

Consortium Agreement



IHEN

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

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CONSORTIUM AGREEMENT

THIS CONSORTIUM AGREEMENT is based upon Regulation (EU) No 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation (2021-2027), laying down its rules for participation and dissemination (hereinafter referred to as “Horizon Europe Regulation”), and on the European Commission’s General Model Grant Agreement and its Annexes, and is made on 1 December 2023, hereinafter referred to as the Effective Date

BETWEEN:

Fundación Privada Instituto de Salud Global Barcelona (ISGlobal), with legal address at C/ Rosselló, 132, 5º 2ª, 08036, Barcelona, Spain

ISGlobal hereinafter referred to as the “Coordinator”.

Universiteit Utrecht (UU), with legal address at Heidelberglaan 8, Utrecht, the Netherlands, for the benefit of the department of Population Health Sciences of the Faculty of Veterinary Medicine.

UU hereafter referred as “co-coordinator”. ISGlobal and UU hereafter referred to as the “Coordination team”

Masarykova Univerzita (MU) with legal address at Zerotinovo namesti 9, 601 77, Brno, Czechia.

Institut National de la Santé et de la Recherche Médicale (INSERM) a public scientific and technological institute having its registered office at 101 rue de Tolbiac, 75654, PARIS, FRANCE, represented by its Chairman and Chief Executive Officer, Mr Didier SAMUEL, having delegated his signing authority for this agreement to the Regional Delegate of Paris IDF Centre Nord delegation, Mrs Claire DE MARGUERIE.

Academisch Ziekenhuis Groningen (UMCG) with legal address at Hanzeplein 1, Groningen 9713 GZ, the Netherlands.

Centre International de Recherche sur le Cancer (IARC) PIC 999520496, with legal address 25 Avenue Tony Garnier, CS 90627, 69366 Lyon Cedex 07, France.

Technologiko Panepistimio Kyprou (CUT) with legal address at Archiepiskopou Kyprianou 23, 3039, Limassol, Cyprus.

Oulun Yliopisto (OULU) with legal address Pentti Kaiteran Katu 1, 90014 OULU, Finland.

Health and Environment Alliance (HEAL) with legal address at RUE DE LA CHARITE 22, SAINT-JOSSE-TEN-NOODE, 1210 Brussels, Belgium.

Agence Nationale de Sécurité Sanitaire de l’Alimentation, de l’Environnement et du Travail (ANSES) with legal address at 14 rue Pierre et Marie Curie 94700 Maisons-Alfort, France.

Health and Environment Response Agency (HERA) with legal address Achrafieh Alfred Naccache Blvd. Facing Hôtel Dieu de France Hospital Achrafieh - Beirut BP. 1100.

ARISTOTELIO PANEPISTIMIO THESSALONIKIS (APTH) - ARISTOTLE UNIVERSITY OF THESSALONIKI (AUTH) with legal address at Tritis Septemvriou, Ktirio KEDEA, Aristotle University Campus, 54636, Thessaloniki, Greece.

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

relating to the Action entitled

INTERNATIONAL HUMAN EXPOSOME NETWORK

in short

IHEN

hereinafter referred to as "Project"

WHEREAS:

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

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

The Parties are aware that this Consortium Agreement is based upon the [DESCA model consortium agreement](#).

NOW, THEREFORE, IT IS HEREBY AGREED AS FOLLOWS:

1 Definitions

1.1 Definitions

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

1.2 Additional Definitions

"Consortium Body"

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

"Consortium Plan"

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

"Granting Authority"

means the body awarding the grant for the Project.

“Defaulting Party”

Defaulting Party means a Party which the General Assembly has identified to be in breach of this Consortium Agreement and/or the Grant Agreement as specified in Section 4.2 of this Consortium Agreement.

“Needed”

means:

For the implementation of the Project:

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

For Exploitation of own Results:

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

“Software”

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

2 Purpose

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

3 Entry into force, duration and termination

3.1 Entry into force

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

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

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

3.2 Duration and termination

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

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

If

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

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

3.3 Survival of rights and obligations

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

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

4 Responsibilities of Parties

4.1 General principles

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

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

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

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

4.2 Breach

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

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

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 other Participants) in the Project remains responsible for carrying out its relevant part of the Project and for such third party's compliance with the provisions of this Consortium Agreement and of the Grant Agreement. Such Party has to ensure that the involvement of third parties does not affect the rights and obligations of the other Parties under this Consortium Agreement and the Grant Agreement.

4.4 Specific responsibilities regarding data protection

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

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

5 Liability towards each other

5.1 No warranties

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

Therefore,

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

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-.

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

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

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 it is prevented from fulfilling its obligations under the Consortium Agreement by Force Majeure.

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

6 Governance structure

6.1 General structure

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

- The General Assembly as the ultimate decision-making body of the consortium
- The Executive Board as the supervisory body for the execution of the Project, which shall report to and be accountable to the General Assembly
- The Coordinator as the legal entities acting as the intermediary between the Parties and the Granting Authority. The Coordinator shall, in addition to its responsibilities as a Party, perform the tasks assigned to it as described in the Grant Agreement and this Consortium Agreement. For the avoidance of doubt, ISGlobal is the Coordinator of the Project and UU the co-coordinator.

6.2 General operational procedures for all Consortium Bodies

6.2.1 Representation in meetings

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

Any Member:

- should be present or represented at any meeting;
- may appoint a substitute or a proxy to attend and vote at any meeting;

and shall participate in a cooperative manner in the meetings.

6.2.2 Preparation and 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	At least once a year	At any time upon request of the Executive Board or 1/3 of the Members of the General Assembly
Executive Board	At least quarterly	At any time upon request of any Member of the Executive Board

6.2.2.2 Notice of a meeting

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

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

6.2.2.3 Sending the agenda

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

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

6.2.2.4 Adding agenda items:

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

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

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

6.2.2.5

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

6.2.2.6

Meetings of each Consortium Body may also be held by tele- or videoconference, or other telecommunication means.

6.2.2.7

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

6.2.2.8

Decisions without a meeting

Any decision may also be taken without a meeting if

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

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

A veto according to Section 6.2.4 may be submitted up to 15 calendar days after receipt of this information.

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

6.2.3 Voting rules and quorum

6.2.3.1

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

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

6.2.3.2

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

6.2.3.3

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

6.2.3.4

Decisions shall be taken by a majority of two-thirds (2/3) of the votes cast.

6.2.4 Veto rights

6.2.4.1

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

6.2.4.2

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

6.2.4.3

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

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

6.2.4.4

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

6.2.4.5

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

6.2.4.6

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

6.2.4.7

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

6.2.5 Minutes of meetings

6.2.5.1

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

6.2.5.2

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

6.2.5.3

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

6.3 Specific operational procedures for the Consortium Bodies

6.3.1 General Assembly

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

6.3.1.1 Members

6.3.1.1.1

The General Assembly shall consist of one representative of each Party (hereinafter General Assembly Member).

6.3.1.1.2

Each General Assembly Member shall be deemed to be duly authorized to deliberate, negotiate and decide on all matters listed in Section 6.3.1.2. of this Consortium Agreement. Members of the General Assembly who are not normally authorized to address some or all of the matters listed below without receiving a mandate of decision-making and advice from their institution, shall ensure that they consult with their institution's legal office or representatives prior to participating in any vote, upon receiving the meeting agenda.

6.3.1.1.3

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

6.3.1.1.4

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

6.3.1.2 Decisions

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

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

The following decisions shall be taken by the General Assembly:

Content, finances and intellectual property rights

- Proposals for changes to Annexes 1 and 2 of the Grant Agreement to be agreed by the Granting Authority
- Changes to the Consortium Plan
- Modifications or withdrawal of Background in Attachment 1 (Background Included)
- Additions to Attachment 3 (List of Third Parties for simplified transfer according to Section 8.3.2)
- Additions to Attachment 4 (Identified entities under the same control)

Evolution of the consortium

- Entry of a new Party to the Project and approval of the settlement on the conditions of the accession of such a new Party
- Withdrawal of a Party from the Project and the approval of the settlement on the conditions of the withdrawal
- Identification of a breach by a Party of its obligations under this Consortium Agreement or the Grant Agreement
- Declaration of a Party to be a Defaulting Party
- Remedies to be performed by a Defaulting Party
- Termination of a Defaulting Party's participation in the Project and measures relating thereto
- Proposal to the Granting Authority for a change of the Coordinator
- Proposal to the Granting Authority for suspension of all or part of the Project
- Proposal to the Granting Authority for termination of the Project and the Consortium Agreement

Appointments

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

- Executive Board Members
- International Board Members

6.3.2 Executive Board

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

6.3.2.1 Members

The Executive Board shall consist of the Coordinator, co-coordinator and the Work Package Leaders and Co-Leaders.

The Coordination team shall chair all meetings of the Executive Board, unless decided otherwise by a majority of two-thirds.

6.3.2.2 Minutes of meetings

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

6.3.2.3 Tasks

6.3.2.3.1

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

6.3.2.3.2

The Executive Board shall seek a consensus among the Parties.

6.3.2.3.3

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

6.3.2.3.4

The Executive Board shall monitor the effective and efficient implementation of the Project.

6.3.2.3.5

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

6.3.2.3.6

The Executive Board shall:

- support the Coordinator in preparing meetings with the Granting Authority and in preparing related data and deliverables
- prepare the content and timing of press releases and joint publications by the consortium or proposed by the Granting Authority in respect of the procedures of the Grant Agreement Article 17 and Annex 5 Section “Communication, Dissemination, Open Science and Visibility” and of Section 8 of this Consortium Agreement.

6.3.2.3.7

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

6.4 Coordinator

6.4.1

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

6.4.2

In particular, the Coordinator shall be responsible for:

- monitoring compliance by the Parties with their obligations under this Consortium Agreement and the Grant Agreement
- keeping the address list of Members and other contact persons updated and available
- collecting, reviewing to verify consistency and submitting reports, other deliverables (including financial statements and related certifications) and specific requested documents to the Granting Authority
- transmitting documents and information connected with the Project to any other Parties concerned
- administering the financial contribution of the Granting Authority and fulfilling the financial tasks described in Section 7.2
- providing, upon request, the Parties with official copies or originals of documents that are in the sole possession of the Coordinator when such copies or originals are necessary for the Parties to present claims.

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

6.4.3

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

6.4.4

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

6.4.5

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

6.5 International Board (IB)

An International Board (IB) will be appointed by the General Assembly and steered by the Executive Board. The IB shall assist and facilitate the decisions made by the General Assembly.

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

By way of exception to Section 6.4.4 above, the Parties mandate the Coordinator to execute, in their name and on their behalf, a non-disclosure agreement (hereafter "NDA") with each member of the IB, in order to protect Confidential Information disclosed by any of the Parties to any member of the IB, either directly or through the Coordinator in the case where the concerned Party gave to the Coordinator its prior written approval for such disclosure.

Its terms shall be not less stringent than those stipulated in this Consortium Agreement, and it shall be concluded no later than 30 calendar days after their nomination or before any confidential information will be exchanged/disclosed, whichever date is earlier. The Coordinator shall write the minutes of the IB meetings and submit them to the General Assembly. The IB members shall be allowed to participate in General Assembly meetings upon invitation but have not any voting rights.

7 Financial provisions

7.1 General Principles

7.1.1 Distribution of Financial Contribution

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

- the Consortium Plan
- the approval of reports by the Granting Authority, and
- the provisions of payment in Section 7.2.

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

7.1.2 Justifying Costs

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

7.1.3 Funding Principles

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

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

7.1.4 Excess payments

A Party has received excess payment

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

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

Amounts which are not refunded by a breaching Party and which are not due to the Granting Authority, shall be apportioned by the Coordinator to the remaining Parties pro rata according to their share of total costs of the Project as identified in the Consortium Budget, until recovery from the breaching Party is possible.

7.1.5 Revenue

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

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

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

In addition, a Defaulting Party shall, within the limits specified in Section 5.2 of this Consortium Agreement, bear any reasonable and justifiable additional costs occurring to the other Parties in order to perform the leaving Party's task and necessary additional efforts to fulfil them as a consequence of the Party leaving the consortium. The General Assembly should agree on a procedure regarding additional costs which are not covered by the Defaulting Party or the Mutual Insurance Mechanism.

7.2 Payments

7.2.1 Payments to Parties are the exclusive task of the Coordinator.

In particular, the Coordinator shall:

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

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

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

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

7.2.2

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

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

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

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

8 Results

8.1 Ownership of Results

Results are owned by the Party that generates them.

8.2 Joint ownership

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

Two or more Parties own Results jointly if:

- they have jointly generated them; and
- it is not possible to: (i) establish the respective contribution of each Party; or (ii) separate them for the purpose of applying for, obtaining, or maintaining their protection.

Unless otherwise agreed:

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

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

8.3 Transfer of Results

8.3.1

Each Party may transfer ownership of its own Results, including its share in jointly owned Results, following the procedures of the Grant Agreement Article 16.4 and its Annex 5, Section Transfer and licensing of results, sub-section "Transfer of ownership".

8.3.2

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

8.3.3

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

8.3.4

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

8.3.5

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

8.4 Dissemination

8.4.1

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

8.4.2 Dissemination of own (including jointly owned) Results

8.4.2.1

During the Project and for a period of 1 year after the end of the Project, the dissemination of own Results by one or several Parties including but not restricted to publications and presentations, shall be governed by the procedure of Article 17.4 of the Grant Agreement and its Annex 5, Section Dissemination, subject to the following provisions.

Prior notice of any planned publication shall be given to the other Parties at least 45 calendar days before the publication. Any objection to the planned publication shall be made in accordance with the Grant Agreement by written notice to the Coordinator and to the Party or Parties proposing the

dissemination within 30 calendar days after receipt of the notice. If no objection is made within the time limit stated above, the publication is permitted.

8.4.2.2

An objection is justified if

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

The objection has to include a precise request for necessary modifications.

8.4.2.3

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

8.4.2.4

The objecting Party can request a publication delay of not more than 90 calendar days from the planned publication date. After 90 calendar days the publication is permitted, provided that the objections of the objecting Party have been addressed.

8.4.3 Dissemination of another Party's unpublished Results or Background

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

8.4.4 Cooperation obligations

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

8.4.5 Use of names, logos or trademarks

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

9 Access Rights

9.1 Background included

9.1.1

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

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

9.1.2

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

9.2 General Principles

9.2.1

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

9.2.2

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

9.2.3

Access Rights shall be free of any administrative transfer costs.

9.2.4

Access Rights are granted on a non-exclusive basis.

9.2.5

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

9.2.6

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

9.2.7

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

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, unless otherwise agreed for Background in Attachment 1.

9.4 Access Rights for Exploitation

9.4.1 Access Rights to Results

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

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

9.4.2

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

9.4.3

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

9.5 Access Rights for entities under the same control

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

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

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

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

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

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

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

9.6 Additional Access Rights

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

9.7 Access Rights for Parties entering or leaving the consortium

9.7.1 New Parties entering the consortium

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

9.7.2 Parties leaving the consortium

9.7.2.1 Access Rights granted to a leaving Party

9.7.2.1.1 Defaulting Party

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

9.7.2.1.2 Non-defaulting Party

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

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

9.7.2.2 Access Rights to be granted by any leaving Party

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

9.8 Specific Provisions for Access Rights to Software

For the avoidance of doubt, the general provisions for Access Rights provided for in this Section 9 are applicable also to Software.

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

10 Non-disclosure of information

10.1

All information in whatever form or mode of communication, which is disclosed by a Party (the "Disclosing Party") to any other Party (the "Recipient") in connection with the Project during its implementation and which has been explicitly marked as "confidential" at the time of disclosure, or when

disclosed orally has been identified as confidential at the time of disclosure and has been confirmed and designated in writing within 15 calendar days from oral disclosure at the latest as confidential information by the Disclosing Party, is “Confidential Information”.

10.2

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

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

10.3

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

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 Grant Agreement;
- the Confidential Information, at any time, was developed by the Recipient completely independently of any such disclosure by the Disclosing Party;
- the Confidential Information was already known to the Recipient prior to disclosure, or
- the Recipient is required to disclose the Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order, subject to the provision Section 10.7 hereunder.

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

10.7

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

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

11 Miscellaneous

11.1 Attachments, inconsistencies and severability

This Consortium Agreement consists of this core text and:

- Attachment 1 (Background included)
- Attachment 2 (Accession document)
- Attachment 3 (List of third parties for simplified transfer according to Section 8.3.2)
- Attachment 4 (Identified entities under the same control)

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

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

11.2 No representation, partnership or agency

Except as otherwise provided in Section 6.4.4, no Party shall be entitled to act or to make legally binding declarations on behalf of any other Party or of the consortium. Nothing in this Consortium Agreement shall be deemed to constitute a joint venture, agency, partnership, interest grouping or any other kind of formal business grouping or entity between the Parties.

11.3 Formal and written notices

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

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

Formal notices:

If it is required in this Consortium Agreement (Sections 4.2, 9.7.2.1.1, and 11.4) that a formal notice, consent or approval shall be given, such notice shall be signed by an authorised representative of a Party and shall either be served personally or sent by mail with recorded delivery with acknowledgement of receipt.

Written notice:

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

11.4 Assignment and amendments

Except as set out in Section 8.3, no rights or obligations of the Parties arising from this Consortium Agreement may be assigned or transferred, in whole or in part, to any third party without the other Parties' prior formal approval.

Amendments and modifications to the text of this Consortium Agreement require a separate written agreement to be signed between all Parties.

11.5 Mandatory national law

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

11.6 Language

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

11.7 Applicable law

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

11.8 Settlement of disputes

The Parties shall endeavour to settle their disputes amicably.

Any dispute, controversy or claim arising under, out of or relating to this contract and any subsequent amendments of this contract, including, without limitation, its formation, validity, binding effect, interpretation, performance, breach or termination, as well as non-contractual claims, shall be submitted to mediation in accordance with the WIPO Mediation Rules. The place of mediation shall be Brussels unless otherwise agreed upon. The language to be used in the mediation shall be English unless otherwise agreed upon.

If, and to the extent that, any such dispute, controversy or claim has not been settled pursuant to the mediation within 60 calendar days of the commencement of the mediation, the courts of Brussels shall have exclusive jurisdiction.

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

Notwithstanding the above, in the event of a dispute with IARC, the Parties agree that all disputes arising out of or in connection with this Consortium Agreement, which cannot be solved amicably or through mediation, shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with the said Rules. At least one of the arbitrators shall be legally educated. The arbitration proceedings shall take place virtually unless otherwise agreed. The language used in the arbitral proceedings shall be English. The Parties shall accept the arbitral award as final.

11.9 Special clauses pertaining to the involvement of IARC, as part of the World Health Organization (WHO)

With regard to IARC, as part of the World Health Organization (WHO) and the United Nations, the provisions contained in this Section 11.9 prevail over any other provisions in this Consortium Agreement (which includes its core text, its Attachments and any other document referred to therein), and will survive the expiration or early termination of this Consortium Agreement.

11.9.1 Audits: With regard to IARC, the "Agreement on the application of the verification clause to operations administered by the United Nations and financed or co-financed by the European Union" annexed to the "Financial and Administrative Framework Agreement" concluded by the Union, represented by the Commission, and the United Nations on 29.04.2003 (also referred to as the "FAFA" - to which WHO adhered on the 11.12.2003), as amended with effect from 01.01.2014, prevails over this Consortium Agreement with regard to any provisions dealing with the same issues.

11.9.2 Reference Law: Concerning IARC, any matter relating to the interpretation or application of this Consortium Agreement not covered by its terms shall be resolved by reference to the law of Belgium, supplemented, where appropriate, by the general principles governing the law of international organisations and the rules of general international law.

11.9.3. Privileges and Immunities -: Nothing in this Consortium Agreement shall be interpreted as a waiver of the privileges or immunities accorded to IARC, as part of WHO, by its constituent documents or international law. As such, IARC is not subject to any national or EU legislation, jurisdiction or enforcement measures.

11.9.4 Regulatory Framework: Notwithstanding anything to the contrary in this Consortium Agreement, all of IARC's actions, obligations, and undertakings within and for the purpose of the Project shall be conducted, pursuant to the terms of this Consortium Agreement, subject always to IARC/WHO's statute, regulations, rules, policies and procedures (the "IARC/WHO Regulatory Framework").

11.9.5 Administration of Funds: In line with the foregoing, funds received by IARC shall be administered in accordance with the Section 7 of this Consortium Agreement, Financial Regulations and Rules, and financial and administrative policies and procedures of IARC/WHO.

11.9.6 Data Protection: Where necessary and applicable, IARC shall ensure an appropriate protection of personal data in accordance with the IARC/WHO Regulatory Framework. Specifically, IARC complies with the Personal Data Protection and Privacy Principles for UN System Organizations, UN-HCLM 2018 (the "UN Principles"), the WHO Personal Data Protection Policy and the IARC Data Protection Policy.

11.10 General provisions

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

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

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

12 Signatures

AS WITNESS:

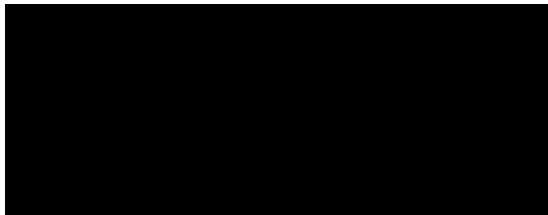
The Parties have caused this Consortium Agreement to be duly signed by the undersigned authorised representatives in separate signature pages the day and year first above written.

Fundación Privada Instituto de Salud Global Barcelona (ISGlobal)

Signature(s)

██████████

General Manager



Universiteit Utre

Signature(s)

[Redacted]

Operations Manag

Date November 21, 2023

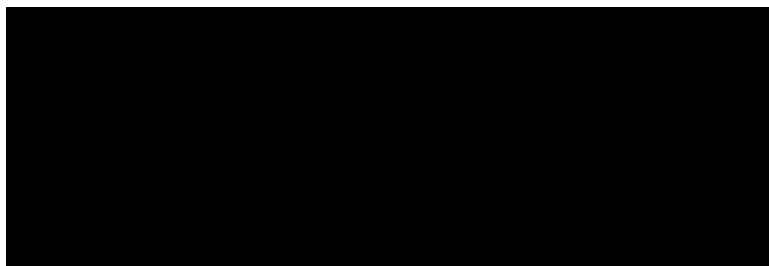
Masarykova Univerzita (MU)

Signature(s)

Name(s) 

Title(s) Director of Research Office

Date



Institut National de la Santé et de la Recherche Médicale (INSERM)

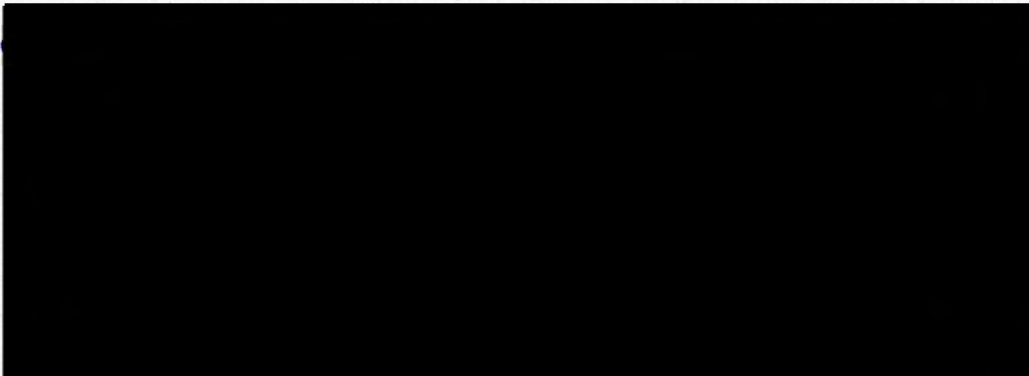
Signature:

Name:



Title: Regional Delegate of Paris IDF Centre Nord delegation

Date



University Medical Center Groningen (UMCG)


Signature(s)

Name(s)

Title Member of the Board of Directors

Date 22-11-2023

Centre International de Recherche sur le Cancer (IARC)

Signature(s) 



Director

Date





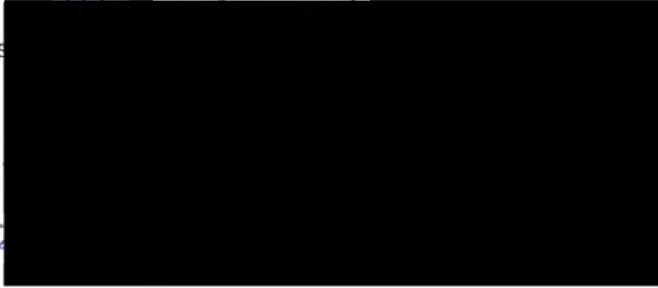
Technologiko Panepistimio Kyprou (CUT)

Signature(s)

Name(s)

Title(s)

Date

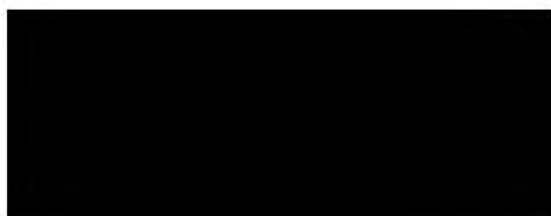


Oulun Yliopisto (OULU)



Dean

Date 22.11.2023



Research Funding Specialist

Date 21.11.2023

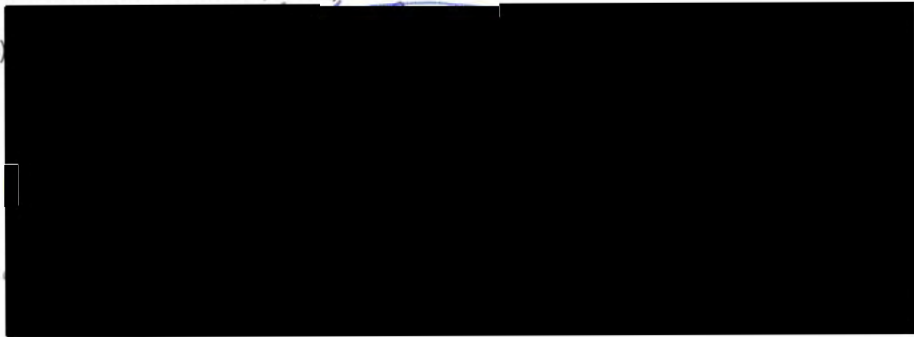
Health and Environment Alliance (HEAL)

Signature(s)

Name(s)

Title(s)

Date



**Agence Nationale de la Sécurité Sanitaire de l'Alimentation, de l'Environnement et du Travail
(ANSES)**

Signature(s)

Name(s) [REDACTED]

Title(s) Director General

Date [REDACTED]



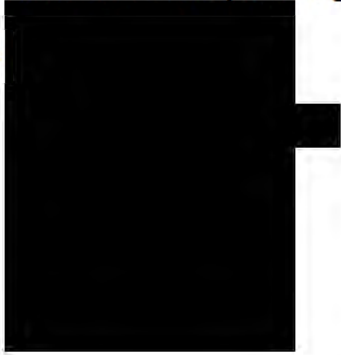
Health and Environment Response Agency (HERA)

Signature(s)

Name(s)

Title(s)

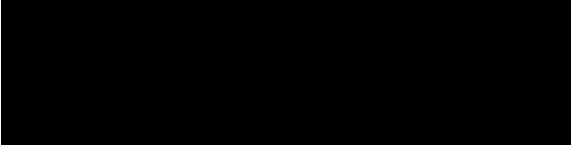
Date



**ARISTOTELIO PANEPISTIMIO THESSALONIKIS (APTH) - ARISTOTLE UNIVERSITY OF
THESSALONIKI (AUTH)Signature(s)**

Name(s) 

Title(s) Vice Rector for Research and Lifelong Learning

Date 

Attachment 1: Background included

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

As to **Fundación Privada Instituto de Salud Global Barcelona (ISGlobal)**, it is agreed between the Parties that, to the best of their knowledge, the following Background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

Describe Background	Specific limitations and/or conditions for implementation (Article 31.2 FPA)	Specific limitations and/or conditions for exploitation
<p>Data, know-how or information generated prior to the IHEN Project by ISGlobal researchers directly involved in the IHEN Project.</p>	<p>Access for implementation is only granted to the extent it is needed for the partners concerned to carry out their tasks in the Project and provided that ISGlobal is able to grant Access Rights to said Background including legal restrictions or limits, including those imposed by third parties. Access rights are subject to written request.</p> <p>All commercial and third party Software is excluded and no Access Rights are granted.</p>	<p>The Fundación Privada Instituto de Salud Global Barcelona (ISGlobal) hereby excludes from its obligation to grant “Access Rights to Background” all Background generated by ISGlobal other than that generated by the scientists or research group/s participating in the Consortium, furthermore, any Background generated by the participating scientists or research group/s which is not directly related to the present project. ISGlobal also considers excluded all Background derived from a non EU-project which ISGlobal due to third party rights is not able to grant access rights to.</p>

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

As to Universiteit Utrecht (UU) it is agreed between the Parties that, to the best of their knowledge,

No data, know-how or information of Universiteit Utrecht (UU) is Needed by another Party for implementation of the Project (Article 16.1 and its Annex 5 Grant Agreement, Section “Access rights to results and background”, sub-section “Access rights to background and results for implementing the action”) or Exploitation of that other Party’s Results (Article 16.1 and its Annex 5 Grant Agreement, Section “Access rights to results and background”, sub-section “Access rights for exploiting the results”).

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

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

Describe Background	Specific restrictions and/or conditions for implementation (Article 16.4 Grant Agreement and its Annex 5, Section “Access rights to results and background”, sub-section “Access rights to background and results for implementing the Action”)	Specific restrictions and/or conditions for Exploitation (Article 16.4 Grant Agreement and its Annex 5, Section “Access rights to results and background”, sub-section “Access rights for exploiting the results”)
<p>Raw high-resolution mass spectrometry datasets of cohort samples (Table 1) analysed via MU functional exposomics platform & associated generation protocols, mass spectral libraries and data processing workflows including identification procedures e.g., via suspect screening approaches; the analysis of newly acquired standards.</p>	<p>Relevant raw data and derived datasets will be made available for the implementation of ENDOMIX alongside capacities of the Biomarker Analytical Labs for spectral acquisition and/or data mining.</p> <p>Access to raw datasets is granted through the RECETOX research infrastructure of MU and, where relevant, third-party data (co)-owner(s).</p> <p>Open access to associated resources (i.e., derived datasets, mass spectra; generation protocols and data processing workflows etc.) is generally granted through the RECETOX research infrastructure of MU.</p>	<p>Raw data owners(s), derived dataset owner(s), and owners(s) of associated resources (i.e., mass spectra; generation protocols and data processing workflows etc.) have to be acknowledged.</p>
<p>Raw 16S rRNA sequencing datasets of cohort samples analyzed via RECETOX Research Infrastructure of MU 16S rRNA amplicon sequencing standard operation protocol and data processing bioinformatic pipeline.</p>	<p>Relevant raw data and derived datasets will be made available for the implementation of ENDOMIX alongside capacities of the Microbiome Labs for spectral acquisition and/or data mining.</p> <p>Access to raw datasets is granted through the RECETOX Research Infrastructure of MU and, where relevant, third-party data (co)-owner(s).</p>	<p>Raw data owners(s), derived dataset owner(s), and owners(s) of associated resources (i.e., sequencing data; generation protocols and data processing workflows etc.) have to be acknowledged.</p>

	Open access to associated resources (i.e., derived datasets, sequencing data; generation protocols and data processing workflows etc.) is generally granted through the RECETOX Research Infrastructure of MU.	
Methods for analysis of toxic metals, legacy and emerging pollutants in biotic and abiotic matrices, and effect directed analysis as well as capacities for these analyses in the accredited trace analytical facility.	Relevant methods will be made available for implementation of this project together with capacities of the accredited laboratories.	Accredited trace analytical laboratory is an open-access research facility listed in the Roadmap of Large Research Infrastructures in the Czech Republic. An access is a subject of approval of the Scientific Committee (within as well as outside this project).
Global Environmental Assessment and Information System (GENASIS, www.genasis.cz): Open access repository of (national and international) data on environmental and human exposure (3 mil. data points) including data analysis and presentation tools.	Open access to primary and/or aggregated data in the GENASIS system is generally granted through the RECETOX research infrastructure of MU (source/owner of data has to be acknowledged) unless specific cases when data is a subject to restrictions imposed by the rights of third parties (data owners).	GENASIS system serves as a long-term storage, presentation and reporting tool for multiple external users (including major global monitoring programmes) and can be used in this project as well as afterwards nationally and internationally (also for exporting available data in aggregated form into the GMP DWH).
Long-term air pollution data (particles, PAHs, POPs, emerging pollutants) collected from the Czech Republic (active continuously since 1988 in frames of EMEP, passive since 2003) and Europe (MONET and GAPS networks).	Open access to primary and/or aggregated data is generally granted through the RECETOX research infrastructure of MU and ACTRIS-CZ (source/owner of data has to be acknowledged).	Open access to primary and/or aggregated data is generally granted through the RECETOX research infrastructure of MU and ACTRIS-CZ (source/owner of data has to be acknowledged).
Laboratory training modules on the topic of sampling, analytical methods development, and analysis of	Open access the analytical methods available, instruments for analysis according the capacities of the Trace analytical laboratory.	Open access to the Trace analytical laboratory according of the capacity granted through the RECETOX research infrastructure of MU.

environmental samples at the customer's request.		
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This represents the status at the time of signature of this Consortium Agreement.

As to Institut National de la Santé et de la Recherche Médicale (INSERM) it is agreed between the Parties that, to the best of their knowledge,

No data, know-how or information of Institut National de la Santé et de la Recherche Médicale (INSERM) is Needed by another Party for implementation of the Project (Article 16.1 and its Annex 5 Grant Agreement, Section "Access rights to results and background", sub-section "Access rights to background and results for implementing the action") or Exploitation of that other Party's Results (Article 16.1 and its Annex 5 Grant Agreement, Section "Access rights to results and background", sub-section "Access rights for exploiting the results").

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

As to **University Medical Center Groningen**, it is agreed between the Parties that, to the best of their knowledge, UMCG contributes MOLGENIS software as background, and there is no legal restriction to the use of this background, because LGPLv3 is a permissive open source. This represents the status at the time of signature of this Consortium Agreement.

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

As to Centre International de Recherche sur le Cancer (IARC) it is agreed between the Parties that, to the best of their knowledge, the following Background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

Describe Background	Specific restrictions and/or conditions for implementation (Article 16.4 Grant Agreement and its Annex 5, Section "Access rights to results and background", sub-section "Access rights to background and results for implementing the Action")	Specific restrictions and/or conditions for Exploitation (Article 16.4 Grant Agreement and its Annex 5, Section "Access rights to results and background", sub-section "Access rights for exploiting the results")
Other data, materials, know-how, expertise, techniques and methods, and any other Background of IARC (or under the custody of IARC) that may be necessary for the implementation of the PROJECT.	Access Rights will be granted to the extent IARC's Background is Needed for implementation of the PROJECT, and to the extent that such Background is not subject to existing contractual obligations that may hinder or prohibit the envisaged Access Rights. IARC's Background will be made available for the purpose of non-commercial research/academic activities within the PROJECT, subject to any specific terms and conditions that may be applicable through separate agreements.	Any other use or commercial exploitation of IARC's Background will be subject to a separate agreement to be negotiated in good faith with IARC.

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

As to Technologiko Panepistimio Kyprou (CUT) it is agreed between the Parties that, to the best of

their knowledge,

No data, know-how or information of Technologiko Panepistimio Kyprou (CUT) is Needed by another Party for implementation of the Project (Article 16.1 and its Annex 5 Grant Agreement, Section “Access rights to results and background”, sub-section “Access rights to background and results for implementing the action”) or Exploitation of that other Party’s Results (Article 16.1 and its Annex 5 Grant Agreement, Section “Access rights to results and background”, sub-section “Access rights for exploiting the results”).

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

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

Describe Background	Specific restrictions and/or conditions for implementation (Article 16.4 Grant Agreement and its Annex 5, Section “Access rights to results and background”, sub-section “Access rights to background and results for implementing the Action”)	Specific restrictions and/or conditions for Exploitation (Article 16.4 Grant Agreement and its Annex 5, Section “Access rights to results and background”, sub-section “Access rights for exploiting the results”)

<p>The Northern Finland Birth Cohorts (NFBC1966 and NFBC1986) are two longitudinal prospective birth cohorts of women and offspring collected at 20-year intervals from the provinces of Oulu and Lapland (http://www.oulu.fi/nfbc/). The NFBC1966 was set with an expected date of birth in 1966, comprising of 12,068 mothers and 12,231 children. The NFBC1986 with an expected date of birth between July, 1st 1985 and June, 30th 1986, comprising 9,362 mothers and 9,479 children. In both data the offspring were followed-up from delivery and at different time points to cover life-course trajectories up until middle age (NFBC1966). At specific follow-up periods, an extensive range of phenotypic, lifestyle, demographic and other data were gathered from questionnaires and clinical examinations. Relevant to the implementation of Lifecycle, the data includes Illumina 450K and EPIC DNA</p>	<p>Access to the NFBC data by individual researchers/research groups is subjected and limited to the data protection regulation, material request approval, data user policies and fees described in more detail at http://www.oulu.fi/nfbc/node/40677. Provided that the preconditions for the permission will be met, permission to use the data will be granted to scientific researchers and the non-profit/for-profit institutions at which the research is conducted. Terms and conditions described in the Data transfer agreement (DTA) apply when data is used outside the University of Oulu.</p> <p>Access rights to Background data needs to be in accordance with local regulations and approvals.</p>	<p>It is not allowed to use the data or data sets derived from the NFBC study for commercial purposed or exploitation; informed consent under which the data has been obtained from participants concerns scientific research use only.</p> <p>Access rights to Background data needs to be in accordance with local regulations and approvals.</p>
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<p>methylation measures from peripheral blood leukocytes.</p> <p>OULU1935 and OULU1945 Cohorts form a study on aging populations and includes individuals born in northern Finland in 1935 and 1945, respectively. These cohorts comprise together 2000 individuals living in the Oulu region with follow-up data from the age of 55 until 80 years (Oulu1935) and until 70 years (Oulu1945).</p>		<p>It is not allowed to use the data or data sets derived from the NFBC study for commercial purposes or exploitation; informed consent under which the data has been obtained from participants concerns scientific research use only.</p> <p>Access Rights to Background data needs to be in accordance with local regulations and ethical approvals.</p>
<p>The researchers at the University of Oulu participating in the NFBC studies provide expertise/research collaboration related to the specific fields of the data collections.</p>	<p>Data and data sets derived from the NFBC collection will always be considered to be the property/Foreground/Results of the University of Oulu, even if the derived data set was generated by a researcher of another Party. For the avoidance of doubt, Results generated by partners with the use of the data or data sets from the NFBC data, will be the property of the Party generating those Results.</p>	<p>Any further use outside the Project requires written permission and may require a commercial license from the University of Oulu; the same limitations and/or conditions will apply to such further use that will apply for the implementation of the Project as set forth in previous column of this table.</p>
	<p>Data and data sets derived from the NFBC are confidential information and researchers/Parties will not try to identify individual study participants the data refers to.</p> <p>NFBC Data transfer agreement is non-negotiable.</p>	

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

As to Health and Environment Alliance (HEAL) it is agreed between the Parties that, to the best of their knowledge,

No data, know-how or information of Health and Environment Alliance (HEAL) is Needed by another Party for implementation of the Project (Article 16.1 and its Annex 5 Grant Agreement, Section “Access rights to results and background”, sub-section “Access rights to background and results for implementing the action”) or Exploitation of that other Party’s Results (Article 16.1 and its Annex 5 Grant Agreement, Section “Access rights to results and background”, sub-section “Access rights for exploiting the results”).

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

As to Agence Nationale de la Sécurité Sanitaire de l’Alimentation, de l’Environnement et du Travail it is agreed between the Parties that, to the best of their knowledge, the following Background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

Describe Background	Specific limitations and/or conditions for implementation (Article 31.2 FPA)	Specific limitations and/or conditions for exploitation
Data, know-how or information generated prior to the IHEN Project by ANSES researchers directly involved in the IHEN Project.	<p>Access for implementation is only granted to the extent it is needed for the partners concerned to carry out their tasks in the Project and provided that ANSES is able to grant Access Rights to said Background including legal restrictions or limits, including those imposed by third parties. Access rights are subject to written request.</p> <p>All commercial and third party Software is excluded and no Access Rights are granted.</p>	<p>The Agence Nationale de la Sécurité Sanitaire de l’Alimentation, de l’Environnement et du Travail (ANSES) hereby excludes from its obligation to grant “Access Rights to Background” all Background generated by ANSES other than that generated by the scientists or research group/s participating in the Consortium, furthermore, any Background generated by the participating scientists or research group/s which is not directly related to the present project. ISGlobal also considers excluded all Background derived from a non EU-project which ISGlobal due to third party rights is not able to grant access rights to.</p>

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

As to Health and Environment Response Agency (HERA) it is agreed between the Parties that, to the best of their knowledge,

No data, know-how or information of Health and Environment Response Agency (HERA) is Needed by another Party for implementation of the Project (Article 16.1 and its Annex 5 Grant Agreement, Section

“Access rights to results and background”, sub-section “Access rights to background and results for implementing the action”) or Exploitation of that other Party’s Results (Article 16.1 and its Annex 5 Grant Agreement, Section “Access rights to results and background”, sub-section “Access rights for exploiting the results”).

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

As to **ARISTOTELIO PANEPISTIMIO THESSALONIKIS (APTH) - ARISTOTLE UNIVERSITY OF THESSALONIKI (AUTH)**, it is agreed between the Parties that, to the best of their knowledge, the following background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

Describe Background	Specific limitations and/or conditions for implementation (Article 25.2 Grant Agreement)	Specific limitations and/or conditions for Exploitation (Article 25.3 Grant Agreement)
<p>- Data, know-how or information generated prior to the IHEN Project by AUTH researchers directly involved in the IHEN Project.</p>	<p>Access for implementation is only granted to the extent it is needed for the partners concerned to carry out their tasks in the Project and provided that AUTH is able to grant Access Rights to said Background including legal restrictions or limits, including those imposed by third parties. Access rights are subject to written request.</p> <p>All commercial and third party Software is excluded and no Access Rights are granted.</p>	<p>The Aristotelio Panepistimio Thessalonikis (AUTH) hereby excludes from its obligation to grant “Access Rights to Background” all Background generated by AUTH other than that generated by the scientists or research group/s participating in the Consortium, furthermore, any Background generated by the participating scientists or research group/s which is not directly related to the present project. AUTH also considers excluded all Background derived from a non EU-project which AUTH due to third party rights is not able to grant access rights to.</p>

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

Attachment 2: Accession document

ACCESSION

of a new Party to

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

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

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

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

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

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

[Date and Place]

[INSERT NAME OF THE NEW PARTY]

Signature(s)

Name(s)

Title(s)

[Date and Place]

[INSERT NAME OF THE COORDINATOR]

Signature(s)

Name(s)

Title(s)

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

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