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for a healthy future

HORIZON2020 Programme
Contract No. 733032 HBM4EU

Attachment: HBM4EU Data Policy

To Deliverable Report

D 10.1

WP 10 - Data Management and Analysis

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Summary

This document, referred to as the HBM4EU data policy, is an attachment to the HBM4EU Data Management Plan. It applies to the research conducted during the course of HBM4EU in all project's pillars and work packages in which data on human subjects are involved. This includes, but is not limited to, exposure data, health data, biometric data, and molecular data. The only purpose of access and use of the data on human subjects is to meet the objectives of the HBM4EU project, as described in the grant agreement:

- **Objective 1:** Laying the foundations for a pan-European HBM platform that builds on national hubs and existing expertise;
- **Objective 2:** Developing a common methodology for the interpretation and use of HBM data in policy-making;
- **Objective 3:** Harmonising and optimising the practices of national HBM programmes, including sample collection, quality assurance and data management;
- **Objective 4:** Identifying gaps where further data are needed to inform current policy questions and design new, targeted studies to address these knowledge gaps;
- **Objective 5:** Including new HBM data and, where possible, existing HBM data in the European Commission's Information Platform for Chemical Monitoring (IPCHEM);
- **Objective 6:** Linking external to internal exposure in order to improve exposure models for risk assessment;
- **Objective 7:** Developing, validating, and applying exposure and effect biomarkers to improve our understanding of the health risks associated with aggregate exposures;
- **Objective 8:** Identifying chemicals of concern through novel methods for the holistic analysis of HBM samples and improving the use of HBM data in assessing exposure to and the risks of chemical mixtures;
- **Objective 9:** Enhancing our understanding of the causal association between chemical exposure and adverse health outcomes by combining mechanistic studies with existing cohort data;
- **Objective 10:** Promoting knowledge through capacity building at national level through training and exchange programmes;
- **Objective 11:** Engaging with stakeholders, including the general public, throughout the programme to ensure the credibility, accountability and legitimacy of activities and results.

The procedures outlined in this document, shall be followed by all members of the consortium. This ensures that data on human subjects are transferred and used in a secure setting; that use of the data is compliant with ethico-legal requirements (including signed informed consent, ethics approval, and the applicable data protection laws, furthermore the EU data protection regulation, which is applicable from May 2018); and that the use of both existing as well as new data occurs in agreement with the Data Owner/Data Provider.



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Management of datasets that include personal information and health information of study participants will be compliant with the General Data Protection Regulation (GDPR, Regulation (EU) 2016/679). The GDPR is a regulation by which the European Parliament, the European Council and the European Commission intend to strengthen and unify data protection for individuals within the European Union (EU).



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1. Definitions

Analysis pipeline	Workflow based on which the data have been analysed, including statistical analysis protocol
Anonymized data	Single measurement data for which re-identification of data subjects is completely impossible. All possible de-identification keys have been destroyed; de-identification is not possible by combining variables or by matching with any other data.
Consortium partners	As specified in the HBM4EU Grant Agreement (H2020 Grant Agreement number 733032, HBM4EU)
Data generated with HBM4EU co-fund	Collection of (part of) the data has been (partly) funded under H2020 Grant Agreement number 733032, HBM4EU. This includes field work and laboratory analysis.
Data not generated with HBM4EU co-fund	No funding from H2020 Grant Agreement number 733032, HBM4EU has been used to collect the data, including field work and laboratory analysis.
Data Owner	The entity that holds the legal ownership of data, and as such can authorise or deny access to data. In terms of GDPR, the Data Owner is to be considered as Data Controller.
Data Provider	The entity (nominated by the Data Owner) in charge of the collection, acquisition, production, management, quality control and/or publication and dissemination of data.
Data User	The entity that uses data the for research purposes. In terms of GDPR, the Data User is to be considered as Data Processor.
Metadata	The metadata are a series of structured information, common to all the single measurement data in one data collection, which facilitate understanding, tracing and working with the data. In particular, metadata means a set of descriptive elements providing information on the “container of the data” (i.e. the title of a data collection, the abstract describing this data collection, etc.). For aggregated data, the metadata includes also information about the statistical method used for the aggregation. Metadata shall be provided via the IPCHEM metadata template.



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Personal data	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
Project Coordinator	German Environment Agency - UBA, as specified in the H2020 Grant Agreement number 733032, HBM4EU.
Pseudonymisation	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, 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
Single measurement data	Data at individual level, that have been obtained from a particular data subject



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2. The HBM4EU repository

Key point in the procedure for data transfer to the HBM4EU project and subsequent access and use of the data for HBM4EU research is the use of the HBM4EU repository. The HBM4EU repository (**Annex 1**) has been set up to be used by the HBM4EU consortium for data sharing. **It is not allowed to share data on human subjects between members of the consortium via any other channel than the HBM4EU repository.** Consortium members will be able to login to the repository only if they accept the general terms and conditions (*will be based on the conditions set out in the data use agreement, Annex 4*). In addition, the repository may be used for experimental non-personal data, to which the GDPR does not apply, to facilitate data sharing within the consortium and to maximize also the use of these data. The use of the repository for this purpose however, goes beyond the scope of this document¹.

The HBM4EU repository:

- Is a platform that facilitates sharing of data, intermediate results, and results
- Is hosted at JRC – (server location: JRC, Ispra, Italy) - as one of the components of the IPCHEM² architecture and allows integrating part of data in the repository into IPCHEM, when agreed with the Data Owners/Data Providers.
- Is needed to enable the analysis of human biomonitoring data, but also of accessory external exposure data and health data to meet the goals of HBM4EU.
- Enables data users to work with selected quality controlled data sets and versions approved by the Data Owners/Data Providers.
- Enables that Data Owners/Data Providers can chose to which research they will contribute with their data; that use of the data can be detailed, diversified, and flexible according to purpose and to interests of the Data Owners/Data Providers
- Aims to reach the highest level of GDPR compliancy, amongst others by:
 - Relying on the EU authentication platform and security protocols for data sharing.
 - Applying a strict policy in granting and revoking access to the data.
 - Logging of user identity during data access, download, and upload, including version control. This enables to restore the availability and access to the data in a timely manner in the event of a physical or technical incident.

¹ Working with experimental non-personal data is not subject to the GDPR. The HBM4EU repository can be used as an instrument to share also experimental non-personal data, to which the GDPR does not apply, between HBM4EU researchers. However, there is no formal procedure regarding harmonization, neither to grant/revoke access to use these data. As such, these data will be, by default, accessible for the whole consortium in the format they are transferred by the data provider (<https://c.deic.dk/hbm4euethics>).

² <https://ipchem.jrc.ec.europa.eu>



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The responsibilities and obligations of data repository managers are specified in the HBM4EU DMP (Section 3.2). The JRC- IPCHEM team, VITO and UBA are co-managers of the data repository, with specific responsibilities. All content in the repository will be visible to co-managers, this does not grant permission to use the data for any other purpose than repository administration.

Contact details repository managers:

VITO: HBM4EU.DATAMANAGEMENT@vito.be

JRC: ipchem-support@jrc.ec.europa.eu

UBA: HBM4EU.DATAMANAGEMENT@uba.de

3. Transfer of data on human subjects to the HBM4EU repository by the Data Owners/Data Providers

The Data Owner is the unique responsible for the accuracy, integrity and quality of its own data. The Data Owner may nominate a Data Provider who on behalf of the Data Owner will be in charge of the collection, acquisition, production, management, and quality control. Quality criteria are provided by WP10. The nominated Data Provider will also be consulted instead of the Data Owner during any decision process of approving/refusing requests for access to use the data (Section 4).

As access to the repository is limited to HBM4EU partners (Grant Signatories and Linked Third Parties), data can only be transferred to the HBM4EU repository by Data Owners/Data Providers that are specified in the HBM4EU grant agreement. In case Data Owners that are not part of the HBM4EU consortium are willing to share data on human subjects for HBM4EU research, they may nominate a partner of the HBM4EU consortium as data provider who on behalf of the Data Owner will be responsible for implementation of the procedures described in the HBM4EU data policy.

The transfer of data on human subjects to the HBM4EU repository is only considered when the following minimal requirements are met:



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1) Informed consents, ethics approval and – when applicable – approval by local data protection authorities cover the purpose that the data are envisaged to be used within HBM4EU and allow transfer of individual or aggregated data to the HBM4EU repository.

2) The Data Owner/Data Provider agrees that metadata are made publically available via IPCHEM, by filling out and signing the IPCHEM Participation Form for HBM4EU project (**Annex 2**). As such, the procedure ensures close linkage with IPCHEM (Objective 5).

3) The Data Owner/Data Provider agrees to transfer data from the Data Owner/Data Provider storage facilities to the dedicated HBM4EU repository and accepts the HBM4EU Data Policy by filling out and signing the HBM4EU data transfer agreement (**Annex 3**). The data transfer agreement is an agreement between the providing and recipient entity (HBM4EU, represented by the project coordinator) that governs the legal obligations and restrictions, as well as compliance with applicable laws and regulations, related to the transfer of the data between the parties.

Data Owners/Data Providers are responsible to transfer their data to the HBM4EU repository after completing and signing the data transfer agreement. By signing the data transfer agreement the Data Owner/Data Provider is responsible to transfer the data to the HBM4EU repository, according to the agreement (and consequently the GDPR), to update the data any time a new version of them is released and also to maintain the data versioning. The Data Owner/Data Provider agrees to provide the metadata, and data via templates provided by WP10 in order to be able to harmonise the different datasets that are provided.

The Data Owner/Data Provider is also requested to indicate via the IPCHEM Participation Form for HBM4EU, to what extent it is allowed to integrate aggregated and/or single measurement data stored in the HBM4EU repository into IPCHEM; and to which user groups they are available for access and use. The metadata in IPCHEM are *by default* openly available to EU Commission and European Agencies; EU National Bodies; HBM4EU consortium; and the general public. Ensuring that all metadata are available via IPCHEM will enable policy makers to identify datasets. For aggregated and/or single measurement data that are not directly integrated into IPCHEM, the Data Owner/Data Provider can be



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contacted. For data that are integrated in IPCHEM, we refer to section 6 of this document for more detailed information.

All data that are transferred to the HBM4EU repository shall be either pseudonymised or completely anonymized. The Data Owner/Data Provider is responsible for the anonymisation or pseudonymisation process and for ensuring that identifiable variables are not transferred to the HBM4EU repository. Directly identifiable variables include – but are not limited to – national ID number, name, phone number, e-mail address, address, geographical coordinates (at a resolution that allows re-identification of study subjects). One shall also be aware that a combination of just a few indirect identifying variables (such as birth data, gender, and zip-code) can be sufficient to re-identify an individual in a dataset. In this context, the Data Owner/Data Provider shall only provide such variables at the lowest possible resolution that is necessary to for analysis, e.g. district instead of zip-code; year of birth or age instead of birth date.

In the data transfer agreement, the Data Owner/Data Provider specifies the general conditions of subsequent data access and use via the HBM4EU data transfer agreement.

- For **data generated with HBM4EU co-fund** during the course of HBM4EU, the Data Owner/Data Provider shall agree that these data are transferred at high level of granularity to the HBM4EU repository (anonymised or pseudonymised single measurement data); and that the accompanying variables of the study that are needed to solve the envisaged research purpose(s) are also provided as single measurement data. This is a necessity to meet the objectives of HBM4EU. Prior to generation of the data, the Data Owner/Data Provider shall confirm ethico-legal compliance of the study in which new data are generated; and fill out and sign the data transfer agreement. Data generated with HBM4EU co-fund and accompanying variables are, *by default*, directly accessible for use within HBM4EU following the procedures outlined in section 4.
- For **existing data, not generated with HBM4EU co-fund**, the Data Owner/Data Provider specifies the level of granularity that data will be transferred: anonymised single measurement data; pseudonymised single measurement data; or aggregated data. The Data Owner/Data Provider indicates for each level of granularity whether the data are directly accessible for use within HBM4EU. In case the Data Owner/Data



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Provider indicates that the data are not directly accessible for use within HBM4EU, the Data Owner/Data Provider will be asked approval when consortium members request access to the data to meet the goals of a particular objective.

All single measurement data shall be either pseudonymized or anonymized before transfer to HBM4EU and shall be transferred using the template foreseen by WP10, as indicated earlier in this document.

The procedure for requesting access to use data from the repository within HBM4EU is described in section 4.

4. Requesting access to use the data from the HBM4EU repository by consortium members

For all data considering human subjects that are transferred to the repository, a list of the studies together with the metadata (based on metadata provided by the Data Owner/Data Provider) will be directly accessible for HBM4EU consortium partners. This information shall be consulted when preparing a request to access and use the data for HBM4EU research.

For data that are not available to the general public and/or HBM4EU project group via IPCHEM, the procedure outlined in figure 1 shall be followed to be granted access to the data. In this it shall be noted that both for directly and not directly accessible data a procedure is in place. A request to be granted access to and use of the data has to be submitted by the researcher that will take the lead in the analysis of the data, defined as the lead data user. Submission of this request has to be done by filling out an online proposal, in which the researcher shall identify for which research purpose the data that are requested will be used; and the studies, variables, and years that are requested. Research purpose(s) as well as studies and variables shall be selected from a drop down list.

- The list of research purposes is compiled from the annual work plan in which the work package leaders identify research questions for which they expect that the use of data on human subjects is needed to solve the research question(s). These research questions are established in the annual work plan, the work package leader will assign partners to the research questions.



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- The list of studies, variables and years that are needed is compiled from the metadata provided by the Data Owner/Data Provider when transferring the data to the HBM4EU repository

In the process of the evaluation of the proposal in order to grant access to the data user(s), we discriminate between 1) data for which the Data Owner/Data Provider has indicated that the transferred data are directly accessible for use within HBM4EU (default option for data generated with HBM4EU co-fund), and 2) data for which the Data Owner/Data Provider has indicated that the transferred data are not directly accessible for use within HBM4EU. After submission of the proposal, the work package leader is requested to confirm whether the proposed research question is not yet being assigned to other HBM4EU consortium partners. For data that are indicated to be directly accessible for use within HBM4EU, the Data Owner/Data Provider will not be consulted upon confirmation by the work package leader. For data that are indicated to be not directly accessible for use within HBM4EU, the proposal is submitted to the Data Owner/Data Provider. The Data Owner/Data Provider shall approve or refuse the proposal for use of the data within HBM4EU within 30 calendar days. The Data Owner/Data Provider is responsible to identify any potential issues regarding ethics compliance.

Upon approval of a proposal, a data use agreement (**Annex 4**) shall be completed by each data user listed in the proposal. Signing the data use agreement, the data user agrees to not abide the specified terms and conditions of data use, accepts the terms and conditions of HBM4EU repository, and accepts the HBM4EU Data Policy. After signing the data use agreement by the project coordinator, the requested data are made accessible to the user via the HBM4EU repository by the HBM4EU repository administrators within 14 calendar days upon signed agreement.

In case any of the following changes occur during the course of the approved original proposal:

- Significant extension of research scope;
- Change of end date;
- Any changes in the list of HBM4EU users;
- Any additional data required



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an amendment to the original proposal must be completed and submitted via the same online system as the original proposal.

	Data generated with HBM4EU co-fund		Data not generated with HBM4EU cofund	
	Directly accessible for use within HBM4EU	Not directly accessible for use within HBM4EU	Directly accessible for use within HBM4EU	Not directly accessible for use within HBM4EU
Granularity of data transferred to the HBM4EU repository by the Data Owner/Data Provider				
Metadata	Default	Option not allowed	Default	Default
Aggregated data	Default	Option not allowed	Optional	Optional
Pseudonymised/anonymised single measurement data	Default	Option not allowed	Optional	Optional
Process of requesting access to aggregated data and/or single measurement data				
Proposal submission by lead data user	Required	Not applicable	Required	Required
Approval needed by WP lead that research question is not yet assigned to other HBM4EU consortium partners	Yes	Not applicable	Yes	Yes
Approval needed by Data Owner/Data Provider that access to use the data shall be granted to specified data user(s) for the research purpose(s) outlined in the proposal	No	Not applicable	No	Yes
Signed data access and use agreement needed between HBM4EU project coordinator and data user(s) outlined in the proposal	Yes	Not applicable	Yes	Yes

Figure 1 – Overview of the process of being granted access to aggregated data and/or single measurement data.



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5. Publication of results based on data obtained from the HBM4EU repository

The procedures described in the HBM4EU publication policy shall be followed considering submission of any papers for publication and/or abstracts for conferences. At latest 30 calendar days prior to submission of any papers for publication considering data that are provided to HBM4EU partners via the HBM4EU repository, the lead author shall contact the Data Owner/Data Provider by sending a title, abstract, and author list. The Data Owner/Data Provider is entitled to request to include 2 co-authors in scientific publications of results considering the provided data. It is advised to consult the Data Owner/Data Provider as early as possible.

6. Access to and use of the data in IPCHEM

It is a principle aim of the project to increase the availability of human biomonitoring data to policy makers, stakeholders and the broader research community, in order to multiply the benefits that can be generated through its use. Hence, metadata are *by default* directly integrated into IPCHEM from the HBM4EU repository. The metadata in IPCHEM are openly available to European Commission services and European Agencies; EU National Bodies; HBM4EU consortium; and the general public. This will allow identification of existing datasets and enable to contact the Data Owner/Data Provider to request access to use the data. Aggregated data and individual data are only directly integrated into IPCHEM if the conditions set by the Data Owner/Data Provider in the “IPCHEM Participation for HBM4EU project” (**Annex 2**) allow. For aggregated and single measurement data, the Data Owner/Data Provider can indicate to grant/revoke access and use permission to *a priori* defined IPCHEM user groups: European Commission services and European Agencies; EU National Bodies; HBM4EU consortium; and the general public. The Data Owner/Data Provider is granted access by default. For terms and conditions of IPCHEM we refer to the IPCHEM data policy³. The IPCHEM participation form has been adapted for HBM4EU, including the option to grant access to the HBM4EU consortium user group explicitly. The selection of this user group is valid only for the embargo period (duration of the HBM4EU project, until 2022). A user may use all data in IPCHEM according to level of granularity to which the user has access and according to the IPCHEM Data Policy Part “Use of data retrieved via IPCHEM” (Art. 12 and 13).

³ https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/documents/IPChEM_DataPolicy_V2_3_25072016.pdf



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7. Service desk on data management

The helpdesk on data management and analysis is available to guide Data Owners/Data Providers, and Data Users through both the process of a) data preparation and harmonisation including advice on pseudonymisation, filling out the template in which the metadata and data are to be provided; b) data transfer to repository; c) integration of data into IPCHEM; d) the process of being granted access to and use of data via the repository; e) making formal data request and administering the necessary paperwork. The helpdesk for data management is accessible via the internal pages of the HBM4EU website. The helpdesk is managed by VITO and UI for HBM4EU consortium partners. Policy makers can address their questions to HBM4EU.DATAMANAGEMENT@vito.be.



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Annexes

Annex 1: JRC DATA REPOSITORY FOR HBM4EU

Annex 2: IPCHEM participation form for HBM4EU project

Annex 3: Data transfer agreement

Annex 4: Data access and use agreement



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Annex 1: JRC DATA REPOSITORY FOR HBM4EU

NAME	OSS: NextCloud 11. (https://nextcloud.com/)
DESCRIPTION	<p>NextCloud 11 is a self-hosted file sync and share server.</p> <ul style="list-style-type: none"> • It provides a safe, secure, and compliant file synchronization and sharing solution on server(s) under user control. I.e. user shares files and folders own computer, and synchronize them with her/his NextCloud server. • It provides access to data through a web interface and also a platform to view, sync and share the files across devices easily — all under user's control. • It uses an open architecture, extensible via API for applications and plugins and it works with any storage. <p>Similar solution, fully compatible and with the same initial development environment, is used at CERN and also at the JRC for uploading, downloading and sharing data/files via secure and control access.</p>
SERVER	A dedicated server will be set up at the JRC (Ispra, Italy), with a specific installation for HBM4EU data.
SECURITY	The HBM4EU specific installation will have a specific JRC Security Assessment.
Access Authentication and Control	<p>EU Login (former ECAS) Access to NextCloud will be carried out via EU Login account.</p> <p>Access by groups It is possible to manage user Groups (this option will be implemented for HBM4EU once the groups, and related members, have been identified).</p>
Federation Option	<p>It is possible to set up a NextCloud federated servers, at National Hubs level. Meaning that each NH can set up its own servers using NextCloud or other compatible solutions (e.g. ownCloud). The user continues to enter and use the same interface but the data are hosted in the decentralised NH servers.</p> <p>Access Control in case of Federation, non-JRC installation may have a different authentication solution (with adequate security level). Each node maps and recognises the user accounts defined by the other nodes.</p>
Versions management	Versioning is managed and can be set up for the HBM4EU installation of NextCloud 11



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Storage Size	In the current release we are working at JRC, each user has 1 GB. This size can be extended when the server is set up. Max size for a single file: 512 Mega
Time for operational	1,5 month max , from the greenlight of the HBM4EU consortium
Alternative	<i>ownCloud 9.1</i> (https://doc.owncloud.org/#) is a compatible product (and interoperable) also OpenSource maintained by a different company.



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Annex 2: IPCHEM Participation form for HBM4EU project



IPCHEM Participation Form for HBM4EU project

To be completed by Data Providers or Data Owners for making their data accessible via IPCHEM - the Information Platform for Chemical Monitoring

1. Purpose of this form

Using this form, Data Owners/Data Providers shall communicate the conditions under which they agree to make their chemical monitoring data, together with the associated metadata, accessible to the Users of the Information Platform for Chemical Monitoring (IPCHEM).

Data Owners/Data Providers are requested to complete one form per data collection.

Guidelines for the participation in IPCHEM along with explanation of any terms used can be found in the "IPCHEM Participation Guidelines" document⁴.

This form is to be completed by the Data Owner/Data Provider and sent by email to the IPCHEM Team at:

ipchem-support@jrc.ec.europa.eu

2. General information

Name of the data collection	
Name of the Data Provider organisation	
Contact name	
Telephone	
E-mail	

Name of the Data Owner organisation (if different from the Data Provider)	
---	--

⁴ <https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/index.html#info>

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Please provide a metadata description of your data collection using the metadata template.

The metadata should be completed by the Data Provider/Owner and sent by email to the IPCHEM team at: ipchem-support@jrc.ec.europa.eu

3. Data access conditions

Data Providers/Owners are requested to complete the table below in order to indicate the conditions under which their data can be made accessible to IPCHEM Users.

Level of data to which users have access	IPCHEM User Groups			
	1. EU Commission and Agencies	2. EU National Bodies	3. General Public	4. HBM4EU project group
a. Metadata	yes	yes	yes	yes
b. Aggregated data	yes/no/not applicable (select an option)	yes/no/not applicable (select an option)	yes/no/not applicable (select an option)	yes/no/not applicable (select an option)
c. Filtered or generalised single measurement data	yes/no/not applicable (select an option)	yes/no/not applicable (select an option)	yes/no/not applicable (select an option)	yes/no/not applicable (select an option)
d. Single measurement data	yes/no/not applicable (select an option)	yes/no/not applicable (select an option)	yes/no/not applicable (select an option)	yes/no/not applicable (select an option)

The option to make the data accessible only to HBM4EU project group follows indications of Articles 10 and 11 of the IPCHEM Data Policy and related to “Use of IPCHEM for projects on chemical monitoring data”.

This extraordinary project-specific accessibility rules can only last temporarily as long as the specific Project Group exists. Upon the dissolution of the specific Project Group, the data generated, collected or analysed in the course of the Project will have to be made accessible to IPCHEM User Groups according to the Open Data Principles and the Exceptional Accessibility Regimes described in Articles 4-7 of the IPCHEM Data Policy.

Data Providers/Owners have the possibility to ask that additional licensing conditions apply to their data, provided that such conditions do not conflict with the Open Data Principles. In such case, the licensing conditions or a reference thereto will be displayed in the metadata section.

Please select an option between: yes/no/not applicable
(it applies only to the table entries labelled as ‘select an option’).

Licensing conditions (if applicable):

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Please select an option:

Yes	No	If yes, please specify by reference to a standard open licence e.g. Creative Commons or provide text:
-----	----	---

In case of aggregated data, please specify if data are provided as:

- A. Spatially aggregated* (the summary statistics represent aggregation of measurements at Country level, NUTS 1,2,3 Level, City level etc.)

Please provide details:

.....

- B. Temporally aggregated* (the summary statistics represent measurements of a sampling aggregated by months, years, etc.)

Please provide details:

.....

- C. Spatially/temporally aggregated* (the combination of a and b)

Please provide details:

.....

- D. Semantically aggregated* (the summary statistics refer to groups of class of targeted population (humans/biota)

Please provide details:

.....

In case of filtered or generalised single measurement data, please specify if data are provided as:

- D. Filtered* (by removing the attributes that directly or indirectly violate the privacy, such as specific address information, precise spatial coordinates, the identity of the target population, etc.)

Please provide details:

.....

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- E. Generalised* (by the replacement of the specific location of the samplings with coordinates representing a symbolic place, such as the centroid of the town centre, or by removing the number of digits indicating longitude and latitude coordinates)

Please provide details:

.....

Signing this form the Data Owner/Data Provider agrees to make their data collection(s) accessible through the IPCHEM platform and accepts the IPCHEM Data Policy.

Date.....

Place.....

Signature of the Data Owner/Data Provider



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Annex 3: Data transfer agreement

Agreement for transfer of data on human subjects to HBM4EU



Name:

Data Owner/Data Provider (Strikethrough whichever does not apply)

Institution:

Country:

E-mail:

Telephone:

Reference number of IPCHEM Participation form for HBM4EU:

Reference number of ethico-legal documentation:

This form shall only be completed upon submission and approval of ethico-legal documentation related to the study (<https://c.deic.dk/hbm4euethics>). This form is to be completed by Data Owners/Data Providers. In case a Data Provider is assigned by the Data Owner, the Data Provider will be responsible for implementation of the procedures described in the HBM4EU data policy and is mandated by the Data Owner to complete and sign this form. The Data Owner/Data Provider is requested to send⁵ the completed and signed form to:

Umweltbundesamt
 Marike Kolossa-Gehring (Project Coordinator HBM4EU)
 P.O. Box 33 00 22
 14191 Berlin
 Germany

⁵ You can send a digital copy of the document to xx@xx.xx (e-mail address is being established) for notification. However, please note that the print version is the binding one



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1. Purpose of this form

Using this form, Data Owners/Data Providers agree to transfer their data into the HBM4EU data repository and communicate the conditions under which they agree to make their data on human subjects (including exposure data, health data, biometric data, and molecular data) accessible for research within HBM4EU. The Data Owner/Data Provider agrees that metadata are made openly available to HBM4EU consortium as minimal requirement. This agreement is linked to the IPCHEM participation form for HBM4EU in which the Data Owner/Data Provider indicates the conditions under which the data transferred to the HBM4EU repository will be integrated into IPCHEM. The metadata will be directly integrated into IPCHEM.

Considering the responsibility of the repository administrator (JRC, UBA, and VITO), we refer to the HBM4EU data policy.

2. General information

Name of the data collection:

Acronym of the data collection:

Literature reference(s) of the data collection, when available:.....

Contact information of the Data Owner/Data Provider

Name of the Data Owner/Data Provider's institution:

Address of the Data Owner/Data Provider's institution:

Contact name:

Telephone:

E-mail:

3. Data transfer conditions

The Data Owner/Data Provider will fill out and sign the IPCHEM Participation Form for HBM4EU project and provide the metadata accordingly to JRC. The metadata will be available to HBM4EU consortium partners via the repository directly.



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All data on human subjects that are transferred to the HBM4EU repository shall be either pseudonymised or completely anonymized, as described in the HBM4EU data policy. Tick the box below to confirm that identifiable variables will not be transferred:

- I confirm that I will not transfer identifiable variables to the HBM4EU repository. Directly identifiable variables include - but are not limited to - national ID number, name, phone number, ZIP-code, e-mail address, address (including GEO-code at a resolution that risks re-identification).

Indicate whether the dataset includes data that have been generated with HBM4EU co-fund.

- Yes, the dataset includes data that have been generated with HBM4EU co-fund.**

I agree that the data that are transferred to the repository are directly accessible as single measurement data for use within HBM4EU. I agree that I will not be consulted to approve use of these data within HBM4EU. I agree that data generated with HBM4EU co-fund will be provided as single measurement data; and that the accompanying variables of the study that are needed for HBM4EU research are also provided.

Indicate from the list below whether data generated with HBM4EU co-fund will be provided as anonymized single measurement or pseudonymized single measurement data.

- Anonymised single measurement data

Re-identification is completely impossible. All possible de-identification keys have been destroyed; de-identification is not possible by combining variables or by matching with any other data.

- Pseudonymised single measurement data

The dataset does not contain directly identifiable variables. However there is a risk of re-identification: e.g. in combination with an identification key, by combining variables in the dataset, or by combining the dataset with any other data.

- No, the dataset does not include data that have been generated with HBM4EU co-fund.**

Indicate from the list below the level of granularity that these data are transferred to HBM4EU repository (multiple options can be selected). Indicate whether these data are made directly accessible for use within HBM4EU.



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Anonymised single measurement data

Re-identification is completely impossible. All possible de-identification keys have been destroyed; de-identification is not possible by combining variables or by matching with any other data.

Directly accesible for use within HBM4EU:

Yes No

Pseudonymised single measurement data

The dataset does not contain directly identifiable variables. However there is a risk of re-identification: e.g. in combination with an identification key, by combining variables in the dataset, or by combining the dataset with any other data.

Directly accesible for use within HBM4EU:

Yes No

Aggregated data

Summary statistics that refer to groups of the targeted population

Directly accesible for use within HBM4EU:

Yes No

The Data Owner/Data Provider has the possibility to ask that additional licensing conditions apply to their data. In such case, the licensing conditions or a reference thereto will be displayed in the metadata section of the relevant datasets.

Do you have already specific Data licensing conditions (if applicable):

Please select an option:

Yes

No

If yes, please specify by providing a reference to: a specific document or a standard open license e.g. Creative Commons or provide text.

The Data Owner/Data Provider declares that transfer of the data to HBM4EU is allowed from ethico-legal perspective.



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The procedures described in <https://c.deic.dk/hbm4euethics> shall be followed prior to transfer of data to the HBM4EU repository. This includes, but is not limited to, documenting signed consent forms of participants and ethics approval that grant use within HBM4EU.

For datasets that are directly accesible for use within HBM4EU, the use of data for all research within HBM4EU shall be allowed from ethico-legal perspective.

Prior to be granted access to use of data that are not directly accesible for use within HBM4EU, HBM4EU consortium participants will have to submit an online proposal as defined in the HBM4EU data policy. The Data Owner/Data Provider will be consulted to either approve or refuse the proposal. The Data Owner/Data Provider is responsible to check ethico-legal compliance to use the data for the purpose(s) indicated in the proposal, and to identify potential conflicts. Access to use the data is only enabled for proposals that are approved by the Data Owner/Data Provider, and for which ethico-legal conflicts have not been identified by the Data Owner/Data Provider.

Signing this form the Data Owner/Data Provider agrees to make their data collection(s) accessible through the HBM4EU repository, in the conditions indicated, and accepts the HBM4EU Data Policy.

Signature of the Data Owner/Data Provider

Name: **Date:**.....
Place:

Signing this form, the HBM4EU coordinator declares that the data that are transferred will be stored in the HBM4EU repository for the course of the project (until 31/12/2021); and that the data in the repository are managed by the procedures described in the HBM4EU data policy.

Signature of the HBM4EU project coordinator

Name: **Date:**.....
Place:



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Annex 4: Data access and use agreement

Agreement for access to and use of data on human subjects within HBM4EU



Name:

Institution:

E-mail:

Role within HBM4EU:

Reference of approved proposal:

End date of the approved proposal:

This form is to be completed by all HBM4EU members that are listed as data user(s) in approved proposals and sent⁶ to:

Umweltbundesamt
 Marike Kolossa-Gehring (Project Coordinator HBM4EU)
 P.O. Box 33 00 22
 14191 Berlin
 Germany

The information obtained within HBM4EU using data on human subjects is of a highly confidential nature and has been given by the study participants on the understanding that it will be treated in the strictest confidence. Please tick each point and sign at the bottom to indicate that you will abide by these rules:

- 1) I have read and understood the HBM4EU data management plan and data policy. I have followed the tutorial webinar ([link](#)). I confirm that I will follow all rules and procedures that are mentioned.

⁶ You can send a digital copy of the document to xx@xx.xx (e-mail address is being established) for notification. However, please note that the print version is the binding one.



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- 2) I will not de-anonymise the dataset and I will not try to identify study participants.
- 3) I will not report results obtained from the requested data in a way that they allow identification of individuals
- 4) I will not use the data for any other purpose than described in the approved proposal.
- 5) I will not attempt to match the dataset that is the subject of this agreement with any other dataset that has been provided within this project, nor with any other dataset that I have access to, with the purpose of de-anonymisation or identification of data subjects; or without explicit agreement of the data provider(s).
- 6) I will upload all derived variables, analysis pipelines, intermediate results, and/or results to the repository upon analysis to a section of the repository dedicated to this agreement. This section of the repository is only open to data user(s) mentioned in the agreement. The Data Owner/Data Provider can be granted access to this section upon request.
- 7) I will not share data that are subject to the approved proposal with unauthorised persons, i.e. people not listed as data user(s) in the proposal. I will solely share data with members of the HBM4EU consortium listed as data user(s) in the proposal, as I understand that these are the only people that have been granted access to the data. To collaborate with these people (sharing derived variables, data analysis pipelines, intermediate results and results), I will solely work via the HBM4EU repository and I will not use e-mail or any other channel. I will not attempt to distribute the data to any other members of the consortium, nor to any other people outside the consortium.
- 8) If it is necessary to store the data on a local machine for analysis, I confirm that no one else will be able to access this machine. I will not store the data on any place that is accessible by others. I will not use cloud services (other than the HBM4EU repository) to store the data. I do not store more data than necessary for conducting the research on a local machine. I will securely destroy all data related to this proposal stored outside the repository - including all possible back-ups as well as (intermediate) results from the analysis - at the latest at the end-date of my approved proposal. All data from the repository
- 9) I confirm that I will follow the procedures described in the HBM4EU publication policy prior to submission of any papers for publication and/or abstracts for conferences. For publications considering data obtained from the HBM4EU



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repository, I will contact the Data Owner/Data Provider as described in the HBM4EU policy and I am aware that the Data Owner/Data Provider can request to include 2 co-authors.

- 10) I will not share login details that permit access to the HBM4EU repository.
- 11) I will report any breaches of data security immediately to the project coordinator xx@xx.xx (*e-mail address is being established*) (+ phone + address)

Signing this form the data user agrees to not abide these rules, accepts the terms and conditions of HBM4EU repository, and accepts the HBM4EU Data Policy.

Failure to abide by these rules will result in immediate exclusion of access to the HBM4EU repository. Breaches of data access and privacy rules will be prosecuted to the full extent of the civic or criminal law.

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 is specified in the Consortium Agreement.

Signature of the data user

Name: **Date:**.....

Place:

Signing this form, the HBM4EU coordinator declares that the data will be made accessible from the HBM4EU repository to the data user for use for the purpose(s) outlined in the proposal.

Signature of the HBM4EU coordinator, also on behalf of VITO and JRC.

Name: **Date:**.....

Place:

