and without requiring the prior consent of the other joint owner(s);
(ii) each joint owners may grant non-exclusive royalty-free licenses to third parties to exploit and have Access Rights to jointly-owned results (without any right to sub-license), exclusively for non-commercial research and/or humanitarian activities, and
(iii) 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 in any event remain free to use on a royalty-free basis and have Access Rights to their Joint Results for non commercial purposes and shall agree with the other joint owners on all protection measures in advance.

8.2.3 Transfer of Results

8.2.3.1 Each Party may transfer ownership of its Own Results following the procedures of the Grant Agreement.

8.2.3.2 It may identify specific third parties it intends to transfer the ownership of its Results to in Attachment (3) to this Consortium Agreement. The other Parties hereby waive their right to prior notice and their right to object to a transfer to listed third parties according to the Grant Agreement Article 30.1.

8.2.3.3 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 will not be affected by such transfer.

8.2.3.4 The Parties recognize 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 the full 45 calendar days prior notice for the transfer as foreseen in the Grant Agreement.

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

8.3 Dissemination

8.3.1 Dissemination of Results

The Parties acknowledge their common interests in publishing Results to obtain recognition within the scientific community and to advance the state of scientific knowledge in their field for the benefit of the public. The Parties also recognize their common interest in obtaining valid intellectual property rights protection.

The Results will be jointly published whenever applicable, notably when such Results are Joint Results. Authorship on joint publications will be based on academic standards and customs.

However, each of the Parties reserve the right to publish their Own Result and Background.

During the Project and for a period of 2 years after the end of the Project, the dissemination of Results by one or several Parties including but not restricted to publications and presentations, shall be 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 writing to the Coordinator and to the Party or Parties proposing the dissemination within 15 calendar days after receipt of the notice. If no objection is made within the time limit stated above, the publication is permitted.

An objection is justified if the protection of the objecting Party's Results or Background would be adversely affected.

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

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.

The objecting Party can request a publication delay of not more than 90 calendar days from the time it raises such an objection. After 90 calendar days the publication is permitted, provided that all reasonable modifications of the objecting Party have been implemented within the publication as indicated by the objecting Party.

8.3.2 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 by the owning Party.

Unless otherwise agreed in the joint ownership agreement, the joint owners shall not include in any dissemination activity the Joint Results as defined in section 8.2.2. without obtaining the joint owning Party's prior written approval.

8.3.3 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.

The Parties are encouraged to produce and disseminate electronic versions of publications including Results for free and without limitations, provided all original formatting, credits and consents are maintained.

In accordance with scientific customs, the Party's contributions will be expressly reflected in all written or oral public disclosures concerning Results by acknowledgment or co-authorship, as appropriate.

8.3.4 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.

All communication (poster, oral and written communication) regarding the Project or Results, shall mention the acronym of the Project and the Funding Authority.

Section 9: Access Rights

9.1 Background included

In Attachment 2, 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 2 shall not be the object of Access Right obligations regarding Background.

Any Party may modify its Background to Attachement 2 during the Project subject to the approval of the Steering Committee. The Attachement 2 together with any amendments thereof shall automatically be incorporated into this Consortium Agreement.

For avoidance of doubt, under non circumstances should the withdrawal of any Background impair the implementation of the Project.

9.2 General Principles

Each Party shall implement its tasks in accordance with Attachment 1 and shall bear sole responsibility for ensuring that its acts within the Project do not knowingly infringe third party property rights.

Notwithstanding the provisions of section 8.2 of this Consortium Agreement, any Access Rights granted expressly exclude any rights to sub-license unless expressly stated otherwise.

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

Access Rights are granted on a non-exclusive basis.

Results and Background shall be used only for the purposes for which Access Rights to it have been granted. To this end, the Parties acknowledge and undertake that Access Rights shall be granted for the purpose of advancing the state of scientific knowledge for the benefit of the public.

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.

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

9.3 Access Rights for implementation

Access Rights to Results and Background if 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 2.

9.4 Access Rights for Exploitation

9.4.1 Access Rights to Results if Needed for Exploitation of a Party's Own Results shall be granted on fair and reasonable conditions, it being understood that the Party owning the Results may grant Access Rights on a royalty-free basis.

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

It is understood and agreed between the Parties that Access Rights to Joint Results by the Parties jointly owning such Joint Results shall be granted according to the provisions of section 8.2.2 above.

9.4.2 Subject to third parties' rights as well as any legal or contractual limitations definded in Attachement 2, Access Rights to Background if Needed for Exploitation of a Party's own Results, including for research on behalf of a third party, shall be granted on fair and reasonable conditions, which shall include appropriate financial terms to be agreed by the concerned Parties upon written separate agreement prior to any use of the Background by the requesting Party.

9.4.3 A request for Access Rights may be made up to 12 months after the end of the Project or, in the case of Section 9.8, after the termination of the requesting Party's participation in the Project.

9.5 Access Rights for Affiliated Entities

Such Access Rights must be requested by the Affiliated Entity 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 Affiliated Entities listed in Attachment 5. Access Rights to Affiliated Entities shall be granted on fair and reasonable conditions and upon written bilateral agreement prior to any use of the Background or Results by the Affiliated Entity.

Affiliated Entities which obtain Access Rights in return fulfil all confidentiality and other obligations accepted by the Parties under this Consortium Agreement as if such Affiliated Entities were Parties.

Access Rights may be refused to Affiliated Entities if such granting is contrary to the legitimate interests of the Party which owns the Background or the Results.

Access Rights granted to any Affiliated Entity are subject to the continuation of the Access Rights of the Party to which it is affiliated, and shall automatically terminate upon termination of the Access Rights granted to such Party.

Upon cessation of the status as an Affiliated Entity, any Access Rights granted to such former Affiliated Entity shall lapse. This entity will however remain subject to any obligation under the Agreement that shall by nature remain in force, in particular obligations relating to Confidential Information.
Further arrangements with Affiliated Entities may be negotiated in separate agreements.

9.6 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.

9.7 Additional Access Rights

For the avoidance of doubt any grant of Access Rights not covered by 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.

9.8 Access Rights for Parties entering or leaving the consortium

9.8.1 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.

9.8.2 Parties leaving the consortium

9.8.2.1 Access Rights granted to a leaving Party

9.8.2.1.1 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 Steering Committee to terminate its participation in the consortium.

9.8.2.1.2 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 according to the terms of section 11.2 below.

It may request Access Rights within the period of time specified in section 9.4.3.

9.8.2.2 Access Rights to be granted by any leaving Party
Any Party leaving the Project shall continue to grant Access Rights pursuant to this Consortium Agreement to the Results developed until the date of the termination of its participation.

Section 10: Non-disclosure of information

10.1 All information, data, documents or other materials, in whatever form or mode of communication, which is disclosed by a Party (the "Disclosing Party") to any other Party (the "Recipient") (i) 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, (ii) related to the Material irrespective of whether such information is labelled or identified as "confidential", and/or (iii) any information which should reasonably be recognised as confidential information are "Confidential Information".

10.2 The Recipients hereby undertake for a period of 4 years after the end of the Project:

- not to use Confidential Information other 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 for as long as the copy is retained.

10.3 The Recipients shall be responsible for the fulfilment of the above obligations on the part of their employees or Affiliated Entities or third parties involved in the Project that have access to the Confidential Information through the Recipients concerned 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.

10.4 Except for Confidential Information constituting Personal Data, 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 in writing 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 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.

10.5 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.

10.6 Each Party shall promptly advise the other Party in writing of any unauthorised disclosure, misappropriation or misuse of Confidential Information promptly after it becomes aware of such unauthorised disclosure, misappropriation or misuse.

10.7 If any Party 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 Confidential Information.

Section 11: Termination and entrance of a new Party

11.1 Termination of a Defaulting Party

The Parties may decide on the total or partial termination of the Agreement with regard to a Party (the Defaulting Party) in the event of non-performance by such latter Party, of one or more of its obligations pursuant to this Consortium Agreement. Such termination may take place 60 calendar days after formal notice sent by the Steering Committee to the Defaulting Party unless, within such period, the Defaulting Party:

- has fulfilled its obligations, or
- has proposed a replacement solution which is as close as possible to the objective sought. This solution must be expressly accepted by the other Parties and the Funding Authority.

The exclusion of the Defaulting Party is pronounced by the Steering Committee.

11.2 Withdrawal

A Party may withdraw from the Agreement for a duly substantiated reason, subject to 60 calendar days notice served by the Steering Committee by registered letter with return receipt requested.

Termination shall not affect any rights or obligations of a Party leaving the Agreement incurred prior to the date of termination, unless otherwise agreed between the Steering Committee and the leaving Party. This includes the obligation to provide all Results, deliverables (such as financial statements and related certifications) and documents for the period of its participation.

11.3 Common provisions

Within the period of 60 calendar days referred to in 11.1 and 11.2, the Steering Committee will hold a meeting to find a replacement solution that is as close as possible to the objective sought in order to ensure the continuity of the Project. In the event that the Parties do not succeed in finding an alternative solution, the provisions of section 11.4 shall be applied.

The leaving Party undertakes to provide to the other Parties or the subrogated third party or the new Party, free-of-charge and without delay, any dossiers and information required in order to enable them

to pursue the execution of the Project in its place and stead. Similarly, the leaving Party undertakes not to enforce its intellectual property rights against the other Parties or the subrogated third party or the new Party for pursuit of the Project and undertakes to grant Access Rights according to the conditions set out in section 9.8 above.

The leaving Party is obliged to fulfill the obligations entered into up until the effective date of termination.

The leaving Party no longer acquires any right with regard to the Results as from the effective date of termination.

The leaving Party shall personally arrange for any repayment of a subsidy or an advance claimed by the Funding Authority according to the provisions of section 7 above.

11.4 Termination by agreement of the Parties

This Agreement may furthermore be terminated automatically, by operation of law, in whole or in part, upon a unanimous decision of the Steering Committee.

11.5 Termination related to the discontinuation of financing

Unless otherwise agreed in writing by the Parties or otherwise expressly specified in this Agreement, the Consortium Agreement may be terminated automatically, by operation of law, in the event of a motivated decision by the Funding Authority to no longer provide financing for the Project and upon a unanimous decision of the Steering Committee.

11.6 Entrance of a new Party

A new Party becomes a Party to this Agreement, subject to the prior approval of the Funding Authority and the written agreement of the Coordinator through the signature of the accession document in Attachment 3. Such new Party agrees to be bound by the terms of this Agreement starting from the date indicated in the accession document.

Section 12: Miscellaneous

12.1 Attachments, inconsistencies and severability

This Consortium Agreement consists of this core text and
Attachment 1: Project description
Attachment 2: List of Background
[Attachment 3: List of Third Parties for simplified transfer according to Section 8.3.2.]
Attachment 4: Accession document
Attachment 5: Affiliated Entities
Attachment 6: Material transfer slip
Attachment 7: Personal data transfer agreement

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 this Consortium Agreement, 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 Notices and other communication

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

Formal notices:
If it is required in this Consortium Agreement (Sections 4.2, 9.8.2.1.1, 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 or telefax with receipt acknowledgement.

Other communication:
Other communication between the Parties may also be effected by other means such as e-mail with acknowledgement of receipt, which fulfils the conditions of a written form.

Any change of persons or contact details shall be notified immediately by the respective Party to the Coordinator. The address list shall be accessible to all Parties.

12.4 Assignment and amendments

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 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.

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.

For any dispute, controversy or claim that may arise, out of or relating to this contract and any subsequent amendments of this contract, between the Parties with regard to the formation, validity, binding effect, interpretation, performance, breach or termination of this Consortium Agreement, the Parties undertake to submit their difference, before submitting it to any courts, to conciliators appointed by each of them, unless they agree on the appointment of a single conciliator. The conciliator(s) shall be appointed within a maximum period of 30 calendar days as from service of notice of the dispute by

one of the Parties to the other Parties. The conciliator(s) will strive to settle the difficulties and to have the Parties agree to an amicable solution within a period of 60 days as from the date of appointment of the conciliator(s). Should the mediation fail to bring about a full agreement between the Parties putting an end to the dispute, sole competent courts will be the courts of Brussels.

Nothing in this Consortium Agreement shall limit the Parties' right to seek injunctive relief in any applicable competent court.

12.9 General provisions

No one except a Party to this Consortium Agreement has any right to prevent the amendment of this Consortium Agreement or its termination, and no one except a Party to this Consortium Agreement may enforce any benefit conferred by this Consortium Agreement, unless provided otherwise.

Forbearance by any of the Parties on one or more occasions from reliance on one or more provisions of this Consortium Agreement shall in no way entail waiver by the interested Party of the possibility to rely thereon in future.

This Consortium Agreement cancels and supersedes any prior written or oral agreement between the Parties and constitutes the entire agreement between the Parties with regard to the subject matter thereof. No addition or change to the terms of this Consortium Agreement will be effective with regard to the Parties unless it is made in writing and signed by their duly authorized representatives.

Section 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.

Signed in five (5) original counterparts.

Inserm

Date:

Name: Jacques CAVAILLE

Title: Regional Delegate

Signature:

Agencia Estatal Consejo Superior de Investigaciones Científicas, M.P. (CSIC)

Date:

Name: Dr. Ángeles Gómez Borrego

Title: Vice-president for International Affairs

By Delegation from the President (Resolution published on the Spanish Official Journal dated 28/01/2021)

Signature:

FUNDACION PARA LA INVESTIGACION BIOMEDICA DEL HOSPITAL INFANTIL UNIVERSITARIO NINO JESUS

Date:

Name:

Title:

Signature:

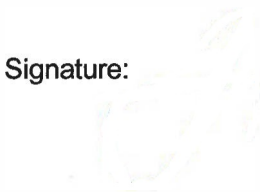
CHARLES UNIVERSITY – FACULTY OF PHARMACY IN HRADEC KRALOVE

Date:

Name: doc. PharmDr. Jaroslav Roh, Ph.D.

Title: Dean of the faculty

Signature:



BEZMIALEM VAKIF UNIVERSITY

Date:

Name: Prof. Dr. Gülaçtı Topçu

Title: Dean of the Faculty

Signature:

Attachment 1: Project description

euronanomed2021-095_fp_project_desc

Attachment 2: List of Background

According to section 1.2 of this Consortium Agreement, Background is defined as "information (…) which is needed for implementing the Project or Exploiting 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.

INSERM

As to 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 mentioned hereunder:

Describe Background	Specific limitations and/or conditions for implementation	Specific limitations and/or conditions for Exploitation
Know-how in production of reconstructed human epidemis Genome editing		
Skin biopsies from patients		
Stratum corneum of dogs (tape striping)		

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

AGENCIA ESTATAL CONSEJO SUPERIOR DE INVESTIGACIONES CIENTÍFICAS, M.P

As to CSIC, it is agreed between the Parties that, to the best of their knowledge, no data, know-how or information of CSIC shall be Needed by another Party for implementation of the Project or Exploitation of that Party's Results.

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

FUNDACION PARA LA INVESTIGACION BIOMEDICA DEL HOSPITAL INFANTIL UNIVERSITARIO NINO JESUS

As to FUNDACION PARA LA INVESTIGACION BIOMEDICA DEL HOSPITAL INFANTIL UNIVERSITARIO NINO JESUS, it is agreed between the Parties that, to the best of their knowledge, no data, know-how or information of FUNDACION PARA LA INVESTIGACION BIOMEDICA DEL HOSPITAL INFANTIL UNIVERSITARIO NINO JESUS shall be Needed by another Party for implementation of the Project or Exploitation of that Party's Results.

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

CHARLES UNIVERSITY – FACULTY OF PHARMACY IN HRADEC KRALOVE

As to Charles University, it is agreed between the Parties that, to the best of their knowledge, no data, know-how or information of Charles University shall be Needed by another Party for implementation of the Project or Exploitation of that Party's Results.

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

BEZMIALEM VAKIF UNIVERSITY

As to Bezmialem Vakif University, it is agreed between the Parties that, to the best of their knowledge, no data, know-how or information of Bezmialem Vakif University shall be Needed by another Party for implementation of the Project or Exploitation of that Party's Results.

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

[Attachment 3: List of Third Parties for simplified transfer according to Section 8.3.2.]

Attachment 4 : Accession document

ACCESSION

of a new Party to

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

[OFFICIAL NAME OF THE NEW PARTY]

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]

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 5: Affiliated Entities

For Inserm:
Inserm Transfert SA located at 7 rue Watt, 75013 Paris, France, held at 99% by Inserm.

Attachment 6 : Material Transfer Slip

As part of the LIPARCI Consortium Agreement entered into force on November 1st, 2020 and signed between:

- INSERM
- AGENCIA ESTATAL CONSEJO SUPERIOR DE INVESTIGACIONES CIENTÍFICAS, M.P
- FUNDACION PARA LA INVESTIGACION BIOMEDICA DEL HOSPITAL INFANTIL UNIVERSITARIO NINO JESUS
- CHARLES UNIVERSITY – FACULTY OF PHARMACY IN HRADEC KRALOVE
- BEZMIALEM VAKIF UNIVERSITY

The Issuing Party (hereinafter defined) agrees to the transfer of the Material -described below- to the Recipient Party (hereinafter defined) to carry out the Project according to the terms and conditions of the consortium agreement referred to above.

Material:	Nature and characteristics : Quantity (for the Samples) : Samples preparation before conditioning : Conditioning (tube, bag, etc. for the Samples) : Format (for the Data) :
Transport of the material :	
Issuing Party :	- name - address - contact information
Contact information of the scientific sending the material	Name : Email : Tel : Fax :
Recipient Party :	- name - address - contact information
Delivery address	Address : Nom de la personne récipiendaire : Email : Tel : Fax :

Made in two (2) original copies, one (1) for each Party.

Issuing Party	Recipient Party
Name:	Name:
Function:	Function:

Date:	Date:
Place:	Place:
Signature:	Signature:

Attachment 7 : Personal Data Transfer Agreement

BETWEEN

NAME OF THE PARTY
[TO BE COMPLETED BY THE PARTY]
represented by,

AND

NAME OF THE PARTY
[TO BE COMPLETED BY THE PARTY]
represented by,

Hereinafter, jointly or individually, referred to as “Parties” or “Party”.

WHEREAS

The Parties seek to implement a data transfer agreement (hereinafter “Agreement”) and agree to transfer and process personal data on the terms set out in this Agreement.

Parties have agreed to process personal data in compliance with any current national law and EU regulation applicable to the processing of these data, and in particular with article 35 of the French Act n 78/17 of 6th of January 1978 on “Information Technology, Data Files and Civil Liberty” and Article 24 of the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 [General Data Protection Regulation (GDPR)]. Therefore, Parties agree this Agreement in order to adduce adequate safeguards with respect to the protection of privacy and fundamental rights and freedoms of individuals for the access, transfer and processing by [Name of the Party] of the personal data pertaining to Inserm and specified in ANNEX B.

NOW, THEREFORE, IT IS HEREBY AGREED AS FOLLOWS

DEFINITIONS

For the purposes of the clauses:

(a) *‘personal data’, ‘special categories of data’, ‘process/processing’, ‘controller’, ‘processor’, ‘data subject’* and *‘supervisory authority/authority'* shall have the same meaning as in the GDPR (whereby “the authority” shall mean the competent data protection authority in the territory in which the data exporter is established);
(b) “the data exporter” shall mean the controller who transfers the personal data;
(c) “the data importer” shall mean the controller who agrees to receive from the data exporter personal data for further processing in accordance with the terms of this Agreement and who is not subject to a third country’s system ensuring adequate protection;
(d) “Agreement” shall mean these contractual clauses and its annexes and possible further amendments, which are a free-standing document that does not incorporate commercial business terms established by the Parties under separate commercial arrangements;

The details of the transfer (as well as the personal data covered) are specified in Annex B, which forms an integral part of the Agreement.

I. OBLIGATIONS OF THE DATA EXPORTER

The details of the access – transfer for process in this Agreement and in particular the special categories of personal data where applicable are specified in ANNEX B.

The data exporter warrants and undertakes that:

a) The personal data have been collected, processed and transferred in accordance with the laws applicable to the data exporter.

b) It has used reasonable efforts to determine that the data importer is able to satisfy its legal obligations under this Agreement.

c) It will provide the data importer, when so requested, with copies of relevant data protection laws or references to them (where relevant, and not including legal advice) of the country in which the data exporter is established.

d) It will respond to enquiries from data subjects and the authority concerning processing of the personal data by the data importer, unless the Parties have agreed that the data importer will so respond, in which case the data exporter will still respond to the extent reasonably possible and with the information reasonably available to it if the data importer is unwilling or unable to respond. Responses will be made within a reasonable time.

e) It will make available, upon request, a copy of the Agreement to data subjects who are third party beneficiaries under clause III, unless the Agreement contain confidential information, in which case it may remove such information. Where information is removed, the data exporter shall inform data subjects in writing of the reason for removal and of their right to draw the removal to the attention of the authority. However, the data exporter shall abide by a decision of the authority regarding access to the full text of the clauses by data subjects, as long as data subjects have agreed to respect the confidentiality of the confidential information removed. The data exporter shall also provide a copy of the Agreement to the authority where required.

II. OBLIGATIONS OF THE DATA IMPORTER

The data importer warrants and undertakes that:

a) It will have in place appropriate technical and organisational measures to protect the personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access, and which provide a level of security appropriate to the risk represented by the processing and the nature of the data to be protected.

b) It will have in place procedures so that any third party it authorises to have access to the personal data, including processors, will respect and maintain the confidentiality and security of the personal data. Any person acting under the authority of the data importer, including a data processor, shall be obligated to process the personal data only on instructions from the data importer. This provision does not apply to persons authorised or required by law or regulation to have access to the personal data.

c) It has no reason to believe, at the time of entering into the Agreement, in the existence of any local laws that would have a substantial adverse effect on the guarantees provided for under the Agreement, and it will inform the data exporter (which will pass such notification on to the authority where required) if it becomes aware of any such laws.

d) It will process the personal data only for purposes described in Annex B, and has the legal authority to give the warranties and fulfil the undertakings set out in the Agreement.

e) It will identify to the data exporter a contact point within its organisation authorised to respond to enquiries concerning processing of the personal data, and will cooperate in good faith with the data exporter, the data subject and the authority concerning all such enquiries within a reasonable time. In case of legal dissolution of the data exporter, or if the Parties have so agreed, the data importer will assume responsibility for compliance with the provisions of clause I(e).

f) At the request of the data exporter, it will provide the data exporter with evidence of financial resources sufficient to fulfil its responsibilities under clause III (which may include insurance coverage).

g) Upon reasonable request of the data exporter, it will submit its data processing facilities, data files and documentation needed for processing to reviewing, auditing and/or certifying by the data exporter (or any independent or impartial inspection agents or auditors, selected by the data exporter and not reasonably objected to by the data importer) to ascertain compliance with the warranties and undertakings in these clauses, with reasonable notice and during regular business hours. The request will be subject to any necessary consent or approval from a regulatory or supervisory authority within the country of the data importer, which consent or approval the data importer will attempt to obtain in a timely fashion.

h) It will process the personal data in accordance with:

i. the data processing principles set forth in Annex A.

Initials of data importer: ZZZ, Executive Director

i) It will not disclose or transfer the personal data to a third party data controller located outside the European Economic Area (EEA) unless it notifies the data exporter about the transfer and

i. the third party data controller processes the personal data in accordance with a Commission decision finding that a third country provides adequate protection, or

ii. the third party data controller becomes a signatory to the Agreement or another data transfer agreement approved by a competent authority in the EU, or

iii. data subjects have been given the opportunity to object, after having been informed of the purposes of the transfer, the categories of recipients and the fact that the countries to which data is exported may have different data protection standards, or

iv. with regard to onward transfers of sensitive data, data subjects have given their unambiguous consent to the onward transfer

III. LIABILITY AND THIRD PARTY RIGHTS

a) Each Party shall be liable to the other Party for damages it causes by any breach of these clauses. Liability as between the Parties is limited to actual damage suffered. Punitive damages (i.e. damages intended to punish a Party for its outrageous conduct) are specifically excluded. Each Party shall be liable to data subjects for damages it causes by any breach of

third party rights under the Agreement. This does not affect the liability of the data exporter under its data protection law.

b) The Parties agree that a data subject shall have the right to enforce as a third party beneficiary this clause and clauses I(b), I(d), I(e), II(a), II(c), II(d), II(e), II(h), II(i), III(a), V, VI(d) and VII against the data importer or the data exporter, for their respective breach of their contractual obligations, with regard to his personal data, and accept jurisdiction for this purpose in the data exporter's country of establishment. In cases involving allegations of breach by the data importer, the data subject must first request the data exporter to take appropriate action to enforce his rights against the data importer; if the data exporter does not take such action within a reasonable period (which under normal circumstances would be one month), the data subject may then enforce his rights against the data importer directly. A data subject is entitled to proceed directly against a data exporter that has failed to use reasonable efforts to determine that the data importer is able to satisfy with its legal obligations under these clauses (the data exporter shall have the burden to prove that it took

IV. LANGUAGE AND LAW APPLICABLE

This Agreement shall be governed by the law of the country in which the data exporter is established, with the exception of the laws and regulations relating to processing of the personal data by the data importer under clause II (h), which shall apply only if so selected by the data importer under that clause.

This Agreement will be written in English language.

V. RESOLUTION OF DISPUTES

a) In the event of a dispute or claim brought by a data subject, a Party or the authority concerning the processing of the personal data against either or both of the Parties, the Parties will inform each other about any such disputes or claims, and will cooperate with a view to settling them amicably in a timely fashion.
b) The Parties agree to respond to any generally available non-binding mediation procedure initiated by a data subject, a Party or by the authority. If they do participate in the proceedings, the Parties may elect to do so remotely (such as by telephone or other electronic means). The Parties also agree to consider participating in any other mediation or other dispute resolution proceedings developed for data protection disputes.
c) Each Party shall abide by a decision of a competent court of the data exporter's country of establishment or of the authority .

VI. DURATION AND TERMINATION

DURATION:
This Agreement enters into force on the date of the last signature by a duly authorised representative of one of the Party and shall continue in full force and effect until complete fulfilment of all obligations undertaken by the Parties under this Agreement.

TERMINATION:

a) In the event that the data importer is in breach of its obligations under the Agreement, then the data exporter may temporarily suspend the transfer of personal data to the data importer until the breach is repaired or the Agreement is terminated.

b) In the event that:

   i. the transfer of personal data to the data importer has been temporarily suspended by the data exporter for longer than one month pursuant to paragraph (a);

   ii. compliance by the data importer with the Agreement would put it in breach of its legal or regulatory obligations in the country of import;

   iii. the data importer is in substantial or persistent breach of any warranties or undertakings given by it under the Agreement;

   iv. a final decision against which no further appeal is possible of a competent court of the data exporter's country of establishment or of the authority rules that there has been a breach of the Agreement by the data importer or the data exporter; or

   v. a petition is presented for the administration or winding up of the data importer, whether in its personal or business capacity, which petition is not dismissed within the applicable period for such dismissal under applicable law; a winding up order is made; a receiver is appointed over any of its assets; a trustee in bankruptcy is appointed, if the data importer is an individual; a company voluntary arrangement is commenced by it; or any equivalent event in any jurisdiction occurs

   then the data exporter, without prejudice to any other rights which it may have against the data importer, shall be entitled to terminate the Agreement, in which case the authority shall be informed where required. In cases covered by (i), (ii), or (iv) above the data importer may also terminate the Agreement.

c) Either Party may terminate the Agreement if (i) any Commission positive adequacy decision under Article 45 of Regulation (EU) 2016/679 (or any superseding text) is issued in relation to the country (or a sector thereof) to which the data is transferred and processed by the data importer, or (ii) Regulation (EU) 2016/679 (or any superseding text) becomes directly applicable in such country.

d) The Parties agree that the termination of the Agreement at any time, in any circumstances and for whatever reason (except for termination under clause VI(c)) does not exempt them from the obligations and/or conditions under the Agreement as regards the processing of the personal data transferred.

VII. VARIATION OF THE AGREEMENT

The Parties may not modify the Agreement except to update any information in Annex B, in which case they will inform the authority where required. This does not preclude the Parties from adding additional clauses where required.

VIII. DESCRIPTION OF THE TRANSFER

The details of the transfer and of the personal data are specified in Annex B. The Parties agree that Annex B may contain confidential business information which they will not disclose to third parties,

except as required by law or in response to a competent regulatory or government agency, or as required under clause I(e). The Parties may execute additional annexes to cover additional transfers, which will be submitted to the authority where required. Annex B may, in the alternative, be drafted to cover multiple transfers.

IX. INTELLECTUAL PROPERTY AND CONFIDENTIALITY

The data shall be the sole property of the Party sending the data. The Party receiving the data shall not fill, or have filed in the name of a third party in any country, any patent application or intellectual property rights claiming the data.

The data importer undertakes to respect and maintain strictly confidential all data received from the data exporter.

X. MISCELLANEOUS

This Agreement has been concluded *intuitu personae* and no rights or obligations of the Parties arising from this Agreement may be assigned or transferred, in whole or in part, to any third party without the other Party's prior and formal approval.

Forbearance by any of the Parties on one or more occasions from reliance on one or more provisions of the Agreement shall in no way entail waiver by the interested Party of the possibility to rely thereon in future.

Should any provision of this Agreement become invalid, illegal or unenforceable, it shall not affect the validity of the remaining provisions of this Agreement. In such a case, the Parties shall make their best efforts to find an alternative solution that is acceptable to the nature of the Agreement.

This Agreement, including its two annexes (A and B) constitutes the entire agreement between the Parties as to its subject matter, and cancels and supersedes any prior oral or written understanding or agreement between the Parties relating to the same subject matter.

No addition or change to the terms of this Agreement will be effective with regard to the Parties, unless it is made in writing and signed by their duly authorised representatives.

AS WITNESS:

The Parties have caused this Agreement to be duly signed by the undersigned authorized representatives in two originals the day and year first above written.

For [Name of the Party]**:**

Name (written out in full):

Position:

Date:

Signature

(stamp of organisation)

For [Name of the Party]

Name (written out in full):

Position:

Date:

Signature

(stamp of organisation)

ANNEX A

DATA PROCESSING PRINCIPLES

1. Purpose limitation: Personal data may be processed and subsequently used or further communicated only for purposes described in Annex B or subsequently authorised by the data subject.

2. Data quality and proportionality: Personal data must be accurate and, where necessary, kept up to date. The personal data must be adequate, relevant and not excessive in relation to the purposes for which they are transferred and further processed.

3. Transparency: Data subjects must be provided with information necessary to ensure fair processing (such as information about the purposes of processing and about the transfer), unless such information has already been given by the data exporter.

4. Security and confidentiality: Technical and organisational security measures must be taken by the data controller that are appropriate to the risks, such as against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access, presented by the processing. Any person acting under the authority of the data controller, including a processor, must not process the data except on instructions from the data controller.

5. Rights of access, rectification, deletion and objection: As provided in Article 15 of Regulation (EU) 2016/679, data subjects must, whether directly or via a third party, be provided with the personal information about them that an organisation holds, except for requests which are manifestly abusive, based on unreasonable intervals or their number or repetitive or systematic nature, or for which access need not be granted under the law of the country of the data exporter. Provided that the authority has given its prior approval, access need also not be granted when doing so would be likely to seriously harm the interests of the data importer or other organisations dealing with the data importer and such interests are not overridden by the interests for fundamental rights and freedoms of the data subject. The sources of the personal data need not be identified when this is not possible by reasonable efforts, or where the rights of persons other than the individual would be violated. Data subjects must be able to have the personal information about them rectified, amended, or deleted where it is inaccurate or processed against these principles. If there are compelling grounds to doubt the legitimacy of the request, the organisation may require further justifications before proceeding to rectification, amendment or deletion. Notification of any rectification, amendment or deletion to third parties to whom the data have been disclosed need not be made when this involves a disproportionate effort. A data subject must also be able to object to the processing of the personal data relating to him if there are compelling legitimate grounds relating to his particular situation. The burden of proof for any refusal rests on the data importer, and the data subject may always challenge a refusal before the authority.

6. Sensitive data: The data importer shall take such additional measures (e.g. relating to security) as are necessary to protect such sensitive data in accordance with its obligations under clause II.

7. Data used for marketing purposes: Where data are processed for the purposes of direct marketing, effective procedures should exist allowing the data subject at any time to “opt-out” from having his data used for such purposes.

8. Automated decisions: For purposes hereof “automated decision” shall mean a decision by the data exporter or the data importer which produces legal effects concerning a data subject or significantly affects a data subject and which is based solely on automated processing of personal data intended to evaluate certain personal aspects relating to him, such as his performance at

work, creditworthiness, reliability, conduct, etc. The data importer shall not make any automated decisions concerning data subjects, except when:

a) i. such decisions are made by the data importer in entering into or performing a contract with the data subject, and

ii. the data subject is given an opportunity to discuss the results of a relevant automated decision with a representative of the parties making such decision or otherwise to make representations to that parties.

or

b) where otherwise provided by the law of the data exporter.

ANNEX B

DESCRIPTION OF THE TRANSFER

Data subjects
The personal data transferred concern the following categories of data subjects:

-

Purposes of the transfer(s)

The transfer is made for the following purposes:

-

Categories of data

The personal data transferred concern the following categories of data:

-

Recipients

The personal data transferred may be disclosed only to the following recipients or categories of recipients:

-

Sensitive data (if appropriate)

The personal data transferred concern the following categories of sensitive data:
none

Data protection registration information of data exporter (where applicable)

n/a

Additional useful information (storage limits and other relevant information)

n/a

Contact points for data protection enquiries

Issuing Party	Recipient Party
Name:	Name:

Function:	Function:
Date:	Date:
Place:	Place:
Signature:	Signature: