Material and associated Data Transfer Agreement to be used in HBM4EU (HBM4EU MDTA)

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Entity	Name of person responsible	Short name of institution	
Work Package Leader	Ulrike Fiddicke	UBA	
Task leader	Dominik Lermen	IBMT	
Responsible author	Dominik Lermen	E-mail	Dominik.lermen@ibmt.fraunhofer.de
Short name of institution	IBMT	Phone	+49 6897 9071 251
Co-authors	Martina Bartel-Steinbach (IBMT), Agneta Åkesson (KI), Marika Berglund (KI), Anna Bergstrom (KI), Karin Leander (KI), Milena Horvat (IJS), Janja Tratnik (IJS), Argelia Castaño Calvo (ISCIII), Marta Esteban (ISCIII)		

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Info: Email: HBM4EU@uba.de
Developed by: IBMT, KI, ISCIII, JSI, VITO

GENERAL DISCLAIMER:

This guidance document has been developed by the HBM4EU task 7.4 team after consulting the HBM4EU data management team.

It is a material and associated data transfer agreement for the transfer and use of materials and the processing of material associated pseudonymised data by a data processor (material recipient) on behalf of a data controller (material provider) within the context of the H2020 project HBM4EU.

This guidance document reflects on our interpretation of GDPR in HBM4EU in which we aim to achieve the highest level of GDPR compliance. However, the application of GDPR is highly fact-specific, and not all aspects and interpretations of GDPR are well-settled.

As a result, this document is provided for informational purposes only and should not be relied upon as legal advice. We encourage you to verify this document with a legally qualified professional of your organization.

HBM4EU Material and associated Data Transfer Agreement (HBM4EU MDTA)

WHEREAS, the Human Biomonitoring initiative HBM4EU has been established as a Consortium of Partners and Third Linked Parties funded by the European Commission co-fund (European Joint Programme, Grant Number 733032), to support the harmonization of Human Biomonitoring activities in Europe.HBM4EU is not a separate legal entity, but is a research project funded by the European Commission.

WHEREAS, the primary objectives of HBMEU are to (i) harmonize procedures for human biomonitoring across 28 countries, to provide policy makers with comparable data on human internal exposure to chemicals and mixtures of chemicals at EU level, (ii) link data on internal exposure to chemicals to aggregate external exposure and identifying exposure pathways and upstream sources. Information on exposure pathways is critical to the design of targeted policy measures to reduce exposure, (iii) generate scientific evidence on the causal links between human exposure to chemicals and negative health outcomes, and (iv) adapt chemical risk assessment methodologies to use human biomonitoring data and account for the contribution of multiple external exposure pathways to the total chemical body burden.

WHEREAS certain specific organizations or groups of organizations (Consortium Members) are participating in HBM4EU and conducting particular HBM4EU Projects in accordance with the Grand Agreement and the Annual Work Plans that are being funded under the grant 733032 from the European Commission.

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WHEREAS HBM4EU Consortium Members (Partners and Third Linked Parties) are all parties to the HBM4EU Data Management Plan and the Data Policy, and its respective agreements on transfer, access and use of data. An updated list of the funded HBM4EU Partners and Third Linked Parties and the above-referenced data management documents are available on the following web site: https://www.hbm4eu.eu/

WHEREAS, the funded Consortium Members fall within one of the following three pillars: Pillar I: Science to policy, Pillar II: European HBM platform, and Pillar III: Exposure and Health.

WHEREAS the HBM4EU governance structure includes the following bodies:
Governing Board: Programme owners in the participating countries, the European Chemicals Agency, the European Environment Agency and the European Food Safety Authority.

Scientific and Administrative Management: the Project Coordinator is supported by the Secretariat, the Co-coordinator, and the Management Board.

National Hubs: a long-term network bringing together national HBM activities and ensuring that they are coordinated, feed their national needs into the European process, contribute to the objectives and learn from the work done in HBM4EU.

Stakeholder Forum: representatives of stakeholders from outside the project that will participate in the prioritization process and provide strategic input in order to enhance the accountability and credibility of our activities.

Advisory Board: including international HBM experts with knowledge and experience to contribute to the project.

WHEREAS the Management Board consists of the Coordinator, the Co- Coordinator, the Pillar Leaders, the National Hub Coordinator, and the leaders of all Work Packages. The European Commission is invited as an observer when deemed relevant. The Management Board is responsible for informing the Governing Board about the ethics and legal framework for the project, implemented through ethics controls and the Data Management Plan.

WHEREAS, it is desired that the handling of Materials and its associated Data provided to or from a Consortium Member and the treatment of Data generated from such Materials be done in a manner consistent with the HBM4EU Data Management Plan and the HBM4EU Data Policy (including to ensure that the objectives of the General Data Protection Regulation, (EU) 2016/679, are met, https://www.hbm4eu.eu/wp-content/uploads/2017/11/Data-Policy.pdf). Hence, the HBM4EU MDTA includes a Data Controller - Data Processor agreement for the exchange of material associated Data according to the requirements of the GDPR.

NOW, THEREFORE, the Parties agree to the following terms and conditions for the transfer of Materials and linked Data with the intention that the terms and conditions are consistent with those that govern the transfer of Materials and Data by HBM4EU Consortium Members under the HBM4EU Data Policy.

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DEFINITIONS

The following terms and their definitions are applicable only to this HBM4EU MDTA, and do not modify any similar terms contained within the HBM4EU Data Policy or any other legal or ethical HBM4EU document:

HBM4EU Data means Data produced by a HBM4EU Consortium Member through the use of Materials provided to it pursuant to this HBM4EU MDTA.

HBM4EU Results means any result conceived as a result of using the Materials provided under the terms of this HBM4EU MDTA.

HBM4EU Projects means the HBM4EU research projects as they have been described as tasks in the annual work plans and conducted by task partners or a single consortium member.

Commercial Purposes means the use of Materials by or on behalf of or for research sponsored by (or transfer of Materials or Data to) a for-profit company.
Data means recorded information.

Personal data means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

Pseudonymisation means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information (key), provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person.

Materials includes, but is not limited to, human body fluids (e.g., spot urine, morning urine, 24-h urine, whole blood, umbilical cord blood, plasma, serum, saliva, breast milk), human tissue samples (e.g., placenta tissue, umbilical cord tissue, adipose tissue), and other human samples (e.g., hair, fingernails), progeny, and unmodified derivatives.

Material associated Data means data that is attributed to each single sample and that identifies its content and sample specific pre-analytical information (e.g., name of study, owner of the study, unique identifier, sampling date, type of sample, sample volume, storage temperature).

For purposes of this definition:

Progeny means unmodified descendants from the original Materials.

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Unmodified Derivatives means substances created by the Recipient which constitute an unmodified functional subunit or product expressed by the original Materials.

Provider means the entity that is providing the Materials and / or having the Materials provided by another entity on its behalf including the principal investigator and / or co-principal investigator or his/her designee employed by such entity who will be physically supplying the Materials. With the material the provider also transfers Material associated Data to the recipient that includes personal data (e.g., a unique identifier) as defined in Art. 4 (1) of the General Data Protection Regulation (GDPR). Hence, for any material transfer under the provisions of this HBM4EU MDTA the provider is also **Data Controller** as defined in Art. 4 (7) of the GDPR.

Recipient means the entity that is receiving the Materials, including the principal investigator or, where applicable, co-principal investigator or his/her designee employed by such entity who will be physically receiving the Materials. With the material the recipient also receives Material associated Data that includes personal data (e.g., a unique identifier) as defined in Art. 4 (1) of the General Data Protection Regulation (GDPR). Hence, for any material transfer under the provisions of this HBM4EU MDTA the recipient is also **Data Processor** as defined in Art. 4 (7) of the GDPR.

Data Controller means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data; where the purposes and means of such processing are determined by Union or Member State law, the controller or the specific criteria for its nomination may be provided for by Union or Member State law

Data Processor means a natural or legal person, public authority, agency or other body which processes personal data on behalf of the Data Controller.

Consortium Member means an individual or entity that is official partner of HBM4EU or a Third Linked Party as defined in the Consortium Agreement and is a party to this HBM4EU MDTA.

Publish or Publishing means the act of communicating to the public, whether through publications, presentations, posters or otherwise, and whether by text or images via written, verbal or electronic means (with such means being referred to collectively as Publications).

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TERMS AND CONDTIONS

1. The terms and conditions of this HBM4EU Material and associated Data Transfer Agreement for use with transfers of Materials and associated Data between HBM4EU Consortium members (HBM4EU MDTA) include the provisions set forth below, as well as the provisions of the HBM4EU Data Policy (https://www.hbm4eu.eu/wp-content/uploads/2017/11/Data-Policy.pdf). In the event that there are any conflicts between the provisions set forth below and those set forth in the HBM4EU Data Policy, the provisions of the HBM4EU Data Policy shall control except as otherwise expressly stated in this HBM4EU MDTA.

2. Transfer of all Materials and associated Data by or to HBM4EU Consortium Members under this HBM4EU MDTA shall be documented through the completion of a Material and associated Data Transfer Record Form (HBM4EU MDTRF; Attachment A). Upon each HBM4EU MDTRF, the Provider shall, among other things, describe the Materials and set forth any additional provisions for the use and the transfer of the Materials with regard to the underlying informed consent of the materials donor, which shall be consistent with and subject to the provisions of this HBM4EU MDTA. In addition, upon each HBM4EU MDTRF, the provider shall describe details concerning the data processing activities performed by the recipient on behalf of the provider. With signing the HBM4EU MDTRF the terms and conditions defined in this HBM4EU MDTA are agreed.

Duplicate originals of this HBMEU MDTRF shall be fully completed and executed and exchanged, **with digital copies of the following legal and ethical documents** defined in the HBM4EU Legal and Ethics Policy Paper (D1.5) Annex 1:

- the filled in Excel Template for Reporting Ethics (D1.5, Annex, https://www.hbm4eu.eu/deliverables/)
- the ethical approval (digital copy)
- the information sheet/material to the recruited participants (digital copy)
- the informed consent template (digital copy)
- the data protection approval (digital copy)
- the biobank approval (digital copy)

to task leader 1.5 (E-mail: liek@sund.ku.dk) and **to the HBM4EU Coordinator UBA** (HBM4EU@uba.de) or to such other e-mail addresses as may be provided by the management board of HBM4EU in the future. Documents in National language have to be explained in English in the Excel Template. Send digital copies **not later than 6 weeks before shipment** and before the analyses of data/samples is planned to start.

3. This HBM4EU MDTA will terminate as regards only Materials and its associated Data transferred under a subject HBM4EU MDTRF on the completion of project the material and its associated is provided for, unless earlier agreed by Provider and Recipient. Upon such termination, Recipient will immediately discontinue its use of the Materials and its associated Data and will, return or destroy any remaining Materials and associated Data as stated by the Provider in the respective HBM4EU MDTRF. Termination of the HBM4EU Project

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(for which the Materials are provided) shall not affect the Provider's rights hereunder. In the event of breach of the integrated Data Controller – Data Processor agreement or the GDPR, the Provider (Data Controller) can instruct the recipient (Data Processor) to stop further processing of the personal data with immediate effect. Upon such termination, Recipient will immediately discontinue its use of the Materials and its associated Data and will, return or destroy any remaining Materials and associated Data as stated by the Provider in the respective HBM4EU MDTRF. Termination of the HBM4EU Project (for which the Materials are provided) shall not affect the Provider's rights hereunder.

4. This HBM4EU MDTA will terminate in its entirety (including but not limited to termination as regards Materials and associated Data transferred under any and all subject HBM4EU Material and associated Data Transfer Record Forms not previously terminated) upon the termination of the HBM4EU Project (31/12/2021).

5. It is acknowledged that the results of the research using the Materials and its associated Data may be important to the Provider or Recipient in its attempts to attract good researchers and secure research funding. Such recognition may be primarily established by Provider making reference to the use of Materials by Recipients, in Publications. It is further acknowledged that the failure to obtain such recognition may adversely affect the Provider's ongoing research activities and funding. Accordingly, the procedures described in the HBM4EU publication policy (https://www.hbm4eu.eu/the-project/, section "knowledge hub") shall be followed considering dissemination of results (such as scientific papers and abstracts for conferences) based on data considered in this agreement. The Recipient shall contact the Provider and provide title, abstract, and author list at latest 30 calendar days prior to submission of material for dissemination. The Data Controller is entitled to request to include 2 co-authors.

6. Any dispute or controversy arising in connection with this HBM4EU MDTA shall first be referred to the parties' respective officers that signed this HBM4EU MDTA, on behalf of the Recipient and Provider, or their successors, for attempted resolution in good faith negotiations within thirty (30) days of notice of such dispute. If such officers are not able to resolve the dispute within the thirty (30)-day period, or any agreed upon extensions, the Recipient and Provider shall be free to resolve the dispute through any dispute resolution mechanism they may individually or collectively choose.

7. If any provision of this HBM4EU MDTA is found to be unenforceable, such provision will be limited or deleted to the minimum extent necessary so that the remaining terms remain in full force and effect.

8. No waiver of any term, provision or condition of this HBM4EU MDTA, whether by conduct or otherwise, in any one or more instances, shall be deemed to be or construed as a further or continuing waiver of the same term, provision or condition, or of any other term, provision or condition of this HBM4EU MDTA.

9. No party shall be liable for any failure to perform as required by this HBM4EU MDTA to the extent such failure to perform is due to circumstances reasonably beyond such party's control, including, without limita-

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tion, labor disturbances or labor disputes of any kind, accident, civil disorders or commotions, acts of aggression or terrorism, acts of God, energy or other conservation measures imposed by law or regulation, explosions, failure of utilities, mechanical breakdowns, material shortages, disease, or other such occurrences..

MATERIAL TRANSFER

10. The Recipient may use the Materials for purposes consistent with the HBM4EU Objectives, as may be further provided in the Material and associated Data Transfer Record Form. The Recipient agrees that Materials (a) will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects, (b) will not be used for Commercial Purposes; and (c) will only be used by individuals who are legally obligated, in the manner and to the extent required in the applicable Material and associated Data Transfer Record Forms, (d) will be provided to HBM4EU Consortium Members only on the terms set forth herein including on the attached Material and associated Data Transfer Record Form.

11. Materials for analysis is provided by the Provider in a pseudonymised form, i.e. coded samples and coded Personal Data so that the individual donor (whether living or deceased) from whom the Materials were obtained (the "Donor") can only be identified with the key for the code (as described below). Note that even encoded or encrypted data is personal data as long as code or encryption key is left. The Provider shall keep the key for the code to the Personal Data for the identification of the Materials and the coded Personal Data during the term of this Agreement. The Recipient acknowledges that Provider will not provide any information to the Recipient about the Materials or Personal Data that can directly identify or be used to identify the Donor. The Recipient acknowledges that since a key exists, the Personal Data and any information derived by Recipient that uses such Personal Data from the Material are deemed to be Personal Data for which the Provider is responsible. Material associated Data transfer must be conducted according to the regulations of the HBM4EU SOP on Sample Exchange and its applicable HBM4EU WP7 Sample Data Transfer Template (available at: https://www.hbm4eu.eu/online-library/). Material associated Data transfer has to be in compliance with the HBM4EU Data Policy and has to follow the provisions defined in the integrated *Data Controller - Data Processor agreement* of this HBM4EU MDTA

12. All Materials shall be shipped following the guidelines and instructions of the respective HBM4EU Standard Operation Procedure (https://www.hbm4eu.eu/online-library/: Standard Operation Procedure (SOP) Shipment) and its further applicable documents. All human body fluids and tissues used in the HBM4EU initiative shall be considered potentially infectious. For this reason, packaging instructions for Category B samples PI650 have to be applied to such materials. Materials will be shipped to Provider's place of business for activities carried out pursuant to this HBM4EU MDTA.

13. With respect to Materials that are transferred to a HBM4EU Consortium Member, the Consortium Member acknowledges that such Materials may be generated using funds independent from the EU Cofund 733032 and may have involved the contributions of institutions that are not Members of the HBM4EU Consortium. Therefore, Materials that were generated from differently funded Institutions or Consortia are subject to the terms and conditions of the HBM4EU Data Policy, as may be revised from time-to-time. The

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HBM4EU Consortium Member agrees to adhere to all of the terms and conditions pertaining to the treatment of data, intellectual property, confidentiality, publication and attribution as expressly stated in the HBM4EU Data Policy and HBM4EU Publication Policy.

14. The use and allocation of ownership or licensing of the Materials and HBM4EU results arising through the use of the Materials is addressed in any attached HBM4EU MDTRF. Such ownership or licensing provisions shall survive termination of this HBM4EU MDTA and shall apply to further transfers of the Material by the Recipient as applicable.

15. Any Materials transferred pursuant to this HBM4EU MDTA are understood to be experimental in nature and may have hazardous properties. The provider makes no representations nor extends any warranties of any kind, either expressed or implied. There are no express or implied warranties of merchantability or fitness for a particular purpose, or that the use of the materials will not infringe any patent, copyright, trademark, or other third party proprietary rights, or that the materials will not pose a health or safety risk.

16. The Recipient and recipient scientist shall use the Materials in accordance with good laboratory practice and the highest standards of skill and care and shall ensure compliance with any applicable laws and regulations governing the transportation, keeping, use and/or disposal of the Materials.

17. Except to the extent prohibited or, where applicable, to the extent authorized by law, Recipient assumes all liability for claims for damages that may arise from its use, storage, and/or disposal of the Materials for activities carried out pursuant to this HBM4EU MDTA. The Provider will not be liable to the Recipient for any loss, claim, or demand made by the Recipient, or made against the Recipient by any other party, due to or arising from the use, storage, and/or disposal of the Materials by the Recipient, except to the extent permitted by applicable law when such loss, claim, or demand is caused by the gross negligence and/or wilful misconduct of the Provider.

18. Provider certifies that, if applicable to the Material being supplied under this HBM4EU MDTA, it has obtained all informed consent(s) and / or other necessary approval(s) and / or authorization(s) in the collection of the Materials necessary to provide the Materials for use in accordance with the HBM4EU MDTRF. Recipient agrees to handle, store, and use the Materials in a safe manner and in compliance with all applicable statutes and regulations, including applicable governmental regulations and guidelines as well as the requirements of relevant regulatory agencies. Recipient certifies that it has obtained any institutional review board and / or ethics committee and / or other approvals that may be required for the use of Materials received under this HBM4EU MDTA as outlined in the respective HBM4EU MDTRF.

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INTEGRATED DATA CONTROLLER - DATA PROCESSOR AGREEMENT ON THE PROCESSING OF PSEUDONYMIZED DATA RELATED TO MATERIAL EXCHANGE IN HBM4EU

Pertaining to the exchange of Materials in HBM4EU under this HBM4EU MDTA, the material Provider equals the Data Controller and the material Recipient equals the Data processor.

Preliminary provisions

This Agreement only includes processing activities entrusted to the Data Processor within the framework of HBM4EU (H2020 Grant Agreement number 733032). The intention of this Data Controller - Data Processor agreement is to regulate the processing of the personal data that the Data Processor handles on behalf of the Data Controller pursuant to the Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data ('GDPR', General Data Protection Regulation). The Data Controller - Data Processor agreement shall ensure that personal data relating to the data subjects is not used unlawfully or comes into the hands of a third party. The Data Controller - Data Processor agreement regulates the Data Processor's processing of personal data on behalf of the Data Controller. The Data Controller - Data Processor agreement stipulates the rights and obligations of both the Data Controller and the Data Processor.

19. The details concerning the processing activities performed by the Data Processor on behalf of the Data Controller are specified in HBM4EU MDTRF (Attachment A), which forms an integral part of this HBM4EU MDTA. Such details are:

- Description of personal data being processed;
- Purpose(s) of the processing;
- Processing activities;
- Adherence to data minimization principle

Only personal data which is mentioned in the HBM4EU MDTRF may and shall be processed by the Data Processor. Furthermore, personal data shall only be processed by the Data Processor in light of the purpose(s) and processing activities which are specified in HBM4EU MDTRF.

In accordance with the HBM4EU data management plan, the Data Controller shall ensure that the data are at least pseudonymised before transfer to the Data Processor; and that only the variables and subset of the data that is needed to perform the processing by the data processor (HBM4EU MDTRF) are transferred.

20. Both Parties explicitly commit to comply with the requirements of the GDPR.

21. The Data Processor processes the personal data only on the documented instructions of the Data Controller set out in the HBM4EU MDTRF and shall not further process the personal data subject to this Data Controller - Data Processor agreement in a manner which is incompatible with these instructions and the provisions laid down in this Data Controller - Data Processor agreement.
The Data Controller can make limited changes to the instructions unilaterally; any changes significantly affecting the core of the Agreement must be agreed upon by both parties. The Data Controller informs the data Processor on limited changes without delay.

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The Data Processor shall immediately inform the Data Controller if, in its opinion, an instruction infringes the GDPR or other Union or Member State data protection provisions to which the Data Processor is subject.

22. The Data Processor shall not engage a sub-Data Processor without prior specific or general written authorization of the Data Controller. In the case of general written authorization, the Data Processor shall inform the Data Controller of any intended changes concerning the addition or replacement of sub-Data Processors, thereby giving the Data Controller the opportunity to object to such changes.

23. In case the Data Processor engages a sub-Data Processor for carrying out specific processing activities on behalf of the Data Controller, the same data protection obligations as set out in this Data Controller - Data Processor agreement shall be imposed on that other sub-Data Processor by way of a contract, in particular providing sufficient guarantees to implement appropriate technical and organizational measures in such a manner that the processing will meet the requirements of the GDPR.

24. Where that other sub-Data Processor fails to fulfil its data protection obligations, the initial Data Processor shall remain fully liable to the Data Controller for the performance of that sub-Data Processor's obligations.

25. The Data Processor commits to handle the personal data and its processing with utter confidentiality. The Data Processor ensures that persons authorized to process the personal data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality.

26. The Data Controller is responsible to enable secure transfer of the data to the Data Processor. The Data Processor shall implement appropriate technical and organizational measures in such a manner that processing will meet the requirements of the GDPR and ensure the protection of the rights of the data subject. The Data Processor shall implement appropriate technical and organizational measures to ensure a level of security appropriate to the risk, according to Article 32 of the GDPR. In assessing the appropriate level of security, account was taken in particular of the risks that are presented by processing, in particular from accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to personal data transmitted, stored or otherwise processed. Where the Data Processor changes the applicable security measures, they shall immediately inform the Data Controller of such changes. The Data Controller reserves the right to suspend and/or terminate this data controller – data processor agreement, where the Data Processor can no longer provide for technical and organizational measures appropriate to the risk of processing. A technical guidance on measures for a secure data transfer is included in HBM4EU SOP Sample exchange: https://www.hbm4eu.eu/deliverables/.

27. The Data Processor shall assist the Data Controller by appropriate technical and organizational measures for the fulfilment of the Data Controller's obligation to respond to requests for exercising the data subject's rights laid down in Chapter III of the GDPR. In case the Data Processor receives a request directly from a data subject, the Data Processor shall first inform the Data Controller within 3 days, without taking any actions. When the Data Processor receives an approved request from the Data Controller, the necessary actions shall be taken in order to fulfil the request within 10 days.

28. The Data Processor shall assist the Data Controller in ensuring compliance with its obligations pursuant to the GDPR. In the case of a personal data breach related to the processing subject of this Data Controller - Data Processor agreement, the Data Processor shall notify the Data Controller and the HBM4EU Coordinator

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(hbm4eu@uba.de) within 24 hours after becoming aware of a personal data breach. This notification shall at least include following information:

the nature of the personal data breach;

the categories of personal data;

the categories and approximate number of data subjects concerned;

the categories and approximate number of personal data records concerned.

Furthermore the Data Processor shall assist the Data Controller in the assessment of the consequences of the personal data breach and the measures taken or proposed to be taken to address the personal data breach, including, where appropriate, measures to mitigate its possible adverse effects. The Data Processor shall assist the Data Controller as they carry out a data protection impact assessment (DPIA) in accordance with Article 35 of the GDPR.

29. The transfer to third parties, in any manner possible is prohibited, unless it's legally required or in case the Data Processor has obtained the explicit consent by the Data Controller to do so. In case a legal obligation to transfer personal data, which are subject to this Data Controller - Data Processor agreement, to third parties, applies, the Data Processor shall - prior to the transfer - notify the Data Controller.

30. The Data Controller is entitled to evaluate the compliance with this Data Controller - Data Processor agreement and has the right to conduct an audit at any time on the location where the processing activities take place. The Data Processor makes available to the Data Controller all information necessary to demonstrate compliance with the obligations laid down in Article 28 of the GDPR and allow for and contribute to audits, including inspections, conducted by the Data Controller or another auditor mandated by the Data Controller, without additional charge.

31. The Data Controller is responsible for obtaining the consent of the data subject for processing his or her personal data according to the provisions of the GDPR. The Data Controller declares that the processing activities subject to this agreement are allowed from ethico-legal perspective. The Data Processor is liable for the damage caused by processing only: where the Data Processor has not complied with obligations of the GDPR specifically directed to Data Processors, where the Data Processor has acted outside or contrary to lawful instructions of the Data Controller. The Data Processor is liable to pay administrative fines which derive from their breach of the provisions of the GDPR. The Data Processor shall be exempt from their liability, if they prove that they are not responsible for the event giving rise to the damage.

32. All Intellectual Property Rights as regards to the personal data and as regards to the databases which contain these personal data are reserved to the Data Controller, unless otherwise contractually agreed upon between the Data Controller and Data Processor.

33. This agreement shall apply upon signature of both parties until the termination of the HBM4EU MDTA (31/12/2021). At the end of this agreement, the data are to be transferred back to the Data Controller and destroyed by the Data Processor, unless a new agreement is made between both parties. The Data Controller declares to maintain a copy of the data for at least 10 years after the end date of this agreement, to enable reproducibility of the results.

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Material and associated Data Transfer Record Form

Provider

Name of the institution:			HBM4EU WP	
Country:				
Partner acronym in HBM4EU: (if available)				
Person in charge	Name:			
	e-mail:			
	phone:			

Recipient

Name of the institution:			HBM4EU WP	
Country:				
Partner acronym in HBM4EU: (if available)				
Person in charge	Name:			
	e-mail:			
	phone:			

The MATERIAL(S) and associated DATA described below are supplied by PROVIDER to the RECIPIENT subject to the terms and conditions of the HBM4EU MDTA, and the HBM4EU Data Policy, which control in the event of any discrepancy between the languages here and there.

Description of the MATERIAL(S): *Briefly describe the MATERIAL(S) being transferred (quantity, type of materials) under the HBM4EU MDTA. Detailed information including the unique identifier of each sample will be provided by the Provider with each shipment as Material associated Data in the HBM4EU WP7.4 Data Transfer Template Form. Add additional pages if required.*

Description of the AGREED USE of the MATERIAL(S) including the termination of this agreement:
Briefly describe how the material will be used (e.g., analysis plan). Add additional pages if required.

State the estimated end date for using the biological materials according to this agreement:

State when the analysis is planned to be finished (year, month):

Samples will be (*please tick box*):

☐ Completely consumed during analysis

☐ Destroyed after analysis. Estimate date for destruction of samples (year, month):

☐ Returned after analysis. Estimate date for return of samples (year, month):

Other:

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Description of the PERSONAL DATA, instructions regarding the processing by the data processor, adherence to data minimization principle, and the termination of this agreement:

This agreement only concerns the variables and subset of the personal data that is needed to perform the processing by the data processor. The data controller is responsible for providing no other information than the variables and subset of the data mentioned below.

Briefly describe the personal data and provide instructions regarding the processing by the data processor.

Estimated end date for data processing according to this agreement (year, month):

The use, transfer, allocation of ownership/licensing of Materials, its associated Data and HBM4EU results that arise from use of the Materials and its associated data shall be consistent with the HBM4EU objectives and intentions. Specific terms and conditions are set forth below:

MATERIAL(S) and its associated Data are to be used for the Agreed Use as stated above only. MATERIAL(S) and its associated Data shall not be transferred by the RECIPIENT to any other party either within or outside HBM4EU without written permission of the PROVIDER. The PROVIDER retains ownership of the MATERIAL(S) and its associated Data. A license to the MATERIAL(S) and its associated Data is granted to the RECIPIENT for the purpose of carrying out the Agreed Use for the period required to complete the Agreed Use or until termination of the HBM4EU MDTA, whichever is earlier. No other licence to the Materials and its associated Data, implied or otherwise, is granted.

The PROVIDER and RECIPIENT, by their duly authorized representatives, hereby accept all terms and conditions expressly stated in the HBM4EU MDTA including its attachment.

Provider	**Recipient**
Date: _____	Date: _____
Signature: _____	Signature: _____

Duplicate originals of this HBMEU MDTRF shall be fully completed and executed and exchanged, **with digital copies sent jointly with the filled in Excel Template for Reporting Ethics** (Annex 1 to D1.5; https://www.hbm4eu.eu/deliverables/) and **digital copies of all legal and ethical documents listed in point 2 of the Terms and Conditions of the HBM4EU MDTA to task leader 1.5** (E-mail: liek@sund.ku.dk) and **to the HBM4EU Coordinator UBA** (HBM4EU@uba.de) or to such other e-mail addresses as may be provided by the management board of HBM4EU in the future. Documents in National language have to be explained in English in the Excel Template. Send digital copies **not later than 6 weeks before shipment** and before the analyses of data/samples is planned to start.

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