encca

European Network for Cancer research in Children and Adolescents

CONSORTIUM AGREEMENT

FINAL VERSION 30-05-2011

European Network for Cancer Research in Children and Adolescents

Based on

DESCA

The Simplified FP7 Model Consortium Agreement

www.DESCA-FP7.eu

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CONSORTIUM AGREEMENT

THIS CONSORTIUM AGREEMENT is based upon
REGULATION (EC) No 1906/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 laying down the rules for the participation of undertakings, research centres and universities in actions under the Seventh Framework Programme and for the dissemination of research results (2007-2013), and the Grant Agreement or EC-GA and Annex II adopted on 10 April 2007, and is made on 2010-11-22, hereinafter referred to as "Effective Date".

1) The Coordinator [ENCCA Partner 1]
St. Anna Kinderkrebsforschung (CCRI) , Austria

And the following parties as identified in the Grant Agreement:

2) Siop Europe (SIOPE), Belgium [ENCCA Partner 2]
3) University College London (UCL) , United Kingdom [ENCCA Partner 4]
4) Christian Albrecht s Universität zu Kiel (CAU) , Germany [ENCCA Partner 5]
5) Institut Gustave Roussy (IGR), France [ENCCA Partner 6]
6) Universita Cattolica del Sacroa Cuore (UCSC) [ENCCA Partner 7]
7) Universitätsklinikum Essen (UKE), Germany [ENCCA Partner 8]
8) Universita' Degli Studi di Milano-Biocca (UNIMIB), Italy [ENCCA Partner 9]
9) Erasmus Universitair Medisch Centrum Rotterdam, (EMC), Netherlands [ENCCA Partner 10]
10) Fundacion para la Investigacion del Hospital Universitario La Fe de la Comunidad Valencia , (LaFe) , Spain [ENCCA Partner 11]
11) Gdanski Uniwersytet Medyczny (MUG), Poland [ENCCA Partner 12]
12) The University of Birmingham (UOB), United Kingdom [ENCCA Partner 13]
13) The Leeds Teaching Hospitals NHS Trust (LTHTNHS), United Kingdom [ENCCA Partner 14]
14) Istituto Giannina Gaslini (IGG), Italy [ENCCA Partner 15]
15) Institut Curie (CURIE), France [ENCCA Partner 16]
16) Foundation for Research and Technology Hellas (FORTH), Greece [ENCCA Partner 17]
17) AIT Austrian Institute of technology GmbH (AIT), Austria [ENCCA Partner 18]
18) Consorzio Interuniversitario Cineca (CINECA), Italy [ENCCA Partner 19]
19) ERSQH Vienna Office – Europäische Gesellschaft für Qualität im Gesundheitswesen – Wiener Büro Verein (ESQH) [ENCCA Partner 20]
20) Academisch Medisch Centrum bij de Universiteit van Amsterdam (AMC), Netherlands [ENCCA Partner 21]
21) Centre Anticancereux Leon Berard (CLB), France [ENCCA Partner 23]
22) Centre International de Recherche sur le Cancer (IARC), France [ENCCA Partner 24]
23) Academisch Ziekenhuis Leiden- Leids Universitair Medisch Centrum (LUMC), Netherlands [ENCCA Partner 26]
24) Karolinska Institutet (KI) , Sweden [ENCCA Partner 27]
25) Universiteit Gent (UGent), Belgium [ENCCA Partner 28]
26) Charite – Universitaetsmedizin Berlin (CHARITÉ), Germany [ENCCA Partner 30]
27) Assistance Publique - Hopitaux de Paris (AP-HP), France [ENCCA Partner 31]

28) Klinikum Stuttgart (OLGA) , Germany [ENCCA Partner 32]
29) European CanCer Organisation (ECCO), Belgium [ENCCA Partner 34]
30) Österreichische Kinder- Krebs-Hilfe Verband der Österreichischen Kinderkrebshilfe Organisationen (ÖK), Austria [ENCCA Partner 35]
31) Universita Degli Studi di Padova (UNIPD), Italy [ENCCA Partner 36]
32) Westfälische Wilhelms-Universitaet Muenster (WWU), Germany [ENCCA Partner 37]
33) University of Southampton (SOUTHAMPTON), United Kingdom [ENCCA Partner 38]

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

relating to the Project entitled

Network of Cancer Research in Children and Adolescents

in short

ENCCA

hereinafter referred to as “Project”

WHEREAS:
The Parties, having considerable experience in the field concerned, have submitted a proposal for the Project to the European Commission as part of the Seventh Framework Programme of the European Community for Research, Technological Development and Demonstration Activities under the funding scheme of “Network of Excellence”.

The Parties wish to specify or supplement binding commitments among themselves in addition to the provisions of the EC-GA.

ENCCA, the European Network for Cancer Research in Children and Adolescents, is looking to establish a durable, integrated clinical and translational research infrastructure in Europe that will define and implement its research strategy and will facilitate the necessary investigator-driven clinical trials to introduce the new generation of biologically targeted drugs into standard of care for children and adolescents with cancer.
The overall aim of ENCCA is to improve both cure and quality of cure of children and adolescents suffering from cancer and facilitate access to innovative therapies and standard care across Europe. ENCCA aims to establish a durable, European Virtual Institute for clinical and translational research in childhood and adolescent cancers. This ‘network of excellence’ endeavours to restructure knowledge-sharing through the integration of the entire chain of stakeholders from the European paediatric oncology community and help to accelerate the development of innovative therapeutic strategies in paediatric oncology.
Therefore, ENCCA intends to

- → foster clinical research employing a fully integrated European database,
- → to promote the training of clinical investigators and translational scientists will also be promoted.
- → establish a platform as a basis for successful partnering with policy makers, industry and other stakeholders.

Patients and their families will be fully integrated in ENCCA and will be informed about the need for and processes of clinical research. Specific aims, the strategy to accomplish them and the work plan to execute the project ENCCA is described in Annex I of the Grant Agreement.

NOW, THEREFORE, IT IS HEREBY AGREED AS FOLLOWS:

1. Section: Definitions

1.1 Definitions

Words beginning with a capital letter shall have the meaning defined either herein or in the Rules for Participation or in the Grant Agreement including its Annexes without the need to replicate said terms herein.

Further definitions of this Consortium Agreement shall apply only to this Consortium Agreement.

"Affiliated Entity" of a Party shall mean any corporation or other entity, which directly or indirectly controls, is controlled by or is under common control with a Party to this Agreement. A corporation or other entity shall be regarded as in control of another corporation or entity if it owns or directly or indirectly controls more than fifty percent (50%) of the voting stock or other ownership interest of the other corporation or entity, or if it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the corporation or other entity or the power to elect or appoint fifty percent (50%) or more of the members of the governing body of the corporation or other entity.

"Background Intellectual Property" shall mean Intellectual Property (as defined below) in existence as of the Effective Date and Controlled by a Party.

"Background Information" shall mean Confidential Information, technical know-how and other Information known and owned by a Party or to which a Party has rights as of the Effective Date of this Agreement and which is needed for carrying out the Project.

"Confidential Information"
Confidential Information shall mean any and all proprietary information, data or know-how disclosed or made available by or on behalf of one Party hereto (the "Disclosing Party") to the other Party hereto (the "Receiving Party"), as defined in section 10.whether before or after execution of this Agreement, including, without limitation, patient data and material, patent applications, trademark applications, technical and scientific information, trade secrets, ideas, techniques, sketches, drawings, works of authorship, models, inventions, discoveries, concepts, improvements, research, development, and designs, compositions, prototypes, physical materials, processes, equipment,

gene sequences, formulations, cell lines, samples, vectors, clones, media, chemical compounds, biological materials, algorithms, software programs, software source documents, financial and commercial information, business plans and strategies, and client, supplier, marketing, and strategic alliance information, and other information relating to the Disclosing Party's product research and development activities, marketing plans and other business activities (whether or not patentable).
Confidential Information shall be information that has been explicitly marked as “confidential”, or when disclosed orally, has been identified as confidential at the time of disclosure and has been confirmed and designated in writing within 15 days from oral disclosure at the latest as Confidential Information by the Disclosing Party.

“Third Party Linked to a Party” Third Party Linked to a Party shall mean legal entities, either public or private, represented in the EC Grant Agreement by a signatory Party according to Special Clause 10 of the EC Grant Agreement.

“Legitimate interest”: shall mean Party’s interests of any kind, included but not limited to commercial interest or interest to the corporate image, which breach would result in such Party’s suffering great harm in the cases provided for in this Consortium Agreement.

1.2 Additional Definitions

“Consortium Plan”
Consortium Plan means the description of the work and the related agreed Consortium Budget, including the payment schedule, as outlined in the Grant Agreement [Attachment 8]: Grant Agreement.

“Consortium Budget”
Consortium Budget shall mean the allocation of all the resources in cash or in kind for the activities as defined in Annex I of the Grant Agreement and in the Consortium Plan thereafter.

“Control or Controlled or Controlling” shall mean, with respect to a particular item, Material, Information, know how or Intellectual Property, a Party (i) owns or (ii) has a license and has the ability to use and/or grant a license or sublicenses (as applicable) to use such without violating the rights of any third Party.

“Defaulting Party”
Defaulting Party shall mean a Party which the General Assembly has identified to be in breach of this Consortium Agreement and/or the Grant Agreement as specified in Article 4.20 of this Consortium Agreement.

“Foreground Information” shall mean Information generated by a Party during performance of this Agreement.

“Foreground Intellectual Property” shall mean Intellectual Property discovered, generated, conceived, first reduced to practice or writing, or developed (in whole or in part) by a Party during performance of this Agreement.

"Information" shall mean ideas, concepts, discoveries, inventions, developments, know how, trade secrets, techniques, methodologies, modifications, innovations, improvements, writings, documentation or data.

"Samples" shall mean any biological material provided by any research organisation in the performance of the Project ENCCA according to the Material Transfer Agreement [Attachment 7]: Material Transfer Agreementwithin the Project ENCCA signed between the Parties.

"Intellectual Property" shall mean any know-how, material, composition of matter, method, process, product, biological material or other tangible or intangible property, regardless of whether such property is patentable or not, or regardless of whether such property is protectable through trademark or copyright, including without limitation, any foreign or domestic (i) patent right together with any extension, registration, reissue, re-examination or renewal thereof, and any pending application, including any continuation, divisional, or continuation in part thereof for any of the foregoing; (ii) trademark; or (iii) copyright.

"MTA" shall mean a material transfer agreement between a Party (the "Providing Party") and another Party (the "Receiving Party") as provided in [Attachment 7]: Material Transfer Agreement.

In relation to the granting of Access-rights
""**Needed**" or "**Need**" shall mean that without the grant of such Access Rights, either the Use of own Foreground would be technically or legally impossible, or carrying out the respective tasks under the Consortium Plan assigned to the recipient Party would be impossible, significantly delayed, require significant additional financial or human resources.

In relation to the Use of own Foreground
Access Rights are Needed if, without the grant of such Access Rights, the Use of own Foreground would be technically or legally impossible.

"Representatives" shall mean a Party's employees, officers, directors, agents, affiliates, consultants, contractors, professional advisors or other authorized representatives.

"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.

"Clinical Database" shall mean all anonymised data collected from clinical studies performed within the Project.

2. Section: Purpose

The purpose of this Consortium Agreement is to facilitate the fulfilment of the Consortium Plan and activities allocated to the Parties under the EC-GA by setting forth the terms and conditions pursuant to which the Parties agreed to function and cooperate in the performance of their respective tasks with respect to the Project under the Consortium Plan.

3. Section: Entry into force, duration and termination

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 upon and as from the date of signature by all Parties and shall have effect from the Effective Date identified at the beginning of this Consortium Agreement.

A new Party enters the Consortium and becomes a Party to this Consortium Agreement upon signature of the accession document [Attachment 3]: Accession document by the new Party and the Coordinator. Such accession shall have effect from the date identified in the Accession document.

3.2 Duration and termination

This Consortium Agreement shall continue in full force and effect until complete fulfilment of all obligations undertaken by the Parties under the EC-GA and under this Consortium Agreement. However, this Consortium Agreement or the participation of one or more Parties to it may be terminated in accordance with the terms of this Consortium Agreement and Annex II of the EC-GA (Article II.37. and II.38.).

If the Commission does not award the EC-GA or terminates the EC-GA or a Party's participation in the EC-GA, this Consortium Agreement shall automatically terminate in respect of the affected Party/ies, subject to the provisions surviving the expiration or termination under Art. 3.3 of this Consortium Agreement.

3.3 Survival of rights and obligations

The provisions relating to Access Rights and Confidentiality, for the time period mentioned therein, as well as for Liability, Applicable law and Settlement of disputes shall survive the expiration or termination of this Consortium Agreement.

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

4. Section: Responsibilities of Parties

4.1 General principles

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

Each Party shall promptly provide all information reasonably required by a Consortium Body (as defined in Section 6 below) or by the Coordinator (as defined in Section 6 be
low) to carry out its tasks in relation to the Project as defined in the Consortium Plan

Specifically, each Party shall use reasonable measures to ensure the accuracy of any information or materials it supplies to the other Parties in relation to the Project and

(a) shall use reasonable endeavours:
    - to notify the Coordinator and each of the Parties promptly of any significant problem and delay in performance; and
    - to inform other Parties of relevant communications it receives from third parties in relation to the Project.

(b) Each Party shall use reasonable endeavours to ensure the accuracy of any information or materials it supplies hereunder or under the Grant Agreement and promptly to correct any error therein of which it is notified. (In addition to the obligations specified in the Grant Agreement, Annex II. 3, each Party agrees not to use knowingly, as part of a deliverable or in the design of such deliverable or in any information supplied hereunder or under the Contract Grant Agreement, any proprietary rights of a third party for which such Party has not acquired the right to grant licenses and user rights to the other Parties in accordance with the Grant Agreement, unless all of the other Parties have accepted such use in writing, such acceptance not to be unreasonably withheld.

(c) Each Party agrees to supply the cell culture and mouse models, data sets and patient tissue samples needed to complete the work described in Annex I to the Grant Agreement and only for work described in Annex I to the Grant Agreement and no other purpose unless conditions for Access rights as described in section 9 exist.

4.2 Breach

In the event a responsible Consortium Body identifies a breach by a Party of its obligations under this Consortium Agreement or the EC-GA, the Coordinator will give written notice to such Party requiring that such breach be remedied within 30 calendar days.

If such breach is substantial and is not remedied within that period or is not capable of remedy, and threatens to prevent the fulfilment of the Consortium Plan, a response defending the actions of the Party should be submitted to the Executive Committee for their opinion.

If such breach remains unresolved, this issue will be discussed by the General Assembly who 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.

If the case is resolved at Executive Committee level the Executive Committee will nonetheless report the breach to the General Assembly. In the case that the Coordinator is the Defaulting Party, the remaining members of the General Assembly may give written notice requiring that such breach be remedied within 30 calendar days.

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 solely responsible for carrying out its relevant part of the Project and for such third party's compliance with the provisions of this Consortium Agreement and of the EC-GA. 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 and the EC-GA e.g. regarding Background and Foreground.

5. Section: Liability towards each other

5.1 Warranties

Each Party shall ensure that its work on the Project complies fully with all applicable local, government and international laws, regulations and guidelines which are effective during the period of the Grant Agreement, including those governing health and safety, data protection, and where relevant, the use of human or animal subjects and good clinical practice. In this regard, each Party shall maintain the confidentiality, in accordance with the applicable laws, regulations and guidelines, of all samples and data relating to the use of human subjects, which is created or used in the course of the Project.

Each Party shall secure all necessary approvals from the relevant research ethics committees before undertaking any part of the Project requiring ethics committee approval and 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 Party involved shall first obtain all necessary approvals, indemnities and agreements from that hospital.

Each Party hereby represents and warrants to the best of its knowledge to the other Parties that such Party is duly authorized to execute and deliver this Consortium Agreement and to perform its obligations hereunder and that this Consortium Agreement does not violate any agreement existing between such Party and any third party.

Each Party warrants that all eventual consents, approvals, authorizations, and insurance required to be obtained by such Party in connection with this Consortium Agreement have been obtained.

The Project shall be conducted in accordance with all applicable laws, rules and regulations. Each Party will notify the other in writing of any deviations from the applicable regulatory or legal requirements.

Each Party agrees that all communication, license or transfer, if any, made under this Consortium Agreement, is made "as is", without any warranty of any kind, express or implied, and in particular, regarding accuracy, completeness, merchantability, fitness, patentability and/or performance.

With regard to any information or materials supplied by one Party to another under the Project, no warranty or representation of any kind is made in particular as to the sufficiency or fitness for purpose or as to the absence of any infringement of any proprietary rights of third parties. This includes materials pertaining to Foreground and Background.

Therefore,

the recipient Party shall in all cases be entirely and solely liable for the use to which it puts such information and materials, and

no Party granting Access Rights shall be liable in case of infringement of proprietary rights of a third party resulting from any other Party (or its Affiliates) exercising its Access Rights.

5.2 Limitations of contractual liability

5.2.1 A Party's liability towards the other Parties collectively shall be limited to once the Party's share of the total amount granted for the Project as identified in Annex I of the EC-GA provided such damage was not caused by a wilful act or gross negligence.

5.2.2 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.

Each Party shall be responsible for losses, damages, costs (including legal costs) and expenses, which are caused by its own gross negligence or wilful misconduct. For the avoidance of doubt, each Party is severally liable for its own acts and omissions.

5.3 Damage caused to third parties

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

5.4 Force Majeure

No Party shall be considered to be in breach of this Consortium Agreement if such breach is caused by Force Majeure. Each Party will notify the competent Consortium Bodies of any Force Majeure as soon as possible. If the consequences of Force Majeure for the Project are not overcome within 6 weeks after such notification, the transfer of tasks and of the related budget - if any - shall be decided by the competent Consortium Bodies.

6. Section: Governance structure

6.1 General structure

6.1.1 Strategic Management

A) GENERAL ASSEMBLY
The General Assembly consists of high-level decision-making representatives of the 33 partners and as the decision-taker of the project is responsible for the project's strategic policy.

B) EXECUTIVE COMMITTEE
The Executive Committee is responsible for the strategic management of the project and consists of 11 members, each with one vote.

Project Coordinator/Network of Excellence Manager (NoEM): the NoEM is the legal entity acting as the intermediary between the Parties and the Commission. The NoEM is part of the executive, integrative and operational management and is Chair of the Executive Committee. The NoEM of ENCCA is the ENCCA Project coordinator by EC terms

Project Manager (PM) supports the NoEM in the day to day interaction with partners, follows the technical and financial reporting and management based on the network's controlling and reporting tools.

Dissemination Manager (DM) is responsible to communicate network achievements to the European community and acts as a network contact point for integrated, complementary activities.

Activities Coordinators: Each Activity Coordinator is responsible for following closely the respective area of activity and supporting the WP leaders to achieve their tasks as needed.
The Activities Coordinators are the following: Integrating Activities Coordinator (IAC), Joint Research Activities Coordinator (JRAC), Spread of Excellence Activities Coordinator (SEAC),

One Representative of the following Committees: Scientific Advisory Committee (SAC);
Ethics Advisory Committee (EAC); Patient/ Parent Advocacy Committee (PAC);
In addition two representatives come from the European Clinical Research Council (ECRC) – one representative of the European paediatric oncology clinical trial groups and one for the national childhood cancer groups.

Two Committees will not be part of the Executive Committee but will either interact on an ad hoc basis or via regular communication:
Intellectual Property Rights Committee (IPRC)
Industry Committee (IC)

C) INTEGRATIVE MANAGEMENT
The integrative management is run through the PROJECT MANAGEMENT TEAM (PMT). The PMT is the supporting body to the NoEM in the management of administrative, contractual and financial aspects in order to ensure an efficiently-run project reflecting EU FP7 stipulations. The

PMT is headed by the NoEM and comprises the project manager (PM), the dissemination manager (DM) and the three Activities Coordinators

D) OPERATIONAL MANAGEMENT

The operational management comprises the activities of the work packages leaders surveyed and guided by the respective activity coordinators and respectively the NoEM. The operational management is supported as needed by the PM and the DM.

6.2 General operational procedures for all Consortium Bodies

6.2.1 Representation in meetings

Any member of a Consortium Body (hereinafter referred to as "Member"):

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

6.2.2 Preparation and organisation of meetings

6.2.2.1 Convening meetings

The relevant Chair of a Body within the Consortium shall convene the meetings of the respective Body.

	Ordinary meeting	Extraordinary meeting
General Assembly (Coordinator/ NoEM as Chair, all Parties)	At least once a year by Teleconference and/or face-to-face	Upon written request of the NoEM, Executive Committee, Project Management Team or 1/3 of the Members of the General Assembly
Project Management Team	Monthly (by Teleconference and/or face-to-face)	Upon written request by any Member of the Project Management Team
Executive Committee	Quarterly meetings (by Teleconference and/or face-to-face)	Upon written request of any Member of the Executive Committee
Advisory Committees (SAC; EAC; PAC; ECRC; IPRC; IC)	Twice per year (by Teleconference and/or face-to-face)	Upon written request by NoEM

Work Package Committees: Activity Leaders and WP Leaders	Monthly by Teleconference and/or face-to-face)	At any time upon written request of any Member of the respective Sub Project

6.2.2.2 Notice of a meeting

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

	Ordinary meeting	Extraordinary meeting
General Assembly	90 calendar days	30 calendar days
Project Management Team	14 calendar days	At any time
Executive Committee	14 calendar days	7 calendar days
Advisory Committees	14 calendar days	7 calendar days
Work Package Committees	14 calendar days	At any time

6.2.2.3 Sending the agenda

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

General Assembly	21 calendar days, 10 calendar days for an extraordinary meeting
Project Management Team	At any time
Executive Committee	7 calendar days
Advisory Committees	7 calendar days
Work Package Committees	At any time

6.2.2.4 Adding agenda items

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

Any Member of a Consortium Body may add an item to the original agenda by written notification to all of the other Members of that Consortium Body up to the minimum number of days preceding the meeting as indicated below to be added as Any Other Business (A.O.B.).

General Assembly	14 calendar days, 7 calendar days for an extraordinary meeting
Project Management Team	At any time
Executive Committee	2 working days
Advisory Committees	5 calendar days
Work Package Committees	At any time

6.2.2.5

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

6.2.2.6

Any decision may also be taken without a meeting if the Coordinator circulates to all Members of the Consortium Body a written document which is then signed by the defined majority (see Article 6.2.3.) of the Members of the Consortium Body.

6.2.2.7

Meetings of each Consortium Body may also be held by teleconference or other telecommunication means.

In any such cases, a formal consent in writing, setting forth the decision so taken, is sent via email by the representatives of the Members having not less than the minimum number of votes that would be necessary to take such decision at a meeting at which all Members entitled to vote on such decision were present and were voting.

6.2.2.8

Decisions will only be binding once the relevant part of the Minutes has been accepted according to Article 6.2.4.

6.2.3 Voting rules and quorum

6.2.3.1 Voting rules

6.2.3.1.1

Each Consortium Body shall not deliberate and decide validly unless two-thirds (2/3) of its Members are present or represented (quorum) by a proxy- to be decided it is the case for all Committees or the General Assembly.

6.2.3.1.2

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

6.2.3.1.3

Defaulting Parties may not vote and they are not part of the quorum.

6.2.3.1.4

On budgetary matters, each Consortium Body will make decisions upon a 75% majority.

6.2.3.1.5

All other matters require a simple majority. In the case of a split vote, the Network of Excellence Manager (NoEM) will carry the deciding vote.

6.2.3.2 Veto rights

6.2.3.2.1

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

6.2.3.2.2

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

6.2.3.2.3

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 days after the draft minutes of the meeting are distributed.

6.2.3.2.4

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

6.2.3.2.5

A Party may not veto decisions relating to its identification as a Defaulting Party. The Defaulting Party may not veto decisions relating to its participation and termination in the Consortium or the consequences of them.

6.2.3.2.6

A Party requesting to voluntarily leave the Consortium before completion of the Project may not veto decisions relating thereto

6.2.4 Minutes of meetings

6.2.4.1

The chairperson of a Consortium Body shall produce written minutes of each meeting and of decisions made without a meeting according to the templates provided in the Quality Assurance Plan, which shall be the formal record of all decisions taken. The chairperson shall send the draft minutes to all Members within 10 calendar days of the meeting or of the decision without a meeting.

6.2.4.2

The minutes shall be considered as accepted if, within 15 calendar days from sending, no Member has objected in writing to the chairperson with respect to the accuracy of the draft of the minutes and no Party has issued a veto of any decision contained within such minutes in accordance with Section 6.2.3.

6.2.4.3

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

6.3 Specific operational procedures for the Consortium Bodies

6.3.1 General Assembly

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

6.3.1.1 Members

6.3.1.1.1

The General Assembly consists of high-level decision-making representatives of the Parties who are responsible for the project's strategic policy. The General Assembly shall consist of one representative of each Party (hereinafter General Assembly Member).

6.3.1.1.2

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

6.3.1.1.3

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

6.3.1.1.4

The Parties agree to abide by all decisions of the General Assembly validly taken.
This does not prevent the Parties to submit a dispute to resolution in accordance with the provisions of Settlement of disputes in Article 11.8

6.3.1.2 Appointments and changes in the appointments of the governing structure of the Project

The General Assembly shall be free to act on its own initiative to formulate proposals and take decisions in accordance with the procedures set out herein. In addition, all proposals made by the Executive Committee shall also be considered and decided upon by the General Assembly.

The following items shall be reported at the General Assembly (and votes may be taken should the need arise):
Decisions concerning the following items shall be taken by the General Assembly:

Content, finances, publications and intellectual property rights

- Proposals for changes to Annex I of the EC-GA to be agreed by the European Commission
- Changes to the Consortium Plan (including the Consortium Budget)
- Withdrawals from and additions to [Attachment 1]: Background Information and Intellectual Property included (Background included)
- Additions to [Attachment 2] Background and Intellectual Property excluded (Background excluded)
- Additions to [Attachment 4]: Listed Affiliated Entities
- (Listed Affiliated Entities)
- Additions to [Attachment 6]: List of Third Parties (List of Third Parties)

Evolution of the Consortium

- 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 and additions to of a Party from the Consortium and the approval of the settlement on the conditions of the withdrawal
- Declaration of a Party to be a Defaulting Party
- Remedies to be performed by a Defaulting Party
- Termination of a Defaulting Party's participation in the Consortium and measures relating thereto
- Proposal to the European Commission for a change of the Coordinator
- Proposal to the European Commission for suspension of all or part of the Project
- Proposal to the European Commission for termination of the Project and the Consortium Agreement Discussing and mediating conflicts with inventions and patent filings of Foreground developed within the Project
- Appointments and changes in the appointments of the governing structure of the Project

6.3.2 Executive Committee

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

6.3.2.1 Members

The Executive Committee is responsible for the strategic management of the project and consists of 11 members (as outlined above 6.1).The Coordinator shall chair all meetings of the Executive Committee, unless decided otherwise.

6.3.2.2 Minutes of meetings

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

6.3.2.3 Tasks

6.3.2.3.1 To the extent that it is legally possible for each of the Parties, develop the European Clinical Research Council (ECRC)

6.3.2.3.2 Prepare high-level topics and decision-making for the General Assembly (GA). It shall seek a consensus among the Parties.

6.3.2.3.3 Prepare overarching European decision-making processes related to numerous items including technicalities, financial issues, work schedules and dissemination methods. The Executive Committee shall be responsible for the proper execution and implementation of the decisions of the General Assembly.

6.3.2.3.4 Call additional GA meetings should it be required. The Executive Committee shall monitor the effective and efficient implementation of the Project.

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

6.3.2.3.6

The Executive Committee shall:

- initiate, coordinate and have organised the Sub Project(s)
- agree on the Members of the Project Management Team, upon a proposal by the Coordinator
- support the Coordinator in preparing meetings with the European Commission and in preparing related data and deliverables
- Consider but not compulsorily follow the advice of the IPRC for the approval of content and timing of press releases and joint publications by the Consortium or proposed by the European Commission in respect of the procedures of the EC-GA Article II 30.3.

6.3.2.3.7

In the case of abolished tasks as a result of a decision of the General Assembly, the Executive Committee shall advise the General Assembly on ways to rearrange tasks and budgets 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 Project Management Team

6.3.3.1 Members

As outlined in 6.1, the PMT consists of the following members who make day-to-day decisions regarding operative management tasks:

Network of Excellence Manager (NoEM) who is the ENCCA Project Coordinator in EC terms, Project Manager (PM), Dissemination Manager (DM),
Integrating Activities Coordinator (IAC), Joint Research Activities Coordinator (JRAC), Spread of Excellence Activities Coordinator (SEAC).

6.3.3.2 Minutes of the meetings

Meeting minutes, once accepted, shall be sent by the Coordinator to the General Assembly Members for information.

6.3.3.3 Tasks

The Project Management Team shall be responsible for

- the proper execution and implementation of the decisions of the General Assembly.
- monitoring the effective and efficient implementation of the Project.
- collecting information at least every 6 months on the progress of the Project,
- examining that information to assess the compliance of the Project with the Consortium Plan and, if necessary,
- proposing modifications of the Consortium Plan to the General Assembly.

Further, the PMT shall

- support the management in carrying out the three main areas of activity and the corresponding work packages and work package tasks
- liaise with the Work Package Leaders (WPLs) of the project to ensure the objectives are achieved and ensure all Partners are performing the tasks set out for them
- be accountable to the General Assembly
- review the progress of the project and assess the status quo of the project resources
- carry out any necessary conflict resolution on technical, financial and/or strategic issues that may arise.
- take day-to-day decisions regarding the operative management tasks on the project (NoEM, PM, DM, Advisory Committees (ACs)) with enrolment of advisory functions only when strategic management tasks need to be solved.
- initiate, coordinate and organise the WP Committee(s)
- support the Coordinator in preparing meetings with the European Commission and in preparing related data and deliverables
- support the DM in preparing the content and timing of press releases and joint publications by the Consortium or proposed by the European Commission in respect of the procedures of the EC-GA Article II 30.3.

6.3.3.4

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

6.3.4 Work Package Leaders

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

6.3.4.1 Members

The Work Package Leader shall chair all meetings of the respective Work Package Committee.

6.3.4.2 Tasks

Each Work Package Leader shall manage the respective Work Package, in particular with regard to:

- The timely delivery of reports and Work Package results to the Project Management Team and the Coordinator
- Assessing the quality of the outputs of their WP deliverables and milestones
- Formulating an implementation plan for the activities within the Work Package for the future period, which can imply proposing to the Management Team changes to the Consortium Plan and/or Annex I of the EC-GA
- Analysing and documenting, at the request of the Project Management Team a presumed breach of responsibilities of a Party under the Work Package and preparing a proposal of remedies to the Project Management Team
- Making proposals to the Project Management Team for the admission of new Parties to the EC-GA and to the Consortium Agreement in order for said new Parties to participate in the Work Package
- Deciding in the frame of 6.2.3.2. upon any exchange of tasks and related budgets between the Parties in a Work Package when such exchange has no impact beyond the scope of the Work Package and its budget.
- Alerting the Project Management Team and the Coordinator in case of delay in the performance of the Work Package, or in case of any discrepancy with the Consortium Plan including any delay in delivery or in case of breach of responsibilities of any Party under said Work Package.
- To refer to the ACs for support in case of a major issue that affects the completion of the work foreseen.
- Communicating any plans, deliverables, documents and information connected with the Work Package between its Members and, if relevant, to the Management Support Team.
- Initiate and participate actively in the technical meetings necessary for the work progress, and provide meeting minutes.
- Coordinating on a day-to-day basis the progress of the technical work under the Work Package
- Following up decisions made by the General Assembly insofar as they affect the Work Package

6.3.5 Coordinator

6.3.5.1

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

6.3.5.2

In particular, the Coordinator, who is the NoEM in the Project, shall be responsible for the following:

- Chairing the General Assembly and Executive Committee
- 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 and other deliverables (including financial statements and related certifications) to the European Commission
- transmitting documents and information connected with the Project to and between Sub Project Leaders, as appropriate, and any other Parties concerned
- administering the Community financial contribution and fulfilling the financial tasks described in Article 7.3.
- providing, upon request, the Parties with official copies or originals of documents which are in the sole possession of the Coordinator when such copies or originals are necessary for the Parties to present claims.
- Conscribing the Advisory Committees as appropriate

6.3.5.3

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

6.3.5.4

The Coordinator shall not be entitled to act or to make legally binding declarations on behalf of any other Party.

6.3.5.5

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

6.3.6 Project Manager (PM)

The PM works at the Coordinator institution.

6.3.6.1

The Project Manager will be working closely with the Network of Excellence Manager (NoEM) to take on responsibility for the financial and administrative management on a day-to-day basis.

6.3.6.2

The PM will support meeting organisations and will be notifying the ENCCA consortium of due dates.

6.3.6.3

The PM will build a Quality Assurance Plan and Methodology using appropriate tools to support the internal management requirements and expedited reporting and to follow-up on the project indicators (Gantt chart, manpower matrix, deliverables list).

6.3.6.4

The PM will survey if the technical objectives are followed and the completion of the project within the approved budget. Hence the PM will be managing the delivery and the follow-up of administrative and financial documents and be monitoring cost performance to detect deviations from plan.

6.3.6.5

The PM will be supporting the reporting through common templates adapted to the ENCCA project and partners for official progress reporting for the EU Commission body, notifying due dates and send out deadline reminders, assisting partners to respect indications and guidelines assigned by FP7 and will be collecting the WP leaders contributions to prepare the consolidated annual (including the final) project progress reports in collaboration with the Network Manager.

6.3.7 Dissemination Manager

In general, tasks of the DM are the following:

6.3.7.1

Publicise the project to all relevant stakeholders.

6.3.7.2

Identify the most appropriate results to be publicised for the relevant target audience, the most relevant publications and information outlets.

6.3.7.3

Detailed tasks are described in the respective WP-Description in the Grant Agreement [Attachment 9]: Grant Agreement.

7. Section: Financial provisions

7.1 General Principles

A Party shall be funded only for its tasks carried out and for the tasks of a Third Party Linked to a Party it may represent in accordance with the Consortium Plan.

7.1.1 Distribution of Financial Contribution

The Community financial contribution to the Project shall be distributed by the Coordinator according to:

- the Grant Agreement regulations
- the Consortium Budget as included in the Consortium Plan
- the approval of reports by the European Commission, and
- the provisions of payment in Article 7.3.

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

In order to ensure the effective use of the Commission's grant, the Consortium agrees on that the Coordinator shall transfer the total amounts as approved by the Commission through the review of the financial reports, withholding interim under-expenditures. Nevertheless, this withholding shall not result in the reduction of the total budget for each individual participant for the whole duration of the project. Instead, this mechanism shall allow the Coordinator to redistribute any funds resources of any Party whose funds requirements fell below its original budget plan.

The Parties agree that they will use their best efforts to reach agreement on the amounts as well as on the payment schedule of the first advance payments to the Parties. If the Parties do not reach such an agreement within 45 days after the coming into force of the EC-GA, the Coordinator shall pay out to each Party an amount pro rata to the amount budgeted for the Project in the Consortium Plan.

7.1.2 Justifying Costs

In accordance with its own usual accounting and management principles and practices, each Party shall be solely responsible for justifying its costs as well as the costs of a Third Party linked to a Party it may represent with respect to the Project towards the European Commission. Neither the Coordinator nor any of the other Parties shall be in any way liable or responsible for such justification of costs towards the European Commission.

7.1.3 Funding Principles

A Party which spends less than its allocated share of the Consortium Budget will be funded in accordance with its actual duly justified eligible costs only.

It is understood in all cases that no other Party shall be liable for any costs of a Party exceeding that Party's budgeting of such cost.

More information on the terms of eligible and non-eligible costs are available in the European Commission's Financial Guidelines, an overview thereof is provided [Attachment 8]: Overview of Eligible Costs according to EC Financial Guidelines
.

7.1.4 Financial Consequences of the termination of the participation of a Party

A Party leaving the Consortium shall refund all payments it has received except the amount of contribution accepted by the European Commission or another contributor. Furthermore a Defaulting Party shall, within the limits specified in Article 5.2 of this Consortium Agreement, bear any additional costs occurring to the other Parties in order to perform its and their tasks.

7.2 Budgeting

The Consortium Budget shall be valued in accordance with the usual accounting and management principles and practices of the respective Parties.

7.2.1 Budgeted costs eligible for 100% reimbursement

These costs shall be budgeted in the Consortium Budget in the following order of priority, as far as comprised in the budget plan of the Grant Agreement:

- banking and transaction costs related to the handling of any financial resources made available for the Project by the Coordinator
- reasonable costs of Parties related to
    - the delivery of certificates on the financial statements according to the EC-GA
    - the delivery of the certificate on the methodology, if any, unless the cost of such certification has already been paid to the beneficiary under a previous EC-GA and the methodology has not changed (EC-GA Article II.4.4 and II.14.1)
    - costs related to calls for new Beneficiaries
- costs related to updating this Agreement
- management costs of the Coordinator and the Management Support Team
- costs related to the tasks of the Executive Committee
- intellectual property costs with regard to legal advice and litigation costs
- costs for publications
- costs for the tasks of chairpersons
- audit costs
- any other costs eligible for 100% reimbursement

- An overview on eligible costs according to FP7-guidelines is listed in [Attachment 8]: Overview on Eligible Costs according to EC Financial Guidelines

7.2.2 Budgeting of coordination costs

Costs of coordination of research which are not allowed as management cost according to Annex II of the EC-GA (EC-GA Article II.16.5) have to be budgeted separately.

7.3 Payments

7.3.1 Payments to Parties are the exclusive tasks of the Coordinator.

In particular, the Coordinator shall:

- notify the Party concerned promptly of the date and composition of the amount transferred to its bank account, giving the relevant references
- perform diligently its tasks in the proper administration of any funds and in maintaining financial accounts
- undertake to keep the Community financial contribution to the Project separated from its normal business accounts, its own assets and property, except if the Coordinator is a Public Body or is not entitled to do so due to statutory legislation.

7.3.2 The payment schedule

The payment schedule, which contains the transfer of pre-financing and interim payments to Parties, will be handled according to grant agreement regulations.

- The Coordinator will transfer, in accordance with the Contract and the budget allocation decided by the Project Coordination Committee, the appropriate sums to the respective Parties with minimum delay, but not later than thirty (30) calendar days from the receipt thereof from the Commission.
- The Coordinator shall notify each Party promptly of the date and amount transferred to its respective bank account, as listed in Annex C, and shall give the relevant references.
- The Coordinator is entitled to withhold any payments due to a Party identified by a responsible Consortium Body to be in breach of its obligations under this Consortium Agreement or the EC-GA" or to a Beneficiary which has not yet signed this Consortium Agreement.
- In correlation to 7.1.1, the Coordinator is entitled to withhold the corresponding amounts to unused funds, until approval of the used grant by a financial certificate, according to each Party's finance Report to the Commission.
- The Coordinator is entitled to recover any payments already paid to a Defaulting Party.

8. Section: Foreground Intellectual Property

Regarding Foreground Intellectual Property, EC-GA Article II.26. - Article II.29. shall apply with the following additions:

Where applicable each Party shall take appropriate steps to protect and exploit their Foreground Intellectual Property at their own cost.

8.1 Joint ownership

Parties' shares of ownership shall be proportional to the inventive contribution in generating that specific Foreground.
For the avoidance of doubt, the Clinical Database generated within the Project is Foreground Intellectual Property.

If a Party identifies Foreground Information capable of protection, notice shall be made to the Coordinator. If Parties identify Foreground Intellectual Property, which is jointly owned by joint owners, a co-ownership agreement shall be negotiated in good faith between the joint owners, a copy of which shall be brought to the attention of the Coordinator.
Any conflicts related thereto shall be brought to the attention of the Coordinator.

As a general principle, and where no joint ownership agreement has yet been concluded:

- each of the joint owners shall be entitled to Use directly their jointly owned Foreground on a royalty-free basis non-transferable basis, without requiring the prior consent of the other joint owner(s), and
- each of the joint owners shall be entitled to grant non-exclusive licenses to third parties, without any right to sub-license, subject to the following conditions:
- at least 45 days prior notice must be given to the other joint owner(s); and
- fair and reasonable compensation must be provided to the other joint owner(s) taking into account each owner's relative ownership.
- the other joint owners' prior written consent must be obtained, which shall not be unreasonably withheld.

In case of joint ownership of Foreground Intellectual Property, if the respective share of the work cannot be ascertained or if the contributions to or features of such Foreground Intellectual Property form an indivisible part thereof, such that it is not possible to separate them for the purpose of applying for, obtaining and/or maintaining the relevant patent protection or any other IPR protection, the Parties (co-owners) shall establish within six (6) month period a specific agreement regarding the allocations and terms of exercising that joint ownership (including arrangements for applying for a patent protection), the protection of patentable results, the division of related costs and all other relevant aspects, including the opportunity not to continue with the joint ownership but decide on an alternative regime. The use or license of such rights for commercial purposes shall include a financial compensation to other co-owners, if not otherwise foreseen in the aforementioned specific agreements between the co-owners.

Notwithstanding the foregoing, where no co-ownership agreement has yet been concluded, each co-owner shall be entitled to use the joint Foreground Intellectual Property for further non-commercial research activities (including research sponsored by third parties) and for training/teaching purpose, without owing any financial compensation to or requiring the consent of the other co-owners. In these cases no specific agreement is needed, but these activities shall be compatible with the protection of intellectual property rights and confidentiality obligations.

8.2 Transfer of Foreground Intellectual Property

8.2.1

Each Party may transfer ownership of its own Foreground Intellectual Property following the procedures of the EC-GA Article II 27.

8.2.2

Each Party may identify specific third parties to which it intends to transfer the ownership of its Foreground Intellectual Property to Parties as listed in [Attachment 6]: List of Third Parties to this Consortium Agreement.

8.2.3

The transferring Party shall, however, notify the other Parties of such transfer and shall ensure that the rights of the other Parties will not be affected by such transfer.
Any addition to [Attachment 6]: List of Third Parties after signature of this Agreement requires an approval of the General Assembly, which shall not unreasonably be withheld.

8.2.4

The Parties recognize that in the framework of a merger or an acquisition of an important part of its assets, a Party may be subject to confidentiality obligations which prevent it from giving the full 45 days prior notice for the transfer as foreseen in the EC-GA, Article II 27.2. However, in that event, such a Party shall give notice as soon as reasonably possible.

8.3 Dissemination

8.3.1 Publication and other Activities

8.3.1.1

Dissemination activities including but not restricted to publications and presentations shall be governed by the procedure of Article II.30.3 of the EC-GA subject to the following provisions.
Prior notice of any planned publication/dissemination activity, with a copy of it, shall be made 45 days before the publication/dissemination activity. Any objection to the planned publication shall be made in accordance with the PMT in writing to the Coordinator and to any Party concerned within 30 days after receipt of the notice. If not resolved through discussion with the PMT, the GA will

ultimately be involved in the decisions making process if suggested and approved by the Executive Committee. If no objection is made within the time limit stated above, the publication is permitted.

If Foreground Information / Intellectual Property or Background Information / Intellectual Property of another Party is needed for publication of a student degree theses, approval for Use shall be obtained from the appropriate Party owing such rights or affected by the Use. The approval of the relevant Parties shall be sought at least 45 days before the latest date of which the contents of the planned publication can be altered. For the avoidance of doubt, no such publication will be made without such approval of a Party who would be adversely affected by that publication. Approval shall not be unreasonably delayed or withheld

8.3.1.2

An objection is justified if based of the following grounds: (i) that the objecting Party considers the protection by intellectual property rights of its Foreground would be adversely affected by the proposed publication, (ii) that the proposed publication includes Confidential Information of the objecting Party, or (iii) the publication of such information would result in disproportionately great harm to the legitimate interests of the objecting Party.

The objection has to include for each part of the publication objected to, the grounds of the objection for each objection, indicating which part of the publication the objection is aimed at (individual paragraphs or sentences) and a precise request for necessary modifications (including deletions).

8.3.1.3.

In the event that an objection is raised in accordance to the above, the Party proposing the publication and the Party objecting shall seek in good faith to agree to a solution whereby the Parties objecting give permission to publish the proposed publication.

In the event parts of a publication are objected to on ground (i) the publication will be permitted after expiry of a period of three (3) calendar months following the first submission of the proposed publication in accordance to 8.3.1.1.

In the event parts of a publication are objected to on grounds (ii) or (iii) the objection(s) will be deemed withdrawn in the event the Party proposing the publication removes the parts objected to from the intended publication.

8.3.2 Publication of another Party's Foreground or Background

For the avoidance of doubt, a Party shall not publish Foreground Information/Intellectual Property or Background Information/Intellectual Property of another Party, even if such Foreground Information/Intellectual Property or Background Information/Intellectual Property is amalgamated with the Party's Foreground Information/Intellectual Property, without the other Party's prior written

approval. The timeframe is defined under 8.3.1.1. which shall not be unreasonably withheld or delayed.

8.3.3 Cooperation obligations

Without prejudice to the provisions of Confidentiality in Section 10 and Dissemination in Section 8, The Parties undertake to cooperate to allow the timely submission, examination, publication and defence of any dissertation or thesis for a degree which includes their Foreground or Background to the extent the latter is linked to the Foreground in order to make it meaningful. However, confidentiality and publication clauses have to be respected.

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.

9. Section: Access Rights

9.1 Background/Intellectual Property Information/Intellectual Property covered

Each Party is and shall remain the sole owner of its intellectual and industrial property rights over its Background.

9.1.1

The Parties shall identify in the [Attachment 1]: Background Information and Intellectual Property included the background to which they are ready to grant Access Rights as outlined in [Attachment 1]: Background Information and Intellectual Property included, subject to the provisions of this Consortium Agreement and the EC-GA. Such identification may be done by e.g.

- subject matter and possibly in addition by
- naming a specific department/research group of a Party
-

9.1.2

The owning Party may provide further instructions to provide Access Rights during the Project by written notice.
However, only the General Assembly can permit a Party to withdraw any of its Background from [Attachment 1]: Background Information and Intellectual Property included

9.1.3

The Parties agree that Access Rights to Background Info/IP listed in Attachment 1 shall be explicitly included for the purpose of Implementation of the Consortium Plan. The Parties agree, however, to negotiate in good faith withdrawals from and additions to Attachment 1 if a Party submits a request to the General Assembly in accordance with Section 6.2.2.4, for a decision under Section 6.3.1.2.

For the avoidance of doubt, the owner is under no obligation to agree to additions of his Background Info/IP to Attachment 1.

9.1.4

In addition, if a Party wishes to list specific Background Info/IP as excluded, it shall identify such Background Information/Intellectual Property in the Attachment 2.
The owning Party may withdraw any of its Background Info/IP from Attachment 2 during the Project by written notice.

9.2 General Principles

9.2.1

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

9.2.2

As provided in the EC-GA Article II.32.3. Parties shall inform the Consortium as soon as possible of any limitation to the granting of Access Rights to Background Information and Intellectual Property or of any other restriction which might substantially affect the granting of Access Rights (e.g. the use of open source code software in the Project).

9.2.3

If the General Assembly considers that the restrictions have such impact, which is not foreseen in the Consortium Plan, it may decide to update the Consortium Plan accordingly.

9.2.4

Any Access Rights granted expressly exclude any rights to sublicense or transfer to a third party unless expressly stated otherwise.
Access Rights shall be free of any administrative transfer costs.
Access Rights are granted on a non-exclusive basis non-transferable basis, if not otherwise agreed in writing by all the Parties according to the EC-GA Article II.32.7.

9.2.5

Foreground and Background shall be used only for the purposes for which Access Rights to it have been granted and only for so long as necessary for those purposes.

9.2.6 All requests for Access Rights shall be made in writing.

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

9.2.7

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

9.2.8 Access Rights for Third Parties Linked to a Party

In the event a Third Party Linked to a Party carries out the work generating foreground, the general conditions of the Grant Agreement regarding intellectual property rights, use and dissemination, access rights to foreground and background (Part C section 2 Access rights of Annex II) and this Consortium Agreement shall apply mutatis mutandis to such Third Party Linked to a Party, as if it was a Party, generating Foreground to the Project."

9.3 Access Rights for implementation

Access Rights to Foreground and Background Needed for the performance of the own work of a Party under the Project shall be granted on a royalty-free basis, unless otherwise agreed for Background In [Attachment 1]: Background Information and Intellectual Property included.

9.4 Access Rights for Use

9.4.1

Access Rights to Foreground if Needed for Use of a Party's own Foreground Information/Intellectual Property including for third-party research shall be granted on fair and reasonable conditions and conditional on the conclusion of separate written agreements between the Parties owning and requesting such Access Rights and shall specify the term and conditions of Use.

Access rights for the Party’s own internal non-commercial research and/or teaching activities shall be granted on a royalty-free basis.

9.4.2

A request for Access Rights may be made up to twelve months after the end of the Project or, in the case of Art. 9.7.2.19.7.2.1.2, after the termination of the requesting Party’s participation in the Project.

9.4.3

Access Rights to Background if Needed for Use of a Party's own Foreground Information/Intellectual Property shall be granted and on fair and reasonable conditions subject to a separate agreement between the Parties concerned, which shall not unreasonably be withheld.

Access rights to Foreground and Background Information/Intellectual Property for internal non commercial research activities and for training/teaching activities shall be granted on a royalty-free basis.

9.5 Access Rights for Affiliated Entities

Affiliated Entities have Access Rights under the conditions of the EC-GA Article II.34.3.

Such Access Rights to Affiliated Entities shall be granted on fair and reasonable conditions and upon written bilateral agreement between the Affiliated Entity and the Party whose Foreground/Background is involved if applicable.

The granting Party shall ensure that the conditions under which Access Rights are granted shall at least include the following conditions:

Affiliated Entities which obtain Access Rights in return grant Access Rights to all Parties, as if such Affiliated Entities were Parties;

Affiliated Entities fulfill all confidentiality and other obligations accepted by the Parties under the EC-GA or this Consortium Agreement, as if such Affiliated Entities were Parties;

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

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 and upon cessation of the status as an Affiliated Entity. The Party concerned shall promptly notify the Coordinator and any Access Rights granted to such former Affiliated Entity shall lapse automatically from the moment of cessation.

Further arrangements with Affiliated Entities may be negotiated in separate agreements at the sole discretion of the party providing such access.

Access Rights to Clinical Database to Affiliated Entities which is needed for Use shall be granted upon an agreement between the Parties concerned.
This agreement shall define the scope, the financial conditions, the duration of the Use and the assigned right.

9.6 Additional Access Rights

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

9.6.1 General principles applicable to Samples

Samples provided in the performance of the Project by any Research organisation shall remain the property of the provider.

9.6.2

When a Party (the "Provider") sends biological material to another Party (the "Recipient") in respect of the Project, a bilateral material transfer agreement (MTA), shall be concluded between such Parties to specify the conditions applying to such transfer of material. The material shall only be used for the purpose of the Project and only for as long as is necessary for that purpose. The Recipient will be entirely responsible for the use of the biological material and the Provider shall have no obligation or liability for the material, except for gross negligence or willful misconduct. The Recipient shall not be entitled to transfer the material to any third party (including another Party) without the Provider's prior written consent.

A template of an MTA is included in [Attachment 7]: Material Transfer Agreement.
Where reasonably possible such template MTA shall be used to cover the transfer of biological material between the Provider and the Recipient in respect of the Project. Each Party using the template MTA is responsible for ensuring that the MTA is completed correctly, adapted to the relevant situation and that it complies with all applicable rules, laws or regulations. In case of conflict between the MTA and the Consortium Agreement, the latter shall prevail. Material provided in the performance of the Project shall remain the property of the Provider.

9.6.3

Samples are provided only for the purpose of the performance of the Project.
The Party providing such Sample shall respect all legal dispositions, regulations, rules and guidelines applicable to this matter.

9.6.4

Notwithstanding the rights of inventorship, the Parties agree that any Proprietary Rights excluding the Clinical Database that has been obtained, discovered, conceived, reduced to practice or otherwise generated in connection with the use of the Sample(s), shall be owned jointly between the Party(ies) who received the Sample and the Party who provided it unless a MTA is signed.
In this case, the rules of joint ownership above-mentioned will be applicable.

9.7 Access Rights for Parties entering or leaving the Consortium

Any Party leaving the Project without granting the Access Rights until the date of leaving to which said Party is obligated shall be deemed as Defaulting Party and therefore shall be liable to a refund within the limits specified in this Consortium Agreement.

9.7.1 New Parties entering the Consortium

All Foreground developed before the accession of the new Party shall be considered to be Background with regard to said new Party.

9.7.2 Parties leaving the Consortium

9.7.2.1 Access Rights granted to a leaving Party

9.7.2.1.1 Defaulting Party

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

9.7.2.1.2 Non-defaulting Party

A non-defaulting Party leaving voluntarily and with the other Parties' written consent shall have Access Rights to the Foreground developed until the date of the termination of its participation. It may request Access Rights within the period of time specified in Art. 9.4.2.

9.7.2.2 Access Rights to be granted by any leaving Party

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

9.8 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.

9.8.1 Definitions relating to Software

"Application Programming Interface"
means the application programming interface materials and related documentation containing all data and information to allow skilled Software developers to create Software interfaces that interface or interact with other specified Software.

"Controlled License Terms" means terms in any license that require that the use, copying, modification and/or distribution of Software or another work ("Work") and/or of any work that is a modified version of or is a derivative work of such Work (in each case, "Derivative Work") be subject, in whole or in part, to one or more of the following:

(a) (where the Work or Derivative Work is Software) that the Source Code or other formats preferred for modification be made available as of right to any third party on request, whether royalty-free or not;
(b) that permission to create modified versions or derivative works of the Work or Derivative Work be granted to any third party;
(c) that a royalty-free license relating to the Work or Derivative Work be granted to any third party.

For the avoidance of doubt, any Software license that merely permits (but does not require any of) the things mentioned in (a) to (c) is not a Controlled License (and so is an Uncontrolled License).

“Object Code” means software in machine-readable, compiled and/or executable form including, but not limited to, byte code form and in form of machine-readable libraries used for linking procedures and functions to other software.

“Software Documentation” means software information, being technical information used, or useful in, or relating to the design, development, use or maintenance of any version of a software programme.

“Source Code” means software in human readable form normally used to make modifications to it including, but not limited to, comments and procedural code such as job control language and scripts to control compilation and installation.

9.8.2 General principles

For the avoidance of doubt, the general provisions for Access Rights provided for in this Section 9 are applicable also to Software as far as not modified by this Article 9.8.

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 Source Code, Object Code or respective Software Documentation in any particular form or detail, but only as available from the Party granting the Access Rights.

The intended introduction of Intellectual Property (including, but not limited to Software) under Controlled License Terms in the Project requires the approval of the General Assembly to implement such introduction into the Consortium Plan.

9.8.3 Access to Software

Access Rights to Software which is Foreground shall comprise:
Access to the Object Code; and,
where normal use of such an Object Code requires an Application Programming Interface (hereafter API), Access to the Object Code and such an API; and,
if a Party can show that the execution of its tasks under the Project or the Use of its own Foreground is technically or legally impossible without Access to the Source Code, Access to the Source Code to the extent necessary.

Background shall only be provided in Object Code unless otherwise agreed between the Parties concerned.

Notwithstanding the above provision, according to an in-depth evaluation of the project goals and the specific contribution of FORTH, AIT and CINECA (partners No 17, 18 and 19), all partners

expressly agree that no Source Code will be provided by FORTH, AIT, and CINECA and made available by the same.

9.8.4 Software license and sublicensing rights

9.8.4.1 Object Code

9.8.4.1.1 Foreground - Rights of a Party

Where a Party has Access Rights to Object Code and/or API which is Foreground for Use, such Access shall, in addition to the access for Use foreseen in Article 9.4, as far as Needed for the Use of the Party's own Foreground, comprise the right:

to make an unlimited number of copies of Object Code and API; and
to distribute, make available, market, sell and offer for sale such Object Code and API alone or part of or in connection with products or services of the Party having the Access Rights;

provided however that any product, process or service has been developed by the Party having the Access Rights in accordance with its rights to use Object Code and API for its own Foreground.

If it is intended to use the services of a third party for the purposes of this Article 9.8.4.1.1, the Parties concerned shall agree on the terms thereof with due observance of the interests of the Party granting the Access Rights as set out in Article 9.2 of this Consortium Agreement.

9.8.4.1.2 Foreground - Rights to grant sublicenses to end-users

In addition, Access Rights to Object Code shall, as far as Needed for the Use of the Party's own Foreground, comprise the right to grant in the normal course of the relevant trade to end-user customers buying/using the product/services, a sublicense to the extent as necessary for the normal use of the relevant product or service to use the Object Code alone or as part of or in connection with or integrated into products and services of the Party having the Access Rights and, as far as technically essential:

- to maintain such product/service;
- to create for its own end-use interacting interoperable software in accordance with the Council Directive of 14 May 1991 on the legal protection of computer programs (91/250/EEC).

9.8.4.1.3 Background

For the avoidance of doubt, where a Party has Access Rights to Object Code and/or API which is Background for Use, Access Rights exclude the right to sublicense. Such sublicensing rights may, however, be negotiated between the Parties.

9.8.4.2 Source Code

9.8.4.2.1 Foreground - Rights of a Party

Where, in accordance with Article 9.8.3, a Party has Access Rights to Source Code which is Foreground for Use, Access Rights to such Source Code, as far as Needed for the Use of the Party's own Foreground, shall comprise a worldwide right to use, to make copies, to modify, to develop, to adapt Source Code for research, to create/market a product/process and to create/provide a service.
If it is intended to use the services of a third party for the purposes of this Article 9.8.4.2.1, the Parties shall agree on the terms thereof, with due observance of the interests of the Party granting the Access Rights as set out in Article 9.2 of this Consortium Agreement.

9.8.4.2.2 Foreground – Rights to grant sublicenses to end-users

In addition, Access Rights, as far as Needed for the Use of the Party's own Foreground, shall comprise the right to sublicense such Source Code, but solely for purpose of adaptation, error correction, maintenance and/or support of the Software.
Further sublicensing of Source Code is explicitly excluded.

9.8.4.2.3 Background

For the avoidance of doubt, where a Party has Access Rights to Source Code which is Background for Use, Access Rights exclude the right to sublicense. Such sublicensing rights may, however, be negotiated between the Parties.

9.8.5 Specific formalities

Each sublicense granted according to the provisions of Article 9.8.4 shall be made by a traceable agreement specifying and protecting the proprietary rights of the Party or Parties concerned.

10. Section: Non-disclosure of information

10.1

The Recipients of Confidential Information hereby undertake in addition and without prejudice to any commitment of non-disclosure under the EC-GA, for a period of 5 years after the end of the Project:

- not to use Confidential Information otherwise than for the purpose for which it was disclosed;
- not to disclose Confidential Information to any third party 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 on demand all Confidential Information which has been supplied to or acquired by the Recipients including all copies thereof and to delete all information stored in a machine readable form. If needed for the recording, the Recipients may however keep a copy for archival purposes only, which copy shall remain subject to the confidentiality provisions stated herein.

10.2

The Recipients shall be responsible for the fulfillment of the above obligations on the part of their employees, affiliated entities and consultants and shall ensure that their employees and consultants remain so obliged, as far as legally possible, during and after the end of the Project and/or after the termination of employment.

10.3

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 becomes publicly available by means other than a breach of the Recipient's confidentiality obligations;
- the Disclosing Party has subsequently informed the Recipient that the Confidential Information is no longer confidential;
- the Confidential Information is communicated to the Recipient without any obligation of confidence by a third party who is in lawful possession thereof and under no obligation of confidence to the Disclosing Party;
- the disclosure or communication of the Confidential Information is foreseen by provisions of the EC-GA;
- the Confidential Information, at any time, was developed by the Recipient completely independently of any such disclosure by the Disclosing Party; or
- the Confidential Information was already known to the Recipient prior to disclosure
- the Confidential Information is required to be disclosed to comply with applicable laws or regulations or with a court or administrative order.

10.4

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

10.5

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

10.6

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 information.

10.7

The confidentiality obligations under this Consortium Agreement and the EC-GA shall not prevent the communication of Confidential Information to the European Commission.

11. Section: Miscellaneous

This Consortium Agreement, the annexes, the Grant Agreement, and when such exists, addendum and any complementary agreement(s), shall constitute the entire agreement among the Parties in respect of the Project, and supersede all previous negotiations, commitments and documents concerning the Project including any memorandum of understanding among the Contractors (whether or not with others) which relate to the Project or its proposal to the European Commission

11.1 Attachments, inconsistencies and severability

This Consortium Agreement consists of this core text and

[Attachment 1]: Background Information and Intellectual Property included: List of all know how, proprietary materials, copyright (software), patent rights to be included here

[Attachment 2]: Background Information and Intellectual Property excluded: List of all know how, proprietary materials, copyright (software), patent rights to be included here

[Attachment 3]: Accession document

[Attachment 4]: Listed Affiliated Entities

[Attachment 5]: Initial list of Members and other contact persons

[Attachment 6]: List of Third Parties

[Attachment 7]: Material Transfer Agreement

[Attachment 8]: Overview of Eligible Costs according to EC Financial Guidelines

[Attachment 9]: Grant Agreement

In case the terms of this Consortium Agreement are in conflict with the terms of the EC-GA, the terms of the latter shall prevail. In case of conflicts between the Attachments and the core text of this Consortium Agreement, the latter shall prevail.

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

11.2 No representation, partnership or agency

The Parties shall not be entitled to act or to make legally binding declarations on behalf of any other Party. 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.

11.3 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 based on the initial list of Members and other contact persons in [Attachment 5]: Initial list of Members and other contact persons.

Formal notices:
If it is required in this Consortium Agreement (Article. 9.7.2.1.1 and 11.4) that a formal notice, consent or approval shall be given, such notice shall be signed by an authorised representative of a Party and shall either be served personally or sent by mail with recorded delivery 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 fulfills the conditions of 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 concerned

11.4 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, which shall not unreasonably be withheld.

Amendments and modifications to the text of this Consortium Agreement not explicitly listed in Article 6.3.1.2 require a separate agreement between all Parties.

11.5 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.

11.6 Language

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

11.7 Applicable law

This Consortium Agreement shall be construed in accordance with and governed by the laws of Belgium.

11.8 Settlement of disputes

All disputes arising out of or in connection with this Consortium Agreement, which cannot be solved amicably, shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce by one arbitrator appointed in accordance with the said Rules. The arbitrators shall settle the dispute in accordance with Belgian law.

The place of arbitration shall be Brussels if not otherwise agreed by the conflicting Parties.

The award of the arbitration will be final and binding upon the Parties.

Nothing in this Consortium Agreement shall limit the Parties' right to seek injunctive relief or to enforce an arbitration award in any applicable competent court of law.

However, should any Party (e.g. a public body) show that certain provisions of its national law prevents it from submitting the relevant dispute to arbitration, then the concerned Parties will submit the dispute to the competent Court in Brussels.

11.9 Special clause

Because of IARC’s particular status as a Specialised Agency of the United Nations (thus being a public body and international organisation as referred to in the EC Contract), having adhered to the UN-EC Financial and Administrative Framework Agreement of 29.04.2003 (FAFA), the Parties agree that the special clauses which have been incorporated to Article 7 of the GA shall also apply to this Consortium Agreement, in particular to clauses 4.1, 11.7, 11.8.

12. Section: Signatures

This Consortium Agreement may be executed in any number of counterparts, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

[Insert the form of signing: separate signature pages or counterparts or accession forms the day and year first above written.]

AS WITNESS:
The Parties have caused this Consortium Agreement to be duly signed by the undersigned authorised representatives in

P1 CCRI

ST. ANNA KINDERKREBSFORSCHUNG e.V.

Legal Representative

Signature(s)

Name(s) Helmut Gadner

Title(s)

Principle Investigator(s)

Signature(s)

Name(s) Ruth Ladenstein

Title(s)

P2 SIOPE

SIOP Europe

Legal Representative

Signature(s)

Name(s) Michel Ballieu

Title(s)

Principle Investigator(s)

Signature(s)

Name(s): Samira Essiaf

Title(s)

P4 UCL

UNIVERSITY COLLEGE LONDON

Legal Representative

Signature(s)

Name(s) Burgess Mark

Title(s)

Principle Investigator(s)

Signature(s)

Name(s) Kathy Pritchard-Jones

Title(s)

P5 CAU

CHRISTIAN-ALBRECHTS-UNIVERSITAET ZU KIEL

Legal Representative

Signature(s)

Name(s) Ingmar Schmidt

Title(s)

Principle Investigator(s)

Signature(s)

Name(s) Martin Schrappe

Title(s)

P6 IGR
INSTITUT GUSTAVE ROUSSY
Legal Representative

Signature(s)

Name(s) Alexander Eggermont

Title(s)

Principle Investigator(s)

Signature(s)

Name(s) Gilles Vassal

Title(s)

P7 UCSC

UNIVERSITA CATTOLICA DEL SACRO CUORE

Authorised Representative

Signature(s)

Name(s) Marco Elefanti

Title(s)

Principle Investigator(s)

Signature(s)

Name(s) Riccardo Riccardi

Title(s)

P8 UKE

UNIVERSITAETSKLINIKUM ESSEN

Legal Representative

Signature(s)

Name(s) Keil Reinhold

Title(s)

Principle Investigator(s)

Signature(s)

Name(s) Angelika Eggert

Title(s)

P9 UNIMIB

UNIVERSITA' DEGLI STUDI DI MILANO-BICOCCA

Legal Representative

Signature(s)

Name(s) Marcello Fontanesi

Title(s)

Principle Investigator(s)

Signature(s)

Name(s) Maria Grazia Valsecchi

Title(s)

P10 EMC

ERASMUS UNIVERSITAIR MEDISCH CENTRUM ROTTERDAM

Legal Representative

Signature(s)

Name(s) Huibert Adriaan Pieter Pols

Title(s)

Principle Investigator(s)

Signature(s)

Name(s) Christian Michel Zwaan

Title(s)

P11 LaFe

FUNDACION PARA LA INVESTIGACION DEL HOSPITAL UNIVERSITARIO LA FE DE LA COMUNIDAD VALENCIANA

Legal Representative

Signature(s)

Name(s) Jose Vicente Castell Ripoll

Title(s)

Principle Investigator(s)

Signature(s)

Name(s) Adela Cañete

Title(s)

P12 MUG

GDANSKI UNIWERSYTET MEDYCZNY

Legal Representative

Signature(s)

Name(s) Janusz Morys

Title(s)

Principle Investigator(s)

Signature(s)

Name(s) Piotr Czauderna

Title(s)

P13 UOB

THE UNIVERSITY OF BIRMINGHAM

Legal Representative

Signature(s)

Name(s) Erica Conway

Title(s) Deputy Director of Finance

Principle Investigator(s)

Signature(s)

Name(s) Pamela Kearns

Title(s)

P14 LTHTNHS

THE LEEDS TEACHING HOSPITALS NATIONAL HEALTH SERVICE TRUST

Legal Representative

Signature(s)

Name(s) Derek Norfolk

Title(s)

Principle Investigator(s)

Signature(s)

Name(s) Ian Lewis

Title(s)

Signature(s)

Name(s) Daniel Stark

Title(s)

P15 IGG

ISTITUTO GIANNINA GASLINI

Legal Representative

Signature(s)

Name(s) Vincenzo Lorenzelli

Title(s)

Principle Investigator(s)

Signature(s)

Name(s) Riccardo Haupt

Title(s)

P16 CURIE

INSTITUT CURIE

Legal Representative

Signature(s)

Name(s) Jean-Nicolas Munck

Title(s)

Principle Investigator(s)

Signature(s)

Name(s) François Doz

Title(s)

P17 FORTH

FOUNDATION FOR RESEARCH AND TECHNOLOGY HELLAS

Legal Representative

Signature(s)

Name(s) Vassilios Dougalis

Title(s)

Principle Investigator(s)

Signature(s)

Name(s) Manolis Tsiknakis

Title(s)

P18 AIT

AIT Austrian Institute of Technology GmbH

Legal Representative

Signature(s)

Name(s) Anton Plimon

Title(s)

Principle Investigator(s)

Signature(s)

Name(s) Günter Schreier

Title(s)

P19 CINECA

CONSORZIO INTERUNIVERSITARIO CINECA

Legal Representative

Signature(s)

Name(s) Emilio Ferrari

Title(s)

Principle Investigator(s)

Signature(s)

Name(s) Marisa De Rosa

Title(s)

P20 ESQH

ESQH VIENNA OFFICE - EUROPAISCHE GESELLSCHAFT FUR QUALITAT IM GESUNDHEITSWESEN - WIENER BURO VEREIN

Legal Representative

Signature(s)

Name(s) Roland Schlesinger

Title(s)

Principle Investigator(s)

Signature(s)

Name(s) Martina Gantschacher

Title(s)

P21 AMC

Academisch Medisch Centrum bij de Universiteit van Amsterdam

Legal Representative

Signature(s)

Name(s) Marcel M. Levi

Title(s)

Principle Investigator(s)

Signature(s)

Name(s) Rogier Versteeg

Title(s)

P23 CLB

CENTRE ANTICANCEREUX LEON BERARD

Legal Representative

Signature(s)

Name(s) Sylvie Negrier

Title(s)

Principle Investigator(s)

Signature(s)

Name(s) Christophe Bergeron

Title(s)

P24 IARC

CENTRE INTERNATIONAL DE RECHERCHE SUR LE CANCER

Legal Representative

Signature(s)

Name(s) Christopher P. Wild

Title(s)

Principle Investigator(s)

Signature(s)

Name(s) Eva Steliarova-Foucher

Title(s)

P26 LUMC

ACADEMISCH ZIEKENHUIS LEIDEN - LEIDS UNIVERSITAIR MEDISCH CENTRUM

Legal Representative

Signature(s)

Name(s) Egbert J. Vos

Title(s)

Principle Investigator(s)

Signature(s)

Name(s) Pancras C.W. Hogendoorn

Title(s)

P27 KI

KAROLINSKA INSTITUTET

Legal Representative

Signature(s)

Name(s) Miles Davies

Title(s)

Principle Investigator(s)

Signature(s)

Name(s) Per Kogner

Title(s)

P28 UGent

UNIVERSITEIT GENT

Legal Representative

Signature(s)

Name(s) Paul Van Cauwenberge

Title(s)

Principle Investigator(s)

Signature(s)

Name(s) Frank Speleman

Title(s)

P30 CHARITÉ

CHARITE - UNIVERSITAETSMEDIZIN BERLIN

Legal Representative

Signature(s)

Name(s) Gerrit Fleige

Title(s)

Principle Investigator(s)

Signature(s)

Name(s) Arend Stackelberg

Title(s)

P31 AP-HP

ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS

Legal Representative

Signature(s)

Name(s) Mireille Faugere

Title(s)

Principle Investigator(s)

Signature(s)

Name(s) André Baruchel

Title(s)

P32 OLGA

KLINIKUM STUTTGART

Legal Representative

Signature(s)

Name(s) Adalbert Erben

Title(s)

Principle Investigator(s)

Signature(s)

Name(s) Stefan Bielack

Title(s)

P34 ECCO

European CanCer Organisation

Legal Representative

Signature(s)

Name(s) Michel Ballieu

Title(s)

Principle Investigator(s)

Signature(s)

Name(s) Françoise Van Hemelryck

Title(s)

P35 ÖK

Osterreichische Kinder-Krebs-Hilfe verband der Osterreichischen kinder krebs hilfe organisationen

Legal Representative

Signature(s)

Name(s) Anita Kienesberger

Title(s)

Principle Investigator(s)

Signature(s)

Name(s) Anita Kienesberger

Title(s)

P36 UNIPD

UNIVERSITA DEGLI STUDI DI PADOVA

Legal Representative

Signature(s)

Name(s) Giuseppe Basso

Title(s)

Principle Investigator(s)

Signature(s)

Name(s) Giuseppe Basso

Title(s)

P37 WWU

WESTFAELISCHE WILHELMS-UNIVERSITAET MUENSTER

Legal Representative

Signature(s)

Name(s) Katharina Steinberg

Title(s)

Principle Investigator(s)

Signature(s)

Name(s) Heribert Juergens

Title(s)

P38 SOUTHAMPTON

UNIVERSITY OF SOUTHAMPTON

Legal Representative

Signature(s)

Name(s) Yan Qiao

Title(s)

Principle Investigator(s)

Signature(s)

Name(s) Colin Kennedy

Title(s)

Support notice for filling up [Attachment 1] Background and Intellectual Property included & [Attachment 2] Background and Intellectual Property excluded Research projects involve the sharing of knowledge.
In general, participants bring to the project their own knowledge (e.g. data, know-how and other assets that may or may not be protected by intellectual property (IP) rights), which may form part of the so-called background as long as it is necessary for another participant to carry out the project work or use its own foreground.

Therefore, the participants are reciprocally using information of other participants.
Under FP7, a user right (often a license) to use this information is called an access right.

[Attachment 1]: Background Information and Intellectual Property included

Please list here background that you explicitly wish to make available to the consortium:

Information and intellectual property rights (Patents, Licenses, copyrights, software) that was generated before the initiation of the project and generated aside from the Project that shall stay in the ownership of a Party but for which access rights (in form of licenses, sub-licenses, or if none of both apply, the agreement on not suing the receiving Parties) is needed to carry out the project and therefore shall be made available to the Consortium for the execution of the work plan.

Specifically, following Background is available to Access Rights:

a)
b)

Following Background is subject to Access Rights for the execution of the work plan only and is subject to further Access at the sole discretion of the owning Party.

a.

b.

...

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

1 CCRI

CCRI makes Access Rights to Background available
-that was generated by working groups directly involved in the project (Laboratory Units of Peter Ambros, Michael Dworzak, Heinrich Kovar, the Unit for Clinical Studies and Statistics S^2IRP, headed by Ruth Ladenstein and the Grant Management Unit headed by Karla Valdés Rodríguez),
-that are not subject to third party rights or for which CCRI needs permission to grant Access Rights.
and
-which are Needed for the execution of the work plan only.

4 UCL

UCL will make available for access rights the Background knowledge which is: a) Needed and relevant to the work packages in which UCL is involved in the “ENCCA” project and b) developed by Prof Kathy Pritchard Jones and c) which include IP of third parties.

The list of Background included. This Background specifically consists of the following:

Biological profiling data on Wilms tumours treated in the SIOP Wilms tumour 2001 trial and other UK Wilms tumour trials, which is subject to the signature of the access agreement with owning Parties.

All other Background is hereby explicitly excluded.

7 UCSC
ENCCA Work Package "Education and Training" is devoted to dissemination of paediatric oncology training syllabus throughout Europe and organization of courses in paediatric oncology. Prof. Riccardo Riccardi, leader of the ENCCA work package "Education and Training", has a well established experience in the organization and management of international training courses in paediatric oncology. He is: ☐ Member of the SIOPE (International Society of Paediatric Oncology – Europe) Education and Training Committee;
☐ Chairman dell'ITCC Trainingand Education Committee, sito web: www.ITCC-consortium.org; ☐ Faculty member of the ECCO-AACR-ASCO Workshop "Methods in Clinical Cancer Research", Flims (Switzerland), 21-27 June 2008, 20-26 June 2009, 19-25 June 2010; ☐ Cochairman of the ESO-SIOPE Masterclass in Pediatric Oncology, Orta San Giulio (Novara, Italy), 14-18 October 2006; Ascona (Switzerland), 7-13 November 2008, Castel Gandolfo (Rome, Italy) 12-18 June 2010; ☐ Chairman of the "ITCC Training Days", Orta San Giulio (Novara, Italy), 5-7 March 2008, Rome (Italy) 22-24 October 2009. ☐ Chairman of the AIEOP (Italian Association for Pediatric Haematology and Oncology) training course "Nuovi Farmaci in Oncologia Pediatrica, dalla ricerca ai trials clinici" ("New Drugs in Paediatric Oncology, from research to clinical trials"), Rome (Italy) 24-25 September 2010.

9 UNIMIB
UNIVERSITA' DEGLI STUDI DI MILANO-BICOCCA (UNIMIB)
Università degli Studi di Milano – Bicocca grants Access rights to all Background which has been accumulated in the field of the ENCCA Project and which has been developed by the specific research group directly involved in carrying out the Project. Access to certain Background and/or Material may be subject to special conditions (MTA, terms of use, etc.).

10 EMC
None
This represents the status at the time of signature of this Consortium Agreement

LaFe: 11 LaFe
Fundación para la Investigación del Hospital Universitario La Fe de la Comunidad Valenciana grants Access rights to all Background which has been accumulated in the field of the ENCCA Project and which has been created and developed by the specific research group from LaFe and Hospital La Fe directly involved in carrying out the Project, included:
a) Protocol and case report forms (CRFs) developing in coordination with the SIOPEN Committee.
Access to certain Background and/or Material may be subject to special conditions (MTA, terms of use, etc.).

MUG: 12 GDANSKI UNIWERSYTET MEDYCZNY

Information and intellectual property rights (Patents, Licenses, copyrights, software) that was generated before the initiation of the project that is not implicitly needed to carry out the project and that you will not make available to the consortium for the execution of the Consortium Plan:
- all Background generated by personnel, scientists or students at the MUG other than those directly involved in the ENCCA project;
- all Background generated by personnel, scientists or students at the MUG that are directly involved in the ENCCA project, which is outside the scope of the tasks to be performed by the MUG according to the Consortium Plan of the ENCCA Project;
- all the Background which the MUG due to existing or pending third party rights, is unable to grant access rights to.

UOB: 13 UOB
Any Background which is owned by the University and was created by the research group led by Dr. Andrew Peet which is directly related to the ENCCA project, except for any Background which is already subject to any third party agreement.

18 AIT
Access Rights to Background made available to the Parties:
a. Web-based Electronic Data Capture (EDC) system including registry, query management, image management, SAE reporting, source data verification, randomization, workflow support, statistics, etc.
b. Rapid prototyping environment for above mentioned EDC system

19 CINECA
Know how of the SISS Department of Cineca on customization of AMR/XMR technology for technologically enhanced data collection, data monitoring , data querying and analysis in the field of Health for specific purposes (e.g. the Project) to the extent that they are of relevance to the other parties' work within the project.

Any costs depending on legally required licensing from third parties will be taken care of by the interested Partner.

The description in the above paragraph represents the status at the time of signature of this Consortium Agreement.

21 AMC
The Academisch Medisch Centrum bij de Universiteit van Amsterdam, designed the bioinformatic platform R2 for swift exploration of tumor-, clinical- and experimental-data without need for expert bioinformatic support. R2 includes mRNA expression profiles of 20,000 tumor and normal tissues and facilitates multiple levels of analyses. Within tumor series, genes with expression levels correlating to a specific gene or parameter like stage, histology or molecular defect can be identified, as well as their prognostic values. Expression levels of specific genes and correlations between two genes can be scanned over all tumor series in the database of R2. Expression signatures obtained by gene or drug manipulation of cell lines can be mapped on tumor series for functional classification of individual tumor samples within a series. Furthermore, functional signatures can be combined to detect tumor-driving interactions.

The R2 platform is developed by the AMC and will continue to be further developed outside the scope of the ENCCA Project. The current version and future upgrades are developed outside the ENCCA Project and all rights remain at the AMC. The AMC does not grant any access rights to the participants outside the scope of the ENCCA Project. The R2 platforms or parts of it will be made available to partners of the ENCCA consortium by means of access to a web-based version of the platform. The funding of the AMC by the ENCCA consortium is solely intended to establish and maintain the interactions with the ENCCA partners to prepare, complete and normalize their data sets, to update them and to teach and instruct ENCCA partners in operating the R2 platform, validate research output generated by the R2 platform and provide general support in these matters to the ENCCA consortium. No Access Rights shall be granted to any improvements, results or updates generated solely by AMC outside the scope of the ENCCA Project.

27 KI
Not specified.

36 UNIPD
Access Rights to its Background which are Needed to carry out the tasks in the Project but restricted to the Background accumulated and developed in the research group directly involved in carrying out the Project (Department of Pediatrics, Prof. Giuseppe Basso).
This represents the status at the time of signature of this Consortium Agreement.

38 SOUTHAMPTON
Access Rights to Background made available to the Parties:

a. Information and Intellectual property owned by Southampton and needed for implementation of the Consortium Plan

[Attachment 2]: Background Information and Intellectual Property excluded

Information and intellectual property rights (Patents, Licenses, copyrights, software) that was generated before the initiation of the project that is not implicitly needed to carry out the project and that you will not make available to the consortium for the execution of the Consortium plan.

For the avoidance of doubt, Background excluded refers to excludes Pre-existing Know How accumulated by the specific research group, research department, or research institute directly involved in carrying out the Project and Information and IP generated aside from the Project.

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

1
CCRI
CCRI excludes Access Rights to Background generated by other than the working groups directly involved in the project (Laboratory Units of Peter Ambros, Michael Dworzak, Heinrich Kovar, the Unit for Clinical Studies and Statistics S^2IRP, headed by Ruth Ladenstein and the Grant Management Unit headed by Karla Valdés Rodríguez), to Background that is not needed for the execution of the project and to Background which is subject to third party rights or for which CCRI needs permission to grant Access Rights.

4 UCL
University College London hereby excludes from its obligation to grant Access Rights to Background including, but not limited to, the following: a) All Background developed by researchers working at UCL who are not participating in the ENCCA project and b) All Background developed by researchers working at UCL and participating in the ENCCA project where this Background falls outside the scope of the Work Tasks allocated to UCL under the project; and c) All Background developed by researchers working at UCL which is subject to third party rights or for which UCL needs to obtain permission to grant Access Rights.

5 CAU
CAU excludes all background deriving from other departments and working groups other than the Department of Paediatrics at the Faculty of Medicine of the Christian-Albrechts-Universität zu Kiel. Further on, CAU excludes all Know-how developed by scientists participating in the Project but which is outside the scope of the Project or which use/access could affect the right of third parties and all Know-how in patents and current patent applications with the named Research Group.

6 IGR
Institut Gustave Roussy
For the purpose of the Project, IGR hereby excludes the following Background from Use by the consortium:
Background that has been, and/or will be derived outside the Project which IGR due to third party rights is not able to grant access rights to.
Background that is covered under specific research agreements and confidentiality agreements and therefore subject to third party rights.

Background which IGR, due to existing or future third party rights, is unable to grant access rights to.

7 UCSC
The following background is excluded:
• All Background and data generated by employees, agents or representatives of UCSC from prior research activities that are held in confidence with other partners and outside of the ENCCA project;
• All Background and data generated by employees, agents or representatives at UCSC other than those directly involved in the ENCCA Project..

8 UKE
UKE excludes all background deriving from other departments and working groups other than the Department of Paediatrics at the Faculty of Medicine of the Universitätsklinikum Essen.
Further on, UKE excludes all Know-how developed by scientists participating in the Project but which is outside the scope of the Project or which use/access could affect the right of third parties and all Know-how in patents and current patent applications with the named Research Group.

9 UNIMIB
Università degli Studi di Milano - Bicocca hereby informs that the following information are excluded:
- all Background generated by personnel, scientists or students at the Università di Milano – Bicocca other than those directly involved in the ENCCA project;
- all Background generated by personnel, scientists or students at the Università di Milano – Bicocca that are directly involved in the ENCCA project, which is outside the scope of the tasks to be performed by the Università di Milano – Bicocca according to the Consortium Plan of the ENCCA Project;
- all the Background which the Università di Milano – Bicocca, due to existing or pending third party rights, is unable to grant access rights to.

10 EMC
Background excluded from Access Rights:

EMC hereby excludes from its obligation to grant Access Rights to Background all Background generated by EMC other than generated or controlled by the ENCCA research team of the Department of Paediatrics. This especially includes — but is not limited to — Background that has been and/or will be created and developed by personnel or students at EMC not directly involved in the Project, as well as Background that has been or will be derived/obtained outside the scope of Project, whether or not such Background may have been developed by the same members of ENCCA research team, and any other Background to which EMC is not able to grant Access Rights due to third party rights. This represents the status at the time of signature of this Consortium Agreement.

11 LaFe
Fundación para la Investigación del Hospital Universitario La Fe de la Comunidad Valenciana hereby excludes from its obligation to grant Access Rights to Background including, but not limited to, the following: a) All Background that had been created or developed by researchers working at

LaFe or Hospital La Fe who are not participating in the ENCCA project and b) All Background that had been created or developed by researchers working at LaFe or Hospital La Fe and participating in the ENCCA project where this Background falls outside the scope of the Work Tasks allocated to LaFe under the project; and c) All Background that had been created or developed by researchers working at LaFe or Hospital La Fe which is covered under specific research agreements and confidentiality agreements and therefore subject to third party rights or for which LaFe needs to obtain permission to grant Access Rights.

12 MUG
Information and intellectual property rights (Patents, Licenses, copyrights, software) that was generated before the initiation of the project that is not implicitly needed to carry out the project and that you will not make available to the consortium for the execution of the Consortium Plan.
Please clearly state which elements of background are excluded (for example a specific patent, an identified software, etc.) ideally in the form of a summarized information which enables the other participants to evaluate whether or not it might be necessary to the project.

13 UOB
The University of Birmingham specifically excludes all Background that is generated outside the direct supervision of Dr. Andrew Peet for this project.
The University of Birmingham specifically excludes all Background that is the subject of an existing third party agreement.
The University of Birmingham specifically excludes all Background that is generated under the direct supervision of Dr. Andrew Peet for this project which is not directly related to this project.
The University of Birmingham specifically excludes any background which is held by the University but owned by a third Party.
The University of Birmingham specifically excludes all know-how in patents and current patent applications.
The University of Birmingham specifically excludes any unpublished work that has been carried out which is not already in the public domain.

P16 CURIE
Curie excludes from its obligation to grant Access Rights to Background developed by research groups or research departments of its institution other than those directly involved in carrying out the Project.
Curie excludes specifically from its obligation to grant Access Rights to Background to which Curie, due to mandatory laws, third party interests or similar, is prohibited to grant Access Rights.

17 FORTH
FORTH excludes all background deriving from all institutes at FORTH and all other working groups at FORTH-ICS. Further on, FORTH excludes all Know-how developed by scientists participating in the Project irrespective whether it is or not outside the scope of the Project and/or which use/access could affect the proprietary and legitimate rights of third parties with respect to such proprietary background or Know-how, whether registered or not.

19 CINECA
1) Core AMR/XMR technology.

2) All background deriving from SISS or other other departments or working groups in Cineca developed in fields unrelated to the objectives of this Project or developed outside the scope of the Project or which use/access could affect the Intellectual Property rights belonging to third parties.

The description in the above paragraph represents the status at the time of signature of this Consortium Agreement.

21 ACADEMISCH MEDISCH CENTRUM BIJ DE UNIVERSITEIT VAN AMSTERDAM
AMC hereby excludes from its obligation to grant Access Rights to Background generated by AMC other than that generated by the members of the research group of Prof. Dr. R. Versteeg who are directly involved in carrying out the Project.

AMC also hereby excludes specifically from its obligation to grant Access Rights to Background to the following Background:

All data, samples, methodologies and know-how not generated through the direct participation in the Project or which AMC is not free to provide.

Databases and software not generated through the direct participation in the Project or which AMC is not free to provide.

All Background resulting from research carried out by the research group of Prof. Dr. R. Versteeg, which was funded in full or in part by external organisations.

AMC also hereby excludes from its obligation to grant Access Rights to Background all Background that has been and/or will be derived outside the Project which AMC due to third party rights are not able to grant Access Rights to or for which AMC needs to get permission to grant Access Rights.

23 CLB hereby informs that the following information are excluded:
Background generated by the personnel, scientists, physicians, other than those directly involved in the ENCCA project
Background that is covered under specific research agreements and confidentiality agreements and therefore subject to third party rights
All the background which the CLB , due to existing or pending third party rights, is unable to grant access rights to.

24 IARC
A) All Background, intellectual property rights and other data, information, material and know-how whether it may be protected under intellectual property laws or not and whether it is protected as a matter of such laws without prior application or registration or not, created or obtained by International Agency for Research on Cancer, its personnel or visitors other than by the members of the research team directly involved in the Project.

B) All Background, intellectual property rights and other data, information, material and know-how whether it may be protected under intellectual property laws or not and whether it is protected as a matter of such laws without prior application or registration or not, that has been or will be created or obtained outside the scope and field of this Consortium Agreement and any such information which is not expressly introduced into the Project.

C) All Background, intellectual property rights and other data, information, material and know-how whether it may be protected under intellectual property laws or not and whether it is protected as a matter of such laws without prior application or registration or not, to which International Agency for Research on Cancer is not able to grant access rights due to third party rights.

25 UGent
Background excluded from Access Rights:
a. All Background generated by personnel, scientists or students at UGent other than those directly involved in the ENCCA Project;
b. All Background generated by personnel, scientists or students at UGent that are directly involved in the ENCCA Project, which is unrelated to the Consortium Plan of the ENCCA Project;
c. All Background which UGent, due to existing or pending third party rights, is unable to grant access rights to.
patenten
d. NEUROBLASTOMA PROGNOSTIC MULTIGENE EXPRESSION SIGNATURE (PCT application number PCT/EP2009/066866; filing date 2009-12-10)
e. MICRORNAS CONTRIBUTING TO CHEMORESISTANCE IN CANCER (US provisional application; filing date 2010-06-17).
f. datasets: high throughput profiling data on primary NB samples: miR, mRNA, aCGH, lncRNA, T-UCR
g. software tools: RTPrimerDB, PrimerXL, arrayCGHbase, R scripts, miRNA bodymap

26 LMUC:
Academisch Ziekenhuis Leiden excludes from its obligation to grant Access Rights to Background:

1. all Background generated by Academisch Ziekenhuis Leiden other than the Background that was generated by the members of the research team of Prof.Dr. P.C.W. Hogendoorn within the Department of Pathology who are directly involved in carrying out the Project;

2. all Background that has been, and/or will be derived outside the scope of the technical field of the Project; and

3. all Background which Academisch Ziekenhuis Leiden, due to third party rights, is not able to grant Access Rights to.

27 KI: Karolinska Institutet hereby excludes from its obligation to grant Access Rights to Background all Background generated by Karolinska Institutet other than that generated by the members of the research group of Prof. Per Kogner , Department of Women's and Children's Health, who are directly involved in carrying out the Project.
Karolinska Institutet also hereby excludes from its obligation to grant Access Rights to Background all Background which is
- generated by individuals that are directly involved in the project, but which is unrelated to the work plan, aims and objectives of the project;
- in all know-how in patents and current patents applications;
- in any unpublished work the Party wants to publish before disclosure to the Consortium; and
- subject to specific research agreements and confidentiality agreements and therefore subject to third party rights;

- all other background which the Party, due to existing third party rights, is unable to grant access rights to.
For the avoidance of doubt, all materials, software, results, data and tests from other research groups of Karolinska Institutet are fully excluded and no Access Rights are granted.

36 UNIPD
Background excluded from Access Rights:
a. All Background generated by personnel, scientists or students at UNIPD other than those directly involved in the ENCCA Project;
b. All Background generated by personnel, scientists or students at The University of Padova that are directly involved in the ENCCA Project, which is unrelated to the Consortium Plan of the ENCCA Project;
c. All Background which The University of Padova, due to existing or pending third party rights, is unable to grant access rights to.

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

37 WWU
"All Background, pre-existing know-how or reagents deriving from research groups, departments and/or institutes of University of Münster other than the research group directed by Prof. Dr. Jürgens. Pre-existing know-how that has been created and developed by personnel and/or scientists and/or students of University of Münster who are not directly involved in the project agreed hereunder. Background, pre-existing know-how that had been created and developed by personnel and/or scientists and/or students of University of Münster who are directly involved in the project agreed hereunder, which however University of Münster will not be able to grant access rights to due to contractual obligations and/or third party rights."

38 SOUTHAMPTON
Information and intellectual property rights (Patents, Licenses, copyrights, software) that was generated before the initiation of the project that is not implicitly needed to carry out the project and that you will not make available to the consortium for the execution of the Consortium Plan.
Please clearly state which elements of background are excluded (for example a specific patent, an identified software, etc.) ideally in the form of a summarized information which enables the other participants to evaluate whether or not it might be necessary to the project.

Background excluded from Access Rights:
a. Health Tracker Ltd "assessment package" software. Not owned by Southampton, but provided to Southampton by Health Tracker Ltd for Southampton to generate an on-line oncology assessment package for assessing quality of life survival in survivors of childhood brain tumours across Europe. Results from use of the on-line package will be disclosed to the Consortium as per normal reporting procedures under the Grant Agreement.
The existing and modified software will remain vested with Health Tracker Ltd.

b. Information and Intellectual Property not needed for the implementation of the Consortium Plan

[Attachment 3]: Accession document

ACCESSION

of a new Party to

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

[OFFICIAL NAME OF THE NEW PARTY AS IDENTIFIED IN THE EC-GA]

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

[OFFICIAL NAME OF THE COORDINATOR AS IDENTIFIED IN THE EC-GA]

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 4]: Listed Affiliated Entities

Affiliated Entities of 4 UCL (University College London)

University College London UCL Business PLC, The Network Building, 97, Tottenham Court Road, London, W1T4TP Tel: + 44 (0)207 679 9000/ Fax: +44 (0) 207 679 9838/ Email: info@uclb.com / Web: http://www.uclb.com

Affiliated Entities of 6 IGR (Institut Gustave Roussy)

IGR&D SA is the Technology Transfer company affiliate of IGR, and IGR has assigned to IGR&D exclusive exploitation rights on its intellectual property rights. IGR&D is established in 39 rue Camille Desmoulins, 94805 Villejuif, France.

Affiliated Entities of 13 UOB (The University of Birmingham)

Alta Innovation Ltd
The University of Birmingham
Birmingham
B15 2SQ
UK

[Attachment 5]: Initial list of Members and other contact persons

Please insert coordinates for your organisation's contact persons

1	ST. ANNA KINDERKREBFORSCHUNG	CCRI	Austria
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Scientific	Family name: Ambros First name: Peter Email: peter.ambros@ccri.at Phone: +43 1 40470 4050 Fax: +43 1 40470 64050		
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4	UNIVERSITY COLLEGE LONDON	UCL	United Kingdom
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2nd LEAR	Family name: Burgess First name: Mark Email: m.burgess@ucl.ac.uk Phone: +44 20 7679 1768 Address: Torrington Place 1-19, WC1E 7HB London – United Kingdom		
First authorised representative	Family name: Browne First name: Michael Email: michael.browne@ucl.ac.uk Phone: + 44 20 310 83 120 Fax: +44 20 781 32 849 Address: Torrington Place 1-19, WC1E 7HB London – United Kingdom		
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Legal)	Email: g.borg-carbott@ucl.ac.uk Phone: +44 20 3108 3033 Fax: +44 20 78113 2849
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5	CHRISTIAN-ALBRECHTS-UNIVERSITAET ZU KIEL	CAU	Germany
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First authorised representative	Family name: Eisoldt First name: Frank Email: Kanzler@praesidium.uni-kiel.de Phone: +494318803003 Fax: +49 49 43 1880 7333		
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6	INSTITUT GUSTAVE ROUSSY	IGR	France
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7	UNIVERSITA CATTOLICA DEL SACRO CUORE	UCSC	Italy
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8	UNIVERSITAETSKLINIKUM ESSEN	UKE	Germany

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9	UNIVERSITA' DEGLI STUDI DI MILANO-BICOCCA	UNIMIB	Italy
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10	ERASMUS UNIVERSITAIR MEDISCH CENTRUM ROTTERDAM	EMC	Netherlands
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11	FUNDACION PARA LA INVESTIGACION DEL H. UNIVERSITARIO La Fe	LaFe	Spain
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12	GDANSKI UNIWERSYTET MEDYCZNY	MUG	Poland
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13	THE UNIVERSITY OF BIRMINGHAM	UOB	United Kingdom

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14	THE LEEDS TEACHING HOSPITALS NHS TRUST	LTHTNHS	United Kingdom
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	Leeds – United Kingdom
Contact person (Scientific)	Family name: Lewis (Prof) First name: Ian Email: ian.lewis@leedsth.nhs.uk Phone: + 44 113 392 8238 Fax:+44 113 392 6397 Address: Hyde Terrace 34, LS2 9LN Leeds – United Kingdom

15	ISTITUTO GIANNINA GASLINI	IGG	Italy
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First authorised representative	Family name: Lorenzelli (Prof) First name: Vincenzo Email: presidenza@ospedale-gaslini.ge.it Phone: +39 0 105 63 6332 Fax:		
Contact person (Administrative & Legal)	Family name: Marinari (Dr) First name: Maria Gabriella Email: gabriellamarinari@ospedalegaslini.ge.it Phone: +39 0 1056 36 461 Fax: + 39 0 1037 76 590		
Contact person (Scientific)	Family name: Haupt (Dr) First name: Riccardo Email: riccardohaupt@ospedale-gaslini.ge.it Phone: + 39 0 105 63 6301 Fax: +39 0 103 77 6590		

16	INSTITUT CURIE	CURIE	France
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First authorised representative	Family name: Munck (Prof) First name: Jean-Nicolas Email: jeannicolas.munck@curie.net Phone: +33 1 44 32 41 00 Fax: +33 1 44 32 41 19
Contact person (Administrative & Legal)	Family name: Thiery First name: Yves Email: yves.thiery@curie.net Phone: +33 1 44 32 41 10 Fax: +33 1 53 10 40 28
Contact person (Scientific)	Family name: Doz (Prof) First name: Francois Email: francois.doz@curie.net Phone: +33 1 44 32 45 57 Fax:+33 1 53 10 40 28

17	FOUNDATION FOR RESEARCH AND TECHNOLOGY HELLAS	FORTH	Greece
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First authorised representative	Family name: Dougalis (Prof) First name: Vassilios Email: dougalis@iacm.forth.gr Phone: +30 28 10 391 800 Fax: + 30 28 10 391 801 Address: PO Box 1385, 71110 Heraklion – Crete - Greece		
Contact person (Administrative & Legal)	Family name: Papatheodorou First name: Zinovia Email: papatheo@admin.forth.gr Phone: + 30 28 10 391 522 Fax: + 30 28 10 391 555 Address: PO Box 1385, 71110 Heraklion – Crete - Greece		
Contact person (Scientific)	Family name: Tsiknakis (Dr) First name: Manolis Email: tsiknaki@ics.forth.gr Phone: + 30 28 10 391 690 Fax: + 30 28 10 391 428		
18	AUSTRIAN INSTITUTE OF TECHNOLOGY GMBH	AIT	Austria

Address: Donau-City-Strasse 1, 1220 Wien - Austria	
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First authorised representative	Family name: Plimon First name: Anton Email: anton.plimon@ait.ac.at Phone: +43 505 50 40 01 Fax: +43 505 50 40 00 and Family name: Knoll First name: Wolfgang Email: wolfgang.knoll@ait.ac.at Phone: +43 505 50 4001 Fax: +43 505 50 4000
Contact person (Administrative & Legal)	Family name: Schröpfer First name: Felix Email: felix.schroepfer@ait.ac.at Phone: + 43 505 50 20 69 Fax: +43 505 50 20 97 Address: Forschungszentrum 2444 Seibersdorf - Austria
Contact person (Scientific)	Family name: Schreier (Dr) First name: Günter Email: guenter.schreier@ait.ac.at Phone: +43 316 58 65 70 Fax: +43 316 58 65 70 12 Address: Reininghausstrasse 13/1, 8020 Graz - Austria

19	CONSORZIO INTERUNIVERSITARIO CINECA	CINECA	Italy
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First authorised representative	Family name: Ferrari (Prof) First name: Emilio Email: e.ferrari@cineca.it Phone: +39 051 6171447 Fax: +39 051 613 2198
Contact person Administrative, Legal **&** Scientific	Family name: De Rosa (Dr) First name: Marisa Email: m.derosa@cineca.it Phone: + 39 051 617 1408 Fax: +39 051 613 2198

20	ESQH VIENNA OFFICE	ESQH	Austria
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First authorised representative	Family name: Schlesinger (Prof) First name: Roland Email: roland.schlesinger@esqh.at Phone: + 43 1 713 9090 32 Fax: + 43 1 713 9090 55		
Contact person Administrative, Legal **&** Scientific	Family name: Gantschacher (Prof) First name: Martina Email: martina.gantschacher@esqh.at Phone: +43 1 713 90 90 33 Fax: +43 1 713 90 90 55		

21	ACADEMISCH MEDISCH CENTRUM BIJ DE UNIVERSITEIT VAN AMSTERDAM	AMC	Netherlands
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First authorised representative	Family name: Levi (Prof) First name: Marcel M. Email: h.j.elstgeest@amc.uva.nl Phone: +31 20 566 6264 Fax: +31 20 691 5462
Contact person Administrative, Legal **&** Scientific	Family name: Versteeg (Prof) First name: Rogier Email: r.versteeg@amc.uva.nl Phone: +31 20 566 52 43 Fax: +31 20 691 54 62

23	CENTRE ANTICANCEREUX LEON BERARD	CLB	France
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First authorised representative	Family name: Negrier (Prof) First name: Sylvie Email: negrier@lyon.fnclcc.fr Phone: +33 4 78 78 29 91 Fax: +33 4 78 78 27 40		
Contact person (Administrative & Legal)	Family name: Vieira First name: Liliana Email: vieira@lyon.fnclcc.fr Phone: +33 4 69 16 66 32 Fax: +33 4 78 78 29 55		
Contact person (Scientific)	Family name: Bergeron (Dr) First name: Christophe Email: bergeron@lyon.fnclcc.fr Phone: + 33 4 78 78 26 06 Fax:+ 33 4 78 78 27 03		

24	CENTRE INTERNATIONAL DE RECHERCHE SUR LE CANCER	IARC	France
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	Fax: + 33 47 27 38 564
First authorised representative	Family name: Wild (Dr) First name: Christopher P. Email: director@iarc.fr Phone: +33 47 273 8485 Fax:
Contact person (Administrative & Legal)	Family name: Kelm (Dr) First name: Olaf Email: kelmo@iarc.fr Phone: + 33 47 273 8494 Fax: + 33 47 27 38 564
Contact person (Scientific)	Family name: Steliarova-Foucher (Dr) First name: Eva Email: steliarova@iarc.fr Phone: +33 47 27 38 466 Fax: + 33 47 27 38 022

26	ACADEMISCH ZIEKENHUIS LEIDEN- LEIDS UNIVERSITAIR MEDISCH CENTRUM	LUMC	Netherlands
Address: Albinusdreef 2, 2333 ZA Leiden - Netherlands			
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First authorised representative	Family name: Vos First name: Egbert J. Email: p.c.w.hogendoorn@lumc.nl Phone: +31 71 526 6639 Fax: +31 71 524 8158		
Contact person Administrative, Legal **&** Scientific	Family name: Hogendoorn (Prof) First name: Pancras C.W. Email: p.c.w.hogendoorn@lumc.nl Phone: +31 71 526 6639 Fax: +31 71 524 8158		

27	KAROLINSKA INSTITUTET	KI	Sweden
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First authorised representative	Family name: Davies (Dr) First name: Miles Email: miles.davies@ki.se Phone: +46 852486593 Fax:+46 8314303
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28	UNIVERSITEIT GENT	UGent	Belgium
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First authorised representative	Family name: Van Cauwenberge (Prof) First name: Paul Email: eu-cel@Ugent.be Phone: +32 9 264 3029 Fax: +32 9 264 3583		
Contact person (Administrative & Legal)	Family name: Vandepitte First name: Nathalie Email: eu-cel@Ugent.be Phone: +32 9 264 3029 Fax: +32 9 264 3583		
Contact person (Scientific)	Family name: Speleman (Prof) First name: Frank Email: franki.speleman@ugent.be Phone: +32 9 33 22 451 Fax: +32 9 33 22 477		

	Adress: De Pintelaan 185, 9000 Ghent - Belgium

30	CHARITE-UNIVERSITAETSMEDIZIN BERLIN	CHARITE	Germany
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First authorised representative	Family name: Fleige (Dr) First name: Gerrit Email: gerrit.fleige@charite.de Phone: +49 30 450 57 01 42 Fax: +49 30 450 57 09 14		
Contact person (Administrative & Legal)	Family name: Frässdorf First name: Eveline Email: eveline.fraessdorf@charite.de Phone: +49 30 450 57 60 24 Fax: +49 30 450 57 69 54		
Contact person (Scientific)	Family name: Stackelberg (Dr) First name: Arend Email: arend.stackelberg@charite.de Phone: +49 30 450 666833 Fax: +49 30 450 566901		

31	ASSISTANCE PUBLIQUE-HOPITEAUX DE PARIS	AP-HP	FRANCE
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First authorised representative	Family name: Faugere First name: Mireille Email: secretariat-direction.drcd@sls.aphp.fr Phone: +33 1 40 27 30 00 Fax: +33 1 40 27 39 70
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32	KLINIKUM STUTTGART	OLGA	Germany
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First authorised representative	Family name: Erben First name: Adalbert Email: a.erben@klinikum-stuttgart.de Phone: +49 711 278 620 10 Fax:		
Contact person (Administrative & Legal)	Family name: Doeringer First name: Christina Email: c.doeringer@klinikum-stuttgart.de Phone: +49 711 278 620 10 Fax: +49 711 278 603 83 Address: Kriegsbergstr 60, 70174 Stuttgart - Germany		
Contact person (Scientific)	Family name: Bielack (Prof) First name: Stefan Email: s.bielack@klinikum-stuttgart.de Phone: +49 711 278 724 60 Fax: +49 711 278 724 82 Address: Bismarckstr 8, 70176 Stuttgart - Germany		

34	EUROPEAN CANCER ORGANISATION	ECCO	Belgium
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LEAR	Family name: Van Hemelryck First name: Françoise Email: francoise.vanhemelryck@ecco-org.eu Phone: +32 2 775 29 38 Fax: +32 2 775 02 00		
First authorised representative	Family name: Ballieu First name: Michel Email: michel.ballieu@ecco-org.eu Phone: +32 2 775 02 09 Fax: +32 2 775 02 00		
Contact person (Administrative & Legal)	Family name: Van Hemelryck First name: Françoise Email: francoise.vanhemelryck@ecco-org.eu Phone: +32 2 775 29 38 Fax: +32 2 775 02 00		
Contact person (Scientific)	Family name: Wren First name: Amanda Email: Email: amanda.wren@ecco-org.eu Phone: +32 2 775 02 48 Fax: +32 2 775 02 00		

35	OSTERREICHISCHE KINDER-KREBS-HILFE VERBAND DER OSTERREICHISCHEN KINDER KREBS HILFE ORGANISATIONEN	ÖK	Austria
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First authorised representative	Family name: Kienesberger First name: Anita Email: oesterreichische@kinderkrebshilfe.at Phone: +43 1 40 288 99 Fax: +43 1 40 288 99 10		
Contact person Administrative, Legal **&** Scientific	Family name: Kienesberger First name: Anita Email: oesterreichische@kinderkrebshilfe.at Phone: +43 1 40 288 99		

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36	UNIVERSITA DEGLI STUDI DI PADOVA	UNIPD	Italy
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First authorised representative	Family name: Basso (Prof) First name: Giuseppe Email: giuseppe.basso@unipd.it Phone: +39 049 821 14 66 Fax: +39 049 821 14 66		
Contact person Administrative, Legal **&** Scientific	Family name: Basso (Prof) First name: Giuseppe Email: giuseppe.basso@unipd.it Phone: +39 049 821 14 66 Fax: +39 049 821 14 66		

37	WESTFAELISCHE WILHELMS-UNIVERSITAET MUENSTER	WWU	Germany
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First authorised representative	Family name: Steinberg (Dr) First name: Katharina Email: katharina.steinberg@uni-muenster.de Phone: +49 25 183 22 151 Fax: +49 25 183 21 501		
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38	UNIVERSITY OF SOUTHAMPTON	SOUTHAMPTON	United Kingdom
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First authorised representative	Family name: Qiao First name: Yan Email: yq2@soton.ac.uk Phone: +44 23 80 593 907 Fax: +44 23 80 592 195		
Contact person (Administrative & Legal)	Family name: Qiao First name: Yan Email: yq2@soton.ac.uk Phone: +44 23 80 593 907 Fax: +44 23 80 592 195		
Contact person (Scientific)	Family name: Kennedy (Prof) First name: Colin Email: crk1@soton.ac.uk Phone: +44 23 80794 457 Fax: + 44 23 80794 760		

Recipients for Notices
Recipients for Notices in Accordance with Section 11 of this Consortium Agreement.

[Attachment 6]: List of Third Parties

The WWU (Westfälische-Wilhems-Universität Münster) has as third party the UKM (Universitätsklinikum GmbH, Münster).

- (WWI) Westfälische-Wilhems-Universität Münster, Schlossplatz 2, 48149 Münster, Germany
- (UKM) Universitätsklinikum GmbH, Domagkstr. 5, 48149 Münster, Germany

The CAU (Christian-Albrechts-Universitaet zu Kiel) has as third party the UKSH (Universitätsklinikum Schleswig-Holstein)

- (CAU) Christian-Albrechts-Universitaet Kiel, Olshausenstrasse 40, 24118 Kiel, Germany
- (UKSH) Ratzeburger Allee 160, 23538 Lübeck, Germany

For more details see Annex I "Description of Work" Part B
B.2.3.5 Third parties on p94-95/148 (Version 10 Sep 2010)

4 UCL
University College London UCL Business PLC, The Network Building, 97, Tottenham Court Road, London, W1T4TP
Tel: + 44 (0)207 679 9000/ Fax: +44 (0) 207 679 9838/ Email: info@uclb.com / Web: http://www.uclb.com

IGR: Institute Gustave Roussy (IGR)
IGR&D SA is the Technology Transfer company affiliate of IGR, and IGR has assigned to IGR&D exclusive exploitation rights on its intellectual property rights. IGR&D is established in 39 rue Camille Desmoulins, 94805 Villejuif, France.

13 UOB

The University of Birmingham

Alta Innovation Ltd
The University of Birmingham
Birmingham
B15 2SQ
UK

[Attachment 7]: Material Transfer Agreement

MATERIAL TRANSFER AGREEMENT

This Material Transfer Agreement (this "Agreement") is entered into by and between _____, having an address ____ ("__"), and _____having an address at _____ ("___") as of _____ (the "Effective Date").

WHEREAS, the Parties have entered into a Consortium Agreement for a collaborative Project entitled Network of Cancer Research in Children and Adolescents (ENCCA); and

WHEREAS, _____ and its affiliates is owner of certain materials described in Exhibit A, and includes any constructs, formulations, strains, portions, derivatives, progeny or improvements obtained from or as a result of the use of the materials (the "Materials"); and

WHEREAS, RECIPIENT wishes to obtain a sample of the Materials for the purpose of as described in Exhibit B (the "Research"); and

WHEREAS, _____ is willing to provide a sample of the Materials as outlined in Exhibit A to RECIPIENT during the Term (as defined below) of this Agreement, in accordance with the terms and conditions contained herein.

NOW THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, and other good and valuable consideration, the receipt and sufficiency of which is hereby mutually acknowledged, the parties agree as follows:

1) Use of Materials.

RECIPIENT shall use the Materials solely for the Research and shall not attempt to reverse engineer or deconstruct. RECIPIENT shall not sell, transfer, disclose, or otherwise provide access to the Materials to any third party without the prior express written consent of _____PROVIDER _, except that RECIPIENT may allow access to the Materials by its Representatives for effecting the Purpose, provided that prior to such access, such individuals shall have been apprised of the proprietary and experimental nature of the Materials. RECIPIENT will take all reasonable steps to ensure that such Representatives use the Materials in a manner that is consistent with the terms of this Agreement, including obtaining appropriate written agreements having terms at least as restrictive as those contained in this Section 2 with all Representatives who have access to the Materials, and shall be responsible for any breach by its Representatives.

_____ PROVIDER shall provide RECIPIENT with all data and information reasonably necessary and known to _____ PROVIDER _ for RECIPIENT to safely handle, store and use the Materials. RECIPIENT understands that the Materials are not to be used for testing in or treatment of humans, and agrees not to use the Materials in such manner.

RECIPIENT acknowledges that the Materials are experimental in nature and may have unknown characteristics and therefore agrees to use prudence and all reasonable care in the use, handling, storage, transportation and disposition and containment of the Materials.

RECIPIENT shall (i) maintain the Materials under suitable containment conditions; (ii) use the Materials in accordance with good laboratory practice and the highest standards of skill and care.

IGR:

This Material Transfer Agreement (this "Agreement") is entered into by and between _____, having an address ____ ("__"), ("PROVIDER"), and _____having an address at _____ ("___") ("RECIPIENT") as of _____ (the "Effective Date").

WHEREAS, _____PROVIDER and its affiliates is owner of certain materials described in Exhibit A, and includes any constructs, formulations, strains, portions, derivatives, progeny or improvements obtained from or as a result of the use of the materials (the "Materials"); and

WHEREAS, RECIPIENT wishes to obtain a sample of the Materials for the purpose of as described in Exhibit B (the "Research") in the framework of Project ENCCA - European network for Cancer Research in Children and Adolescents; and

WHEREAS, _____ PROVIDER is willing to provide a sample of the Materials as outlined in Exhibit A to RECIPIENT during the Term (as defined below) of this Agreement, in accordance with the terms and conditions contained herein.

NOW THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, and other good and valuable consideration, the receipt and sufficiency of which is hereby mutually acknowledged, the parties agree as follows:

IGR: 1. Use of Materials.

RECIPIENT shall use the Materials solely for the Research and shall not attempt to reverse engineer or deconstruct. RECIPIENT shall not sell, transfer, disclose, or otherwise provide access to the Materials to any third party without the prior express written consent of _____, PROVIDER, except that RECIPIENT may allow access to the Materials by its Representatives for effecting the Purpose, provided that prior to such access, such individuals shall have been apprised of the proprietary and experimental nature of the Materials. RECIPIENT will take all reasonable steps to ensure that such Representatives use the Materials in a manner that is consistent with the terms of this Agreement, including obtaining appropriate written agreements having terms at least as restrictive as those contained in this Section 2 with all Representatives who have access to the Materials, and shall be responsible for any breach by its Representatives.

_____ PROVIDER shall provide RECIPIENT with all data and information reasonably necessary and known to _PROVIDER_____ for RECIPIENT to safely handle, store and use the Materials. RECIPIENT understands that the Materials are not to be used for testing in or treatment of humans, and agrees not to use the Materials in such manner.

RECIPIENT acknowledges that the Materials are experimental in nature and may have unknown characteristics and therefore agrees to use prudence and all reasonable care in the use, handling, storage, transportation and disposition and containment of the Materials.

RECIPIENT shall (i) maintain the Materials under suitable containment conditions; (ii) use the Materials in accordance with good laboratory practice and the highest standards of skill and care.

2) Payments.

The Materials are supplied to RECIPIENT under conditions which have to be decied between PROVIDER and RECIPIENT.

3) Reports and Supportive Data.

RECIPIENT shall provide _____ PROVIDER __ with a written report describing in detail all studies conducted in the Research using the Materials and all results thereof, including all raw data. _____ PROVIDER __ may use such reports and data therein for any purpose

Concurrently with the delivery of the written report, RECIPIENT shall provide to _____ PROVIDER ___ such of RECIPIENT's Confidential Information as is necessary or useful to interpret the results of the written report. _____ PROVIDER _ shall have the right to disclose such Confidential Information to (a) third parties in connection with business discussions regarding the Materials, under conditions of confidentiality at least as restrictive of those contained herein or (b) to regulatory agencies in connection with filings related to the Materials.

4) Intellectual Property.

a) Limited license granted. _____ PROVIDER __ hereby grants to RECIPIENT a nonexclusive, non-transferable license to use the Materials solely for the conduct of the Research. Only the license granted pursuant to the express terms of this Agreement shall be of any legal force or effect. No other license or other rights shall be granted or created by implication, estoppels or otherwise.
b) Ownership of Background Intellectual Property. For the avoidance of doubt, Background Information and Background Intellectual Property used in connection with the Research shall remain the property of the Party Controlling the same as of the Effective Date.
c) Materials. _____ PROVIDER ___ shall retain the right to use the Materials itself and/or to provide such Materials to third parties, as it deems appropriate.
d) RECIPIENT shall promptly inform the PROVIDER if he either intends to commercialize, to file a patent application claiming, or to assert any intellectual property rights in any research results obtained using the Materials. RECIPIENT and PROVIDER agree to negotiate in good faith their respective ownership of the research results and any intellectual property rights therein based on their relative contributions to such rights.
e) In this case, the rules of joint ownership of the Consortium Agreement are applicable.
f) Patent Filings. RECIPIENT shall not (a) file any patent applications relating in any way to (i) any Materials, formulations, modifications, alterations, or uses thereof, or (ii) the results of the studies conducted by RECIPIENT with the Materials, or (b) use any data or information regarding the foregoing to support any patent application, in each case, without the prior written consent of _____PROVIDER__, which _____PROVIDER____ may withhold in its sole discretion.

IGR: 4) Intellectual Property.

5) Confidential Information

The same regulations shall apply as defined in section 10 of the Consortium Agrement.

6) Publication

RECIPIENT may publish the results of scientific investigations involving Research, provided that _____ Confidential Information is not disclosed and that _____ is provided a copy of the manuscript thirty days (30) prior to submission for publication for its review and approval which shall not unreasonably withheld. In the event that _____ determines that patent protection should be obtained for information contained in a proposed publication, the submission of the proposed publication shall be withheld at _____'s request until appropriate patent applications can be filed. It us understood that delays shall not exceed a total of ninety days from the time of a copy of the prospective publication has been provided to Provider

RECIPIENT will inform PROVIDER, in confidence, of research results related to the Material by personal written communication. In accordance with scientific custom, the contribution of the PROVIDER will be expressly noted in all written or oral public disclosures, by acknowledgement or co-authorship, as appropriate. Subject to respect of the provisions of the Grant Agreement and the Consortium Agreement, the PROVIDER shall be free to use published data and information for any purpose. The RECIPIENT may publish or present results from its Use of Material, in accordance with Section 8.3 "Dissemination" of the Consortium Agreement.

7) Limited Warranties.

THE MATERIALS ARE EXPERIMENTAL IN NATURE AND PROVIDED "AS IS" WITHOUT WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER WARRANTY, EXPRESS OR IMPLIED. _____PROVIDER___ makes no representation and gives no warranty or undertaking, in relation to the Materials.

Each Party represents and warrants to the other that (i) it is permitted to enter into this Agreement and perform the obligations contemplated hereby, (ii) it is the owner of the Confidential Information and/or Materials it makes available to the other Party or is free to disclose it to the other Party without breaching or violating any other obligation and (iii) the terms and obligations of this Agreement are not inconsistent with any other obligation which it may have.

8) Term/Termination.

ECM:
This Agreement will have a term of 12 months for the Effective date, with an option for a further extension upon agreement by both Parties. _PROVIDER_____ may terminate this Agreement for any reason upon thirty days prior written notice to the other Party.

The Materials shall remain the property of _____PROVIDER__ and shall be immediately returned or safely destroyed upon the earlier of (i) the end of the Term, (ii) termination of this Agreement, (iii) the event that RECIPIENT is in breach of any of the conditions of this Agreement, or (iv) at any other time on _____PROVIDER___'s request. If destroyed, RECIPIENT shall provide _____PROVIDER ____ with written certification of such destruction within 30 days of termination.

9) Independent Contractors.

Nothing in this Agreement shall be construed as creating an association, partnership, or joint venture between the Parties, it being understood and agreed that the Parties are independent contractors and that neither shall have the authority to bind the other in any way.

10) Liability and Indemnification.

_____PROVIDER__ shall have no liability to RECIPIENT, whether in contract, tort or otherwise, in relation to the supply of the Materials to RECIPIENT or their use or keeping by RECIPIENT or by any other person, or the consequences of their use, to the maximum extent permitted under applicable law.

RECIPIENT shall indemnify and hold harmless _____PROVIDER__, and its Affiliates and their respective Representatives from and against any and all, losses, claims, damages, liabilities, obligations, penalties, judgments, awards, costs, expenses, and disbursements, including, without limitation, the costs, expenses and disbursements, as and when incurred, of investigating, preparing, or defending any action, suit, proceeding, or investigation asserted by a Third Party (including, without limitation, reasonable attorneys fees and expenses), caused by, relating to, based upon, arising out of, or in connection with RECIPIENT's use or keeping of the Materials.

11) Headings/Counterparts

The section headings contained in this Agreement are inserted for convenience only and shall not affect in any way the meaning or interpretation of this Agreement. The parties may execute this Agreement in counterparts, each of which is deemed an original and all of which constitute only one agreement.

12) Severability

Any term or provision of this Agreement that is invalid or unenforceable in any situation in any jurisdiction shall not affect the validity or enforceability of the remaining terms and provisions hereof or the validity or enforceability of the offending term or provision in any other situation or in any other jurisdiction.

In the event this Material Transfer Agreement is in conflict with any provisions of the ENCCA Consortium Agreement ,the later shall prevail.

13) Amendment

The parties may not amend this Agreement except by written agreement duly signed by parties expressly amending this Agreement

14) Assignment And Delegation

RECIPIENT shall not assign this Agreement or any rights or obligations hereunder without _____'s prior written consent, which may be withheld in its sole discretion. _____ may assign this Agreement to affiliates and third parties to whom _____ transfers substantially all of the products, business or services to which this Agreement relates. All other assignments of rights are prohibited under this subsection, whether they are voluntary or involuntary, by merger, consolidation, dissolution, operation of law or any other manner.

IN WITNESS WHEREOF, authorized representatives of the parties have executed this Agreement.

RECIPIENT

By:	By:
Title:	Title:
Date:	Date:

By:	By:
Title:	Title:
Date:	Date:

EXHIBIT A
MATERIALS provided by _____-

EXHIBIT B
RESEARCH PLAN

Screening of 20 _____anti-MIF antibodies against Normal Tissue Panels using ____ tissue microarray technology according to quotation
Nr. _____

[Attachment 8]: Overview on Eligible Costs according to EC Financial Guidelines

For the avoidance of doubt, Parties are solely responsible for justifying their costs towards the European Commission. The exhaustive detailed description on eligible costs arises therefore solely from the EC Financial Guidelines, which can be found at the following weblinks:

http://cordis.europa.eu/fp7/how_en.html

ftp://ftp.cordis.europa.eu/pub/fp7/docs/financialguide_en.pdf

To be considered eligible costs must be:

actual (Article II.14.1.a) of ECGA. *Costs must be actually incurred (actual costs). That means that they must be real and not estimated, budgeted or imputed.*

incurred by the beneficiary (Article II.14.1.b) of the ECGA). *Supporting documents proving occurrence, the bookkeeping and the payment of the costs by the beneficiaries must be kept for all costs and for up to five years after the end of the project.*

incurred during the duration of the project, with the exception of costs relating to final reports and certificates on the financial statements (Article II.14.1.c) of the ECGA), e.g.: Salaries of staff for the last month of the project which are paid following the end of the project. For beneficiaries working on cash-based accounting, the date when the costs are incurred is the date when the payment is executed. NB: Costs related to the drafting of the Consortium Agreement are not eligible insofar the Consortium Agreement is deemed to have been concluded by the time of the signature of the GA, in other words, it must be finalised before (Article 1 of the ECGA). Costs related to updating the Consortium Agreement, however, are eligible.

Determined according to the usual accounting and management principles and practices of the beneficiary identifiable and verifiable (Article II.14.1.d) of the ECGA)

used for the sole purpose of achieving the objectives of the project and its expected results, in a manner consistent with the principles of economy, efficiency and effectiveness (Article II.14.1.e) of ECGA)

recorded in the accounts of the beneficiary and, in the case of any contribution from third parties, recorded in the accounts of the third parties (Article II.14.1.f) of the ECGA)

have been indicated in the estimated overall budget annexed to the ECGA – Annex I (Article II.14.1.g) of the ECGA)

Non-Eligible costs:

identifiable indirect taxes including value added tax
duties : mean the amount assessed on an imported or (less often) exported item, nearly equivalent to taxes, embracing all taxation or charges levied on persons or things [or the tax imposed on the importation, exportation, or consumption of goods],
interest owed,
provisions for possible future losses or charges,
exchange losses, cost related to return on capital, *e.g.: Cost related to return on capital e.g. if there are dividends paid as remuneration for the work in the project.*
costs declared or incurred, or reimbursed in respect of another EU/Euratom project, (avoiding double funding)
debt and debt service charges, excessive or reckless expenditure: Excessive must be understood as paying significantly more for products, services or personnel than the prevailing market rates, resulting in an avoidable financial loss to the project. Reckless means failing to exercise care in the selection of products, services or personnel resulting in an avoidable financial loss to the project'

[Attachment 9]: Grant Agreement

Attached as a seperate4 document

P17 FORTH

FOUNDATION FOR RESEARCH AND TECHNOLOGY HELLAS

Legal Representative

Signature(s)

Name(s) Vassilios Dougalis

Title(s) VASSILIOS DOUGALIS
Chairman of the Board of Directors of FORTH &
Acting-Director of the Central Administration of FORTH

Principle Investigator(s)

Signature(s)

Name(s) Manolis Tsiknakis

Title(s) Principal Researcher