European Joint Programme

The European Human Biomonitoring Initiative

Consortium Agreement

Version 1, UBA, 2016-11-03

Table of Content

Consortium Agreement

THIS CONSORTIUM AGREEMENT

is based upon REGULATION (EU) No 1290/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" (hereinafter referred to as "Rules for Participation"), and the European Commission Multi-beneficiary General Model Grant Agreement and its Annexes, and is made on 01 January 2017, hereinafter referred to as the Effective Date.

Between

1. GERMAN ENVIRONMENT AGENCY, UBA, Germany
2. UMWELTBUNDESAMT GMBH, EAA, Austria
3. INSTITUT SCIENTIFIQUE DE SANTE PUBLIQUE, WIV-ISP (IPH), Belgium
4. VLAAMSE INSTELLING VOOR TECHNOLOGISCH ONDERZOEK N.V., VITO, Belgium
5. SCHWEIZERISCHES TROPEN- UND PUBLIC HEALTH-INSTITUT, SWISS TPH, Switzerland
6. MINISTRY OF HEALTH OF THE REPUBLIC OF CYPRUS, MOH-CY, Cyprus
7. MASARYKOVA UNIVERZITA, MU, Czech Republic
8. REGION HOVEDSTADEN, REGIONH, Denmark
9. DANMARKS TEKNISKE UNIVERSITET, DTU, Denmark
10. DET NATIONALE FORSKNINGSCENTER FORARBEJDSMILJO, NRCWE, Denmark
11. EUROPEAN ENVIRONMENT AGENCY, EEA, Denmark
12. ARISTOTELIO PANEPISTIMIO THESSALONIKIS, AUTH, Greece
13. ETHNIKO KAI KAPODISTRIAKO PANEPITIMIO ATHINON, UOA, Greece
14. INSTITUTO DE SALUD CARLOS III, ISCIII, Spain
15. TERVEYDEN JA HYVINVOINNIN LAITOS, THL, Finland
16. TYOETERVEYSLAITOS, FIOH, Finland

17. INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM), INSERM, France
18. HRVATSKI ZAVOD ZA JAVNO ZDRAVSTVO, CIPH, Croatia
19. HEALTH SERVICE EXECUTIVE HSE, HSE, Ireland
20. MINISTRY OF HEALTH, MOH-IL, Israel
21. HASKOLI ISLAND, UNIVERSITY OF ICELAND, UI, Iceland
22. INSTITUTO SUPERIORE DI SANITA (INSTITUTO SOPERIORE DI SANITA), ISS, Italy
23. MINISTERO DELLA SALUTE, MOH-IT, Italy
24. NACIONALINE VISUOMENES SVEIKATOS PRIEZIUROS LABORATORIJA, MPHSL, Lithuania
25. MOKSLO INOVACIJU IR TECHNOLOGIJU AGENTURA, MITA, Lithuania
26. VALSTS IZGLITIBAS ATTISTIBAS AGENTURA, VIAA, Latvia
27. RIGAS STRADINA UNIVERSITATE, RSU, Latvia
28. RIJKSINSTITUUT VOOR VOLKSGEZONDHEID EN MILIEU (NATIONAL INSTITUTE FOR PUBLIC HEALTH AND THE ENVIRONMENT), RIVM, The Netherlands
29. NASJONALT FOLKEHELSEINSTITUTT (NORWEGIAN INSTITUTE OF PUBLIC HEALTH), NIPH, Norway
30. INSTYTUT MEDYCYNY PRACY IMIENIA PROF. DRA MED. JERZEGO NOFERA W LODZI, NIOM, Poland
31. FUNDACAO PARA A CIENCIA E A TECNOLOGIA, FCT, Portugal
32. INSTITUTO NACIONAL DE SAUDE DR. RICARDO JORGE, INSA, Portugal
33. NATURVARDSVERKET, SEPA, Sweden
34. NACIONALNI INSTITUT ZA JAVNO ZDRAVJE, NIJZ, Slovenia
35. INSTITUT JOSEF STEFAN, JSI, Slovenia
36. SLOVENSKA ZDRAVOTNICKA UNIVERZITA BRATISLAVE, SZU, Slovakia
37. ÚRAD VEREJNÉHO ZDRAVOTNÍCTVA SR, UVZ, Slovakia
38. DEPARTMENT OF HEALTH (PUBLIC HEALTH ENGLAND), DH, United Kingdom

Hereinafter, jointly or individually, referred to as "Parties" or "Party" relating to the Action entitled **The European Human Biomonitoring Initiative** in short **HBM4EU** hereinafter referred to as "Programme"

Whereas:

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

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 Funding 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:

Back to: TABLE OF CONTENT

Section 1: Definitions

1.1 Definitions

Words beginning with a capital letter shall have the meaning defined herein, and when not defined herein, they shall have the meaning defined in the Grant Agreement.

1.2 Additional Definitions

"Access Right"

Access Right means the right of a **Party** or **Linked Third Party** or other subcontractor to obtain and use **Background** or **Results** owned by another **Party** or **Linked Third Party** or other subcontractor needed to implement the HBM4EU Programme or to exploit **Own Results**, as defined and regulated under Section 9 of the **Consortium Agreement**.

"Annual Work Plan (AWP)"

The **Annual Work Plan** is the description of the action and the related agreed budget for a given year of the HBM4EU Programme as agreed by the **Consortium Bodies** and the **Funding Authority** and attached to the **Grant Agreement** in Annex 7.

"Background"

Background means information which is held by **Parties**, including their **Linked Third Parties** or other subcontractors, prior to their accession to the **Consortium Agreement** or generated by such entities separately from the HBM4EU Programme, as well as copyrights or other intellectual or industrial property rights pertaining to such information, and which is **Needed** for carrying out the Programme or for exploiting **Results** of the Programme.

"Consortium Body"

Consortium Body means any management body described in the **Governance Structure** section of this **Consortium Agreement**.

Back to: TABLE OF CONTENT

"Consortium Agreement"

Consortium Agreement means this body text, its **Attachments**, and its possible further amendments.

"Data"

Data means any information or **Data** collected in the framework of the Programme and which is implemented in the system under supervision of the Coordinator. **Data** shall include personal **Data** as defined by the Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and/or any relevant EU legislation.

"Defaulting Party"

Defaulting Party means a **Party** which the **Governing Board** 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**.

"Description of Action (DoA)"

The **Description of Action** is the general work plan for the HBM4EU Programme as defined in the **Grant Agreement**, Annex 1.

"Force Majeure"

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

Back to: TABLE OF CONTENT

"Funding Authority"

Funding Authority means the European Commission as the body awarding the grant for the Programme.

"Grant Agreement"

Grant Agreement means the multi-beneficiary **Grant Agreement** concluded between the **Funding Authority** and the **Main Beneficiary** under the Horizon 2020 Programme for the conduct and financing of the HBM4EU Programme.

"Internal Funding Rules"

Internal Funding Rules means the rules according to which eligible costs under the HBM4EU Programme are reimbursed by the **Funding Authority** under the **Grant Agreement**, as defined in Section 7.4 of the **Consortium Agreement**.

"Joint Results"

Joint Results means **Results** developed under the Programme jointly by two or more **Parties**, their **Linked Third Parties** or other subcontractors and whose characteristics are such that it is not possible to identify or separate the intellectual contribution of each of the said entities in order to request or obtain intellectual property rights separately.

"Linked Third Party"

A **Linked Third Party** is an affiliated entity or a third party with a legal link to a **Party** and that is listed in **Attachment** 5 to this **Consortium Agreement**.

"Main Beneficiary"

The **Main Beneficiary** is the German Environment Agency as the **Party** that signs the **Grant Agreement** together with the **Funding Authority**.

Back to: TABLE OF CONTENT

"Needed"

Means for the implementation of the Programme:

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.

Means 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.

"Own Results"

Own Results means **Results** developed by a single **Party** or **Linked Third Party** or another subcontractor pursuant to the Programme, without any scientific, technical, intellectual, material or other contribution by another entity.

"Party"

Party means a legal entity listed at the head of the **Consortium Agreement** and having signed the **Agreement**, and/or any new legal entity having acceded to the **Consortium Agreement** in accordance with the provisions of this **Consortium Agreement**; and **Parties** means any two or more or all of them.

"Programme Owner"

Programme Owner means the administrative body of a participating country which contributes with a specified national or regional research Programme to the implementation of HBM4EU, as listed in **Attachment** 4.

"Results"

Results means any information produced within the HBM4EU Programme, including, concepts, methods, schemes for quality assurance and quality control, **Data**, and interpretation of **Data**, but excluding **Background**.

Back to: TABLE OF CONTENT

"Sample"

Sample means any tissue or material or any derivatives of such animal or human biological material such as stem cells or cell lines and any animal or human biological product, provided or collected for the purpose of, or generated during, the Programme.

"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.

Back to: TABLE OF CONTENT

Section 2: Purpose

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

Back to: TABLE OF CONTENT

Section 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 identified at the beginning of this Consortium Agreement.

A new entity becomes a 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.

A Party (the "non-defaulting Party") may withdraw from this Consortium Agreement for a duly substantiated reason, subject to a sixty (60) calendar days' notice served to the Coordinator who immediately informs the other Parties and the Chair of the Governing Board. The non-defaulting Party undertakes to provide to the other Parties, including their Linked Third Parties or other subcontractors, or to any subrogated new Party, free of charge and without delay, any dossiers and information required in order to enable them to pursue the execution of the Programme in its place and stead. The non-defaulting Party is obliged to fulfil the obligations entered into up until the effective date of termination and no longer acquires any right with regard to the Results as from the effective date of termination.

This Agreement may furthermore be terminated automatically, in whole or in part, upon a unanimous decision of the Governing Board. Unless otherwise agreed in writing by the Parties or otherwise expressly specified in this Agreement, the Agreement will be terminated automatically in the event of a decision by the Funding Authority to no longer provide financing for the Programme.

Back to: TABLE OF CONTENT

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 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 Consortium incurred prior to the date of termination, unless otherwise agreed between the Governing Board and the leaving Party. This includes the obligation to provide all input, deliverables and documents for the period of its participation.

Back to: TABLE OF CONTENT

Section 4: Responsibilities of Parties

4.1 General principles

Each Party undertakes to take part in the efficient implementation of the Programme, 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, in accordance with the governance structure of the Programme, any significant information, fact, problem or delay likely to affect the Programme.

Each Party shall promptly provide all information reasonably required by a Consortium Body or by the 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 submit to the Coordinator a semi-annual report on the progress of work under its responsibility, specified by tasks and including work of its Linked Third Parties and its other subcontractors.

Each Party shall inform the Coordinator and the Funding Authority immediately about any changes in its legal status.

4.2 Breach

In the event that the Governing Board identifies a breach by a Party of its obligations under this Consortium Agreement or the Grant Agreement (e.g. improper implementation of the Programme), the Coordinator or, if the Coordinator is in breach of its obligations, the Party appointed by the Governing Board, 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 Governing Board may decide according to section 6.3.1.2 to declare the Party to be a Defaulting Party and to define the consequences thereof which may include termination of its participation.

Back to: TABLE OF CONTENT

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

A Party that enters into a subcontract or otherwise involves third parties shall conclude a written contract with that third party that ensures these obligations and submit a copy of the contract to the Coordinator.

4.4 Social cover for staff

Each of the Parties, including their Linked Third Parties and other subcontractors, shall be responsible for providing social cover for their staff in accordance with applicable legislation in the field of social security, accidents at work and occupational diseases which applies to them and shall carry out the formalities that they are required to accomplish, even when such staff carries out its allocated work on the premises of another such entity.

Back to: TABLE OF CONTENT

Section 5: Liability towards each other

5.1 No warranties

In respect of any information or materials (incl. Results and Background) supplied by one Party or Linked Third Party or other subcontractor to another such entity under the Programme, 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 any other entity.

Therefore,

- the recipient entity shall in all cases be entirely and solely liable for the use to which it puts such information and materials, and
- no Party or Linked Third Party or other subcontractor granting Access Rights shall be liable in case of infringement of proprietary rights of any other entity resulting from any other Party or Linked Third Party or other subcontractor exercising its Access Rights.

5.2 Limitations of contractual liability

No Party or Linked Third Party or other subcontractor shall be responsible to any other such entity for any indirect or consequential loss or similar damage such as, but not limited to, loss of profit, loss of revenue or loss of contracts, provided such damage was not caused by a wilful act or by a breach of confidentiality.

For any remaining contractual liability, a Party's aggregate liability towards the other Parties, including their Linked Third Parties and other subcontractors, collectively shall be limited to once the Party's share of the total costs of the Programme as identified in Annex 2 of the Grant Agreement provided such damage was not caused by a wilful act or gross negligence.

The terms of this Consortium Agreement shall not be construed to amend or limit the statutory liability of any Party or its Linked Third Parties or other subcontractors.

Back to: TABLE OF CONTENT

5.3 Damage caused

Each Party or its Linked Third Party or other subcontractor shall be solely liable for any loss, damage or injury to any other entity resulting from the performance of the said entity's obligations by it or on its behalf under this Consortium Agreement or from its use of Results or Background.

The liabilities of the Parties, their Linked Third Parties and other subcontractors shall not be joint and several.

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 competent Consortium Bodies of any Force Majeure without undue delay. If the consequences of Force Majeure for the Programme are not overcome within 6 weeks after such notification, the transfer of tasks - if any - shall be decided by the competent Consortium Bodies.

5.5 Compliance

Each Party shall ensure that its work on the Programme complies fully with all applicable local, national, European and international laws, regulations and guidelines which are effective during the period of the Programme, including those governing health and safety, Data protection, and where relevant, the use of human or animal subjects and good clinical practice (including national legislation implementing the Parliament's Directive 2001/20/EC on good clinical practice). In this regard, each Party shall maintain the confidentiality, in accordance with Section 10 of this Consortium Agreement, of all samples and Data relating to the use of human subjects, which is created or used in the course of the Programme.

5.6 Insurance

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

Back to: TABLE OF CONTENT

Section 6: Governance structure

6.1 General structure

6.1.1 The organizational structure of the Consortium shall comprise the - following HBM4EU Bodies:

- the Governing Board as the ultimate decision-making body of the HBM4EU Programme;
- the Management Board as the supervisory body for the execution of the Programme, which shall report and be accountable to the Governing Board;
- the Stakeholder Forum providing the opportunity for stakeholders to feed their knowledge and perspectives into priority setting and the implementation of the Programme;
- the Advisory Board providing scientific and policy advice;
- the Ethics Board providing advice on the ethically correct conduct of the Programme.

6.1.2 The organizational structure of the HBM4EU Programme shall also comprise the following functions:

- The Coordinator is responsible for the scientific and administrative management. He or she is supported by the secretariat for the administrative management, and by the Co-Coordinator, and the Management Board for the scientific management. The Coordinator is the legal entity acting as the intermediary between the Parties and the Funding 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.
- The three Pillar Leaders (Pillar 1: "Science to Policy"; Pillar 2: "European HBM platform"; Pillar 3: "Exposure and Health") are responsible for the coordination and interaction within their respective Pillars, as well as across the Pillars.
- The National Hub Coordinator contributes to building a long-term HBM European Programme/infrastructure, by bringing together national HBM activities and ensuring that they are coordinated, feeding in their national needs into the European process, contributing to the objectives and learning from the work carried out in HBM4EU.
- The Work Package Leaders are responsible for the proper implementation of the obligations of their respective Work Package.

Back to: TABLE OF CONTENT

- The Task Leaders are responsible for the proper implementation of the obligations of their respective tasks.
- The Chemical Substance Group Leaders contribute to the elaboration of the Annual Work Plan by providing advice on research tasks related to policy relevant questions for the substances under their remit.

6.2 General operational procedures for all HBM4EU Bodies

6.2.1 Representation in meetings

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

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

6.2.2 Preparation and organization of meetings

6.2.2.1 Convening meetings

The Coordinator of the Consortium shall convene meetings of the Consortium Bodies, if not otherwise provided in the rules of procedure of the respective Consortium Body.

HBM4EU Bodies	Ordinary meeting	Extraordinary meeting
Governing Board	Once a year in person	At any time upon written request of the Management Board or 1/3 of the Members of the Governing Board
Management Board	At least quarterly, in the first year every 2 month in person	At any time upon written request of any Member of the Management Board
Stakeholder Forum	Once a year	
Advisory Board	Once a year	As required by decision of the Management Board
Ethics Board	Once a year	As required by decision of the Management Board

Back to: TABLE OF CONTENT

6.2.2.2 Notice of a meeting

Unless otherwise provided for in the rules of procedure of the respective Consortium Body, the Coordinator 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.

HBM4EU Bodies	Time for notice of a meeting
Governing Board	45 calendar days for ordinary meetings, 30 calendar days for extraordinary meetings
Management Board	30 calendar days for ordinary meetings, 7 calendar days for extraordinary meetings
Stakeholder Forum	30 calendar days
Advisory Board	30 calendar days for ordinary meetings, 10 calendar days for extraordinary meetings
Ethics Board	30 calendar days for ordinary meetings, 10 calendar days for extraordinary meetings

Ordinary meetings should be scheduled at least 6 months in advance.

6.2.2.3 Sending the agenda

Unless otherwise provided for in the rules of procedure of the respective Consortium Body, the Coordinator shall prepare and send each Member of the Consortium Body a written (original) agenda no later than the minimum number of days preceding the meeting as indicated below.

HBM4EU Bodies	Time for sending the agenda
Governing Board	21 calendar days for ordinary meetings, 10 calendar days for extraordinary meetings
Management Board	7 calendar days for ordinary meetings, 5 calendar days for extraordinary meetings
Stakeholder Forum	21 calendar days
Advisory Board	21 calendar days for ordinary meetings, 7 calendar days for extraordinary meetings
Ethics Board	30 calendar days for ordinary meetings, 10 calendar days for extraordinary meetings

Back to: TABLE OF CONTENT

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.

HBM4EU Bodies	Time for adding agenda items
Governing Board	14 calendar days for ordinary meetings, 7 calendar days for extraordinary meetings
Management Board	3 calendar days
Stakeholder Forum	7 calendar days
Advisory Board	7 calendar days
Ethics Board	7 calendar days

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

Meetings of each Consortium Body may also be held by teleconference or other telecommunication/ electronic means except regular meetings of the Governing Board and the Management Board.

6.2.2.5 Written procedure

Any decision may also be taken without a meeting if the Coordinator circulates to all Members of the Consortium Body a written document. Such document shall include the deadline for responses. Decisions taken without a meeting shall be considered as accepted if, within a period of 15 days, not more than one third of the Members has sent an objection in writing to the chairperson. The decisions will be binding after the chairperson has sent to all Members of the Consortium Body and to the Coordinator a written notification of this acceptance.

Back to: TABLE OF CONTENT

6.2.3 Quorum and voting rules

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 Coordinator, or the chairperson of the Consortium Body if so provided for in the rules of procedure of that Body, shall convene another ordinary meeting within 30 calendar days, and for the Management Board within 15 calendar days. If in this meeting the quorum is not reached once more, the Coordinator, or the chairperson of the Consortium Body if so provided for in the rules of procedure of that Body, shall convene an extraordinary meeting which shall be entitled to decide even if less than the quorum of Members are present or represented. The extraordinary meeting may take place immediately after the end of the second ordinary meeting. The voting conditions of ordinary meetings apply to extraordinary meetings.

6.2.3.2 Each Member of a Consortium Body present or represented in the meeting shall have one vote, if not otherwise provided for in this Consortium Agreement.

6.2.3.3 A Party which the Governing Board has declared according to Section 4.2 to be a Defaulting Party may not vote.

6.2.3.4 Each Consortium Body shall strive to make decisions by consensus. If consensus cannot be achieved, decisions on proposals shall be taken by a majority of two-thirds (2/3) of the votes cast. For voting rules of the Governing Board the provisions contained in section 6.3.1.shall apply.

6.2.3.5 For matters that may require unanimity for adoption, abstentions are not counted so as to allow delegates to express disagreement without blocking the adoption.

6.2.3.6 Personal matters, including but not limited to the appointment of Chairs and Vice-Chairs, Leaders of Pillars, Work Packages and Tasks, shall be decided by secret ballot.

Back to: TABLE OF CONTENT

6.2.4 Veto rights in exceptional cases

6.2.4.1 A Party may not exercise a veto with respect to a decision or relevant part of a decision adopted by a Consortium Body, unless it can show that its own work according to the Description of Action and Annual Work Plan as adopted by the Governing Board, including time for performance, costs, liabilities, intellectual property rights or other legitimate interests, would be severely affected by this decision or part of this decision.

6.2.4.2 When a decision of a Consortium Body is foreseen on the original agenda, a Member of that Body may veto such a decision only on grounds according to 6.2.4.1 and only during the meeting, including telephone or video conferences.

6.2.4.3 When a decision has been taken on a new item added to the agenda of a Consortium Body or when a decision has been taken without a meeting, e.g. by written procedure, a Party may veto such decision on grounds according to 6.2.4.1 within 8 calendar days after the decision has been communicated.

6.2.4.4 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 and the Parties that are not Members.

6.2.4.5 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.

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

Back to: TABLE OF CONTENT

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 from sending, 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 archive them. If requested the Coordinator shall provide authenticated duplicates to Parties.

6.2.5.4 Decisions will only be binding once the relevant part of the minutes has been accepted as accurately reflecting the decisions taken in the meeting.

6.3 Specific operational procedures for the Consortium Bodies

6.3.1 Governing Board

The rules described in Section 6.2 and Section 6.3.1.1 shall be proposed to the Governing Board for incorporation into the Board´s rules of procedures (Terms of Reference) to be adopted by the Governing Board.

6.3.1.1. Additional operational procedures

6.3.1.1.1 The Governing Board will elect a Chair and a Vice-Chair. The Chair and the Vice-Chair shall be elected by a majority of two-thirds (2/3) of the votes cast.

6.3.1.1.2 It will set down its rules of procedures during its first meeting. A draft of the rules of procedures will be circulated by the Coordinator fifteen (15) calendar days in advance of the first meeting for comments. The first meeting will be convened by the Coordinator. The Coordinator will chair the meeting until the Governing Board Chair is elected.

Back to: TABLE OF CONTENT

6.3.1.1.3 The Management Board shall be consulted regarding the agenda of Governing Board meetings and the proposed decisions of the Governing Board.

6.3.1.1.4 The Funding Authority will participate as observer to the Governing Board. EU agencies other than those mentioned under Section 6.3.1.2.2 with competences in the field of the HBM4EU Programme may participate as observer at the invitation of the Governing Board. The Governing Board can invite external experts to its meetings as considered appropriate.

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

6.3.1.1.6 The Governing Board may delegate any decision to the Management Board. The delegation shall specify the subject matter to be decided by the Management Board. The Governing Board may revoke the delegation or overrule the decision of the Management Board at any time.

6.3.1.2 Binding Governing Board Decisions

6.3.1.2.1 The Parties agree to abide by all decisions of the Governing Board as provided for in this Consortium Agreement, including the rules of this Section 6.3.1.2. This does not prevent the Parties to submit a dispute to resolution in accordance with the provisions of settlement of disputes in Section 11.8.

6.3.1.2.2 The Governing Board shall consist of the Programme Owners, the European Environment Agency (EEA), the European Chemicals Agency (ECHA), and the European Food Safety Authority (EFSA) (hereinafter Governing Board Members).

6.3.1.2.3 A Governing Board Member shall participate by one representative duly authorized to deliberate, negotiate and decide on all matters to be decided by the Governing Board, including those listed in Section 6.3.1.2.8 of this Consortium Agreement, accompanied by not more than one technical expert from the Consortium per country or European agency.

Back to: TABLE OF CONTENT

6.3.1.2.4 The Programme Owner of a participating country, the EEA, the ECHA, and the EFSA have one vote each. A country that is represented by more than one Programme Owner shall have only one vote and notify the Chair of who is the voting delegate for each agenda point before the start of the meeting. The Programme Owner of a participating country shall not have a vote, if the Consortium Agreement is not valid for a Party of that country.

6.3.1.2.5 Decisions on matters that affect funding (i.e. Annual Work Plan), the acceptance of a new Party or the termination of a Defaulting Party according to Section 4.2. shall be taken by a majority of two-thirds (2/3) of the votes cast, representing at least two-thirds (2/3) of assigned person months according to the current Annual Work Plan on a country-by-country basis.

6.3.1.2.6 Decisions on other matters shall be taken by a majority of more than 50% of the votes cast, representing at least 50% of assigned person months according to the current Annual Work Plan on a country-by-country basis, unless otherwise provided for in this Consortium Agreement.

6.3.1.2.7 In the exceptional case that the Governing Board does not decide, or is repeatedly unable to decide, on a proposal presented to it (i.e. no approval or no rejection) or that it adopts a decision that is not in conformity with the Consortium Agreement, including the provisions of this Section, the Coordinator may appoint the Management Board as acting procurator for taking a decision on that very matter. However, in order for this decision to be valid, Management Board will have to receive, within two weeks, written electronic agreement from at least two-third (2/3) of the Parties (representing at least two-third (2/3) of assigned person months.

6.3.1.2.8 Tasks

The Governing Board shall take all decisions provided for in this Consortium Agreement, in particular:

Content, finances and intellectual property rights

- Approval of the Annual Work Plans and annual summary reports before submission to the European Commission;

Back to: TABLE OF CONTENT

- Proposals for amendments of Annexes 1 (Description of Action) and 2 (Estimated Budget of the Action) of the Grant Agreement, to be agreed by the Funding Authority, upon proposal by the Management Board;
- Monitoring and approval of the achievement of the most significant milestones;
- Approval of ethical, legal and data management frameworks developed;
- Recommendations for the development of a long-term sustainability plan for Human Biomonitoring (HBM) in Europe;
- Decision on the continuation of membership in the Management Board according to Section 6.3.2.2;
- Decision on criteria for the selection of members for the Advisory Board and the Stakeholder Forum upon proposal by the Management Board;
- Approval of the composition of the Advisory Board and the Stakeholder Forum upon proposal by the Management Board;
- Approval of schemes for quality assurance and quality control;
- Approval of topics for internal calls upon proposal by the Management Board.

Evolution of the consortium

- Adoption of amendments to the Consortium Agreement, to be signed by the Parties according to Section 11.4.2, upon proposal by the Management Board;
- Adoption of amendments to the Grant Agreement to be agreed by the European Commission upon proposal by the Management Board;
- Amendment of Attachments to the Consortium Agreement upon proposal by the Management Board;
- Entry of a new Party to the consortium and approval of the settlement on the conditions of the accession of such a new Party;
- Withdrawal of a Party from the consortium and the approval of the settlement on the conditions of the withdrawal;
- Identification of a breach by a Party of its obligations under this Consortium Agreement or the Grant Agreement according to Section 4.2;
- Declaration of a Party to be a Defaulting Party according to Section 4.2;
- Remedies to be performed by a Defaulting Party according to Section 4.2;
- Termination of a Defaulting Party's participation in the consortium according to Section 4.2 and measures relating thereto;
- Proposal to the Funding Authority for a change of the Coordinator;
- Proposal to the Funding Authority for suspension of all or part of the Programme;
- Proposal to the Funding Authority for termination of the Programme and the Grant Agreement.

Back to: TABLE OF CONTENT

6.3.2 Management Board

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

6.3.2.1 Members

The Management Board shall consist of the Coordinator, the Co-Coordinator, the Pillar Leaders, the National Hub Coordinator, and the Work Package Leaders except the Leader of Work Package 3 (Management Board Members). The Leader of Work Package 3 will be invited as observer when internal calls are on the agenda in order to ensure the independence of the internal calls management. The European Commission will be invited as an observer when deemed relevant.

The Coordinator shall chair the meetings of the Management Board.

Membership in the Management Board will cease upon demission by a member or a decision of the Governing Board.

The Management Board Members commit themselves to undertake their tasks in an unbiased way.

6.3.2.2 Decision making procedures and participation in meetings

Every Management Board Member has one vote.

Every Management Board Member shall attend every Management Board meeting in person and participate in a cooperative manner. In exceptional situations, a Management Board Member may be represented by a competent and fully mandated substitute or proxy. If a Management Board Member has not attended two or more Management Board meetings in person and has not been substituted by a competent and fully mandated substitute or proxy two times, the Governing Board shall decide on a renewal of the membership in the Management Board or a replacement of this member.

6.3.2.3 Veto Rights

The Coordinator may exercise a veto with respect to a decision or a relevant part of a decision if the decision or a relevant part of the decision is in contradiction to the Grant Agreement and the Consortium Agreement.

Back to: TABLE OF CONTENT

6.3.2.4 Minutes of meetings

Minutes of the Management Board meetings, once accepted, shall be sent by the Coordinator to the Governing Board Members and the Parties for information.

6.3.2.5 Tasks

The Management Board shall

- monitor the effective and efficient implementation of the Programme without affecting the obligations of the Coordinator according the Grant Agreement (especially § 41.2);
- collect information at least every 6 months on the progress of the Programme, examine that information to assess the compliance of the Programme with the Description of Action and the Annual Work Plan and, if necessary, propose modifications of the Description of Action to the Governing Board;
- set down its rules of procedures (Terms of Reference) during its first meeting. The draft rules of procedures will be circulated to the members of the Management Board two weeks in advance of its first meeting;
- support the Coordinator in preparing meetings with the Funding Authority and in preparing related reports and deliverables;
- prepare the content and timing of press releases and joint publications by the consortium or proposed by the Funding Authority in compliance with the requirements set in Article 29of the Grant Agreement;
- propose to the Governing Board the selection criteria for the Members of the Stakeholder Forum, the Advisory Board and the Ethics Board member;
- propose to the Governing Board a list of candidates for membership in the Stakeholder Forum, Advisory Board and Ethics Board;
- appoint a new National Hub Coordinator, if necessary, taking into account suggestions by the National Hub Contact Points;
- appoint a new Pillar Leader, if necessary, upon suggestion by the respective Pillar participants;
- appoint a new Work Package Leader, if necessary, upon suggestion by work package participants;
- appoint a new Task Leader, if necessary, upon suggestion by the work package Leader;
- be in charge of adopting solutions to any problem encountered during the implementation of the Programme;
- submit proposals for decisions to be taken by the Governing Board based on input from Pillar Leaders and Work Package Leaders;
- inform the Governing Board about the ethical, legal and data management frameworks developed by HBM4EU and seek its agreement;

Back to: TABLE OF CONTENT

- inform the Governing Board about any connections established with sister initiatives at national, EU and international level;
- elaborate the draft Annual Work Plan, including priorities, the accompanying budget, and the attribution of the reserve budget, for approval by the Governing Board;
- ensure suitable communication among the Work Packages, Pillars and Consortium Bodies;
- suggest to the Governing Board changes in budget allocation and the mobilization of additional resources to start additional activities;
- adopt plans for publication, dissemination and exploitation and monitor their implementation;
- arbitrate address any conflicts within the Programme and negotiate solutions attempt to resolve to any problem between the Consortium and external bodies;
- be responsible for the proper execution and implementation of the decisions of the Governing Board;
- seek a consensus among the Parties;
- advise the Governing Board on ways to rearrange tasks and budgets of the Parties concerned if a task is abolished as a result of a decision of the Governing Board. Such rearrangement shall take into consideration the legitimate commitments taken prior to the decisions, which cannot be cancelled;
- fulfil all other tasks provided for in this Consortium Agreement.

6.3.3 Advisory Bodies

The advisory bodies may set down their own rules of procedures (Terms of Reference).

6.3.3.1 Stakeholder Forum (SF)

The Stakeholder Forum shall provide advice to the Governing Board and the Management Board on the conduct of the HBM4EU Programme that will be taken into account by the Management Board when preparing the proposal for the next Annual Work Plan. It will be composed of stakeholders, in particular from NGOs, industry, and civil society.

Its members will be appointed by the Governing Board upon proposal by the Management Board according to selection criteria prepared by the Management Board and approved by the Governing Board. The Stakeholder Forum will be convened by the Environment Agency Austria (EAA) and elect its own Chair by a majority of 50 percent of the members present and voting. It will meet once a year.

Back to: TABLE OF CONTENT

6.3.3.2 Advisory Board (AB)

The Advisory Board will provide advice to the Management Board on the conduct of the HBM4EU Programme that will be taken into account by the Management Board when preparing the proposal for the next Annual Work Plan. It will be composed of experts from large Human Biomonitoring initiatives of countries that are not participating in the HBM4EU Programme, of coordinators or representatives of other European and international projects and other relevant experts.

Its members will be appointed by the Governing Board upon proposal by the Management Board according to selection criteria prepared by the Management Board and approved by the Governing Board. The Advisory Board will be convened by the Coordinator and elect its own Chair by a majority of 50 percent of the members present and voting. It will meet as required, at a minimum once a year.

6.3.3.3 Ethics Board (EB)

The Ethics Board will assess the deliverables related to the development of an ethical, legal, and data management framework and provide quality assurance for these frameworks. It will also review the annual ethics report and ensure that all required documents are mentioned or attached. It will be composed of specialists in legal and ethical matters from the HBM4EU Programme. The Ethics Board will be convened and chaired by the Task Leader for the Ethical Task. It will meet as required, at a minimum once a year.

6.4 Roles and Functions within the HBM4EU Programme

6.4.1 Coordinator and Co-Coordinator

6.4.1.1 The Coordinator shall be the intermediary between the Parties and the Funding Authority and shall perform all tasks assigned to him/her as described in the Grant Agreement and in this Consortium Agreement. The Coordinator is supported by the Co-Coordinator and the Secretariat.

6.4.1.2 If the Coordinator is temporarily not be able to fulfil her/his responsibilities within the Consortium, the Co-Coordinator shall substitute her/him, except in matters which are directly related to the responsibilities and obligations of the Main Beneficiary. The Co-Coordinator is a Work Package Leader appointed by the Management Board.

Back to: TABLE OF CONTENT

6.4.1.3 Tasks

The Coordinator is responsible for:

- managing the overall Programme on a day-to-day basis, including overall contractual, scientific, ethical, financial and administrative aspects;
- fulfilling the reporting obligations under the Grant Agreement and the Consortium Agreement;
- compiling for submission to the Management Board semi-annual reports prepared by the Parties on the progress of work under their responsibility, specified by tasks and including work of their Linked Third Parties and other subsidiaries;
- consolidating the Programme planning, the progress reports, milestone reports, cost statements, budget overviews, or any other document that has to be jointly produced through the Consortium;
- monitoring compliance by the Parties with their obligations:
- monitoring compliance with ethical aspects and keeping stock of relevant ethical permits;
- ensuring financial payments to the Parties in accordance with their obligations under the Description of Action and Annual Work Plan and the internal funding rules set out in Section 7.4;
- keeping the address list of Parties and other contact persons updated and available;
- collecting reports, other deliverables (including financial statements and related certifications) and specific requested documents from the Parties and reviewing their consistency and submitting them to the Funding Authority;
- transmitting documents and information connected with the HBM4EU Programme to any other Parties concerned;
- administering the financial contribution of the Funding Authority and fulfilling the financial tasks described in Section 7.3;
- 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;
- signing the Grant Agreement;
- ensuring implementation of decisions taken by the Governing Board in accordance with this Consortium Agreement;
- managing the Program’s reserve budget according to the Annual Work Plan;
- overseeing deadlines and milestones of activities and controlling the quality of deliverables.

Back to: TABLE OF CONTENT

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

6.4.1.5 If the Coordinator fails in its coordination tasks, the Governing Board may propose to the Funding Authority and the Parties, by a majority of two-thirds (2/3) of the votes cast representing at least two-thirds (2/3) of assigned person months on a country-by-country basis, to change the Coordinator.

6.4.1.6 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.

6.4.1.7 The Coordinator shall not enlarge her/his role beyond the tasks specified in this Consortium Agreement and in the Grant Agreement.

6.4.2 Pillar Leaders (PL)

6.4.2.1 A Pillar leader is a Work Package Leader appointed by the Management Board who will support the coordination and interaction of the Work Package Leaders within a Pillar, as well as across Pillars.

6.4.2.2 Tasks

The Pillar leaders are responsible for:

- coordinating activities across the work packages of their respective pillars to deliver a coherent set of results within the pillar and promoting knowledge transfer within the pillar;
- coordinating and ensuring collaboration across pillars and promoting knowledge transfer across pillars with a view to ensuring that the overall outcomes of the HBM4EU Programme are coherent and complementary and together generate a robust and harmonized knowledge base for policy making on chemicals;
- ensuring that tasks are not duplicated and promoting complementarities and synergies;

Back to: TABLE OF CONTENT

- coordinating with the Chemical Substance Group Leaders in order to ensure that their work is fully integrated into the design and delivery of all Work Packages;
- coordinating the contributions of the Work Package Leaders to the draft Annual Work Plans;
- collecting and integrating the contributions of the Work Package Leaders to the annual reports;
- monitoring compliance of the deliverables from the Work Packages of their respective pillars with the requirements defined in the Description of Action and Annual Work Plan and report the results of this assessment to the Coordinator for discussion in the Management Board;
- collecting training needs from the pillar work packages and reporting them to the leader of Task 2.5 (RUCM);
- working collaboratively with the other Pillar Leaders, Work Package Leaders, the National Hub Coordinator, and the Coordinator.

6.4.3 Work Package Leaders (WPL)

6.4.3.1 The Work Package Leaders are responsible for the proper implementation of the obligations of their respective Work Package and its tasks according to the Annual Work Plan and the Description of Action, including timely submission of milestones and deliverables.

6.4.3.2 Tasks

The Work Package Leaders are also responsible for:

- supporting the coordination and interaction of the Task Leaders within their respective Work Package, as well as across work packages;
- defining before the start of activities related to the Work Package the standards of structure, content and quality of the deliverables, reports and other documents that are to be generated within the tasks of that work package and for submitting the definition of the standards to the Management Board for approval.
- informing the Pillar Leaders and the Coordinator about any deviations from the Description of Action and Annual Work Plan and developing contingency plans;
- coordinating with other Work Package Leaders together with the Pillar Leaders with a view to ensuring that the overall outcomes of the HBM4EU Programme are coherent and complementary and together generate a robust and harmonized knowledge base for policy making on chemicals;
- ensuring good communication and the flow of information within the work package;

Back to: TABLE OF CONTENT

- identifying any bottlenecks or obstacles, as well as links, synergies and overlaps across work packages, and reporting them to the Pillar Leaders and the Coordinator;
- submitting formal reports of progress to the Pillar Leaders and the Coordinator for discussion at the Management Board meetings, and contributing the sections of the HBM4EU annual report relating to their work packages;
- cooperating with the Chemical Substance Group Leaders to ensure implementation of activities proposed in the scoping documents for priority chemicals;
- ensuring compliance within their work package with the ethical and legal framework and contributing to the ethics report by ensuring that all partners in the work package deliver required information and documents;
- contributing to the development of the annual communication plan to be developed in Work Package 2, and feeding the results of their work packages into the Knowledge Hub;
- contributing to the prioritization tasks under Work Package 4;
- developing and submitting the contribution of their respective work package for upcoming draft Annual Work Plans integrating the views of the work package participants.

6.4.4 Task Leaders (TL)

6.4.4.1 The Task Leaders are responsible for the proper implementation of the obligations of their respective tasks as agreed in the Annual Work Plan and the Description of Action, including timely submission of milestones and deliverables.

6.4.4.2 Tasks

The Task Leaders shall be responsible for:

- supporting the Work Package Leaders in the implementation of specific task within a Work Package;
- the technical management of a task that has been assigned to him/her under a work package;
- coordinating the activities all partners involved in this task;
- coordinating scientific and research activities related to this task;
- reporting to Work Package Leaders all problems and needs related to their task ensuring good communication and the flow of information within the task;
- developing and submitting the contribution of their respective task for upcoming draft Annual Work Plans, and submitting them to the Work Package Leaders and the Pillar Leaders; integrating the views of the task participants.
- providing input to training measures.

Back to: TABLE OF CONTENT

6.4.5 Chemical Substance Group Leaders

Chemical Substance Group Leaders contribute to the elaboration of the Annual Work Plan by providing, in consultation with Work Package 4, advice to the Management Board on research tasks related to policy relevant questions identified under Work Package 4. They attend upon request a meeting of the Management Board prior to the development of the Annual Work Plan.

For new prioritized substances, new Chemical Substance Group Leaders will be proposed by the Management Board and appointed by the Governing Board.

6.4.6 National Hub Coordinator (NHC)

The NHC is a Work Package Leader appointed by the Management Board and will in collaboration with the National Hub Contact Points (NHCP) oversee the needs and the output of the National Hubs to transfer them to the Work Package Leaders for consideration in the development of the Annual Work Plans, including the training needs of the National Hubs. The NHC will contribute to the overall coordination of training and capacity building in Work Package 6. The NHC will also be responsible for ensuring a good information flow to the National Hubs about the activities and outcome of the HBM4EU Programme. The NHC will chair and convene regular meetings of the NHCPs.

6.5 Ethics

6.5.1 Studies of ethical concern

All studies of ethical concern will be carried out according to existing guidance in ethics such as laid down in the Universal Declaration on Bioethics and Human Rights adopted by UNESCO's General Conference on 19th October 2005, the Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (1997) and as specified in the Helsinki Declaration (2000), the Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal Data and on the free movement of such Data. Current EU legislation and national legislation will be adhered to, including 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 the free movement of such data (General Data Protection Regulation) applicable as of May 2018. Each Party shall address challenges with respect to sharing personal Data and sharing samples, also cross boundary issues and, if appropriate, request expert advice from the Ethics Board.

Back to: TABLE OF CONTENT

6.5.2 Requirements

The Parties are responsible for contributing timely and efficiently to the annual ethics report as set out in the DoA and shall observe the following requirements:

- The Parties, including their Linked Third Parties and other subcontractors, must declare use of human embryos and human foetal tissue/cells and Data derived from studies with these elements.
- HBM4EU will ensure compliance with national regulations by obtaining appropriate consent from adults and from parents and assent from participating children and appropriate consent from relatives with persons unable to consent, when making use of available and new samples from children and adults from existing biobanks and new collections. The Parties will provide the relevant documents to the Coordinator and make them available to the European Commission on request.
- A policy on providing the sample donors with individual and personal results will be developed. The policy will take measures to avoid stigmatization of particular social groups, political or financial retaliation and malevolent use. The policy shall be made in accordance with all applicable local, national and EU legislation and may be inspired by the policies of information feedback with genetic testing and provided to the Commission before grant signature.
- The collection, handling and use of personal Data and samples must comply with national and EU legislation. The partners are committed to adhering to the data protection policy developed by the Consortium in the legal and ethical policy document and the data management plan and provide all relevant documents to the Coordinator.
- All planned measures with animals must comply with national and EU legislation respecting the principles of “Replace, Reduce, and Refine” (3Rs). The partners shall provide all relevant documents to the Coordinator.
- For the cohorts included, the principal investigators have to prove that they obtained ethical approval for contributing to specific tasks of the HBM4EU Programme by their respective ethical committees. Existing written consent forms will be made available for review in Work Package 4 in cooperation with Work Package 1. Copies of all ethical approvals will be provided to the Coordinator to be made available to the European Commission on request.
- New results that are medically important for sample donors will be communicated to the sample donors unless the sample donor has declared in writing his/her intention not to be informed by the Programme.

Back to: TABLE OF CONTENT

Section 7: Financial provisions

7.1 General Principles

7.1.1 Distribution of Financial Contribution

A Party shall only be funded after having duly signed the Consortium Agreement and the Accession Form to the Grant Agreement.

A Party shall be funded only for its tasks carried out in accordance with the Description of Action and the valid Annual Work Plan with respective amendments, including the tasks carried out by its Linked Third Parties and its other subcontractors.

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

- The Description of Action and the Annual Work Plan and amendments;
- The approval of reports and deliverables by the Funding Authority, and
- The provisions of payment in Section 7.3 and the Internal Funding Rules of Section 7.4.

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 Programme towards the Funding Authority. Neither the Coordinator nor any of the other Parties shall be in any way liable or responsible for such justification of costs towards the Funding Authority.

Each beneficiary of funding through an internal call will be responsible for the justification, allocation, and management of the resources received under the internal call. If the beneficiary of funding through an internal call is a Linked Third Party or another subcontractor of a Party, justification of costs and payments are channelled through that Party.

7.1.3 Funding principles

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

Back to: TABLE OF CONTENT

7.1.3.2 A Party that spends more than its allocated share of the budget as set out in the Description of Action, in the Annual Work Plan, and in this Consortium Agreement will be funded only in accordance with its duly justified eligible costs up to an amount not exceeding that share.

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

7.1.3.4 To avoid cross payments, the Coordinator is entitled to recover undue payments by deducting the respective amount from subsequent due payments to the respective Party, if appropriate and concerted with that Party.

7.1.3.5 In case a Party earns any receipt that is deductible from the total funding as set out in the Description of Action, in the Annual Work Plan, and in this Consortium Agreement, 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 Annual Work Plan, the Party shall reimburse the funding reduction suffered by other Parties.

7.1.3.6 The funding principles also apply to Linked Third Parties and other subcontractors and shall be part of the contracts with them.

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

A Party leaving the consortium shall refund all payments it has received except the amount of contribution accepted by the Funding Authority according to the Description of Action, the Annual Work Plan, and this Consortium Agreement. 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.

Back to: TABLE OF CONTENT

7.2 Budgeting

The budget set out in the Annual Work 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 task of the Coordinator.

7.3.1.1 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 central administration of any funds and in maintaining financial accounts;
- undertake to keep the Funding Authority's financial contribution to the Programme 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 Articles 21.2 and 21.3.2 of the Grant Agreement, no Party shall before the end of the Programme 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.

7.3.1.2 The Coordinator is entitled to use the support of external accounting services.

7.3.2 The payment schedule, which contains the transfer of pre-financing and interim payments to Parties, will be handled according to the following:

7.3.2.1 Funding of costs included in the Description of Action and the Annual Work Plan will be paid to Parties without undue delay after receipt from the Funding Authority in separate instalments as agreed below:

7.3.2.2 Pre-financing for year 1:

Each Party will receive a pre-financing of 20% of the maximum grant amount according to its ratio to the Program's maximum grant amount.

Back to: TABLE OF CONTENT

The pre-financing received by a Party will comprise the payments for that Party's Linked Third Parties and other subcontractors. An additional amount corresponding to 5% of the maximum grant amount is retained by the Funding Authority and transferred into the "Guarantee Fund".

7.3.2.3 Interim payments for years 2 to 4:

Each party will receive after submission and acceptance of the annual period reports and deliverables by the Funding Authority the amount envisaged in the valid Annual Work Plan according to the Internal Funding Rules of Section 7.4 as an interim payment. Payment will not be made until at least 80% of the funds received in the previous year has been spent.

7.3.2.4 Each party will receive after the finalization of the Programme and submission and acceptance of the final report and deliverables by the Funding Authority the balance of payment. The balance is calculated according to the Annual Work Plan and the Internal Funding Rules of Section 7.4 by deducting the total amount of pre-financing and interim payments already made from the final grant amount.

7.3.2.5 The total amount of pre-financing and interim payments transferred from the Coordinator's account to the Parties shall not exceed 85% of the maximum grant amount set out in Article 5.1. of the Grant Agreement. Regarding the European Environment Agency, the implementation of this article will be aligned with Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union, and Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012.

7.3.2.6 Payments according to Sections 7.3.2.3 and 7.3.2.4 will be made dependent on the progress of each Party´s individual work-programme as documented by reports and deliverables by each Party individually and as approved by the Coordinator according to standards defined by the respective Work Package Leader.

Back to: TABLE OF CONTENT

7.3.2.7 A Party will not receive funding unless the submitted deliverables, reports, or supporting documents as agreed upon in the Annual Work Plan have been accepted by the Funding Authority. If submissions are not made in due time, payments will be made in the following regular budgeting period.

7.3.2.8 The Coordinator examines the progress documentation, including reports and deliverables, and its conformity with the approved standards, including the ethical obligations and the Annual Work Plan. In case the Coordinator does not approve the conformity with approved standards, including the ethical obligations and the Annual Work Plan, she/he shall submit the issue immediately to the Management Board for decision on how to proceed with forwarding the documentation to the Funding Authority.

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

7.3.3 Costs accepted by the Funding Authority in accordance with Section 7.4. will be paid to the Party concerned. The Coordinator is entitled to recover any payments already paid to a Defaulting Party. The Coordinator is equally entitled to withhold payments to a Party when this is suggested by or agreed with the Funding Authority.

7.4 Internal Funding Rules

7.4.1 Whereas the overall funding rate of the Programme is 70% of the accepted, eligible costs of the activities according to the Annual Work Plan justified by the Parties, the Parties agree to use different Internal Funding Rates for specific activities according to the Description of Action. The Coordinator will be responsible for distributing the received funding to the Parties according to the internal funding rates.

Back to: TABLE OF CONTENT

7.4.2 The agreed internal funding rates are as follows:

Activity	Internal Funding Rate [%]
Personal costs of Work Package 1 and 3 and of the National Hub Coordinator	100
Personal costs of Work Packages 4 to 16	70
Other direct costs of all Work Packages	70
Fieldwork for HBM studies	50
Quality assurance/quality control Programme (reference materials, consumables, sample transport, organization and coordination)	70
Quality assurance/quality control Programme (free participation)	0
Analysis of samples in Human Biomonitoring studies	50

7.4.3 Costs related to participation in conferences are generally not eligible for funding under the HBM4EU Programme. Upon proposal by the Leader of Work Package 2, the Management Board may approve funding, if the participation in a conference is of high interest for the HBM4EU Programme and includes an active contribution. Travel costs are reimbursed according to the most economic conditions, but not beyond second class train ticket and economy class flight ticket.

Back to: TABLE OF CONTENT

Section 8: Results

8.1 Ownership of Background

Background developed by a Party or a Linked Third Party or other subcontractor of a Party will remain the property of that Party, Linked Third Party or other subcontractor, regardless of the property rights claimed with respect to Results developed in this Programme, and notwithstanding the use of such Background to develop Results in this Programme. For the sake of clarity, each Party may list its Background, and the Background of its Linked Third parties and other subcontractors, related to the Programme before the start of the Programme in Attachment 1 of this Consortium Agreement, or communicate additional Background during the execution of the Programme in writing to the Coordinator for subsequent inclusion in Attachment 1 by decision of the Governing Board.

8.2 Ownership of Results generated within the HBM4EU Programme

Results generated within the HBM4EU Programme are owned by the entity that generates them, including but not limited to Parties and Linked Third Parties. Results that are jointly generated by two or more entities are jointly owned by these entities. Generation of Results includes, but is not limited to preparation, development of study design and questionnaires, conduct of the study, quality assurance, measurements, Data management, evaluation and interpretation of Data.

In case of joint ownership, the joint owners shall make their best efforts to establish a joint-ownership agreement regarding the allocation and terms of exercising such joint ownership as soon as possible and within a maximum of six (6) months as from the date on which the respective Results have been generated. In the meantime, and until this agreement enters into force each of the joint owners shall be entitled to use the jointly generated Results as it sees fit for internal research purposes on a non-exclusive, non-transferable basis. Unless otherwise agreed, the joint owners may only use the jointly owned results for commercial purposes or grant licenses to third parties subject to, in both cases, the following conditions:

a) The other joint owners' must give their prior written consent, which shall not be unreasonably withheld; and
b) Fair and reasonable compensation must be provided to the other joint owners.

Back to: TABLE OF CONTENT

The rules of joint ownership shall not hinder a Party, including its Linked Third Parties and other subcontractors, to place the deliverables of these entities developed under the HBM4EU Programme on the HBM4EU website. The Management Board may adopt rules of conduct for the publication of jointly owned Results.

8.3 Transfer of Results

8.3.1 Each Party may transfer ownership of its own Results following the procedures of the Grant Agreement Article 30.

8.3.2 Each Party may identify specific entities including, but not limited to Linked Third Parties, to which it intends to transfer the ownership of its Results, as listed in Attachment (3) to this Consortium Agreement. The other Parties, including their Linked Third Parties and other subcontractors, hereby waive their right to prior notice and their right to object to a transfer to listed third parties according to Article 30.1 of the Grant Agreement.

8.3.3 The transferring entity 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, including their Linked Third Parties and other subcontractors, will not be affected by such transfer. Any addition to Attachment 3 after signature of this Consortium Agreement requires a decision of the Governing Board.

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.

8.3.5 The obligations above apply only for as long as other Parties, including their Linked Third Parties and other subcontractors, still have - or still may request - Access Rights to the Results.

Back to: TABLE OF CONTENT

8.4 Data management and protection

8.4.1 Data management

8.4.1.1 In managing and protecting data, all Parties, including their Linked Third Parties and other subcontractors, shall respect the requirements set out in the data management plan and the ethical and legal framework. The data management plan will follow the objectives of Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European Community (INSPIRE), as well as the 2008 Communication on a Shared Environmental Information System. The management and protection of existing Data as well as of Data produced outside the HBM4EU Programme will follow the boundaries set by the ethical and legal frameworks under which those Data were originally collected. In addition, in cases where the HBM4EU data management plan and the HBM4EU legal and ethical framework are stricter than the original conditions of collection, then these stricter conditions will apply.

8.4.1.2 New Data produced and funded under the HBM4EU Programme shall be stored in the Information Platform for Chemical Monitoring (IPChem). Existing Data as well as Data produced outside the HBM4EU Programme should also be fed into this database if the ethical agreement, the data protection rules of the respective study, and existing intellectual property rights so allow. A data management plan shall be elaborated that specifies the extent of the Data stored in IPCheM and how the Data will be shared and protected.

8.4.1.3 The data management plan will specify procedures for sharing and protecting both new and existing Data in order to combine data from different Parties, including their Linked Third Parties and other subcontractors, and allow for joint analyses. All Data shared for the purpose of statistical analysis will be anonymized, and/or, where relevant, de-identified, and will be provided at the lowest possible level of aggregation, while respecting ethical and legal restraints.

8.4.1.4 For the avoidance of doubt "anonymized Data" means that the clinical Data is processed in order to protect, notably during the transfer of the clinical Data from one Party to another, the fundamental rights and freedoms of natural persons. Anonymized data remains personal data as previously defined in section 1.

Back to: TABLE OF CONTENT

A de-identified Data refers to Data from which all personally identifiable information has been removed, i.e. Data that has been rendered unidentified by stripping out any information that would allow someone to determine an individual's identity. A de-identified Data is not considered as a personal Data as defined by the Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995.

8.4.1.5 Data owners are responsible for the assurance of quality, accuracy, and integrity and control of their Data. For new Data, the data management plan will specify a harmonized codebook and quality assurance and control procedures. Data owners can authorize or deny access to existing Data as well as to Data produced outside the HBM4EU Programme. The Data owner is the entity that holds the legal ownership of Data.

8.4.2 Data protection

8.4.2.1 The personal rights of sample donors shall be protected. Only aggregated Data shall be reported. No individual name of a sample donor shall be associated with any published or unpublished report of Results from the HBM4EU Programme.

8.4.2.2 Only anonymized, and/or, where relevant, de-identified, Data shall be provided for statistical analysis. Names and addresses (the identifiable private information) shall be kept decentralized with the cohort owner in a separate database (linked to a personal identification number) in a place physically separated from all other information. All files containing personally identifiable information shall be stored in password protected computer files, preferably on secure servers.

Access to these files shall be limited to authorized Programme personnel. Hard copy records or computer generated records containing personally identifiable information shall be stored in locked cabinets in an office with limited access. All Programme personnel shall be trained in the importance of confidentiality of individual records and required to sign a confidentiality agreement.

8.4.3 Making Data available to other users

8.4.3.1 The Results of the Programme shall be widely communicated and Data be made available to external researchers, policy makers and other stakeholders, including the public, via IPCheM.

Back to: TABLE OF CONTENT

8.4.3.2 Data owners of both new and existing Data shall collaborate with the IPCheM contact point for the human Biomonitoring module, the EEA, and the European Commission's Joint Research Centre to make human Biomonitoring Data and the associated metadata available via IPCheM.

8.4.3.3 For all existing datasets, dedicated metadata webpages on the IPCheM website shall identify the Data owner and a contact point in order to allow external users to approach the Data owner with a specific request for Data access.

8.4.3.4 The Results of the HBM4EU Programme, especially quality assured Data, shall be made available to the European Commission, the EU Agencies and the governments of the participating countries of the Programme without any delay. Further publication and dissemination of the Results have to be agreed with the Data owners.

8.5 Dissemination

8.5.1 For the avoidance of doubt, nothing in this Section has impact on the confidentiality obligations set out in Section 10.

8.5.2 Dissemination of own Results

8.5.2.1 Unless it goes against their legitimate interests, each owner of Results must - as soon as possible - disseminate its Results by disclosing them to the public by appropriate means, in particular through scientific publications and contributions to other media. During the Programme and for a period of 1 year after the end of the Programme, the dissemination of own Results by one or several Parties or Linked Third Parties or other owners of Results including but not restricted to publications and presentations, shall be governed by the procedure of Article 29.1 of the Grant Agreement subject to the following provisions.

8.5.2.2 The Management Board shall adopt upon proposal by the Leader Work Package 2, within the first year, publication rules that aim at ensuring speedy publication of Results and avoiding conflicts of authorship and that take into account the legitimate interests of all Parties and owners of Results.

Back to: TABLE OF CONTENT

Until the adoption and entry into force of such rules the following provisions apply.

8.5.2.2.1 Scientific publications that use HBM4EU results, including Data, shall acknowledge support and funding with the following clause: "This project has received funding from the European Unions´ Horizon 2020 research and innovation Programme under grant agreement No 733032 HBM4EU". Authors should ensure open access that grants online access free of charge for any user.

8.5.2.2.2 Any Party or Linked Third Party or other subcontractor can propose a publication that uses Data or other results from the HBM4EU Programme by submitting a written publication proposal to the Coordinator.

The publication proposal shall specify:

- The proposer and his or her affiliation;
- The target journal;
- A working title;
- An outline of the manuscript;
- A proposed work schedule and date of submission for publication;
- A proposed leader;
- A tentative manuscript group.

8.5.2.2.3 The Coordinator submits the proposal to the Management Board for decision and informs the proposer of the decision. The manuscript is prepared by a manuscript group and overseen by a leader. Authors shall be significant contributors to the design of the study including questionnaires, quality assurance protocols and programs, Data preparation, analysis, design of the publication, and/or writing. They shall be consulted by the leader at key stages and have seen and approved the final draft before submission to the Coordinator. Data and other Results from the HBM4EU Programme may be used for the analysis only with written approval from the owner of these Results. The owner can propose additional members to the manuscript group. The lead author shall inform the Coordinator of the publication of the manuscript.

8.5.2.3 Publications shall be made available in the Knowledge Hub and disseminated to relevant policy bodies at national and EU levels when deemed useful.

Back to: TABLE OF CONTENT

8.5.3 Dissemination of another owner´s unpublished Results or Background

A Party shall not include in any dissemination activity another owner's Results or Background without obtaining that owner's prior written approval, unless they are already published. Parties shall ensure in their contracts with Linked Third Parties and other subcontractors that this obligation is extended to their Linked Third Parties and other subcontractors.

8.5.4 Cooperation obligations

The Parties, including their Linked Third Parties and other subcontractors, 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.

8.5.5 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, including their Linked Third Parties and other subcontractors, or any of their logos or trademarks without their prior written approval.

Back to: TABLE OF CONTENT

Section 9: Access Rights

9.1 Background included

9.1.1 In Attachment 1, the Parties have identified and agreed on the Background for the Programme 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 In Attachment 1, the Parties shall also identify the Background of their Linked Third Parties and other subcontractors.

9.1.3. Any Party may propose to add further Background owned by itself or its Linked Third Parties or other subcontractors to Attachment 1 during the Programme by written notice to the Coordinator to be approved by the Governing Board.

9.2 General Principles

9.2.1 Each Party, including its Linked Third Parties and other subcontractors, shall implement its tasks in accordance with the Description of Action and Annual Work Plan and shall bear sole responsibility for ensuring that its acts within the Programme do not knowingly infringe third party property rights.

9.2.2 Any Access Rights granted expressly 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.

Back to: TABLE OF CONTENT

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 or Linked Third Parties or other subcontractor must show that the Access Rights are needed.

9.2.8 Parties shall ensure in their contracts with Linked Third Parties and other subcontractors that the obligations of the present section are extended to such entities.

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.

Linked Third Parties and other subcontractors have Access Rights under the conditions of the Grant Agreement Articles 25.4 and 31.4. Such Access Rights must be requested by such entities from the Party or Linked Third Party or other subcontractor that holds the Background or Results. Alternatively, the entity 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 Linked Third Parties or other subcontractors. Access Rights to Linked Third Parties and other subcontractors shall be granted upon written bilateral agreement.

Linked Third Parties and other subcontractors which obtain Access Rights in return fulfil all confidentiality and other obligations accepted by the Parties under the Grant Agreement or this Consortium Agreement as if such entities were Parties. Access Rights granted to any Linked Third Party and other subcontractor 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 a Linked Third Party or other subcontractor, any Access Rights granted to such entity shall lapse. Further arrangements with Linked Third Parties and other subcontractors may be negotiated in separate agreements.

Back to: TABLE OF CONTENT

9.4 Access Rights for Exploitation

9.4.1 Access Rights to Results if needed for Exploitation of Own Results of a Party, a Linked Third Party or other subcontractor shall be granted on fair and reasonable conditions. Access rights to Results for internal research activities shall be granted on a royalty-free basis.

9.4.2 Access Rights to Background if needed for exploitation of Own Results of a Party, a Linked Third Party or other subcontractor, Including for research on behalf of a third party, shall be granted on fair and responsible conditions and upon written bilateral agreement.

9.4.3 A request for Access Rights may be made up to twelve months after the end of the Programme or, in the case of Section 9.6.2.1.2, after the termination of the requesting Party's participation in the Programme.

9.5 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 owner and subject to such terms and conditions as may be agreed between the owning and receiving entities.

9.6 Access Rights for Parties entering or leaving the consortium

9.6.1 New Parties entering the consortium

9.6.1.1 As regards Results developed before the accession of the new Party, the new Party, including its Linked Third Parties or other subcontractors, will be granted Access Rights on the same conditions as when applying for Access Rights to Background.

Back to: TABLE OF CONTENT

9.6.2 Parties leaving the consortium

9.6.2.1 Access Rights granted to a leaving Party

9.6.2.1.1 Defaulting Party

Access Rights granted to a Defaulting Party, including its Linked Third Parties or other subcontractors, and such entities' right to request Access Rights shall cease immediately upon receipt by the Defaulting Party of the formal notice of the decision of the Governing Board to terminate its participation in the consortium.

9.6.2.1.2 Non-defaulting Party

A non-defaulting Party leaving voluntarily and with the other Parties' consent, including its Linked Third Parties or other subcontractors, 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.

9.6.2.1.3 Access Rights to be granted by any leaving Party

Any Party, including its Linked Third Parties or other subcontractors, leaving the Programme 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 Programme.

9.7 Specific Provisions for Access Rights to Software

9.7.1 For the avoidance of doubt, the general provisions for Access Rights provided for in this Section 9 are applicable also to software. The Access Rights of Parties, including its Linked Third Parties or other subcontractors, 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 entity granting the Access Rights.

9.7.2 Any Party, including its Linked Third Parties or other subcontractors, which develops software as part of the work Programme, shall make this software available free of charge to the Parties, their Linked Third Parties and other subcontractors for implementation of their tasks under the HBM4EU Programme and for their internal research purposes.

This provision shall not be limited in time and shall continue after the end of the Programme.

Back to: TABLE OF CONTENT

10. Section: Non-disclosure of information

10.1 All information in whatever form or mode of communication, which is disclosed by a Party, including its Linked Third Parties and other subcontractors (the "Disclosing Entity") to any other Party including its Linked Third Parties and other subcontractors (the "Recipient") in connection with the Programme 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 Entity, is "Confidential Information".

The Recipients hereby undertake in addition and without prejudice to any commitment on non-disclosure under the Grand Agreement:

- 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 Entity;
- 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 Entity, or destroy, on request all Confidential Information that has been disclosed to the Recipients including all copies thereof and to delete all information stored in a machine readable form to the extent practically possible. The Recipients may keep a copy to the extent it is required to keep, archive or store such Confidential Information because of compliance with applicable laws and regulations or for the proof of on-going obligations provided that the Recipient complies with the confidentiality obligations herein contained with respect to such copy for as long as the copy is retained.

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

10.3 The above shall not apply for disclosure or use of Confidential Information, if and in so far as the Recipient can show that:

Back to: TABLE OF CONTENT

- The Confidential Information has become or becomes publicly available by means other than a breach of the Recipient's confidentiality obligations;
- The Disclosing Entity 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 Entity;
- 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 Entity; or
- 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 10.6 hereunder.

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

10.5 Each Party, including its Linked Third Parties or other subcontractors, shall promptly advise the Disclosing Entity in writing of any unauthorized disclosure, misappropriation or misuse of Confidential Information after it becomes aware of such unauthorized disclosure, misappropriation or misuse.

10.6 If any Party, including its Linked Third Parties or other subcontractors, 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 Entity, and
- comply with the Disclosing Entity's reasonable instructions to protect the confidentiality of the information.

10.7 Parties shall ensure in their contracts with Linked Third Parties and other subcontractors that the obligations of the present section are extended to such entities.

Back to: TABLE OF CONTENT

Section 11: Miscellaneous

11.1 Attachments, inconsistencies and severability

11.1.1 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 acc. to Section 8.3.2)
- Attachment 4 (List of Programme Owners)
- Attachment 5 (List of Linked Third Parties

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

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 for in this Consortium Agreement, no Party, including its Linked Third Parties and other subcontractors, shall be entitled to act or to make legally binding declarations on behalf of any other Party, including its Linked Third Parties and other subcontractors, 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 or their Linked Third Parties or their other subcontractors.

11.3 Notices and other communication

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

Back to: TABLE OF CONTENT

11.3.1 Formal notices

If it is required in this Consortium Agreement (Sections 4.2, 9.6.2.1.1, and 11.4) 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 or telefax with receipt acknowledgement.

11.3.2 Other communication

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

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

11.4 Assignment and amendments

11.4.1 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.

11.4.2 Amendments and modifications to the text of this Consortium Agreement with the exception of attachments to this agreement require a separate written agreement to be signed by all Parties. However, in case of two or more Parties from one country, written agreement by one of these Parties shall be deemed to be made in the name of all of these Parties.

11.4.3 Amendments and modifications to the Attachments to this Consortium Agreement are adopted by the Governing Board not more frequently than once a year.

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.

Back to: TABLE OF CONTENT

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

11.8.1 The parties shall endeavor to settle their disputes amicably.

11.8.2 The Parties shall endeavor to settle their disputes, controversies or claims arising under, out of or relating to this Consortium Agreement and any subsequent amendments of this Consortium Agreement, including, without limitation, its formation, validity, binding effect, interpretation, performance, breach or termination, as well as non-contractual claims, amicably within the consortium before using mediation or arbitration.

11.8.3 Mediation

Any dispute, controversy or claim arising under, out of or relating to this Consortium Agreement and any subsequent amendments of this Consortium Agreement, 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.

11.8.4 Arbitration

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, it shall, upon the filing of a Request for Arbitration by either Party, be referred to and finally determined by arbitration in accordance with the WIPO Expedited Arbitration Rules.

Back to: TABLE OF CONTENT

Alternatively, if, before the expiration of the said period of 60 calendar days, either Party fails to participate or to continue to participate in the mediation, the dispute, controversy or claim shall, upon the filing of a Request for Arbitration by the other Party, be referred to and finally determined by arbitration in accordance with the WIPO Expedited Arbitration Rules.

The place of arbitration shall be Brussels unless otherwise agreed upon. The language to be used in the arbitral proceedings shall be English unless otherwise agreed upon.

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

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

Back to: TABLE OF CONTENT