



CONSORTIUM AGREEMENT

Related to the Project

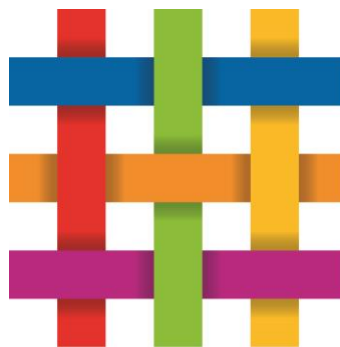
ONCOBIOME

« Gut OncoMicrobiome Signatures (GOMS) associated with cancer incidence, prognosis and prediction of treatment response »

Call Identifier H2020-SC1-BHC-2018-2020

Grant Agreement ref-[825410]

Based on



DESCA

Horizon 2020 Model
Consortium Agreement
www.DESCA-2020.eu

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BETWEEN:

INSTITUT GUSTAVE ROUSSY, a French Comprehensive Cancer Center, located at 39 rue Camille Desmoulins, 94805 Villejuif Cedex, France, represented by its General Director [REDACTED], duly authorized

- Hereinafter “**Gustave Roussy**” or the “**Coordinator**” -

INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE, located at 101, rue de Tolbiac –75013 Paris, represented by its Chairman and Chief Executive Officer, who has delegated signing authority for this Agreement to the Regional Delegate Paris 6, [REDACTED]

- Hereinafter “**Inserm**” -

UNIVERSITA DEGLI STUDI DI TRENTO located at VIA CALEPINA 14, 38122 Trento (ITALY), represented by [REDACTED] acting in his capacity of Rector and duly authorized for the purposes hereof

- Hereinafter “**UNITN**” -

FONDAZIONE IRCCS ISTITUTO NAZIONALE DEI TUMORI, located at Via Giacomo Venezian 1, 20133 Milano, Italy represented by [REDACTED], Presidente

- Hereinafter “**INT**” -

MASARYKOVA UNIVERZITA, located at Žerotínovo nám. 617/9, 601 77 Brno, Czech Republic, represented by its Rector, Assoc. Prof. Mikuláš Bek, Ph.D.

- Hereinafter “**MU**” -

UNIVERSITATSKLINIKUM ERLANGEN, Maximiliansplatz 2, 91054 Erlangen, represented by its Head of Office of EU grants and contracts, [REDACTED]

- Hereinafter “**UKER**” -

STICHTING KATHOLIEKE UNIVERSITEIT DOING BUSINESS AS RADBODU UNIVERSITY MEDICAL CENTER, having its offices at Geert Grooteplein 10 P.O Box 9101, 6500HB in Nijmegen, the Netherlands registered with the company register of the chamber of Commerce and Industries for Centraal Gelderland, Arnhem the Netherlands as number 41055629/4 hereinafter referred to as “**RUMC**”.

- Hereinafter “**RUMC**” -

ITALIAN INSTITUTE FOR GENOMIC MEDICINE FOUNDATION private Foundation located at Via Nizza 52, 10126 Torino, Italy, represented by its President [REDACTED].

- Hereinafter “**IIGM**” -

THE CHANCELLOR MASTERS AND SCHOLARS OF THE UNIVERSITY OF CAMBRIDGE, a higher education institution whose physical place of business is The Old Schools, Trinity Lane, Cambridge, CB2 1TN, England

- Hereinafter “**UCAM**” -

KAROLINSKA INSTITUTET, Department of Microbiology, Tumor and Cell Biology S-17177 Stockholm, Sweden.

- Hereinafter “**KI**” -

CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL, a constituted corporation under *An Act Respecting Health Services and Social Services*, C.Q.R.L., chapter S-4.2, a law of Quebec, Canada, having its head office at 850 St-Denis St, Pavilion S, Montréal, Quebec, H2X 0A9, Canada.

- Hereinafter “ **CHUM** ” -

UNICANCER, located at rue de Tolbiac 101, Paris 75013, France represented by its Managing Director, [REDACTED] and, by delegation, by its General Director, [REDACTED]

- Hereinafter “ **UNICANCER** ” -

CHARITE - UNIVERSITAETSMEDIZIN BERLIN, Charitépl. 1, 10117 Berlin, represented by its Dean, [REDACTED]

- Hereinafter “ **CHARITE** ” -

GBG FORSCHUNGS GMBH, Martin-Behaim-Straße 12, 63263 Neu-Isenburg represented by its CEO, [REDACTED]

- Hereinafter “ **GBG** ” -

HALIODX, company registered in Marseille RCS under the number B 805 269 271, located at Luminy Biotech Entreprises, 163 avenue de Luminy, 13009 Marseille, France, represented by its President [REDACTED],

- Hereinafter “ **HalioDx** ” -

EVERIMMUNE, company registered in Creteil RCS under the number 820 536 803, located at 39 rue Camille Desmoulins, 94800 Villejuif, FRANCE represented by its CEO [REDACTED]

- Hereinafter “ **Everimmune** ” -

ALGOE, company registered in Lyon RCS under the number B 352 885 925, located at 9 bis route de Champagne, CS 60208, 69 134 Ecully Cedex, France, represented by its CEO, [REDACTED],

- Hereinafter “ **Algoe** ” -

- hereinafter, jointly or individually, referred to as “**Parties**” or “**Party**” -

relating to the Action entitled

“Gut OncoMicrobiome Signatures (GOMS) associated with cancer incidence, prognosis and prediction of treatment response”

in short

ONCOBIOME

hereinafter referred to as “Project”

WHEREAS:

The Parties, having considerable experience in the field concerned, have submitted a proposal for the Project to the Funding Authority as part of the Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020).

The objectives of this Project are to achieve the validation of microbiota signatures associated with either low risk of developing cancer, good prognosis at diagnosis and/or responses to therapy (without severe adverse effects) or

high risk of developing cancer, bad prognosis at diagnosis, and/or resistance to therapy, in order to predict, prevent and better cure cancer through the development of personalized diagnosis tests, and *ad hoc* therapies.

The Funding Authority has announced its intention to make the Grant in respect of the Project, subject to the terms of the Grant Agreement, and subject to the Parties entering into an agreement governing their collaboration (the “Consortium Agreement”).

The Parties are aware that this Consortium Agreement is based upon the DESCAs model consortium agreement.

NOW, THEREFORE, IT IS HEREBY AGREED AS FOLLOWS:

1 Section: Definitions

1.1 Definitions

Words beginning with a capital letter appearing in this Consortium Agreement shall have the meaning defined either herein or in the Rules for Participation or in the Grant Agreement including its Annexes.

1.2 Additional Definitions

“Access Right”: means rights to use Results or Background under the terms and conditions laid down in this Consortium Agreement;

“Affiliated Entity”:

(1) means any legal entity that is under the direct or indirect control of a Party, or under the same direct or indirect control as the Party, or that is directly or indirectly controlling a Party. Control may take either of the following forms:

- a) the direct or indirect holding of more than 50 % of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
- b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.

The following relationships between legal entities shall not in themselves be deemed to constitute controlling relationships:

- (i) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50 % of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
- (ii) the legal entities concerned are owned or supervised by the same public body;

(2) Cancer centers members of UNICANCER as listed in Attachment D.

“Background” means any information or technical, medical and / or scientific knowledge, patented or not, patentable or not, including any know-how, invention, trade secret or business secret, software (in its source code version and object code version), method, tool, process, specific component, material, folder, plan, diagram, drawing, image, formula, other data, including Data, or database and / or any other type of information, in any form whatsoever, and all rights thereto, developed or acquired by one or more Parties (or any of their subcontractors), that cumulatively:

- a. are held by the Parties prior to the Effective Date of this Consortium Agreement or added to the Background after the Effective Date of this Consortium Agreement according to section 9.1.2,
- b. are needed to implement the Project or to exploit the Results of the Action, and
- c. are identified by the Parties in accordance with Article 9 in Attachment C of the Consortium Agreement;

“Call” means the Call within which the Funding Authority has announced its intention to fund the Action (H2020-SC1-BHC-2018-2020 focused on “Better Health and care, economic growth and sustainable health systems”, Topic: SC1-BHC-03-2018 called “Exploiting research outcomes and application potential of the human

microbiome for personalized prediction, prevention and treatment of disease” Type of action: Research and Innovation Action

“Clinical Trial” means the research involving human person carried out as part of the Project and listed in the Consortium Plan carried out according to the European legislation on clinical studies and applicable national laws and regulations (including but not limited to national legislation implementing the Parliament’s Directive 2001/20/EC on good clinical practice and Regulation 536/2014/EU on clinical trials on medicinal products for human use) under the responsibility of the Sponsor

“Commercial Exploitation”: means the development, sale, license, lease, export, transfer or other distribution to a person or entity not party to this Consortium Agreement for financial gain or other commercial purposes and/or the use of Results, Background or any other information: (a) to provide a service to a person or entity not party to this Agreement for financial gain; (b) to develop, produce or manufacture products for general sale or products for use in the manufacture of products ultimately intended for general sale; (c) in connection with proficiency testing service(s), including but not limited to, providing the service of determining laboratory performance by means of comparing and evaluating calibrations or tests on the same or similar items or materials in accordance with predetermined conditions; or (d) to file any documentation to any regulatory authority for any application (e.g. clinical trial, marketing authorization etc.).

“Consortium Agreement”: means this agreement and all of its appendices, together with amendments validly agreed in writing amongst the Parties;

“Consortium Body”: means any management body described in the Governance section (Article 6) of this Consortium Agreement;

“Consortium Plan”: means the Description of the action and the related agreed budget as first defined in the Grant Agreement and which may be updated by the Board of Directors (Attachment A);

“Data”: means the patient-related information and any type of data disclosed by a Party for the realization of the Project;

“Data Protection Law and Regulations”: means all applicable privacy and data protection laws including the General Data Protection Regulation ((EU) 2016/679) (“**GDPR**”) and any applicable national implementing laws and regulations relating to the processing of Data;

“Data Subject”: means the person (irrespective of the state of health) to whom Data refers and who has been informed of the purpose for which the Data is held and has given his/her informed consent thereto;

“Database”: means the structure organizing and storing the Data and metadata directly or indirectly linked to metagenomics including the database management software, data processing algorithms and the data model. The Database does not include Data;

“Defaulting Party”: means a Party which the Board of Directors has identified to be in breach of this Consortium Agreement and/or the Grant Agreement as specified in Section 4.2 of this Consortium Agreement;

“Effective Date”: means December 1st 2018;

“Fair and reasonable condition”: means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the Results or Background to which access is requested and/or the scope, duration or other characteristics of the Research Use envisaged and/or the scope, duration or other characteristics of the exploitation envisaged.

“Funding Authority”: means the body awarding the grant for the Project;

“Grant Agreement”: means the grant agreement signed between the Parties and the Funding Authority establishing basic conditions for the Project financing and start date;

“Linked Third Parties”: means any legal entity which has a legal link to a Party implying collaboration that is not limited to the Action as listed in Article 14.1 of Grant Agreement;

“Materials”: means all types of tangible chemical, biological and/or physical materials, including biological samples (particularly patient samples) and products, transferred by a Party to another Party in the performance of the Project.

“Needed”: means:

For the implementation of the Project:

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

For Exploitation of own Results:

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

“Patent Manager” means the Party or its technology transfer entity that is entitled to manage all actions relating to the preparation, filing, extension, delivery and maintenance of the Intellectual Property rights (including but not limited to patent and patent applications, copyrights, drawings and models, trademarks...) related to Results in the name and on behalf of all the Parties.

“Research Use”: means the use of Results (or Background necessary to use Results according the Access Rights), for all purposes other than for completing Commercial Exploitation, and which includes but is not limited to the application of Results as a tool for research and teaching.

“Results” means any information or technical, medical and / or scientific knowledge, patented or not, patentable or not, including any know-how, invention, trade secret or business secret, software (in its source code version and object code version), method, tool, process, specific component, material, folder, plan, diagram, drawing, image, formula, other data or database and / or any other type of information, in any form whatsoever, and all rights thereto, developed or acquired by one or more Parties (or any of their subcontractors) and resulting from the Project.

“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.

“Sponsor”: an individual, company, institution or organization which takes responsibility for the initiation, management and/or financing of a clinical trial

“Workpackage(s)”: means all work assigned to one or more Parties. The Project is divided in several Work Packages which are listed in Attachment A;

2 Section: Purpose

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

3 Section: Entry into force, duration and termination

3.1 Entry into force

This Consortium Agreement will enter into force from the Effective Date identified under Section 1 of this Consortium Agreement.

A new entity becomes a Party to the Consortium Agreement after having been accepted within the Project by an unanimous Board of Directors' decision according to Section 6.2.3.4, such approval being formalized upon signature of (i) the accession form (Attachment B) by said new entity and the Coordinator and (ii) an amendment to the Grant Agreement. Such accession shall have effect from the date identified in the accession form.

3.2 Duration and termination

This Consortium Agreement shall continue in full force and effect until complete fulfillment of all obligations undertaken by the Parties under this Consortium Agreement. The Project duration is five (5) years.

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.

This Consortium Agreement may also be extended in compliance with the executed Grant Agreement.

If

- the Grant Agreement is not signed by the Funding Authority or a Party, or
- the Grant Agreement is terminated, or
- a Party's participation is stopped by this Party's decision or by a Board of Directors' decision in accordance with the Section 6.3.2.3, this Consortium Agreement shall automatically terminate in respect of the affected Party/ies, subject to the provisions surviving the expiration or termination under Section 9.7.2. of this Consortium Agreement. In either case, the remaining Parties may elect either to assume themselves the work of the withdrawing Party or to entrust a third party with all or part of the work to be carried-out. The consent of the Funding Authority funding the Project has to be obtained according to Article 50.2 of the Grant Agreement.

3.3 Survival of rights and obligations

The provisions relating to Access Rights, (including Access Rights for exploitation), Intellectual Property, Dissemination, Data Protection and Confidential Information, for the time period mentioned therein, as well as for liability, applicable law and settlement of disputes shall survive the expiration or termination of this Consortium Agreement.

Termination shall not affect any rights or obligations of a Party leaving the Consortium incurred prior to the date of termination, unless otherwise agreed between the Board of Directors and the leaving Party or stipulated in this Consortium Agreement. This includes the obligation to provide all input, deliverables and documents for the period of the leaving Party's participation in the Project.

4 Section: Responsibilities of Parties

4.1 General principles

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

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

Each Party shall promptly provide all information reasonably required by a Consortium Body or by the Coordinator/Project Coordinator to carry out its tasks.

Each Party shall take reasonable measures to ensure the accuracy of any information or materials it supplies to the other Parties. Each Party shall be responsible to obtain permits, authorizations or declarations required to achieve any work. Each Party shall carry out and document its part of the Project scientifically diligently.

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 are 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. Where any part of the Project takes place in a hospital, the Party involved shall first obtain, if applicable, all necessary approvals, indemnities and agreements from that hospital.

4.2 Breach

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

If such breach is substantial and is not remedied within that period or is not capable of remedy, the Board of Directors 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.

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 or Third Parties linked to a Party identified under Section 14 of the Grant Agreement) in the Project remains responsible for carrying out its relevant part of the Project and for such third party's compliance with the provisions of this Consortium Agreement. Said Party has to ensure that the involvement of third parties does not affect the rights and obligations of the other Parties under this Consortium Agreement and that such third party is bound by obligations not less strict than the obligations under this Consortium Agreement, including but not limited to the Intellectual Property, confidentiality obligations and Data protection ruled under Articles 8, 10 and 12, and notably underlined under Article 12.1.16 of this Consortium Agreement stipulates that no Data provided by another Party may be processed by subcontractors before the latter have been authorized by Data Provider.

5 Section: Liability towards each other

5.1 No warranties

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

Therefore,

- the recipient Party shall in all cases be entirely and solely liable for the use to which it puts such information (including Confidential Information), Data or materials (including Materials, Results and Background), and

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

Regarding any such information (including Confidential Information), Data or materials (including Materials, Results and Background), each Party undertakes to comply with all applicable European and national laws concerning its use of this type of information, material.

5.2 Limitations of contractual liability

No Party shall be responsible to any other Party for any indirect or consequential loss or similar damage such as, but not limited to, loss of profit, loss of revenue or loss of contracts, provided such damage was not caused by a willful act or gross negligence.

For any remaining contractual liability, a Party's aggregate liability towards the other Parties collectively shall be limited to the funding received by that Party from the Funding Authority or if no funding is provided by the Funding Authority, the Party's liability is limited to the said Party's share of the total costs of the Project provided that such damage was not caused by a willful act or gross negligence.

The terms of this Consortium Agreement shall not be construed to amend or limit any Party's statutory liability including the responsibility of sponsors of clinical trials.

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 Results 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.

'Force majeure' means pursuant to the Grant Agreement, any situation or event that cumulatively:

- prevents a Party from fulfilling its obligations under this Consortium Agreement,
- was unforeseeable, exceptional situation and beyond the concerned Party's control,
- was not due to error or negligence on its part (or on the part of third parties involved in the Project), and
- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as Force Majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,
- labour disputes or strikes, or
- financial difficulties.

Each Party will notify the competent Consortium Body of any Force Majeure without undue delay, stating the nature, likely duration and foreseeable effects. The Board of Directors must immediately take all the necessary steps to limit any damage due to Force Majeure, if the consequences of Force Majeure for the Project are not overcome within four (4) weeks after such notification, the transfer of tasks - if any - shall be decided by the competent Consortium Body.

6 Section: Governance structure

6.1 General structure

The organizational structure of the Consortium shall comprise the following Consortium Bodies, defined in detail in Attachment G:

- Coordinator
- General Assembly (GA) as information body, composed by representatives from Beneficiaries, Linked Third Parties and external Stakeholders;

- Board of Director as the ultimate decision-making body of the Consortium, composed by Beneficiaries’ decision-makers;
- Steering Committee as Supervisory body for the execution of the Action, composed by WP Leaders, scientific representatives for each Beneficiary;
- Valorization Committee for valorization of the results and communication policy, composed by IP specialists from each Beneficiary, Technical and Administrative Managers;
- Work Package Committee, technical committee, composed by WP Leaders and technical Staff;
- Scientific Advisory Board, consultative body, composed by External Experts;
- Clinical and Ethical Committee, clinical and ethical control body, composed by External Experts;

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;
- 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 organization of meetings

6.2.2.1 Convening meetings

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

	Ordinary meeting	Extraordinary meeting
General Assembly	Once a year	
Board of Directors	Twice a year and when required (once backed to the General Assembly; once in conference call)	At any time upon written request of the Coordinator
Steering Committee	Every quarter (once backed to the General Assembly; others backed to international conferences or in conference call)	
Valorization Committee	At least once a year and upon request of the Board of Directors	
WP Committee	As much as it is necessary at the discretion of the WP Leader	
Scientific Advisory Board	At least once a year (backed to the General Assembly) and upon request of the Board of Directors	
Clinical and Ethical Committee	At least once a year (backed to the General Assembly) and upon request of the Board of Directors	

6.2.2.2 Notice of a meeting

The chairperson of a Consortium Body 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	45 calendar days	
Board of Directors	21 calendar days	7 calendar days
Steering Committee	14 calendar days	
Valorization	14 calendar days	

Committee		
WP Committee	7 calendar days	
Scientific Advisory Board	7 calendar days	
Clinical and Ethical Committee	7 calendar days	

6.2.2.3 Sending the agenda

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

General Assembly	21 calendar days
Board of Directors	7 calendar days, 2 calendar days for an extraordinary meeting
Steering Committee	7 calendar days
Valorization Committee	7 calendar days
WP Committee	2 calendar days
Scientific Advisory Board	7 calendar days
Clinical and Ethical Committee	7 calendar days

6.2.2.4 Adding agenda items:

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

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

General Assembly	14 calendar days
Board of Directors	2 calendar days, 1 calendar day for an extraordinary meeting
Steering Committee	1 calendar day
Valorization Committee	2 calendar days
WP Committee	1 calendar day
Scientific Advisory Board	2 calendar days
Clinical and Ethical Committee	2 calendar days

6.2.2.5 Meeting – Decisions

Use of web conferencing services, conference calls, etc. will be preferred for Meetings of Consortium Body, whenever possible.

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

Decisions will only be binding once the relevant part of the minutes has been accepted according to Section 6.2.5.

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 agreed by the defined majority (see Section 6.2.3) of all Members of the Consortium Body. Such document shall include the deadline for responses.

Decisions taken without a meeting shall be considered as accepted if, within the period set out in article 6.2.4.4, no Member has sent an objection in writing to the chairperson. The decisions will be binding after the chairperson sends to all Members of the Consortium Body and to the Coordinator a written notification of this acceptance.

6.2.3 Voting rules and quorum

- 6.2.3.1 Each Consortium Body shall not deliberate and decide validly unless two-thirds (2/3) of its Members are present or represented (quorum). If the quorum is not reached, the chairperson of the Consortium Body shall convene another ordinary meeting within 15 calendar days. If in this meeting the quorum is not reached once more, the chairperson shall convene an extraordinary meeting which shall be entitled to decide even if less than the quorum of Members are present or represented.
- 6.2.3.2 Each Party represented by a member in a Consortium Body, as listed in Attachment G, present or represented in the meeting shall have one vote.
- Defaulting Parties may not vote or participate in any further Consortium Body following the declaration of default, nor shall their presence account for the relevant quorum. However, if the person who attends the meeting is not authorized by his or her institution or company to make a proposed decision on behalf of that institution or company, the Member will ensure that he or she will refer such decision to the authorized representative of his or her institution or company at the earliest time possible and will inform the Coordinator of such referral.
- 6.2.3.3 A Party which the Board of Directors has declared according to Section 4.2 to be a Defaulting Party may not vote.
- 6.2.3.4 Except for the acceptance of a new entity among the Parties by a Board of Directors' decision which has to be unanimous (see Article 3.1's second paragraph), decisions shall be taken by a majority of two-thirds (2/3) of the votes cast.

6.2.4 Veto rights

- 6.2.4.1 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. Such veto shall be reasonable and duly justified.
- 6.2.4.2 When the decision is foreseen on the original agenda, a Member may veto such a decision during the meeting only.
- 6.2.4.3 When a decision has been taken on a new item unanimously added to the agenda before or during the meeting, a Member may veto such decision during the meeting and within 15 calendar days after written notification of the draft minutes of the meeting. A Party that did not participate said meeting may veto a decision within the same number of calendar days after the draft minutes of the meeting are sent.
- 6.2.4.4 When a decision has been taken without a meeting a Member may veto such decision within 15 calendar days after written notification by the chairperson of the outcome of the vote.
- 6.2.4.5 In case of exercise of veto, the Members of the related Consortium Body shall make every effort to resolve the matter which occasioned the veto to the general satisfaction of all its Members.
- 6.2.4.6 A Party may neither veto decisions relating to its identification to be in breach of its obligations nor to its identification as a Defaulting Party. The Defaulting Party may not veto decisions relating to its participation and termination in the consortium or the consequences of them.
- 6.2.4.7 A Party requesting to leave the consortium may not veto decisions relating thereto.

6.2.5 Minutes of meetings

- 6.2.5.1 The chairperson of a Consortium Body shall produce written minutes of each meeting which shall be the formal record of all decisions taken. He/she shall send the draft minutes to all Members within 10 calendar days of the meeting.
- 6.2.5.2 The minutes shall be considered as accepted if, within 15 calendar days after written notification, no Member has sent an objection in writing to the chairperson with respect to the accuracy of the draft of the minutes.
- 6.2.5.3 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 the Parties.

6.3 Specific operational procedures for the Consortium Bodies

The representatives of the Parties in the Consortium Bodies are provided in Attachment G.

6.3.1 General Assembly

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

6.3.1.1 Members

The General Assembly shall consist in particular of one representative of each Party, associated stakeholders, the Project Officer from the European Commission, SAB members (hereinafter “General Assembly Member”).

Each General Assembly Member shall be deemed to be duly authorized to participate on all matters listed in Section 6.3.1.2. of this Consortium Agreement. The Project Coordinator shall chair all meetings of the General Assembly.

6.3.1.2 Role

The General Assembly is dedicated to information exchange at the Project level.

The General Assembly shall:

- Provide the opportunity to share views and progress across partners, topics and activities, within Work Packages.
- Make recommendations for the orientations of the project if needed,
- Support the dissemination activities.

6.3.2 Board of Directors

The Board of Directors is the decision-making body of the consortium. In addition to the rules in Section 6.2, the following rules shall apply:

6.3.2.1 Members

The Board of Directors shall consist of the Project Coordinator and a representative of each Party. Each Board of Directors Member shall be deemed to be duly authorized to deliberate on all matters listed in Section 6.3.2.3. of this Consortium Agreement. However, if a Board of Directors Member indicates that he or she first needs to obtain additional authorization for a decision, that Board of Directors Member shall have a period of 5 working days after the meeting to obtain authorization for a decision. In that case the decision shall be delayed for a period of 5 working days. If no decision is sent to the Coordinator by the that Board of Directors Members (or unanimity of other Board of Directors Members for a decision related to a new Party entry) concerned within the aforementioned period of five working days, that Board of Directors Member shall be deemed to be duly authorized to support a decision as is made by the majority of Board of Directors Member. In case of tied votes, the decision of the relevant Board of Directors Member shall be deemed to be identical to that of the Coordinator.

The Parties agree to abide by all decisions of the Board of Directors, subject to Section 6.2.4. This does not prevent the Parties to submit a dispute to resolution in accordance with the provisions of Settlement of disputes under Section 13.8.

The Project Coordinator shall chair all meetings of the Board of Directors.

6.3.2.2 Minutes of meetings

Minutes of Board of Directors meetings, once accepted, shall be sent by the Project Coordinator to the representative of each Party. The Parties agree to abide by all decisions of the Board of Directors.

6.3.2.3 Tasks

The Board of Directors is the ultimate decision-making body of the Project.

The Board of Directors shall:

Relations with the Steering Committee

- Deliberate and validate the proposals emitted by the Steering Committee
- Deliberate and validate modifications of the members of the Consortium Bodies (Attachment G)
- Declare a Party to be a Defaulting Party and validate the remedies proposed by the Steering Committee and measures relating thereto
- Approve the settlement on the conditions of the accession of a new Party

Strategic Role

- Modify or reorient the Project following major events
- Implement or correct strategy to overcome difficulties and eventual conflicts to perfect the progression of the Project
- Discuss about the revision of the present Consortium Agreement and of Annex I (Description of the Action) to the Grant Agreement, if necessary

Relations with the Funding Authority

- Propose to the Funding Authority the suspension of all or part of the Project
- Propose to the Funding Authority the termination of the Project and the Consortium Agreement

6.3.3 Coordination

6.3.3.1 Coordinator/Project Coordinator

The Coordinator is the Party which is the intermediary between the Parties and the Funding Authority and shall perform all tasks assigned to it as described in the Grant Agreement and in this Consortium Agreement.

In particular, the Coordinator shall be responsible for:

- Leading and coordinating the Project
- monitoring compliance by the Parties with their obligations, the status of the Project progress and any deviations or risks, which may occur, in cooperation with the Steering Committee
- keeping the address list of Members and other contact persons updated and available
- collecting, reviewing to verify consistency and submitting reports, other deliverables (including financial statements and related certifications) and specific requested documents to the Funding Authority
- transmitting documents and information connected with the Project to any other Parties concerned if necessary
- providing, upon request, the Parties with official copies or originals of documents that are in the sole possession of the Coordinator when such copies or originals are necessary for the Parties to present claims.

- Being the interface with the Funding Authority of which he will be the main contact point, including for the distribution of funds to the Parties, and answering all formal requests
- Invite experts to Consortium Bodies meetings. If the invited expert is not representative of a Party, the Coordinator will make him sign, on behalf of the Parties, a non-disclosure agreement at least as restrictive as the dispositions of this Consortium Agreement.
- Maintain a complete and updated list of the Background (including related restriction to the use of Background) of the Parties and informing the Parties of addition of Background after the Effective Date

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

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

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

The Project Coordinator is the physical person representing the Coordinator for the interactions between the Parties and scientific matters.

6.3.3.2 Technical Manager

The Technical Manager is a Member of the Steering Committee and provides a technical approach to the Project organization.

The Technical Manager shall:

- Review the work performed by the Parties including deliverables
- Coordinate the technical section in reports and deliverables to be submitted to the Funding Authority
- Coordinate and manage resolution of conflicts related to technical issues
- Report on technical progress during meetings of the General Assembly, the Board of Directors and the Steering Committee

6.3.3.3 Administrative Manager

The Administrative Manager is a Member of the Steering Committee and plans and coordinates administrative, financial and quality control procedures with a close help of the Project Coordinator.

The Administrative Manager shall:

- Perform a regular analysis of the management plan
- Contribute to the preparation and delivery of the quality plan of the Project
- Contribute to the definition of the deliverable reviewing method and procedure
- Update the action list every 3 months
- Hold the risks register
- Ensure quality check of each deliverable before submission to the Funding Authority
- Manage the Project's collaborative platform and other tools for storing and exchanging all information, documents, news, etc.

6.3.4 Steering Committee

The Steering Committee is the supervisory body for the execution of the project.

6.3.4.1 Members

The Steering Committee shall consist of one scientific representative from each Party as listed in Attachment G, the Project Coordinator, Technical Manager and the Administrative Manager.

The Project Coordinator shall chair all meetings of the steering Committee.

6.3.4.2 Role

The following tasks shall be undertaken by the Steering Committee:

Content, finances and intellectual property rights:

- Propose changes to the Consortium Plan (Attachment A) to the Board of Directors
- Validate addition of Background (Attachment C)
- Propose solutions to the Board of Directors on the main issues of the Project and especially regarding resources and technical/scientific matters

Evolution of the consortium

- Proposal of the entry of a new Party to the Consortium Agreement to the Board of Directors
- Withdrawal of a Party from the consortium and the approval of the settlement on the conditions of the withdrawal
- Identification of a breach by a Party of its obligations under this Consortium Agreement
- Identify a Defaulting Party and report it to the Board of Directors
- Propose remedies to be performed by a Defaulting Party
- Keep the Project Coordinator and the Board of Directors informed of the status of the Project progress and of any deviations or risks, which may occur
- Propose modification of the members of the Consortium Bodies (Attachment G)

Project

- Approve all publications, abstracts, presentations or manuscripts related to the Project
- Propose/validate/amend the publication plan and determine authorship rules for publications
- Make recommendations for the orientations of the Project if needed
- Support the dissemination activities
- Report all strategic matters requesting decision from Parties to the Board of Directors
- Ensure the proper execution and implementation of strategic decisions
- Monitor the implementation of the Project (process and deliverables following the Consortium Plan)
- Identify intellectual property issues and report them to the Valorization Committee

The Steering Committee may appoint any other advisory internal sub-committees, such as WP Leaders, Work Package Committee and Valorization Committee to support the Steering Committee in the execution of its tasks.

6.3.5 Valorization Committee

6.3.5.1 Members

The Valorization Committee shall consist of one representatives of each Party as listed under Attachment G. The Project Coordinator shall chair all meetings of the Valorization Committee.

6.3.5.2 Role

The Valorization Committee shall:

- Help to define the intellectual property strategy if requested by Co-owners or Steering Committee: industrial transfer of Results, Results protection and/or valorization, communication policy about research progress and their outcomes
- Turn the knowledge into value suitable for economic and social application, in compliance with the executed Grant Agreement and this Consortium Agreement

- Boosting the valorization activities

6.3.6 Work Package Committees

Each Work Package will constitute a Work Package Committee which will be led by a WP Leader.

The WP Leader shall:

- Be responsible for the coordination of the Work Package
- Mitigate and report all potential risks of the Work Package affecting the Project to the Steering Committee
- Solve technical issues and actions allocated to their Work Package and report to the Steering Committee

The Work Package Committee is constituted by the WP Leader and operational representatives involved in each Work Package designated by the WP Leader.

Missions of the Work Package Committee are:

- To identify and validate the results of each Work Package and pronounce operational decisions
- To recommend adaptation and new orientation for each integrated research programs.
- To harmonize the practices, protocols and processes to ensure the well sharing of information within their respective Work packages

6.3.7 Scientific Advisory Board

The Scientific Advisory Board (SAB) will provide the Project with technical insights on the state-of-the-art solutions in the field and will contribute with market-oriented advice and expectations which will be used for developing the exploitation strategy of the project

The SAB will gather external experts from research institutes and academia, business stakeholders and consultancies invited by the Coordinator.

The Coordinator is authorized to execute with each member of the SAB a non-disclosure agreement on behalf of members of the Consortium Agreement (template in Attachment I)

The SAB shall provide professional and purely consultative advices to the decisional instances about the strategic orientations of the Project.

6.3.8 Clinical and Ethical Committee

The Clinical and Ethical Committee will be composed by experts outside the influence of the Project specialized in Ethical issues, Clinical trials, Statistics, Data Management and a representative of the patients..

The Clinical and Ethical Committee shall control the well-being and the safety of the patients and provide advisory opinions in an ethical and consensual way, without meaning to substitute the local and national ethic approvals requested to each Party.

The Coordinator is authorized to execute with each member of the Clinical and Ethical Committee, a non-disclosure agreement on behalf of members of the Consortium Agreement (template in Attachment I).

The Clinical and Ethical Committee will be chaired by the external Ethics Advisor: [REDACTED].

Meetings will be held at least once a year, and at any moment required. Following those meetings, the Ethics Advisor will report yearly on ethical aspects of the project, both to the Steering Committee and the Scientific Advisory Board.

7 Section: Financial provisions

7.1 General Principles

7.1.1 Distribution of Financial Contribution

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

- the Consortium Plan (Attachement A) as included in the Grant Agreement,
- reported costs,
- the approval of reports by the Funding Authority, and
- the provisions of payment in the executed Grant Agreement and in Section 7.3 of this Consortium Agreement.

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

7.1.2 Justifying Costs

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

7.1.3 Funding Principles

A Party that spends less than its allocated share of the budget as set out in the Consortium Plan or – in case of reimbursement via unit costs - implements less units than foreseen in the Consortium Plan will be funded from the Funding Authority's financial contribution in accordance with its actual duly justified eligible costs only.

A Party that spends more than its allocated share of the budget as set out in the Grant Agreement and in the Consortium Plan will be funded only in respect of duly justified eligible costs up to an amount not exceeding said share. No Party shall be liable for any costs of a Party, exceeding that Party's budgeting of such cost.

7.1.4 Return of excess payments; receipts

7.1.4.1 In any case of a Party having received excess payments, the Party has to return the relevant amount to the Coordinator without undue delay.

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

7.1.5 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 Funding Authority or another contributor. Furthermore a Defaulting Party shall, within the limits specified in Section 5.2 of this Consortium Agreement, bear any reasonable and justifiable additional costs occurring to the other Parties in order to perform its and their tasks.

7.2 Budgeting

The budget set out in the Consortium Plan shall be valued in accordance with the usual accounting and management principles and practices of the respective Parties.

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 Funding Authority's financial contribution to the Project separated from its normal business accounts, its own assets and property, except if the Coordinator is a Public Body or is not entitled to do so due to statutory legislation.
- With reference to Grant Agreement, no Party shall before the end of the Project receive more than its allocated share of the maximum grant amount from which the amounts retained by the Funding Authority for the Guarantee Fund and for the final payment have been deducted.

8 Section: Results

8.1 Ownership of Results

Results are owned by the Party and/or the researchers if applicable that generates them alone without any human, Material, financial and intellectual contribution of another Party during the Project and the potential Intellectual Property rights linked to these Results shall be filed on behalf of and at the exclusive expense of said proprietary Party. Said Party will inform the Coordinator/Project Coordinator of such filing without delay.

If the researchers of a Party are entitled to claim rights to the Result pursuant to national laws, the Party must, at first, try to get the right assignment in compliance with said national laws. If the first option is not possible, Researchers are in this exceptional case Co-owners, and the Party concerned must ensure that the researchers comply with the obligations under the Grant Agreement and this Consortium Agreement.

The Parties must ensure to comply with the Rights and obligations related to Results under the Grant Agreement and this Consortium Agreement. Rights and obligations related to Results generated under the Project are ruled under Subsection 3, Article 26 of the Grant Agreement.

8.2 Joint ownership of Results

8.2.1 Property

Joint ownership is governed under Subsection 3, Article 26.2 of the Grant Agreement with the following additions:

Where Results are generated from work carried out jointly by two or more Parties (involving human, Material, Data and/or intellectual contribution of at least two Parties) and it is not possible to separate such joint invention, design or work for the purpose of applying for, obtaining and/or maintaining the relevant patent protection or any other intellectual property right, the Parties shall have joint ownership of these Results.

It is understood between the co-owner Parties ("Co-owners") that the share of co-ownership of each of the Co-owners to the jointly owned Results and linked Intellectual Property shall be defined in good faith between the Co-owners according to inventorship, and to the human, Material and Data, financial and intellectual effective contributions of each Co-owner.

Co-owners agree to cooperate to ensure the protection of the co-owned Results by intellectual property rights and/or any other means.

The Database will be jointly owned by the Parties that generate it with intellectual, Material and Data contribution.

8.2.2 Valorization Agreement

Co-owners shall establish, in a separate joint ownership agreement (“**Valorization Agreement**”), how the ownership is divided between the joint Co-owners (including their researchers if applicable as stated in 8.1.), how the jointly owned Results will be protected, including issues concerning the division of the related cost of protection (e.g. patent filing and examination fees, renewal fees, prior state-of-the-art searches, infringement actions, etc.), Access Rights, Commercial Exploitation rules (including a division, if any, between the Commercial fields that may be attributed to each Co-owner) following the generation of a Result and before any Commercial Exploitation of such Result., being underlined that Article 9.4.4 provides for a specific exploitation option of Everimmune and HalioDx when one of the Co-owners is Everimmune or HalioDx. Any Commercial Exploitation subject to direct or indirect remuneration by a Co-owner shall include retribution to the other Co-owners (including their researchers if applicable), according to the terms and conditions described in the Valorization Agreement.

In compliance with the Grant Agreement, if the concerned Parties decide to protect a jointly owned Result, the Valorization Agreement shall specify:

- The designation of the Patent Manager. The Patent Manager shall be identified without any delay to ensure the valorization strategy of Results. If the Coordinator is one of the Co-owners of a Result, it will be automatically the Patent Manager of this Result unless otherwise decided and in case one of the Co-owners is an industrial organization (Everimmune or HalioDx); it will be automatically the Patent Manager of this Result unless otherwise decided.
- The conditions of filing, issuance and maintenance of the Intellectual Property right on the Result coordinated by the Patent Manager
- The conditions of information of the other Co-owners by the Patent Manager
- The condition of Payment of the Intellectual Property direct or indirect costs. These costs shall be anticipated by the Patent Manager and then reimbursed to the Patent Manager by the other Co-owners according to the agreed conditions of payment negotiated in the Valorization agreement. During the option period as specified in Article 9.4.4, it is agreed between the co-owning parties that Everimmune and HalioDx shall bear the patent costs for patents regarding the Results they respectively co-own.
- The Commercial Exploitation conditions
- The Co-owners remuneration. Each Co-owner will be in charge of the remuneration of its inventors and/or authors.

Unless otherwise agreed in the Valorization Agreement and subject to the option period or negotiation period set in Section 9.4.4 for Results that are jointly owned by Everimmune or HalioDx:

- each of the Co-owners shall be entitled to use their jointly owned Results for internal Research Use on a royalty-free basis for research and teaching activities, and without requiring the prior consent of the other Co-owner(s), and
- each of the Co-owners shall be entitled to otherwise Commercially Exploit the jointly owned Results and associated Intellectual Property rights and to grant non-exclusive licenses to third parties (without any right to sub-license), if the other Co-owners are given:
 - (a) at least 45 calendar days advance notice; and
 - (b) Fair and Reasonable compensation,

provided that a Co-owner may veto the grant of such sublicense based on a reasonably justified and acceptable reason.

8.2.3 Organization

Co-owners agree to:

- Communicate to each other all technical or administrative documents and information necessary to the filing, maintain or defense of Intellectual Property rights

- Mention the names of the inventors and/or authors in the Intellectual Property titles, if applicable, in accordance with the legal dispositions
- Make sure that their employees and personnel (including, but not limited to, interns and subcontractors' employees if applicable), cited as inventors, provide all signatures and accomplish all formalities necessary to the filing, maintain or defense of Intellectual Property rights

8.3 Transfer of Results

- 8.3.1 Each Party may transfer ownership of its own Results following the procedures of the Grant Agreement.
- 8.3.2 It may identify specific third parties it intends to transfer the ownership of its Results in Attachment D to the present Consortium Agreement. The other Parties hereby waive their right to prior notice and their right to object to a transfer to listed third parties according to the Grant Agreement Article 30.1.
- 8.3.3 The transferring Party shall, however, at the time of the transfer, inform the other Parties of such transfer and shall ensure that the rights of the other Parties will not be affected by such transfer. Any addition to Attachment D after signature of this Agreement requires a decision of the Board of Directors.
- 8.3.4 The Parties recognize that in the framework of a merger or an acquisition of an important part of its assets, it may be impossible under applicable EU and national laws on mergers and acquisitions for a Party to give the full 45 calendar days prior notice for the transfer as foreseen in the Grant Agreement (Article 30.1).
- 8.3.5 The obligations above apply only for as long as other Parties still have - or still may request - Access Rights to the Results.

8.4 Dissemination

- 8.4.1 For the avoidance of doubt, nothing in this Section 8.4 has an impact on the confidentiality obligations set out in Section 10. In case of doubt, Section 10 shall prevail.

8.4.2 Dissemination of own Results

- 8.4.2.1 During the Project and for a period of one (1) year after the end of the Project, the dissemination of own Results by one or several Parties including but not restricted to publications and presentations, shall be governed by the related procedure of the executed Grant Agreement subject to the following provisions.

Prior notice of any planned publication, together with sufficient information on the Results it will disseminate, shall be given to the other Parties at least forty five (45) calendar days before submission of such publication project. Any objection to the planned publication shall be made in accordance with the Grant Agreement in writing to the Coordinator and to the Party or Parties proposing the dissemination within thirty (30) calendar days after receipt of the notice. If no objection is made within the time limit stated above, the publication is permitted.

- 8.4.2.2 An objection is justified if
- (a) the protection or intellectual property strategy related to the objecting Party's Results or Background would be adversely affected
 - (b) the objecting Party's legitimate academic or commercial interests in relation to the Results or Background would be significantly harmed.
 - (c) and/or if a Party's confidential information (including, but not limited to, its know-how) is divulged in the publication project
 - (d) the protection by secret of Results is envisaged by the Co-owners and the publication project contains said Results or part of them.

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

- 8.4.2.3 If an objection has been raised, the involved Parties shall discuss how to overcome the justified grounds for the objection on a timely basis (for example by amendment to the planned publication and/or by protecting information before publication) and the objecting Party shall not unreasonably continue the opposition if appropriate measures are taken following the discussion. In case the peer-reviewed publication to a scientific journal which are subject to specific submission deadlines, the Parties involved will do their best efforts to solve the issue amicably to enable the timely submission of the abstract or publication.

The objecting Party can request a publication delay of not more than 90 calendar days from the time it raises such an objection. After 90 calendar days the publication is permitted, provided that Confidential Information of the objecting Party has been removed from the Publication as indicated by the objecting Party.

If a Party intends not to protect its Results, in agreement with other Co-owners, if any, and in compliance with the Grant Agreement, it may need to formally notify the Funding Authority before dissemination takes place, under the conditions foreseen in the executed Grant Agreement.

Authorship on publications will be based on academic standards and custom. In accordance with normal academic practice, all investigators and contributors to a publication will be acknowledged, always in compliance with recognized standards concerning publication and authorship, including the most recent "Recommendation for the Conduct, Reporting, Editing and Publications of Scholarly Work in Medical Journals" developed by the International Committee of the Medical Journal Editors (ICMJE).

8.4.3 Dissemination of another Party's unpublished Results or Background

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

8.4.4 Cooperation obligations

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

8.4.5 Use of names, logos or trademarks

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

8.4.6 Open access

Each Party is responsible for the fulfillment of the requirements in the Grant Agreement regarding Open Access publications involving that Party (Section 29.2). If two or more Parties are publishing together they shall agree upon the cost for the fulfillment of the requirements in the Grant Agreement before they publish.

8.5 Exclusive License

Where a Party wishes to grant an exclusive license to its Results and seeks the written waiver of the other Parties pursuant to the Article 30.2 of the Grant Agreement, the other Parties shall respond to the requesting Party within 45 calendar days of the request. Any Party's failure to respond (whether in the negative or the positive) to the request within such 45 calendar days shall be deemed to constitute written approval of the waiver by the non-responding Party.

9 Section: Access Rights

9.1 Background included

9.1.1 For the avoidance of doubt, all Background used in connection with the Project shall remain the property of the Party owning the same. In Attachment C, the Parties have identified and agreed on the Background needed for the use for the Project and have also, where relevant, informed each other that access to specific Background is subject to legal restrictions or limits.

Anything not identified in Attachment C shall not be the object of Access Right obligations regarding Background unless provided otherwise in Section 9.1.2 herein.

9.1.2 Any Party may add further own Background, which could be useful for another Party to carry out the Project after the Effective Date, to Attachment C during the Project by written notice to the Coordinator, which, following to the approval procedure under Section 6 of this Consortium Agreement, will update Attachment C and inform the other Parties. However, approval of the Steering Committee is needed should a Party wish to modify or withdraw its Background in Attachment C.

9.1.3 The Parties agree to negotiate in good faith additions to Attachment C if a Party asks them to do so and those are Needed. For the avoidance of doubt, the owner is under no obligation to agree to additions of his Background to Attachment C after the Effective Date.

9.2 General Principles

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

Parties shall inform the Steering Committee as soon as possible of any limitation to the granting of Access Rights to Background or of any other restriction which might substantially affect the granting of Access Rights. If the Steering Committee considers that the restrictions have such impact, which is not foreseen in the Consortium Plan, it may decide to update the Consortium Plan accordingly.

Any Access Rights granted herein exclude any rights to sublicense unless expressly stated otherwise. Any Access Rights related to Software exclude any access to the code source (unless expressly stated otherwise and agreed by the Party which owns such Software).

Access Rights for the implementation of the Project shall be free of any administrative transfer costs.

Access Rights for the implementation of the Project are granted on a non-exclusive basis.

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

All requests for Access Rights shall be made in writing to the Coordinator. 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. For the avoidance of doubt, the provisions shown in Section 4.1 of this Consortium Agreement shall apply in respect of the specific conditions covering the granting of Access Rights to biological material for implementation of the Project.

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

9.3 Access Rights for implementation

Access Rights to Results and Background Needed for the performance of the own work of a Party under the Project shall be granted on a royalty-free basis.

9.4 Access Rights for Exploitation

9.4.1 Access rights among beneficiaries, for exploiting their own results are governed under Article 25.3 of the Grant Agreement with the following additions.

9.4.2 Access Rights to Results if Needed for Commercial Exploitation of a Party's own Results shall be granted on Fair and Reasonable conditions and upon written bilateral agreement among the Parties concerned.

Access rights to Results for internal Research Use shall be granted on a royalty-free basis, for academics, provided that no Results shall be accessed by or transferred or licensed to any third party without the owning Party's consent.

9.4.3 Access Rights to Background if Needed for Exploitation of a Party's own Results, including for research on behalf of a third party, shall be subject to the conditions stated in Attachment C and when possible granted on Fair and Reasonable conditions.

9.4.4 A request for Access Rights for Commercial Exploitation may be made up to twelve months after the end of the Project or, in the case of Section 9.7.2., after the termination of the requesting Party's participation in the Project.

9.4.4. Unless otherwise agreed between the Co-owners:

- If Everimmune is the co-owner of a Result in the therapeutic field (including Results related to therapeutic target, cancer treatment or therapeutic applications but excluding prediction and monitoring of response to an anti-cancer treatment), it shall have an exclusive, royalty-bearing, exploitation option in this field.
- If Everimmune is co-owner of a Result related to a biomarker or method for prediction or monitoring of response to an anti-cancer treatment, such biomarker or method being related to microbiota, Everimmune shall have an exclusive, royalty-bearing, exploitation option in this field. HalioDx shall have a right of first refusal to be Everimmune's diagnostic partner for the development and commercialization of a diagnostic test or companion diagnostic test if HalioDx is also co-owner of said Result or part of Results.

In such a case, HalioDx' first right of refusal shall apply for a six (6) months period upon notification of Everimmune that it exercise the exploitation option according to this Section 9.4.4. In the event HalioDx notifies Everimmune of its interest in such a partnership, Everimmune and HalioDx agree to negotiate in good faith an agreement for development and commercialization of such a diagnostic test or companion diagnostic test.

- If HalioDx is the co-owner of a Result on the diagnostic field (including Results related to biomarker(s) or method(s) for detection, diagnosis, prognosis, staging or stratification of cancer, but excluding prediction and monitoring of response to an anti-cancer treatment and therapeutic field), it shall have an exclusive royalty-bearing, exploitation option in this field. If HalioDx is co-owner of a Result related to a biomarker or method for prediction or monitoring of response to an anti-cancer treatment, such biomarker or method being related to related to immune response against the tumor and/or tumor microenvironment (excluding microbiota), HalioDx shall have an exclusive, royalty-bearing, exploitation option in this field.

Such exploitation option shall commence upon signature of this Consortium Agreement and will extend for a period of six (6) months after the notification of a Result (the "**Option Period**"). At any time during the Option Period, Everimmune and HalioDx may notify the Coordinator that it exercises the exploitation option. After the Option Period, in the case Everimmune and/or HalioDx have notified the Coordinator and the concerned Co-owners that it exercises the exploitation option, Everimmune and/or HalioDx and other concerned Co-owners agree to negotiate, in good faith, in order, to establish the conditions of exploitation (in the Valorization Agreement or in a separate license agreement including, at least, the following provisions: license fees, royalty payments, milestones, a commitment by licensee to do its commercial best effort to commercialize the object of the license, the right for the Co-owners to terminate the license if the licensee does not meet specified milestones ("License"). If the negotiation of the License fails nine (9) months after the end of the Option Period,

the option will be cancelled (provided that the nine (9) months- period can be extended by mutual agreement of the Co-owners). The other Co-owners shall then be free to license the concerned Results to third parties.

9.5 Access Rights for Affiliated Entities

Affiliated Entities have Access Rights under the condition of the Grant Agreement Articles 25.4 and 31.4, if they are identified in Attachment D (Identified Affiliated Entities) to this Consortium Agreement. Such Access Rights must be requested by the Affiliated Entity to the Party that holds the Background or Results. Alternatively, the Party granting the Access Rights may individually agree with the Party requesting the Access Rights to have the Access Rights include the right to sublicense to the latter's Affiliated Entities, listed in Attachment D. Access Rights to Affiliated Entities shall be granted on Fair and Reasonable conditions and upon written bilateral agreement.

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

Access Rights may be refused to Affiliated Entities by the Party which owns the Background or the Results based on a reasonable and justified reason.

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

Upon cessation of the status as an Affiliated Entity, to be communicated without delay to the Coordinator by the Party to which it is affiliated, any Access Rights granted to such former Affiliated Entity shall lapse. Further arrangements with Affiliated Entities may be negotiated in separate agreements.

9.6 Additional Access Rights

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

Any access to the Material/Data of a Party in the scope of the Project shall be made in accordance with the rules of this Consortium Agreement and of the Party providing such Material/Data.

9.7 Access Rights for Parties entering or leaving the consortium

9.7.1 New Parties entering the consortium

All Results developed before the accession of the new Party shall be considered to be Background with regard to said new Party provided it has been unanimously accepted by a Board of Directors' decision.

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

9.7.2 Parties leaving the consortium

9.7.2.1 Access Rights granted to a leaving Party

9.7.2.1.1 Defaulting Party

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

9.7.2.1.2 *Non-defaulting Party*

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

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

9.7.2.2 **Access Rights to be granted by any leaving Party**

Any Party leaving the Project shall continue to grant Access Rights pursuant to 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**

Administrative Manager will give access right, to each Party, to a collaborative management platform that will be set up for the project (AlgoeCollab could be used or Project Place). To access such collaborative platform, each Party shall have to complete the form in Attachment J.

10 Section: Non-disclosure of information

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

10.2 The Recipients hereby undertake in addition and without prejudice to any commitment of non-disclosure, during the Project and for a period of five (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 of the Disclosing Party;
- the Recipient may provide Disclosing Party's Confidential Information solely to its employees or consultants, agents ("Representatives") on a strictly need-to-know basis; provided, however, that (a) any such Representatives are bound by written obligations of confidentiality at least as restrictive as those set forth in this Agreement; and (b) Recipient remains liable for the compliance of such Representatives with such obligations.; and
- to return to the Disclosing Party, or destroy, on request all Confidential Information that has been disclosed to the Recipients including all copies thereof and to delete all information stored in a machine readable form to the extent practically possible, except one copy for archival purposes and/or copies of electronically exchanged or stored Confidential Information which are necessary for routine information technology back-up. The Recipients may keep a copy to the extent it is required to keep, archive or store such Confidential Information because of compliance with applicable laws and regulations or for the proof of on-going obligations provided that the Recipient comply with the confidentiality obligations herein contained with respect to such copy for as long as the copy is retained.

- 10.3 The Recipient shall be responsible for the fulfillment of the above obligations on the part of their Representatives or third parties involved in the Project and shall ensure that they remain so obliged, as far as legally possible, during and after the end of the Project and/or after the termination of the contractual relationship with the Representative or third party.
- 10.4 The above shall not apply for disclosure or use of Confidential Information, if and in so far as the Recipient can show that:
- the Confidential Information has become or becomes publicly available by means other than a breach of the Recipient's confidentiality obligations;
 - the Disclosing Party subsequently informs the Recipient that the Confidential Information is no longer confidential;
 - the Confidential Information is communicated to the Recipient without any obligation of confidentiality by a third party who is to the best knowledge of the Recipient in lawful possession thereof and under no obligation of confidentiality to the Disclosing Party;
 - the disclosure or communication of the Confidential Information is foreseen by provisions of the present Consortium Agreement;
 - the Confidential Information, at any time, was developed by the Recipient completely independently of any such disclosure by the Disclosing Party;
 - the Confidential Information was already known to the Recipient prior to disclosure, or
 - the Recipient is required to disclose the Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order, subject to the provision Section 10.7 hereunder.
- 10.5 The Recipient shall apply the same degree of care with regard to the Confidential Information disclosed within the scope of the Project as with its own confidential and/or proprietary information, but in no case less than reasonable care
- 10.6 Each Party shall promptly advise the other Party in writing of any unauthorized disclosure, misappropriation or misuse of Confidential Information after it becomes aware of such unauthorized disclosure, misappropriation or misuse.
- 10.7 If any Party becomes aware that it will be required, or is likely to be required, to disclose Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order, it shall, to the extent it is lawfully able to do so, prior to any such disclosure:
- notify the Disclosing Party, and
 - comply with the Disclosing Party's reasonable instructions to protect the confidentiality of the Confidential Information.
- 10.8 Notwithstanding anything to the contrary in this Section 10, personal data as defined in the Regulation (EU) 2016/679 of the European Parliament and of Council of 27 April 2016 on the protection of natural persons with regard to the processing of the personal data and on the free movement of such data, and repealing Directive 95/46/EC ("GDPR"), ("Personal data") shall always be treated as confidential, and shall be protected with an adequate level of safety and confidentiality, subject to any applicable legal, regulatory or contractual requirements. Therefore, the above mentioned time period of five (5) years is not applicable to Personal Data.
- 10.9 Unlimited liability of a Party shall not arise from a breach of its confidentiality obligations to comply with laws or from inadvertent, accidental, unauthorized or mistaken disclosure by its Representatives of information obtain pursuant to this Agreement, provided that:
- a) Such Receiving Party used the same degree of care (but no less than a reasonable degree of care) as it uses to protect its own proprietary or confidential information of like importance, and
 - b) Upon discovery of such disclosure, such receiving Party shall to the extent legally permitted, notify the disclosing Party and shall endeavor to prevent further disclosure of use.

- c) Recipient shall give the Disclosing Party prompt written notice thereof and Recipient will take all reasonable and lawful actions to avoid or minimize the degree of such disclosure. Recipient will cooperate reasonably with the Disclosing Party in any efforts to seek a protective order

11 Section: Material Transfer

If any Materials are transferred for the performance of the Project from one Party (“**Material Provider**”) to another (“**Material Recipient**”) each Recipient and Provider shall be bound by the following provisions and will be specified in the form in Attachment F. Each transfer will be the object of a separate form.

Material Recipient shall have all required authorizations under all applicable laws and regulations to perform the use on the Materials. Materials shall be used in full compliance with all applicable laws and regulations.

Materials shall be used solely for the performance of the Project in accordance with this Consortium Agreement. Materials shall under no circumstances be administered to humans, unless this is specifically required in the Consortium Plan. The Materials or animals treated therewith shall under no circumstances be used as food for humans or animals. The Materials shall not be analyzed or modified except as necessary for the purpose of the Project.

Materials shall not be transferred or made available to any Representatives other than those under the supervision and control of the Material Recipient.

Upon completion, expiry or termination of this Consortium Agreement, any unused Materials will be either returned to the Material Provider, which made them available, or to the Material Provider’s discretion disposed of/destroyed in accordance with all applicable laws and regulations and Material Recipient to provide Material Provider with a written confirmation of such disposal or destruction within two (2) months of such completion, expiry or termination.

Materials are transferred with no warranties, express or implied, of merchantability or fitness for a particular purpose or otherwise. In particular, no Material Provider represents or warrants that the use of the Materials will not infringe or violate any patent or proprietary rights of third parties.

Notwithstanding the above paragraph, the Material Provider warrants that it is duly authorized to transfer such Material and particularly has all necessary authorizations and written consents, according GDPR, from Data Subjects (in particular patients) that are involved in the Material.

Materials are to be used with caution and prudence in any experimental work, since not all of the characteristics are necessarily known. The Material Recipient using the Materials shall bear all risk to it and/or any other risks resulting, directly or indirectly, from its use, application, storage or disposal/destruction of the Materials.

In case that a Party requires more stringent clauses in order to protect the transferred Materials, the relevant parties may agree to enter into a separate material transfer agreement.

Shipping costs will be charged according to Consortium Plan. Should shipping costs have not been foreseen in the Consortium Plan, the Material is provided at no cost for Material Provider.

12 Section: Data processing

12.1 Data transfer

Parties processing Data are designated as « joint-controllers » under the article 26 of the GDPR.

For each data transfer, the Provider of the Data (“**Data Provider**”) and the Recipient of the Data (“**Data Recipient**”) will be specified in the form in Attachment E.

12.1.1 Regulation

The Data Recipient shall process Data in accordance with the requirements of Data Protection Law and Regulations.

Terms and definitions set forth in the Data Protection Law and Regulations also apply to the interpretation of this Agreement except as otherwise provided.

12.1.2 Description of joint-processing

Data Recipient shall process Data as described in the form in Attachment E ("Data transfer form"), which will precise:

- Nature and purpose of the processing
- Subject matter and duration of the processing
- Data processed
- The Data Subject categories
- Data types

12.1.3 Obligations of the Data Recipient

Data Recipient agrees and warrants that:

- Data processing, including their transfer, has and will continue to be carried out in accordance with the relevant provisions of the Data Protection Law and Regulation (and, where applicable, has been notified to the relevant authorities) and does not violate the relevant provisions and the instructions documented in the Data transfer form. Data Recipient will notify Data Provider if, in its opinion, the Data Provider's instruction would not comply with the Data Protection Law and Regulations and shall be entitled to stop to process Data until appropriate amended instructions are received. Recipient must not transfer or otherwise process Data outside the European Economic Area ("EEA") without obtaining Data Provider's prior written consent.
- Data shall be processed according to the present Agreement and Data Provider's written instructions. If Data Recipient deems that a Data Provider's instruction breaches applicable laws, it will immediately inform Data Provider.
- Data will be processed exclusively according to the purposes of the Project
- Data Recipient's Representatives, engaged in the processing of Data under the present Agreement:
 - o Are informed of the confidential nature of Data
 - o Have received appropriate training on their responsibilities and have executed written confidentiality agreements.

Data Recipient shall ensure that such confidentiality obligations survive the termination of the Representative engagement. Data Recipient shall ensure that access to Data is limited to those Representatives performing the Project in accordance with the Agreement.
- Data shall be processed under strict confidentiality
- Taking into account the state of the art, the cost of implementation and the nature, scope, context and purposes of processing as well as the risks of varying likelihood and severity for rights and freedoms of Data Subjects posed by the processing, the Data controllers and processors (as defined in the GDPR) shall, both at the time of the determination of the means for processing and at the time of the processing itself, implement appropriate technical and organizational measures for ensuring Data protection according to Data Protection Law and Regulations in force..

12.1.4 Data Subject's right to information

The Data Provider shall inform the Data Subject about the processing of its Data according to Articles 13 or 14 of the GDPR.

12.1.5 Data Subject rights

Given the nature of the processing, the Data Recipient shall assist the Data Provider to reply to the Data Subject rights requests.

When Data Recipient is informed by Data Provider that one or several people requested Data Provider to exercise their rights, Data Recipient has twenty (20) working days to realize the operations necessary for the processing of their request.

Data Recipient shall notify Data Provider within five (5) business days if it receives a request from a Data Subject to exercise the Data Subject's right of access, right to rectification, restriction of processing, erasure data portability, object to the Processing, or its right not to be subject to an automated individual decision making. Taking into account the nature of the processing, Data Recipient shall assist Data Provider by appropriate technical and organizational measures, insofar as this is possible, for the fulfillment of Data, Data Provider's obligation to respond to a Data Subject request.

12.1.6 Notification of Data breach

Data Recipient shall notify Data Provider within a maximum period of twenty-four (24) hours upon Data Recipient or any subcontractors becoming aware of a Data breach affecting Data (e.g. loss, destruction, damage, corruption), providing Data Provider, with sufficient information, to allow Data Provider to meet any obligations to report or inform Data Subjects of the Data breach including :

- Nature of the Data breach
- Number of Data Subjects involved
- Categories of Data Subjects involved
- Categories of Data concerned
- Estimated number of Data violated
- Action taken to rectify this Data breach and where appropriate measures to limit detrimental effects and possible risks
- description of the likely consequences of the Data breach

12.1.7 Data Protection Impact Assessment ("DPIA")

A DPIA will be conducted by the Parties involved in a Data processing on a Party's request according to "Guidelines on Data Protection Impact Assessment (DPIA) and determining whether processing is "likely to result in a high risk" for the purposes of Regulation 2016/679".

Parties agree which methodology and which tools shall be used to realize the DPIA.

12.1.8 Security

Data Recipient shall implement appropriate technical and organizational measures to ensure an appropriate security level, including, as appropriate, the actions referred to in Article 32 of GDPR. In assessing the appropriate security level, Data Recipient shall take account in particular of the risks that are presented by processing.

12.1.9 Deletion or return of Data

Upon the expiration or earlier termination of the Agreement, Data Recipient will cease processing of any Data and will in the absolute discretion of the Data Provider:

- permanently delete and procure the deletion of all copies of those Data so the Data is unreadable or;
- Send back to the Data Provider all Data and procure the deletion of all copies of those Data, or;
- Send Data to a subcontractor designated by the Data Provider and procure the deletion of all copies of those Data

Recipient shall comply with any such written request within thirty (30) days of the cessation date.

Recipient shall provide written certification to Provider that it and its subcontractors have fully complied with this section 12.1.9 within ninety (90) days of the cessation date.

For the avoidance of doubt, notwithstanding anything contained in this Agreement or the express instructions of the controller, the processor shall always be entitled to retain one (1) copy of personal data for as long as this is required by applicable law, in accordance with Article 5 (e) GDPR.

12.1.10 Data Protection Officers

On the day of last signature of the present Agreement, the Data Protection Officers of each Party or a representative competent with personal data if the Party is not established in the EEA are listed in Attachment G.

12.1.11 Accountability

Data Recipient shall maintain a record of processing activities under its responsibility comprising information referred to in Article 30 of GDPR and keep it available to Data Provider within thirty (30) days upon request.

12.1.12 Documentation

Data Recipient shall provide to Data Provider, on request, all records to demonstrate compliance with this Agreement and shall allow for and contribute to audits, including inspections, by Data Provider or an auditor mandated by Data Provider.

12.1.13 Data Provider's Obligations

Data Provider agrees that it will do its outmost to:

- provide pseudonymized Data to the Data Recipient as established in the Data transfer form;
- provide written instructions about Data processing to the Data Recipient

12.1.14 Audit rights

Data Provider shall have the right to audit the relevant record and the respect of data regulation and obligation under this agreement of the Data Recipient before the beginning of Data processing and at any time during the Project.

During said audit, Data Provider may choose one of the following options:

- Data Provider may request Data Recipient to provide information and written records from the Data Recipient linked to the audit object;
- Data Provider may request Data Recipient to provide an existent certificate issued by an independent expert.

The Data Provider shall notify any supplementary need for audit to Data Recipient. Data Recipient may provide a reply to this additional need. If it considers it appropriate, the Data Provider shall have the possibility to conduct on-site inspections at any time, during normal business hours, subject to a five (5) working days prior written notice with return receipt requested (mail, fax, e-mail) or outsource these inspections to a qualified third party.

All fees and expenses engaged by the Data Recipient or the Data Provider related to eventual audits of the Data Provider will be paid by the Data Provider. The Data Provider will reimburse the Data Recipient or its subcontractors duly appointed the hours spent working on the Data Provider audits in an appropriate way.

12.1.15 Data processing area

Data Recipient shall maintain Data processing operations in countries that are inside the EEA.

12.1.16 Subprocessors

The Data Recipient shall not subcontract any of its processing operations performed on behalf of the Data Provider without the prior written consent of the Data Provider. Where the Data Recipient subcontracts all or

part of the processing of data according to this Consortium Agreement, with the consent of the Data Provider, it shall do so only by way of a written agreement with the subprocessor which imposes at least the same obligations on the subprocessor as are imposed on the Data Recipient under this Consortium Agreement. Where the subprocessor fails to fulfill its data protection obligations under such written agreement the Data Recipient shall remain fully liable to the Data Provider for the performance of the subprocessor's obligations under such agreement.

12.2 Metagenomic Database

Parties shall negotiate a Data Sharing Agreement to provide guidance on the use of the Database including the following provisions:

- The access policy for the Parties, Affiliated entities to the Database
- The modalities for third parties to this Consortium Agreement to access Database
- The name of the Data Manager and its obligations
- The modalities to maintain the integrity of the dataset
- Constitution of a Data Access Board to evaluate the access to the Database
- Storage place for the Database and modalities to keep copies on remote storage
- The legal framework

No data transfer form shall be signed before the subscription of said Data Sharing Agreement.

It is expressly understood that each Party contributing to the Database with its Data and/or Material being analyzed in the Project, shall receive the data/metadata issued from the analysis of its own Data/Material and shall be granted a worldwide, non-exclusive, royalty-free and perpetual license to use this data/metadata for its academic research, publications and teaching purposes subject to compliance with applicable Law to the Data and according the modalities planned in the Data Sharing Agreement.

13. Section: Miscellaneous

13.1. Attachments, inconsistencies and severability

This Consortium Agreement consists of this core text and
Attachment A (Consortium Plan)
Attachment B (Accession form)
Attachment C (Background included)
Attachment D (Affiliated Entities)
Attachment E (Data transfer form)
Attachment F (Material transfer form)
Attachment G (Composition of the Consortium Bodies)
Attachment H (Data Protection Officers)
Attachment I (Confidential Disclosure Agreement form)
Attachment J (Request form for Collaborative Platform (Access Right or Account suppression))

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

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

13.2. 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.

13.3. Notices and other communication

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

Formal notices:

If it is required in this Consortium Agreement that a formal notice, consent or approval shall be given, such notice shall be signed by an authorized representative of a Party and shall either be served personally or sent by mail with recorded delivery.

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

13.4. 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 approval shall not be unreasonably withheld. Amendments and modifications to the text of this Consortium Agreement require a separate written agreement to be signed between all Parties.

13.5. 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.

13.6. Language

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

13.7. Applicable law

This Consortium Agreement shall be construed in accordance with and governed by Belgian Law excluding its conflict of law provisions.

13.8. Settlement of disputes

The Parties shall endeavor to settle their disputes amicably.

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

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

13.9. Ethical Commitments

The Parties commit to respect the general principles and rules set by the European Convention for the Protection of Human Rights and Fundamental Freedoms, the directives and recommendations of the International Labour Office (particularly with regard to child protection) and all applicable laws and regulations relating to the protection of the environment, to the extent these provisions are applicable to this Consortium Agreement.

14. Section: Signatures

AS WITNESS:

The Parties have caused this Consortium Agreement to be duly signed by the undersigned authorized representatives in separate signature pages the day and year first written above.

(Signature pages follow)

Gustave Roussy

Date:

████████████████████
████████████████

Insert

Date:

Università Degli Studi Di Trento

Date:

[Redacted]
[Redacted]

FONDAZIONE IRCCS ISTITUTO NAZIONALE DEI TUMORI (INT)

Date:

██████████
██████████

MASARYKOVA UNIVERZITA

Date:

[Redacted]
[Redacted]

EVERIMMUNE

Date:

[Redacted]
[Redacted]

ALGOE

Date:

██████████
██████

UNIVERSITÄTSKLINIKUM ERLANGEN

Date:

Name : [REDACTED]

Title: [REDACTED]

STICHTING KATHOLIEKE UNIVERSITEIT doing bussiness as Radboud university medical center

Date:

[Redacted]
[Redacted]

Date:

[Redacted]
[Redacted]

Date:

[Redacted]
[Redacted]

THE CHANCELLOR MASTERS AND SCHOLARS OF THE UNIVERSITY OF CAMBRIDGE

Date:

Name:

Title:

Research Operations Office

KAROLINSKA INSTITUTET

Date:

[Redacted]

[Redacted]

[Redacted]

[Redacted]

Date:

[Redacted]

[Redacted]

I acknowledge that I have read and agree to be bound by the above terms and conditions and I undertake to ensure that all personnel working in the Project will be aware of and accept all terms and conditions of this agreement.

Date:

[Redacted]

[Redacted]

[Redacted]

UNICANCER

Date:

[Redacted]
[Redacted]

Date:

[Redacted]
[Redacted]

CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL (CHUM)

Date:

[Redacted]
[Redacted]
[Redacted]

Date:

[Redacted]
[Redacted]

CHARITE - UNIVERSITAETSMEDIZIN BERLIN

Date:

[Redacted]
[Redacted]

Date:

[Redacted]
[Redacted]

GBG FORSCHUNGS GMBH

Date:

██████████
██

HALIODX

Date:

[Redacted]
[Redacted]

Attachment A:

Consortium Plan

Attachment B: Accession form

ACCESSION

of a new Party to

ONCOBIOME Consortium Agreement, signed [..., YYYY-MM-DD]

[OFFICIAL NAME OF THE NEW PARTY]

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

INSTITUT GUSTAVE ROUSSY

hereby certifies that the consortium has accepted in the Board of Directors meeting held on [date] and in accordance with the procedures provided by the Consortium Agreement, 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]

INSTITUT GUSTAVE ROUSSY

Signature(s)

Name(s)

Title(s)

Attachment C: Background included

INSTITUT GUSTAVE ROUSSY

Background type	Background	Co-Owner of the Background	Restriction to the use of your Background	Related WP
[REDACTED]				
[REDACTED]				
[REDACTED]				
[REDACTED]				
[REDACTED]				
[REDACTED]				

INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE

Background	Owner of the Background	Restriction to the use of your Background	Related WP

UNIVERSITA DEGLI STUDI DI TRENTO

Background	Owner of the Background	Restriction to the use of your Background	Related WP
[REDACTED]			

FONDAZIONE IRCCS ISTITUTO NAZIONALE DEI TUMORI

Background	Owner of the Background	Restriction to the use of your Background	Related WP
[REDACTED]			

MASARYKOVA UNIVERZITA

Background	Owner of the Background	Restriction to the use of your Background	Related WP

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UNIVERSITÄTSKLINIKUM ERLANGEN

Background	Owner of the Background	Restriction to the use of your Background	Related WP

STICHTING KATHOLIEKE UNIVERSITEIT doing business as the Radboud university medical center

Background	Owner of the Background	Restriction to the use of your Background	Related WP

IIGM FOUNDATION

Background	Owner of the Background	Restriction to the use of your Background	Related WP

THE CHANCELLOR MASTERS AND SCHOLARS OF THE UNIVERSITY OF CAMBRIDGE

Background	Owner of the Background	Restriction to the use of your Background	Related WP

KAROLINSKA INSTITUTET

Background	Owner of the Background	Restriction to the use of your Background	Related WP

CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL

Background	Owner of the Background	Restriction to the use of your Background	Related WP

--	--	--	--	--

UNICANCER

Background	Owner of the Background	Restriction to the use of your Background	Related WP

CHARITE - UNIVERSITAETSMEDIZIN BERLIN

Background	Owner of the Background	Restriction to the use of your Background	Related WP

GBG FORSCHUNGS GMBH

Background	Owner of the Background	Restriction to the use of your Background	Related WP

HALIODX

Background	Owner of the Background	Restriction to the use of your Background	Related WP

EVERIMMUNE

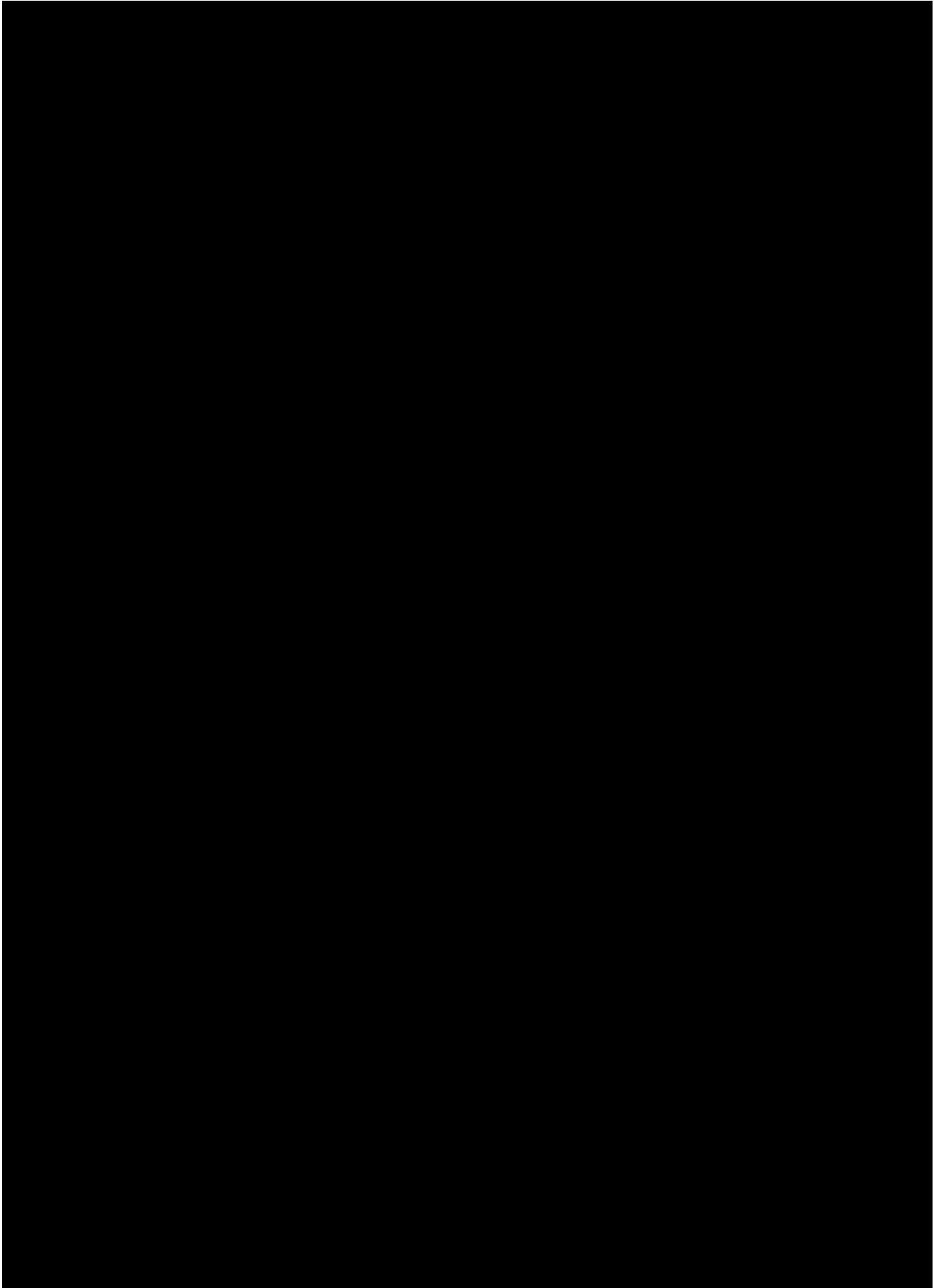
Background	Owner of the Background	Restriction to the use of your Background	Related WP

ALGOE

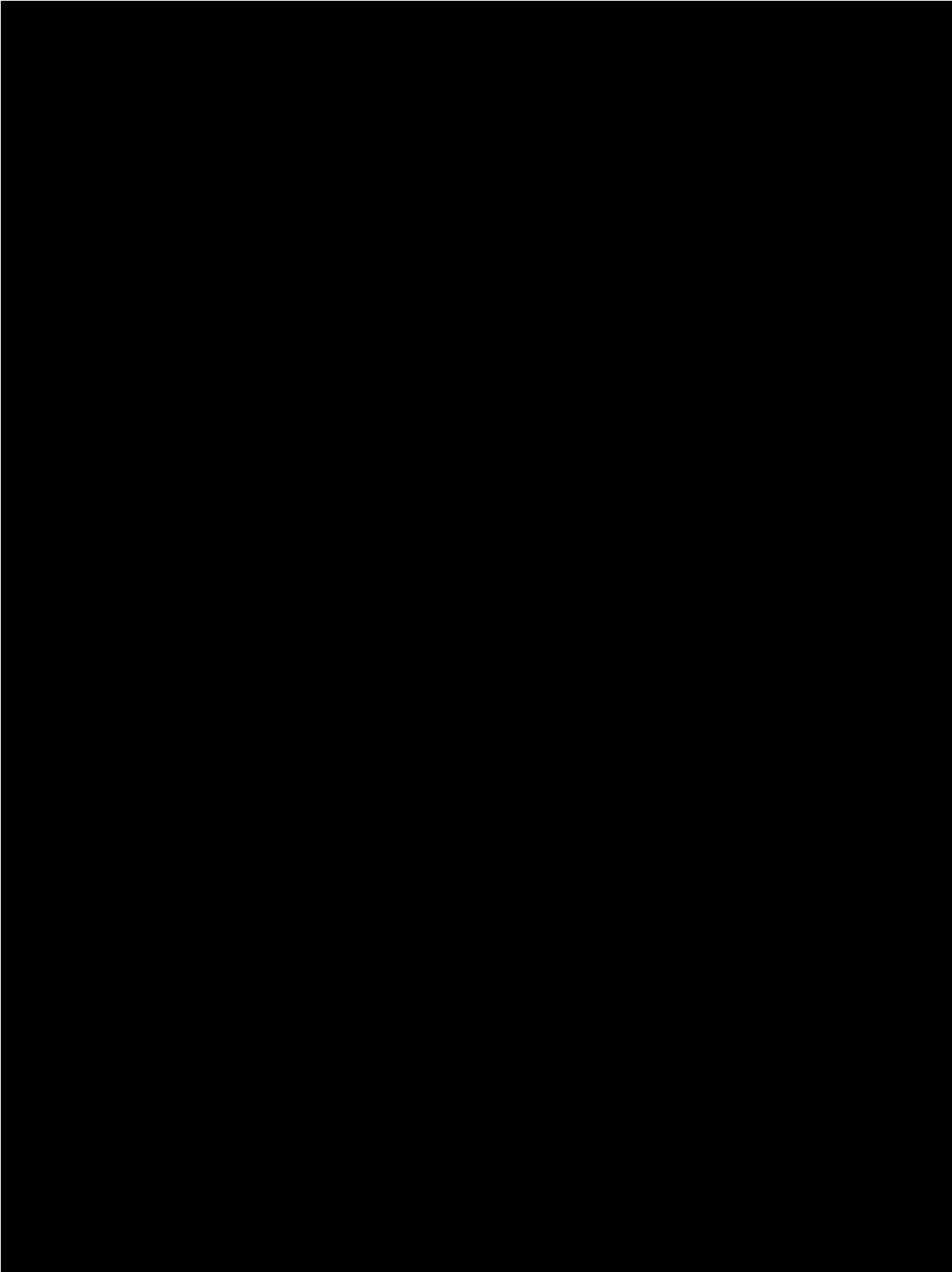
Background	Owner of the Background	Restriction to the use of your Background	Related WP

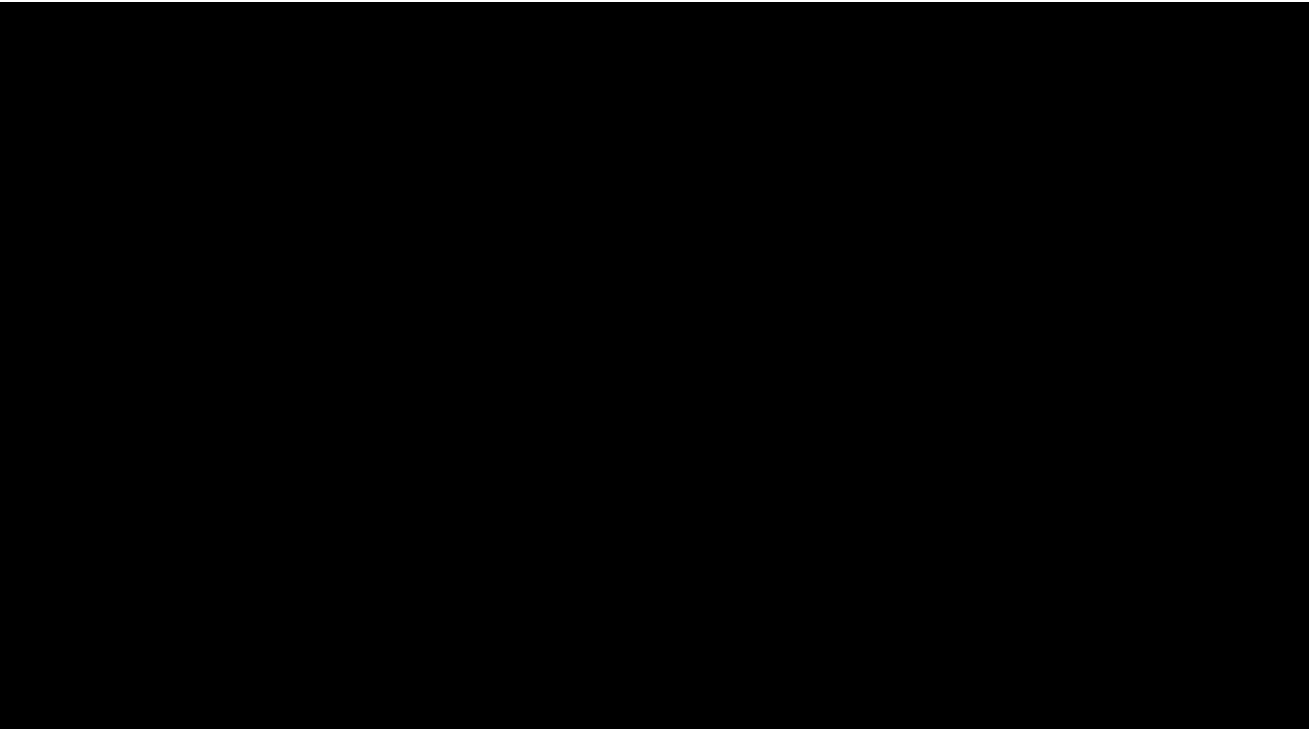


Attachment D: Listed Affiliated Entities

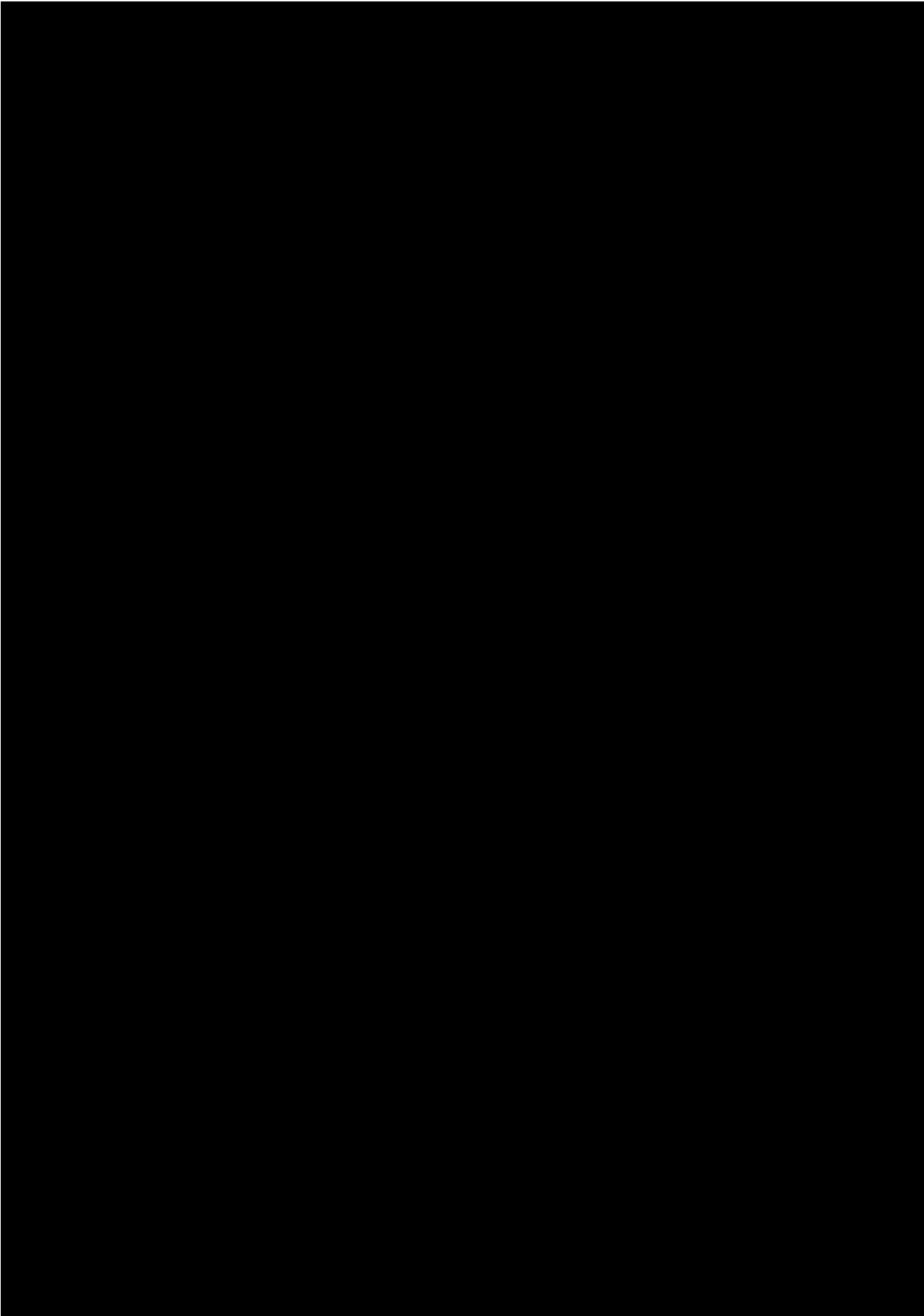


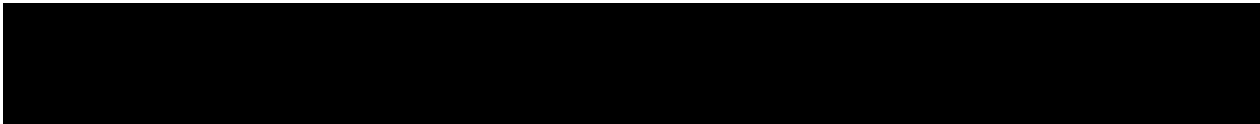
Attachment E: Data transfer form





Attachment F: Material transfer form







Attachment G: Composition of the Consortium Bodies

Coordination

Coordinator		
Project Coordinator		
Technical Manager		
Administrative Manager		

General Assembly representatives

Gustave Roussy	
Inserm	
UNITN	
INT	
MU	
UKER	
RU	
IIGM	
UCAM	
KI	
CHUM	
Unicancer	
Charité	
GBG	
HalioDx	
Everimmune	
Algoé	

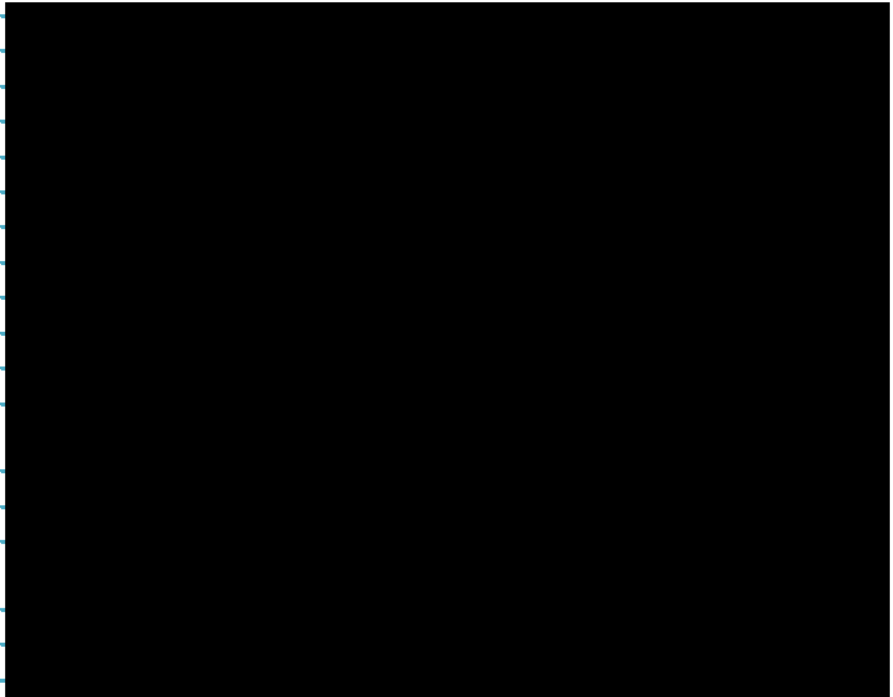
Board of Directors representatives

Gustave Roussy	
Inserm	
UNITN	
INT	
MU	
UKER	
RU	
IIGM	
UCAM	
KI	
CHUM	
Unicancer	
Charité	
GBG	
HalioDx	
Everimmune	

Algoé

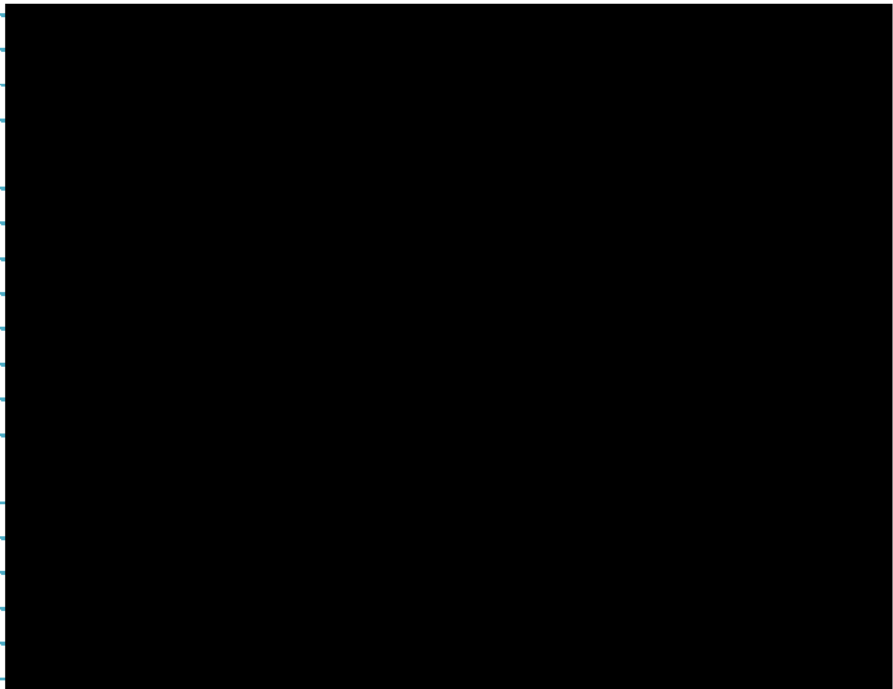
Steering Committee representatives

Gustave Roussy
Inserm
UNITN
INT
MU
UKER
RU
IIGM
UCAM
KI
CHUM
Unicancer
Charité
GBG
HalioDx
Everimmune
Algoé



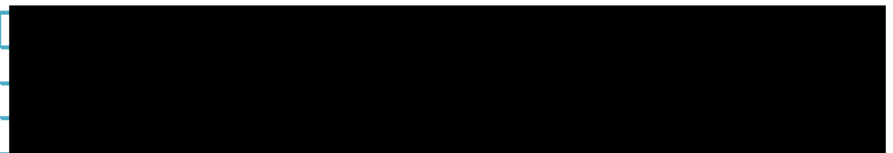
Valorization Committee

Gustave Roussy
Inserm
UNITN
INT
MU
UKER
RU
IIGM
UCAM
KI
CHUM
Unicancer
Charité
GBG
HalioDx
Everimmune
Algoé



WP Leader

WP1
WP2
WP3
WP4



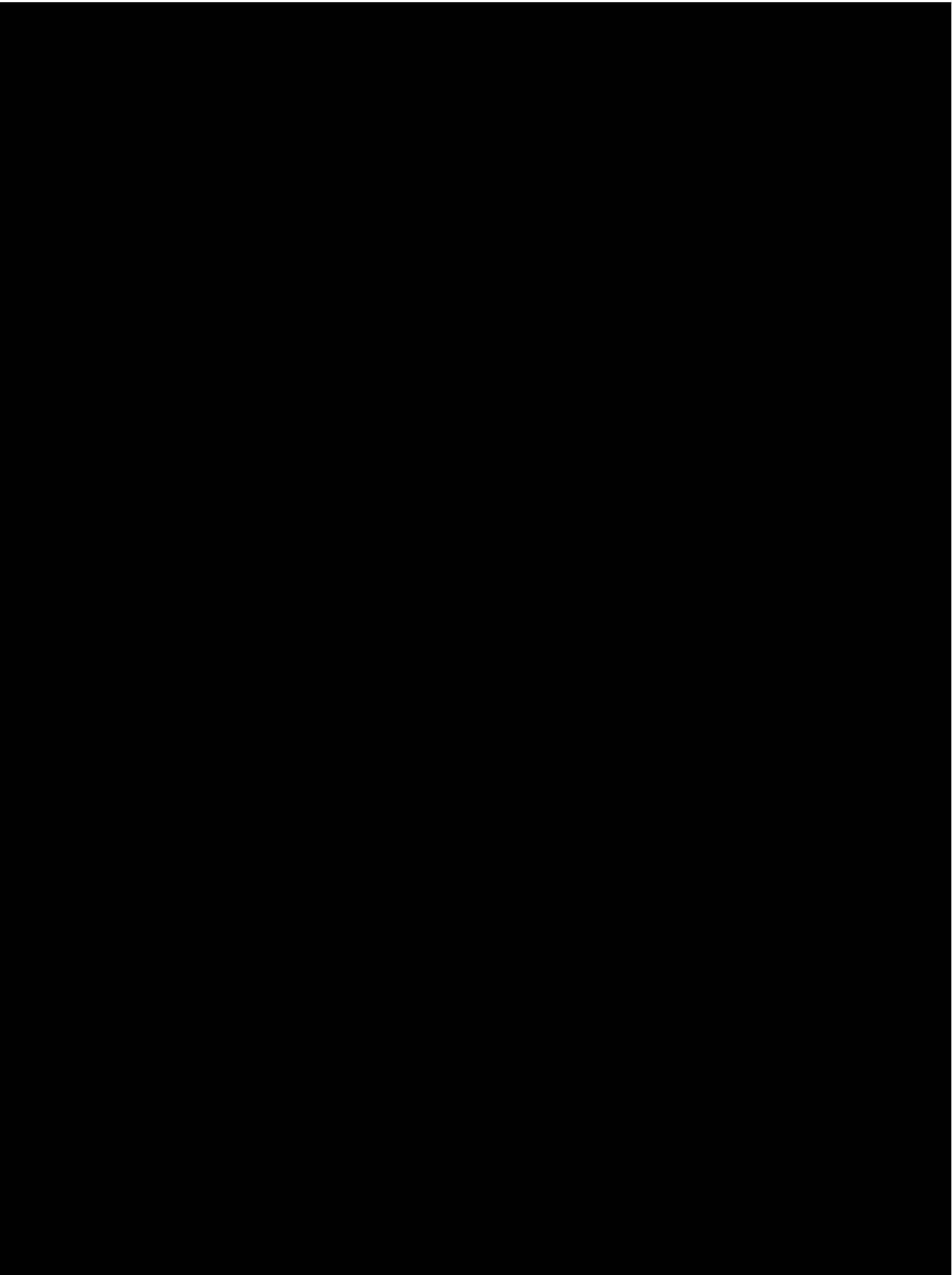
WP5	
WP6	
WP7	
WP8	

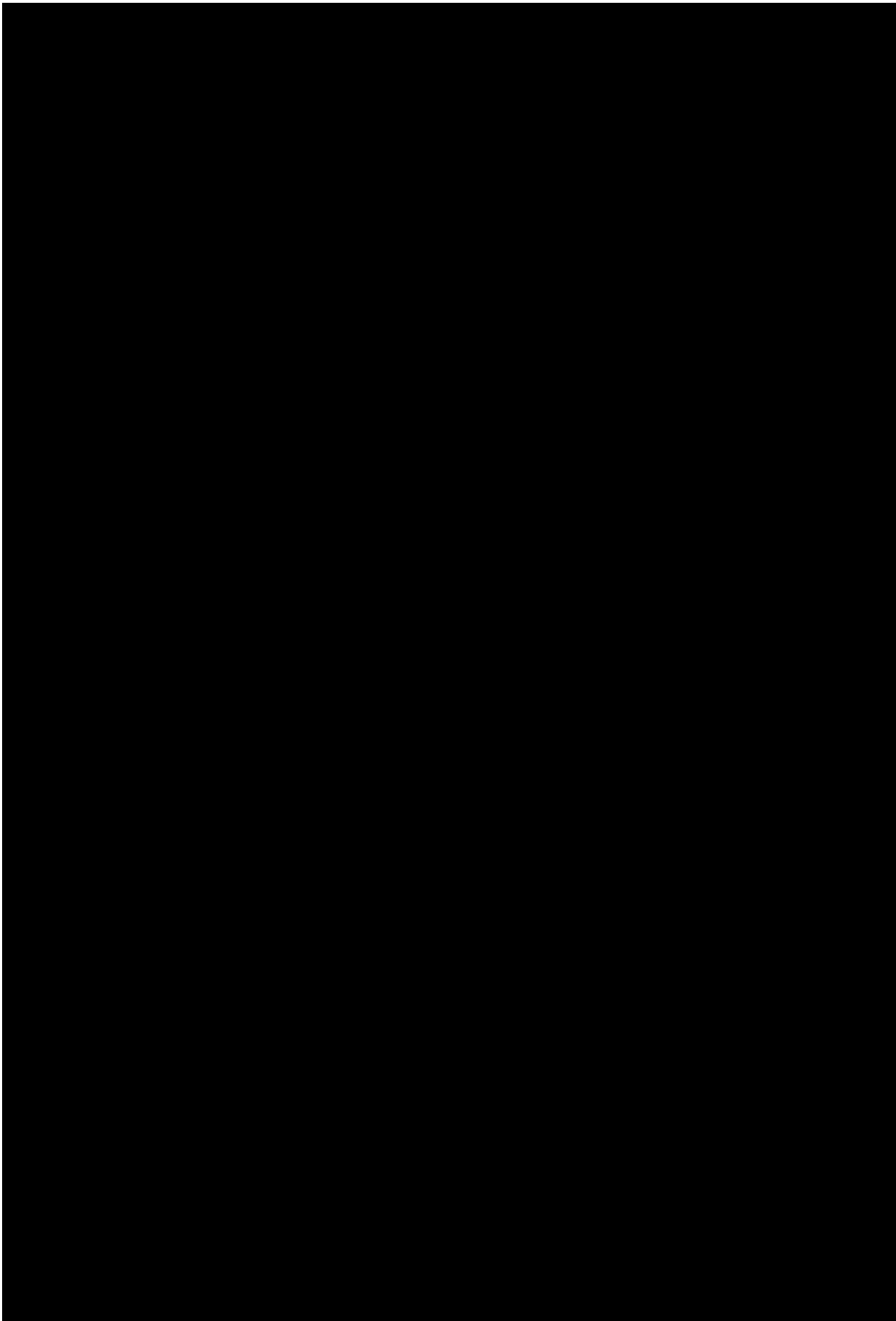
Attachment H: Data Protection Officers

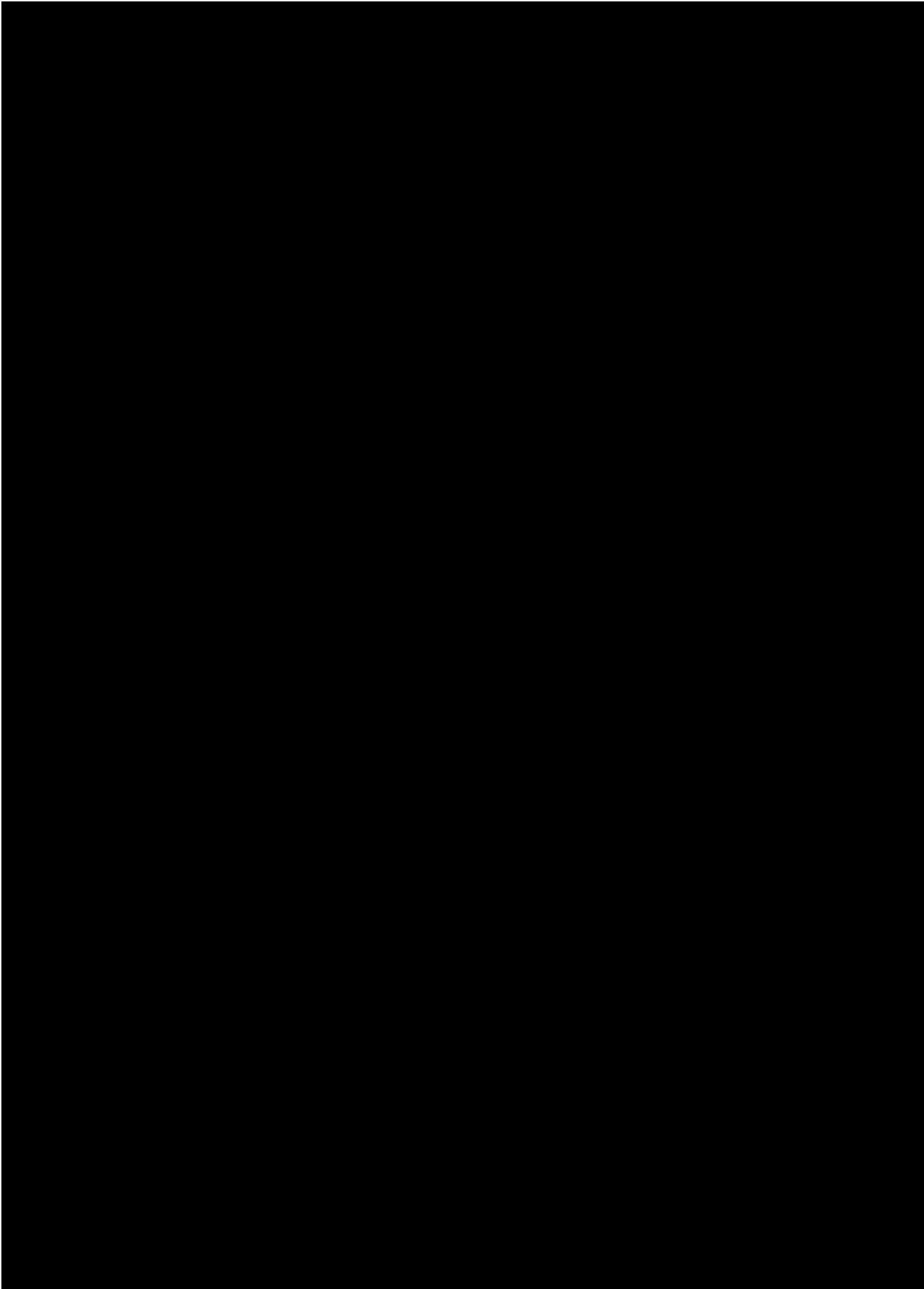
Data Protection Officers

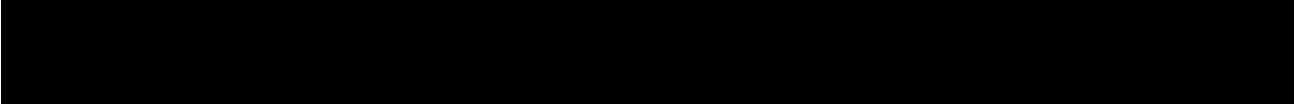
Gustave Roussy	
Inserm	
UNITN	
INT	
MU	
UKER	
RU	
IIGM	
UCAM	
KI	
CHUM	
Unicancer	
Charité	
GBG	
HalioDx	
Everimmune	
Algoé	

Attachment I: Confidential Disclosure Agreement Form









EXECUTED as of the Effective Date.

Gustave Roussy

XXX

By: _____

By: _____

Name: [Redacted]

Name:

Title: [Redacted]

Title:

Attachment J: Request form for Access Right to the Collaborative Platform used in the framework of ONCOBIOME

This form must be completed for any creation of a new account or suppression of an existing account to the Collaborative Platform. It must be signed by the Scientific leader of each requesting Beneficiary and submitted to the Coordinator for approval.

After approval, the signed Form must be submitted at least 48 hours in advance by mail to the Administrative Manager (Algoé) to the following representatives:

- [REDACTED]
- (in copy) [REDACTED]

I, undersigned [Title, Name of the Beneficiary's head, function], request by this Form (choose between the 2 options):

- the creation of Access Rights to the following staff members:

Full Name	Function	Mail	Access Right Activation date

- the deletion of Access Rights to the following staff members:

Full Name	Function	Mail	Effective date of Access deletion

Important: It is the responsibility of each Scientific Leader to inform the Administrative Manager about any staff member departure in order to accordingly cut off access to the information contained in the Collaborative Platform.

Date
Full Name
Function
Signature