HBM4EU project

Data management and safeguarding privacy

Lisbeth E. Knudsen,

2ndHBM4EU Training School 2018

B02-Ethics, Session 7:
Information and recruitment of participants
Tuesday, Nov 20th, 11.15-11.45

Data for HBM4EU

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 ethics-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 of DMP.

Data Policy

The Data Policy describes the data management procedures to be followed by the consortium. These procedures ensure that data on human subjects are transferred and used in a secure setting, in compliance with ethico-legal requirements.

Requirements are set under:

1. *Consent forms signed by survey participants*
2. *Ethics approvals at national level*
3. *Data protection laws at national level*
4. *The EU General Data Protection Regulation*
5. *The HBM4EU Data Transfer Form signed by the data owner or provider*

Data Management Plan

1. *The **Data Management Plan** describes the data management life cycle for all datasets collected, processed and generated under the project. It describes:*
2. *How research data is handled during and after the project*
3. *What type of data will be collected, processed and used*
4. *What methodologies and standards will be applied*
5. *Whether and how the data will be made accessible*
6. *How the data are stored*

HBM4EU repository

To share data on human subjects between HBM4EU partners, a secure platform has been established: the HBM4EU repository.

Beyond this, 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.

HBM4EU repository

As such, metadata of all datasets that are subject to this data policy will be directly integrated into IPCheM – the Information Platform for Chemical Monitoring - as a minimal requirement.

This will allow identification of existing datasets and enable to contact the Data Owner/Data Provider to request access to use the data.

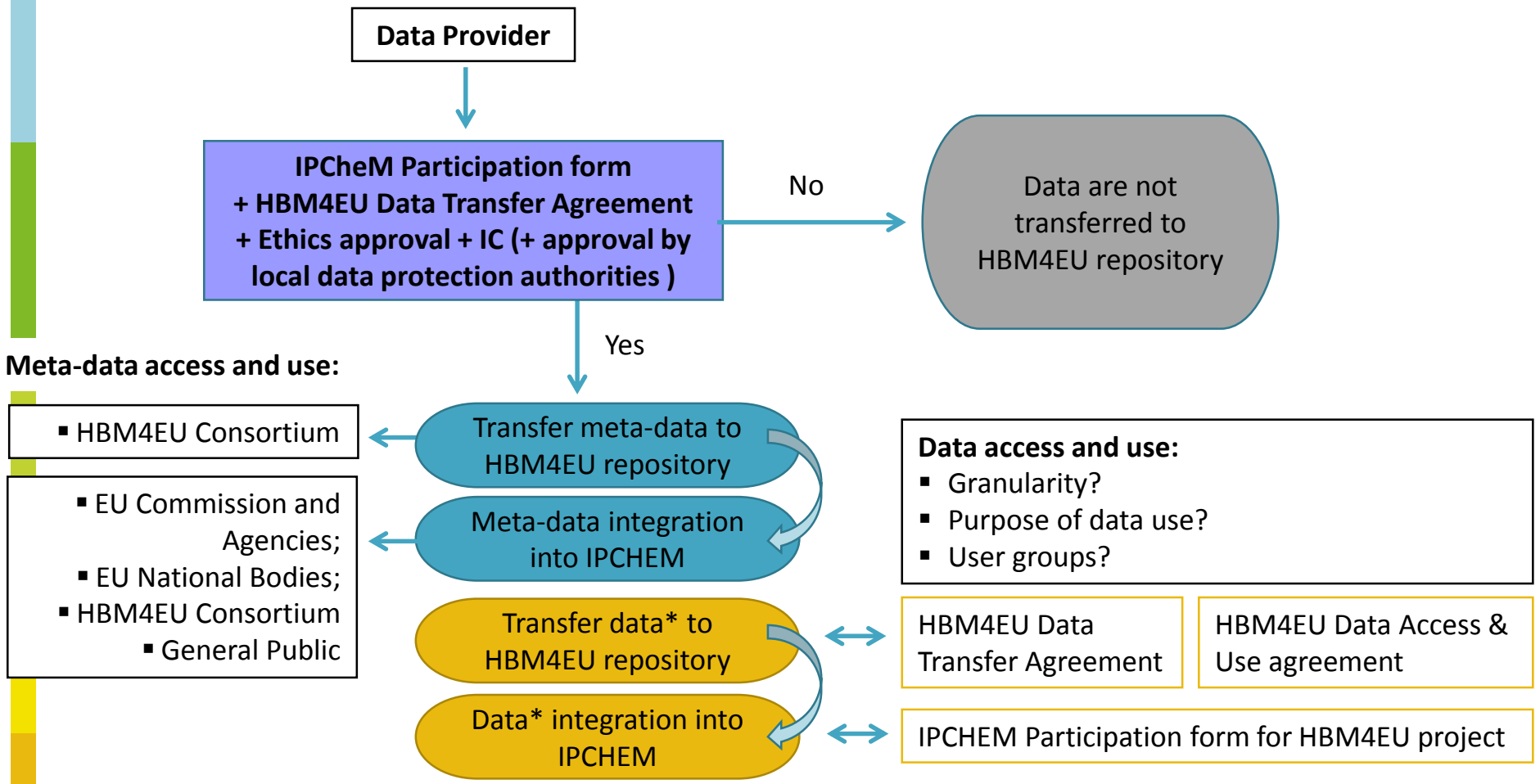
Integration of aggregated and single measurement data will be stimulated, while respecting the ethics–legal framework.

Making data openly accessibly

Points to consider

1. Specify which data will be made openly available? If some data is kept closed provide rationale for doing so
2. Specify how the data will be made available
3. Specify what methods or software tools are needed to access the data? Is documentation about the software needed to access the data included? Is it possible to include the relevant software (e.g. in open source code)?
4. Specify where the data and associated metadata, documentation and code are deposited
5. Specify how access will be provided in case there are any restrictions

Overview of Procedures



HBM4EU repository set up

1. Is a platform that facilitates sharing of data, intermediate results, and results
2. Is hosted at JRC – (server location: JRC, Ispra, Italy) - as one of the components of the IPCheM architecture and allows integrating part of data in the repository into IPCheM, when agreed with the Data Owners/Data Providers.
3. 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.
4. Enables data users to work with selected quality controlled data sets and versions approved by the Data Owners/Data Providers.
5. 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
6. Aims to reach the highest level of GDPR compliancy, amongst others by:
7. o Relying on the EU authentication platform and security protocols for data sharing.
8. o Applying a strict policy in granting and revoking access to the data.
9. o 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.

Granted access

	Data generated with HBM4EU co-fund		Data not generated with HBM4EU cofund	
	Openly accessible for use within HBM4EU	Not openly accessible for use within HBM4EU	Openly accessible for use within HBM4EU	Not openly accessible for use within HBM4EU
Granularity of data transferred to the HBM4EU repository by the Data Owner/Data Provider				
Meta-data	Default	Option not allowed	Default	Option not allowed
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

Procedure

1. Identification of data and samples to be used

2. WPL informs Task 1.5 Leader about selected studies

3. Partner, responsible for the study, provides required ethics documents to the Task 1.5 Leader

At least 6 weeks time interval

Work on data/samples can start

4. List of included studies on the HBM4EU website, updated every 4 weeks

5. Ethics documents provided to the Coordinator

6. The Coordinator uploads documents to the EC/Participant Portal

Information Leaflet

Template p1-2

HBM4EU science and policy for a healthy future

GOVERNMENT / INSTITUTE LOGO

HORIZON 2020

Information for Participants

[HBM4EU biomonitoring study on the exposure to [XX and other harmful chemicals]

How exposed are you to potentially harmful chemicals?
Help us find out and let's create a healthier Europe together

Information for study participants

You are invited to take part in a research study. Before you decide whether or not you wish to take part, please read the following information to understand why the research is being done and what it involves. We are happy to answer any questions or concerns you may have. Your participation is voluntary and may opt out at any time.

HBM4EU and its importance to you and to public health

We are all exposed to a complex mixture of chemicals on a daily basis. Some chemicals may harm health and for this reason they must be regulated in the environment, consumer products, food and drinking water and certain workplaces. HBM4EU (Human Biomonitoring for Europe) is a European study which will use **human biomonitoring** (measurements of environmental chemicals, their metabolites[1] or reaction products in biological samples collected from people) to understand human exposure to such chemicals and the related health risks.

The results will be used to evaluate people's chemical exposure nationally and at European level and wherever appropriate, introduce or adapt relevant laws and interventions. By engaging with participants like you, HBM4EU will help to raise awareness among the public and promote actions to prevent exposures to harmful chemicals.

The study is funded by the European Commission and national governments and includes experts from 28 countries and European Union agencies. It started in 2017 and will run until 2021. In [your country] HBM4EU is under the responsibility of [specify Program Owner].

Learn more at https://www.hbm4eu.eu/

Why is this study being done and who approved it?

'This research study is taking place to [explain research questions, e.g.]

- … find out if the current safety and control measures used across Europe can protect the public from the exposure to [harmful chemicals
- … develop new methods to assess the exposure to these chemicals.
- Investigate potential associations between exposure to these agents and adverse health events
- Identify good practices and propose relevant harm reduction policies
- … other]

The study has been approved by the [*national Bioethics Committee*] and complies with the European General Data Protection requirements[2].

Why am I asked to take part?

[1] A metabolite is the result of the processing of a chemical substance inside the human body

[2] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), *OJ L 119, 4.5.2016, p. 1–88*

AD-IL V3/18

You have been randomly selected [Explain how the selection took place, eg. registry?] to represent [describe the study population in easy to understand terms] in [your country]. If recruiting through an intermediary organization: The [relevant organization] has consented to participate in the study and has agreed to allow the HBM4EU researchers to extend an invitation to you to participate if you decide to do so.
Representativeness and usefulness of the results of the study will depend on people we contact to get involved.

How will the study be carried out?

The study will take [specify time period] in [your country] and [number] other European countries. It will include a total of [number] participants and [number] of them will come from [your country]. Each participant will provide biological samples and will complete a questionnaire. We will analyze this information to determine your exposure to a variety of potentially harmful environmental chemicals.

What do I have to do if I agree to take part?

If you agree to participate, please complete and return the enclosed **green** reply card ("I want to participate") within XX days from its receipt.

OPTION 1: ANONYMOUS orange card, with non-responder questionnaire replies (i.e. no GDPR requirements):
If you do not want to participate, you can help us improve future studies by returning the **orange** reply card within XX days from its receipt. By answering a few optional questions completely anonymously, you can help us to understand how the people who choose not to take part in the study compare to the people who want to take part.

OPTION 2: EPONYMOUS orange card, with non-responder questionnaire replies (i.e. GDPR requirements apply):
If you do not want to participate, please complete and return the **orange** reply card, which contains some optional questions to help us improve future studies. Your information will be kept private and confidential and will be used only according to your consent.

What happens after you receive my reply card? [needs to be adopted according to the national study plan]

1. On receiving your green "yes" card, we will confirm if you are eligible to participate in the study. This study will include volunteers that must meet the following requirements: xxxxxxxx and we can only include participants that fulfill them, up to a maximum of XXX individuals
2. If you do not fulfill the eligibility requirements or the maximum participation limit of this study has been reached by the time when we received your green card, you will receive a letter about it. You may also be asked whether you wish to be contacted by your national study coordinator for participation in future HBM4EU studies.
3. If your participation is confirmed, we will contact you to agree on a suitable date for your appointment with our research team at [OPTION A: our Examination Centre [specify location] and your travel costs will be covered by us / OPTION B: your home].
4. You will be asked to confirm your willingness to participate in the study by completing and signing the enclosed consent form in duplicate. You will keep one copy for your records and

2

we will keep the other for our records. You could ask any questions you wish and request adequate time to clarify your concerns prior to signing.

5. Prior to the appointment, you will receive a pre-visit letter providing you with notice of any preparations required before the appointment. You may also receive a reminder message via phone / SMS / post, if you wish.

How do I prepare for the visit?
No special preparation is necessary. If any preparation is required, you will be informed beforehand.

What will happen during our appointment?
[On arrival at the Examination Centre a member of our team will be available to answer any questions you may have / A member of our research team will visit you at home.] You will have time to ask any questions you may have and receive answers.
If you have not already completed and signed a consent form prior to the appointment, you must do so at this point.
A code will be assigned by the study coordinator, who will then remove all personal identifiable information to protect your privacy and make it impossible to track data or samples back to you.
The researcher will take your [specify biological samples].
We will ask you to compile a questionnaire to collect information about your personal data, living conditions, food intake, your workplace and your possible contact with chemicals.
The visit will last no longer than [XX minutes].[Only if the appointment takes place in an examination centre: You will be given a fixed payment to cover your travel expenses.

What will happen to my samples, data and results?

Your samples will be used only according to your informed consent. The results of the study will not be traceable back to you or any other participant.

We will transfer your coded samples to specialized laboratories for analysis [Specify where the analysis will be contacted for each country]. Your samples will be examined to measure your exposure to [explain which chemical contaminants will be analyzed and why]. Your samples will then be stored at [specify place and length of storage] for possible use in future ethically approved studies of chemical exposure. Coded data collected from you and other participants will be stored and used for research purposes and may be combined with other data from different sources.

The results of the study will be provided to national and European authorities to support policy actions related to chemical management for public health protection. They will also be disseminated to other stakeholders, including the general public, scientists and other interested parties. The sharing of data will be facilitated through dedicated data infrastructures and/or Information systems (e.g. through IPCHEM, which is the European Commission Information platform for Chemical Monitoring[3]).

How can I learn about the results of the study?
When the study is completed [specify according to study plan: in approximately XX weeks/months], you will be informed by NNNN about your *personal* results [for specify], unless you expressed a wish not to receive them on your certificate of informed consent].

[3] https://ipchem.jrc.ec.europa.eu

In the event that high levels of chemicals are detected, you will be advised to review your results with your family / personal doctor.
You will also be informed about the *collective* results of the study. These will be published as a study report and will be openly accessed at https://www.hbm4eu.eu/.

How will my privacy be protected?
HBM4EU complies with the European Data Protection Regulation (EU) 2016/679. Your name will be replaced by a code and all electronic and paper records will be blocked from unauthorized access to protect your private information. Published reports of the study will not contain information that can trace back to you. Third parties will not have access to your personal results, unless you consent to.

Why do you need my written consent?
Your written consent confirms that you volunteer to take part in the study after understanding what is required from you and what your rights are. You have the right to withdraw your participation without any consequence at any point (including any data or samples already provided, if they have not been completely anonymized and so impossible to be traced back to you) and the right to choose if you want to receive your individual results or not. You will also confirm that we can contact you in the future to tell you about your personal results or for historical, statistical or scientific purposes. A copy of the Certificate of Informed Consent, which you will be asked to complete and sign before taking part in the study, is attached to this leaflet and you can keep it for future reference.

How will I benefit if I participate?

- You will have the opportunity to receive a specialized medical briefing, which is not typically available during your routine medical assessment. However, please note that this examination is only complementary to and not a substitute for your regular health care checks.
- You will receive information regarding your exposure to specific chemicals and the associated potential health impact.
- You will have the right to receive your personal results (if you wish) [by law any new high incidence of chemical levels should be reported], which you may subsequently further examine with your doctor.
- You will learn about selected chemicals, their possible effect on health and ways to avoid exposure
- [Describe any other incentives, if applicable]
- You and all people like you in [your country] and in Europe will benefit from the collective results of the study, which will be used to [understand the exposures of people to harmful chemicals and how these can affect the human body / develop harmonized / new methods to measure exposures / develop better chemical management policies across Europe.]

Are there any risks if I join the HBM4EU study?
Some participants may experience minor discomfort during the collection of [blood] samples. All sampling will be conducted by qualified and specially trained health professionals. [If applicable: study participants will be covered by insurance for any adverse events relevant to their participation without any charge]

Are there any costs to me?
No, the study will be conducted at no cost to you. Participation is voluntary, without reimbursement. [If applicable: Travel and out of pocket expenses can be claimed back through [specify how].

What if I have any concerns or complaints while I'm taking part in the study?

Information Leaflet

Template p5

Your wellbeing is our foremost priority and we will take all necessary precautions to ensure your comfort and safety. If you have any concerns during your appointment, please discuss them with our research team or at any time by contacting the study leader ([Title, Name, Tel: [xxxxxxx], Email [xxxxxxx]). You have the right to opt out of the study at any time. In the unlikely event that want to file a complaint about the study, you may do so by contacting [Title, Name, Tel: [xxxxxxx], Email [xxxxxxx], who is not formally connected to the study and serves as an independent overseer of its implementation.

How can I quit the study?
You are free to withdraw from the study at any time, without any consequences by [sending an e-mail to / calling XXX]. We will ask you to confirm your wishes by signing the attached withdrawal form. On this form you can indicate one of the following options:

- "No further contact but samples and data can be used".
  We will no longer contact you, but have your permission to retain and use information and samples that you have already provided.
- "No further contact and my samples and data cannot be used".
  We will no longer contact you and will destroy your samples and data, unless they have been completely anonymized and we cannot trace them back to you. We will retain your signed consent and withdrawal forms as a record of your wishes and for audit purposes.

You can request a copy of this form from us using the contact details provided below.

Who do I contact if I'm unsure about anything or would like further information about the study?
You can contact us on [name, phone number, email] for any further clarifications or visit https://www.hbm4eu.eu/

Thank you for your time and consideration!

Informed consent template

Draft

HBM4EU science and policy for a healthy future

GOVERNMENT / INSTITUTE LOGO

HORIZON 2020

CERTIFICATE OF INFORMED CONSENT

Study description	
Title	Study Code: GS/XX/YY Participant Code: XXXXXXXX

Researcher identifier	
Researcher Name	Telephone
Department	Email
Institution	
Address	

			Initials
I, the undersigned, hereby confirm the following:			
1		I understand that my participation is voluntary in the research as defined in the 'Study description' and that I am free to withdraw at any time (without giving any reason, without our medical care or legal rights being affected), by following the steps explained in the attached information leaflet	
2	a	I have been given the "Information for Participants" leaflet, which explains what my participation involves, including my rights (to be forgotten, to withdraw and remove any data/samples provided, to choose whether I wish to be informed of my personal results) and commitments relevant to the research study.	
	b	I have had the opportunity and time (at least 24 hours) to consider and comprehend the information in the "Information for Participants" leaflet, which provided me a comprehensive understanding on the research plan of the study.	
	c	I have had the opportunity to ask questions and I received satisfactory answers.	
	d	I am aware that in case I withdraw my current consent, my data will be used only for the purpose of the research to be continued.	
3		I consent to < *long-term OR specify duration* > storage and use of my < *specify type* > samples and personal data collected in this study for [OPTION A (OCCUPATIONAL STUDY): the assessment of my occupational exposure to XYZ and its potential health impact / or OPTION B (GENERAL POPULATION STUDY): public and environment health-related research purposes, even in the event of my death or being made incapacitated.	
4		I consent that the < *Specify organization, represented by ..... (specify position in Organization of principal investigator)* > will have the exclusive access to my personal information and will encode my data and samples with a method - according to the currently available safeguards – so that other users of my data cannot trace back to me, identifying my/our individual track.	
5		I consent that my coded samples and/or data can be transferred to specialized laboratories, biobanks, databases, data infrastructures, research establishments, administrative authorities and institutions in the European Union and associated countries or used for public announcements and reports within the scope of the study.	
6		I consent that the < *Specify organization, represented by ..... (specify name and full contact details of principal investigator* > may contact me in the future for public and environment health-related research purposes.	
7		I understand that I will not benefit financially from taking part in this study	
8		I understand that I have the right to receive my personal results as stated in the information leaflet and I indicate my preference as follows: *Please mark **one** option only.* ☐ I wish to **receive** my personal results ☐ I wish to **receive** my personal results **only if** they exceed the health-based guidance values used in the study ☐ I do not wish **to receive** my personal results	

To be completed if the participant is unable to provide signature:

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Thumb print of participant

Name of person taking consent	Signature of person taking consent	Date

Statement by the researcher/person taking consent

I have read out the information leaflet and consent form to the potential participant, and to the best of my ability I have made sure that they understand that the following will be done:

1. <<.....>>
2. <<.....>>
3. <<.....>>
4. <<.....>>

I confirm that they were given an opportunity to ask questions about the study, and all the questions asked have been answered truthfully and to the best of my ability. I confirm that the individuals have not been coerced into giving consent, and that consent has been given freely and voluntarily without any objection raised.

A copy of this Informed Consent has been provided to the participant.

Print Name of Researcher / person taking the consent	Signature of Researcher / person taking the consent	Date

2

AD-CF V3/18

Data Transfer

Form to be used

HBM4EU Data Transfer Form	
Purpose of the form and signatures	P. 1

Version Number of the HBM4EU Data Transfer Form: 2

Release Date: 15/12/2017

---

1) Purpose of this form:

The data transfer documentation 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 management plan and data policy.

Using this form, Data Owners/Data Providers indicate under which conditions the data to which this agreement applies (Part A) are transferred to the HBM4EU repository (Part B) and integrated into IPCHEM (Part C). The metadata shall be made openly available via IPCHEM as minimal requirement.

2) Signatures:

Signing this form the Data Owner/Data Provider:

1) agrees to make the data collection(s) (specified in Part A of this form),

Data Transfer

Form to be used

HBM4EU Data Transfer Form	
Purpose of the form and signatures	P. 1

Version Number of the HBM4EU Data Transfer Form: 2

Release Date: 15/12/2017

---

1) Purpose of this form:

The data transfer documentation 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 management plan and data policy.

Using this form, Data Owners/Data Providers indicate under which conditions the data to which this agreement applies (Part A) are transferred to the HBM4EU repository (Part B) and integrated into IPCHEM (Part C). The metadata shall be made openly available via IPCHEM as minimal requirement.

2) Signatures:

Signing this form the Data Owner/Data Provider:

1) agrees to make the data collection(s) (specified in Part A of this form),

Data Transfer

Form to be used

HBM4EU Data Transfer Form	
Purpose of the form and signatures	P. 2

To be filled out by the Data Owner

Name Data Owner *(contact mentioned as Data Owner in Part A)*	Lisbeth E. Knudsen
Date *Format: DD/MM/YYYY*	27/03/2018
Place *Format: City, Country*	Copenhagen, Denmark
e-Signature Data Owner *!! All fields in this form are locked upon submission of signature, except the table with signature of the project coordinator. Please make sure all fields are filled out properly before signing this document*	Lisbeth E. Knudsen Digitalt signeret af Lisbeth E. Knudsen Dato: 2018.03.27 13:22:19 +02'00'
Inkt Signature Data Owner	

Data Transfer

Form to be used

To be filled out by the Data Provider (in case a Data Provider has been mandated by the Data Owner)

Name Data Provider *(mentioned as Data Provider in Part A)*	.....
Date *Format: DD/MM/YYYY*	.....
Place *Format: City, Country*	.....
e-Signature Data Provider	.....
Inkt Signature Data Provider	.....

To be filled out by the HBM4EU Project Coordinator

Name HBM4EU Project Coordinator	.....
Date *Format: DD/MM/YYYY*	.....
Place *Format: City, Country*	.....
e-Signature Project Coordinator (also on behalf of VITO, for HBM4EU repository management tasks) !! All fields in this form are locked upon submission of signature	.....
Inkt Signature Project Coordinator (also on behalf of VITO, for HBM4EU repository management tasks)	.....

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 HBM4EU repository are managed by the procedures described in the HBM4EU data policy".

Data Transfer

Form to be used

HBM4EU Data Transfer Form	
Purpose of the form and signatures	P. 3

3) Submission of the form:

The Data Owner/Data Provider is requested to send the completed and signed (inkt signature) form to: Umweltbundesamt, Marike Kolossa-Gehring (Project Coordinator HBM4EU), P.O. Box 33 00 22, 14191 Berlin, Germany. The print version with inkt signature is the binding one.

Furthermore, it is requested to submit the completed electronic form using the "Submit form" button. In case of technical issues submitting the form, please send it via e-mail to HBM4EU.DATAMANAGEMENT@vito.be. Including e-signature will enable to progress faster to the process of transfer of the data. However, the print version with inkt signature shall arrive no later than 4 weeks upon submission of the electronic form at the above mentioned address.

The form must be named using the following rules:
Acronym of the organisation_Acronym/short name of the data collection_HBM4EUData TransferForm, e.g. UBA_ESB_HBM4EUDataTransferForm

UCPH _DK-DEMOCOPHES……_HBM4EUDataTransferForm.pdf

Part B: HBM4EU Data Transfer Agreement

1) Purpose of Part B

In this part, Data Owners/Data Providers indicate the conditions under which they agree to make their data (Part A) accessible for research within HBM4EU via the HBM4EU repository.

Prior to be granted access to use of data that are indicated as not directly accessible for use within HBM4EU, the Data Owner/Data Provider is consulted. The Data Owner/Data Provider will be consulted to either approve or refuse a proposal that is submitted for use of the data. The contents of the proposal and the process for submitting a proposal is outlined in detail in the HBM4EU Data Policy. 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.

Data Transfer

Form to be used

2) Data transfer conditions

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 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 anonymised single measurement or pseudonymised 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.

Data Transfer

Form to be used

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

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

☐ 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 accessible 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 accessible for use within HBM4EU:

☐ Yes ☐ No

☑ Aggregated data

Summary statistics that refer to groups of the targeted population, e.g. by sex

Directly accessible for use within HBM4EU:

☑ Yes ☐ No

Data Transfer

Form to be used

Part C: 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

Filling out Part C of the 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 User Group(s) 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" document[1].

2) Metadata provision

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 VITO HBM4EU data management team at: HBM4EU.DATAMANAGEMENT@vito.be that collects the metadata on behalf of the IPCHEM team, in charge to create the corresponding metadata page for each data collection publicly available in the IPCHEM platform.

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 (HBM4EU harmonised[2])	☐ *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. Aggregated data (own format)	☐ *yes* ☐ *no* ☐ *not applicable*	☐ *yes* ☐ *no* ☐ *not applicable*	☐ *yes* ☐ *no* ☐ *not*	☐ *yes* ☐ *no* ☐ *not*

Data Transfer

Form to be used

	(select an option)	*(select an option)*	*applicable (select an option)*	*applicable (select an option)*
d. Single measurement data (HBM4EU format[3])	☐ *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)*
e. Filtered or generalised single measurement data (own format)	☐ *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)*
f. Single measurement data (own format)	☐ *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 Transfer

Form to be used

In case of aggregated data (own format-not harmonised according to the HBM4EU Codebook), 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.)

[3] Single measurement data can be integrated into IPCHEM in own format or in HBM4EU harmonized format. HBM4EU has generated a harmonized template to provide single measurement data. Providing the data in HBM4EU harmonized format improves comparability with other studies as the data are displayed in the same unit of measurement, the same protocol is used for categorical data, … It will be clearly visible for end users whether the individual data have are available in HBM4EU harmonized format.

Data transfer

Form to be used

☐ 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:

☐ E. *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:

.....

☐ F. *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:

.....

Metafiche

DK DEMOCOPHES

Data collection Name/Title (Mandatory)	Denmark-DEMOnstration of a study to COordinate and Perform Human biomonitoring on a European Scale
Data collection short name/acronym (Mandatory)	DK-DEMOCOPHES
Level of data granularity (Mandatory)	Metadata (only)
Data collection language (Mandatory)	Other
If "Other", please specify	Danish
Version number (Recommended, when applicable)	
Version issue date (Recommended, when applicable)	

Metafiche

DK DEMOCOPHES

General aim and description of the data collection (Mandatory)	The Danish part of the large European Human biomonitoring pilot project DEMOnstration of a study to COordinate and Perform Human biomonitoring on a European Scale (DEMOCOPHES) investigated the urine, hair and blood concentrations of 66 different environmental chemicals in a group of 145 Danish school children aged 6–11 years and their mothers from rural and urban areas in autumn 2011. Mercury was measured in hair and cotinine, phthalate metabolites, and cadmium in urine samples. In urine, supplementary measurements of parabens, phenols, including paracetamol, and organophosphates were made. In supplementary bloodsamples persistent chemicals (including biomarkers of polychlorinated biphenyls (PCBs), hexachlorobenzene (HCB), beta-hexachlorocyclohexane (β-HCH), dichlorodiphenyltrichloro-ethane (DDT), polyfluoroalkyl substances (PFASs) and polybrominated diphenyl ethers (PBDEs) which are all classified as (POPs) were measured. Also, micronucleus and dioxinlike activity were measured in blood.
Specific monitoring reason(s) (Recommended)	To harmonize HBM in Europe to allow comparison of data among countries and provide tools for follow-up of temporal and spatial trends in chemical exposures pilot project.
Target Population (Recommended)	General population (non-clinical population)

Metafiche

DK DEMOCOPHES

	Starting date of the data collection campaign (Mandatory, at least mm-yyyy)		19-09-2011
	Ending date of the data collection campaign (Mandatory, at least mm-yyyy)		16-12-2011

Information about the conditions of data access and use	
License of use (Mandatory)	2011-41-6607 and 2011-41-6766 (Danish Data Protection Agency). H-3-2011-075 (regional ethics committee). Additional regional ethics approval H-1-2014-004. The authorisation is valid until 31st December 2021. Processing (including storing) of personal data after the expiry of the authorisation period is a violation of the Danish Act on Processing of Personal Data, cf. § 70
or: Link (URL) to License	
Access conditions (Mandatory)	Public
or: Link (URL) to Access conditions	

Text for acknowledgement/Disclaimer (Recommended)	Original publications reporting the results from Danish DEMOCOPHES participants: Knudsen et al. (2017) Biomonitoring of Danish school children and mothers including biomarkers of PBDE and glyphosate Doi: 10.1515/reveh-2016-0067; Egsmose et al. (2015) Associations between plasma concentrations of PCB 28 and possible indoor exposure sources in Danish school children and mothers; Mørck et al. (2016) Micronucleus frequency in Danish schoolchildren and their mothers from the DEMOCOPHES population Doi: 10.1093/mutage/gev054; Mørck et al. (2015) The Danish contribution to the European DEMOCOPHES project: A description of cadmium, cotinine and mercury levels in Danish mother-child pairs and the perspectives of supplementary sampling and measurements Doi: 10.1016/j.envres.2014.07.028; Mørck et al. (2015) PFAS concentrations in plasma samples from Danish school children and their mothers Doi: 10.1016/j.chemosphere.2014.07.018; Nielsen et al. (2015) N-acetyl-4aminophenol (paracetamol) in urine samples of6–11-year-old Danish school children and their mothers Doi: 10.1016/j.ijheh.2014.07.001; Frederiksen et al. (2013) Urinary excretion of phthalate metabolites, phenols and parabens in rural and urban Danish mother-child pairs Doi: 10.1016/j.ijheh.2013.02.006; Mørck et al. (2014) PCB concentrations and dioxin-like activity in blood samples from Danish school children and their mothers living in urban and rural areas Doi: 10.1111/bcpt.12214; Mørck et al. (2016) Organophosphate metabolites in urine samples from Danish children and women Measured in the Danish DEMOCOPHES population. Published by: The Danish Environmental Protection Agency, available at: https://www2.mst.dk/Udgiv/publications/2016/08/978-87-93529-03-8.pdf;

Metafiche

DK DEMOCOPHES

Ethical approval (Mandatory)			
Ethical approval			
If yes, by whom?			
Institutional policy			FALSK
Ethics committee			SAND
Deontology committee			FALSK
Other		A	
If "other", please specify		Danish Data Protection Agency	
Point of contact for ethic documents (Recommended)			
Name		Lisbeth E. Knudsen	
Affiliation		UCPH	
Phone		+45 35 32 76 53	
Email		liek@sund.ku.dk	

Yes No

Responsible organisation of the data and contact points	
Name of the Institution responsible of the data (Mandatory)	UCPH
Role (Mandatory)	Data Owner
Type of Institution (Recommended)	University
Name of the Principal Investigator (Mandatory)	Lisbeth E. Knudsen
Point of contact for data and information on data (Mandatory)	
Name	Lisbeth E. Knudsen
Affiliation	Section of Environmental Health, Department of Public Health, University of Copenhagen, Øster Farimagsgade 5, 1410 Kbh K, Copenhagen, Denmark

In case of other organisations involved (Recommended, when applicable)	
Other Institution involved during the data collection, analysis, creation and/or publication	SDU, Southern University of Denmark
Role	Data Processor
Other Institution involved during the data collection, analysis, creation and/or publication	Region H, Department of Growth and Reproduction, Section 5064, Rigshospitalet, Copgenhagen University Hospital, Blegdamsvej 9, 2100 Copenhagen, Denmark
Role	Data Processor
Other Institution involved during the data collection, analysis, creation and/or publication	Institute for Prevention and Occupational Medicine of the German Social Accident Insurance (IPA), Institute of the Ruhr University Bochum
Role	Data Processor
Other Institution involved during the data collection, analysis, creation and/or publication	Flemish Institute for Technological Research NV (“VITO”), Belgium
Role	Data Processor

Sampling related information

Type of biological samples/matrix collected (Mandatory)	Number of samples (Mandatory)	Volume of samples (Recommended)	Unit of Measurement for Volume (Recommended)	If "Other" UoM for Volume (Recommended)	Sampling method (Recommended)	In case of combined population (Mandatory)
Blood-whole blood	259	20	mL	☑	venipuncture	Mother and child pairs population
Blood -plasma				☐		
Blood -serum				☐		
Cord blood-whole blood				☐		
Cord blood-plasma				☐		
Cord blood-serum				☐		
Urine-spot				☐		
Urine-24h				☐		
Urine-morning urine	288	15-860	mL	☐	First morning void	Mother and child pairs population
Saliva/sputum				☐		
Semen				☐		
Hair	289	3	cm	☑	closest to the scalp	Mother and child pairs population
Breast milk				☐		
Adipose Tissue/Fat				☐		
				☑		
If other, please specify:				☐		
				☐		
For urinary samples: availability of information on the dilution level (Mandatory, if available)				☐		
No information		FALSK				
Creatinine		SAND				
Specific gravity		FALSK				

Metafiche

DK DEMOCOPHES

Group	Chemical name (Mandatory)	Acronym/ Sinonym	CAS (Mandatory, if available)	Bio-specimen/matrix of the sampling (Mandatory)	If "Other" Bio-specimen/matrix of sampling (Mandatory)	Starting date of the sampling (Mandatory)	Ending date of the sampling (Mandatory)	In case of combined population (Mandatory)	Unit of Measurement (Mandatory)	If "Other" Unit of Measurement (Mandatory)	LOD (Fixed number, range or not available) (Mandatory)	LOD value if "Fixed" (Mandatory)	Min. LOD value if "Range" (Mandatory)
Phthalates and Hexamoll® DINCH	Diethyl phthalate (DEP)												
	Monomethyl phthalate	MEP		Urine-morning urine		19-09-2011	16-12-2011	Mother (in Mother and child pairs population)	µg/L		Fixed	0.53	
	Monomethyl phthalate	MEP		Urine-morning urine		19-09-2011	16-12-2011	Child pairs (in Mother and child pairs population)	µg/L		Fixed	0.53	
	Diisobutyl phtalate (DiBP)												

Study population information

Population addressed (Mandatory)		Number of participants (Mandatory)	
General population		FALSK	
Adults	☐	FALSK	
Children	☐	FALSK	
Adolescents	☐	FALSK	
Elderly	☐	FALSK	
Mother-newborn pairs	☐	FALSK	
Mother and child pairs	☐	SAND	145 pairs
Pregnant women	☑	FALSK	
Specific sub-population	☐	FALSK	
Case-control	☐	FALSK	
Other	☐	FALSK	
	☐		
If "Other" please specify			
The Study Population information collected are:	Different for each addressed population		

FOR EACH ADDRESSED POPULATION:

☑ Personal factors information available for each participant (Reccomended)						
First addressed population (Mandatory)		Mother (in Mother and child pairs population)				
Mean age						SAND
Range age						FALSK
From age (Mandatory):		31 Year				
To age (Mandatory):		52 Year				
Sex of participants (Mandatory)			Women			
Height						SAND
Weight						SAND
Educational level						SAND
Race/Ethnicity						FALSK
Income						SAND
Medical data/history						FALSK
Place/Country of birth						SAND

Metafiche

DK DEMOCOPHES

Lifestyle information available for each participant (Optional)	
Smoking behaviour	SAND
Alcohol consumption	SAND
Occupation	SAND
Cosmetics use	SAND
Time activity patterns	SAND
Sociodemographic variables	SAND
Housing information	SAND
Combustion behaviour	SAND
Parity	FALSK
Breastfeeding	FALSK
Physical exercise	FALSK
Personal hygiene	SAND
Personal behaviour	FALSK
Food and feed information available for each participant (Optional)	
Food consumption	SAND
Environmental factors information available for each participant (Optional)	
Consumption of local food/feed	SAND
Urban versus non-urban	SAND

☑ Personal factors information available for each participant (Reccomended)						
Second addressed population (Mandatory, when applicable)		Child pairs (in Mother and child pairs population)				
Mean age						SAND
Range age						SAND
From age (Mandatory):		6 Year				
To age (Mandatory):		11 Year				
Sex of participants (Mandatory)		Both				FALSK
Height						SAND
Weight						SAND
Educational level						SAND
Race/Ethnicity						FALSK
Income						SAND
Medical data/history						FALSK
Place/Country of birth						SAND
Lifestyle information available for each participant (Optional)						

HBM4EU science and policy for a healthy future

Submission of documents related to research ethics and data/material transfer

Version 2018-28-05

Name of the study	In national language	
	In English	
	Used acronym	
	Country	Country ?
	Webpage of study	
Owner of the study	Institute	
	Contact person(s) name(s) and e-mail address(es)	
	Partner in HBM4EU	Partners ?
	For LTP, the beneficiary	Beneficiary ?

Please note: The filename should be descriptive of the contents and should include as prefix "InstituteAcronym_StudyAcronym_". For the different document types a different suffix: "InformedConsent","InformationLeaflet","EthicalApproval", ... or whatever is relevant as naming (e.g. UBA_ESB_InformedConsent).
Avoid that the documents are named in national languages.

We emphasize to please use the same acronym for institute and study when filling out all other documentation regarding their data collection (such as the metadata fiche, data transfer agreement, material transfer agreement, ...).

			Comments:
Informed consent	Copy of the informed consent(s) and related information material in national language	Drop down	file name:
	Copy of the informed consent(s) and related information material in English, in available	Drop down	file name:

HBM4EU science and policy for a healthy future

Submission of documents related to research ethics and data/material transfer

Version 2018-28-05

Name of the study	In national language	
	In English	
	Used acronym	
	Country	Country ?
	Webpage of study	
Owner of the study	Institute	
	Contact person(s) name(s) and e-mail address(es)	
	Partner in HBM4EU	Partners ?
	For LTP, the beneficiary	Beneficiary ?

Please note: The filename should be descriptive of the contents and should include as prefix "InstituteAcronym_StudyAcronym_". For the different document types a different suffix: "InformedConsent","InformationLeaflet","EthicalApproval", ... or whatever is relevant as naming (e.g. UBA_ESB_InformedConsent).
Avoid that the documents are named in national languages.

We emphasize to please use the same acronym for institute and study when filling out all other documentation regarding their data collection (such as the metadata fiche, data transfer agreement, material transfer agreement, ...).

			Comments:
Informed consent	Copy of the informed consent(s) and related information material in national language	Drop down	file name:
	Copy of the informed consent(s) and related information material in English, in available	Drop down	file name:

Template

			Comments:
Ethical approval	Copy of the ethical approval in national language	Drop down	file name:
	Copy of the ethical approval in English, if available	Drop down	file name:
	If English version not available, provides a short summary of the contents	Free text field	
	Is secondary use of data/samples in HBM4EU allowed	Drop down	
	Name of the body/bodies issuing the ethical approval	Free text field	
	Date of approval		
	Identification number for approval	Free text field	
	Expiration date for approval		
			Comments:
Data protection	Copy of the data protection approval in national language	Drop down	file name:
	Copy of the data protection approval in English, if available	Drop down	file name:
	If English version not available, provides a short summary of the contents		
	Can aggregated data be transfered to HBM4EU repository	Drop down	
	Can single measurement data be transfered to HBM4EU repository	Drop down	
	Can aggregated data be transfered to HBM4EU repository	Drop down	
	Name of the body/bodies issuing the data protection approval		
	Date of approval	Date:	
	Identification number for approval		
	Expiration date for approval	Date:	

Template

Biobank	Copy of the biobank approval in national language	Drop down	
	Copy of the biobank approval in English, if available	Drop down	
	If English version not available, provides a short summary of the contents		
	Is secondary use of data/samples for HBM4EU allowed	Drop down	
	Name of the body/bodies providing approval		
	Date of approval	Date:	
	Identification number for approval		
	Expiration date for the approval	Date:	
Renewal of the approval(s) is required before use in		Drop down	
Which documents require renewal?		Approval ?	

Template

			Comments:
According to the documentation provided, the following operations can be considered, after consultation of the data controller	Use of single measurement data for specific HBM4EU objectives	Drop down	
	Use of single measurement data for all HBM4EU research	Drop down	
	Use of single measurement data without purpose limitation	Drop down	
	Use of aggregated data for specific HBM4EU objectives	Drop down	
	Use of aggregated data for all HBM4EU research	Drop down	
	Use of aggregated data without purpose limitation	Drop down	
Information on planned data use		WP?	Other WP / tasks:
	To be used by WP		
	To be used in Task	Task?	
	The work will start	Calender	
Information on planned material use		WP?	
	To be used by WP		
	To be used in Task	Task 1.4	
	The work will start	Calender	

			Comments:
Information on planned data use	Copy of the datatransfer agreement - name of file dates	Drop down	file name:
	Copy of the material transfer agreement - name of file dates	Drop down	file name:

Local ethics expert	Name	
	E-mail address	
	Telephone number	
	Date	Calender
Data Controller	Name	
	E-mail address	
	Telephone number	
	Date	Calender
Person filling in this form	Name and capacity (data controller or processor)	
	E-mail address	
	Telephone number	
	Date	Calender
Date when received by the leader of Task 1.5		Calender

Informeret samtykke til deltagelse i DEMOCOPHES

Erklæring fra forsøgspersonen:

Jeg har fået skriftligt og mundtlig information og jeg ved nok om formål, metode, fordele og ulemper til at sige ja til at deltage.

Jeg ved, at det er frivilligt at deltage, og at jeg altid kan trække mit samtykke tilbage uden begrundelse.

Jeg giver samtykke til, at deltage i forskningsprojektet og til, at mit biologiske materiale udtages med henblik på opbevaring i en forskningsbiobank i 10 år til brug i senere forskning vedrørende miljø og folkesundhed. Jeg har fået en kopi af dette samtykkeark samt en kopi af den skriftlige information om projektet til eget brug.

Jeg ønsker at bidrage med hår- og urinprøver: _____ (sæt x)

Jeg ønsker at bidrage med blodprøver: _____ (sæt x)

Hvis der kommer nye væsentlige helbredsoplysninger frem om dig i forskningsprojektet vil du blive informeret. Vil du **frabede** dig information om nye væsentlige helbredsoplysninger, som kommer frem i forskningsprojektet bedes du markere her: ____ (sæt x)

Forsøgspersonens navn: _____

Dato: _____ Underskrift _____

Ønsker du at blive informeret om de samlede resultater af undersøgelsen?

Ja: _____ (sæt x) Nej: _____ (sæt x)

Må forskerne kontakte dig igen vedrørende deltagelse i fremtidige undersøgelser?

Ja: _____ (sæt x) Nej: _____ (sæt x)

Erklæring fra den forsøgsansvarlige:

Jeg erklærer, at forsøgspersonen har modtaget mundtlig og skriftlig information om forsøget og har haft mulighed for at stille spørgsmål til mig.

Efter min overbevisning er der givet tilstrækkelig information til, at der kan træffes beslutning om deltagelse i forsøget.

Den forsøgsansvarliges navn: _____

Dato: _____ Underskrift: _____

Samtykke til forældremyndighedens indehaver(e) til deres barns deltagelse i DEMOCOPHES

Erklæring fra indehaveren af forældremyndigheden:

Jeg har fået skriftligt og mundtlig information og jeg ved nok om formål, metode, fordele og ulemper til at give mit samtykke.

Jeg ved, at det er frivilligt at deltage, og at jeg altid kan trække mit samtykke tilbage uden begrundelse.

Jeg giver samtykke til, at _____ (barnets navn) deltager i forskningsprojektet og til, at hans/hendes biologiske materiale udtages med henblik på opbevaring i en forskningsbiobank i 10 år til brug i senere forskning vedrørende miljø og folkesundhed. Jeg har fået en kopi af dette samtykkeark samt en kopi af den skriftlige information om projektet til eget brug.

Jeg giver samtykke til at mit barn bidrager med hår- og urinprøver: _____ (sæt x).

Jeg giver samtykke at mit barn bidrager med blodprøver: _____ (sæt x).

Hvis der kommer nye væsentlige helbredsoplysninger frem om dit barn i forskningsprojektet vil du blive informeret. Vil du **frabede** dig information om nye væsentlige helbredsoplysninger, som kommer frem i forskningsprojektet bedes du markere her: ____ (sæt x)

Navnet eller navnene på forældremyndighedens indehaver (e):

_____ _____

Dato: _____ Underskrift: _____

Dato: _____ Underskrift: _____

Ønsker du/I at blive informeret om de samlede resultater af undersøgelsen?

Ja: _____ (sæt x) Nej: _____ (sæt x)

Må forskerne kontakte dig/jer vedrørende deltagelse i fremtidige undersøgelser?

Ja: _____ (sæt x) Nej: _____ (sæt x)

Erklæring fra den forsøgsansvarlige:

Jeg erklærer, at forsøgspersonen har modtaget mundtlig og skriftlig information om forsøget og har haft mulighed for at stille spørgsmål til mig.
Efter min overbevisning er der givet tilstrækkelig information til, at der kan træffes beslutning om deltagelse i forsøget.

Den forsøgsansvarliges navn: _____

Dato: _____ Underskrift: _____

Fuldmagt fra den ene forældremyndighedsindehaver til den anden vedrørende deltagelse i forskningsprojektet DEMOCOPHES

Jeg, som er medindehaver af forældremyndigheden over:

_____ (barnets navn/CPR nr),

giver hermed fuldmagt til:

_____ (forælderens navn/CPR nr).

Fuldmagtshaver kan træffe beslutning om barnets deltagelse i DEMOCOPHES udført Afdeling for Miljø og Sundhed på Institut for Folkesundhedsvidenskab ved af Københavns Universitet. Fuldmagten gælder indtil DEMOCOPHES afsluttes ved udgangen af 2012.

Navn og CPR nr. på fuldmagtsgiver: _____

Dato: _____ Underskrift: _____

Approvals

Ethics

Region Hovedstaden

Koncern Sekretariatet

De Videnskabsetiske Komiteer
i Region Hovedstaden

Kongens Vænge 2
3400 Hillerød

Telefon 48 20 50 00
Direkte 48205729
Fax 48 20 57 77
Web www.regionhovedstaden.dk

CVR/SE-nr. 29 19 08 23

Journal nr.: H-3-2011-075

Dato: 6. september 2011

Professor, Lisbeth Ehlert Knudsen
Københavns Universitet
Afdeling for Miljø og Sundhed, Institut for Folkesundhedsvidenskab
Østre Farimagsgade 5, bygn.5, 2. sal
1353 København K

DEMOCOPHES (DEMOnstration of a study to COordinate and Perform Human biomonitoring on a European Scale)
Journal nr. H-3-2011-075
Dansk oversættelse: Demonstration af et studie, som koordinerer og gennemfører human biomonitering på europæisk niveau.

Den Videnskabsetiske Komite E for Region Hovedstaden har behandlet sagen på sit møde den 30. august 2011 og truffet følgende

Afgørelse:

Projektet godkendes i henhold til lov om et videnskabsetisk komitésystem, lov nr. 402 af 28. maj 2003 med senere ændringer.

Godkendelsen gælder for de anmeldte forsøgssteder, den anmeldte forsøgsansvarlige i Danmark samt for den angivne forsøgsperiode.

Godkendelsen gælder til den 31. december 2011 og omfatter følgende dokumenter:

Protokol af 12.07.2011, version 3
Oversigt over website af 16.06.2011, version 1
Information website af 12.07.2011, version 3
Deltagerinformation (e-mail) af 12.07.2011, version 3
Brev vedlagt urinprøvesæt af 08.07.2011, version 2
Samtykkeerklæringer af 12.07.2011, version 3
Spørgeskema af 16.06.2011, version 1
Spørgeskema supplerende målinger i DK af 16.06.2011, version 1
Spørgeskema urinprøve af 16.06.2011, version 1
Spørgeskema hårprøve af 16.06.2011, version 1

Komiteen diskuterede anmeldelsespligten af projektet, og var enige om, at projektet var anmeldelsespligtigt som et biomedicinsk forskningsprojekt, da der var tale om en systematiseret indsamling af viden.

Iværksættelse af projektet i strid med godkendelsen kan straffes med bøde eller fængsel, jf. komitélovens § 29.

Ændringer:

Foretages der væsentlige ændringer i protokolmaterialet under gennemførelsen af projektet, skal disse anmeldes til komiteen i form af tillægsprotokoller. Ændringerne må først iværksættes efter godkendelse fra komitéen, jf. komitélovens § 23, stk. 1, nr. 1.

Anmeldelse af tillægsprotokoller skal ske elektronisk på www.drvk.dk med det allerede tildelte anmeldelsesnummer og adgangskode.

Væsentlige ændringer er bl.a. ændringer, der kan få betydning for forsøgspersonernes sikkerhed, fortolkning af den videnskabelige dokumentation, som projektet bygger på samt gennemførelsen eller ledelsen af projektet. Det kan fx være ændringer i in- og eksklusionskriterier, forsøgsdesign, antal forsøgspersoner, forsøgsprocedurer, behandlingsvarighed, effektparametre, ændringer om de forsøgsansvarlige eller forsøgssteder samt indholdsmæssige ændringer i det skriftlige informationsmateriale til forsøgspersonerne.

Hvor nye oplysninger betyder, at forskeren overvejer at ændre proceduren eller stoppe forsøget, skal komiteen orienteres om det.

Bivirkninger og hændelser:

Komiteen skal omgående underrettes, hvis der under projektet optræder alvorlige bivirkninger eller alvorlige hændelser, jf. komitélovens § 22, stk. 3.

Én gang årligt i hele forsøgsperioden skal komitéen have tilsendt en liste over alle alvorlige bivirkninger og alvorlige hændelser, som er indtruffet i forsøgsperioden sammen med en rapport om forsøgspersonernes sikkerhed, jf. komitélovens § 22, stk. 4.

Materialet skal være på dansk. Listen over alvorlige bivirkninger og alvorlige hændelser kan dog være på engelsk, hvis der er vedlagt et dansk resumé.

Afslutning:

Den forsøgsansvarlige skal senest 90 dage efter afslutningen af projektet underrette komiteen herom, jf. komitélovens § 22, stk. 5.

Afbrydes projektet tidligere end planlagt, skal en begrundelse herfor sendes til komiteen senest 15 dage efter, at beslutningen er truffet, jf. komitélovens § 22, stk. 5.

Hvis projektet ikke påbegyndes, skal dette samt årsagen hertil meddeles komiteen.

Komiteen beder om kopi af den afsluttende forskningsrapport eller publikation, jf. komitélovens § 22, stk. 2. Vi skal i den forbindelse gøre opmærksom på, at der er pligt til at offentliggøre såvel negative som positive forsøgsresultater, jf. komitélovens § 14, stk. 1, nr. 6.

Tilsyn:

Komiteen fører tilsyn med, at projektet udføres i overensstemmelse med godkendelsen, jf. komitélovens § 22, stk. 1.

Følgende komitémedlemmer deltog i mødebehandlingen:

Niels Vidiendal Olsen, Erik R. Gregersen, Inge-Merete Sams, Karsten Skawbo-Jensen, Mogens Fenger, Alice Rudkjær, Morten Wøjdemann, Walther Fischer, Trine Stougaard Madsen, Inger Merete Jørgensen

Med venlig hilsen

Niels Vidiendal Olsen
Formand for Komite E

Scannet kopi til:
- Janne Fængel Jensen
- Lisbeth Ehlert Knudsen

Approvals

Ethics

Region Hovedstaden

KOPI

Koncern Sekretariatet

De Videnskabsetiske Komiteer i Region Hovedstaden

Kongens Vænge 2
3400 Hillerød

Telefon 48 20 50 00
Direkte 48 20 57 22
Fax 48 20 57 77
Web www.regionhovedstaden.dk

EAN-nr: 5798001555203
Bank: Danske Bank 3100 3100142287
CVR/SE-nr: 29 19 06 23

Protokol nr.: H-3-2011-075

Journal nr.: H-3-2011-075
Ref.: SFT/slm

Dato: 6. oktober 2011

Professor Lisbeth Ehlert Knudsen
Københavns Universitet
Afdeling for Miljø og Sundhed, Institut for Folkesundhedsvidenskab
Østre Farimagsgade 5, bygn.5, 2. sal
1353 København K

DEMOCOPHES (DEMOnstration of a study to COordinate and Perform Human biomonitoring on a European Scale)
Journal nr. H-3-2011-075
Dansk oversættelse: Demonstration af et studie, som koordinerer og gennemfører human biomonitering på europæisk niveau.

Sekretariatet for De Videnskabsetiske Komiteer for Region Hovedstaden modtog den 29. september 2011 tillægsprotokol, anm.nr. 31434.

Afgørelse:

Tillægsprotokollen er godkendt i henhold til lov om et videnskabsetisk komitésystem, lov nr. 402 af 28. maj 2003 med senere ændringer.

Godkendelsen omfatter følgende dokumenter:

Deltagerinformation af 28. september 2011, version 4

Med venlig hilsen

Simon Francis Thomsen
Formand for Komite A

Kopi pr. e-mail til:
- Janne Fangel Jensen samt forsøgsansvarlige

Region Hovedstaden

Center for Sundhed

De Videnskabsetiske Komiteer

Region Hovedstaden
Regionsgården
Kongens Vænge 2
3400 Hillerød

Opgang H
Telefon 3868 6395
Direkte 38686327
Mail vek@regionh.dk

Web www.regionh.dk/vek

EAN-nr: 5798001555203
Bank: Danske Bank 3100-3100280301
CVR/SE-nr: 30113713

Protokol nr.: H-1-2014-004

Dato: 3. marts 2014

Professor
Lisbeth Ehlert Knudsen
Københavns Universitet
Institut for Folkesundhedsvidenskab, Afd. Miljø og Sundhed
Østar Farimagsgade 5, 5B, 2. sal
1014 København K

Dispensation fra indhentning af samtykke i forbindelse med registerforsknings-projektet:
Befolkningens eksponering for pesticider, paracetamol og metabolitmønster ved måling i urin samt DNA-methylering ved måling i blod – Opfølgende undersøgelser på prøver indsamlet til den danske del af DEMOCOPHES i 2011.

Den Videnskabsetiske Komite E for Region Hovedstaden har behandlet sagen på sit møde den 25. februar 2014 og truffet følgende

Afgørelse
Projektet godkendes i henhold til lov om et videnskabsetisk komitésystem, 593 af 14. juni 2011 om videnskabsetisk behandling af sundhedsvidenskabelige forskningsprojekter med senere ændring.

Komiteen giver dispensation fra samtykket, jf. komitelovens § 10, stk. 1.

Godkendelsen gælder for de anmeldte forsøgssteder, den anmeldte forsøgsansvarlige i Danmark samt for den angivne forsøgsperiode.

Godkendelsen gælder til den 31. december 2015 og omfatter protokol som modtaget d. 2. februar 2014, på dokumentet angivet, version 2, 06.06.2014.

Iværksættelse af projektet i strid med godkendelsen kan straffes med bøde eller fængsel, jf. komitelovens § 41.

Ændringer
Forestages der væsentlige ændringer i protokolmaterialet under gennemførelsen af projektet, skal disse anmeldes til komiteen i form af tillægsprotokoller. Ændringerne må først iværksættes efter godkendelse fra komiteen, jf. komitélovens § 27, stk. 1.

Anmeldelse af tillægsprotokoller skal ske elektronisk på www.drvk.dk med det allerede tildelte anmeldelsesnummer og adgangskode.

Væsentlige ændringer er bl.a. ændringer, der kan få betydning for forsøgspersonernes sikkerhed, fortolkning af den videnskabelige dokumentation, som projektet bygger på samt gennemførelsen eller ledelsen af projektet. Det kan fx være ændringer i in- og eks-

Approvals

klusionskriterier, forsøgsdesign, antal forsøgspersoner, forsøgsprocedurer, behandlingsvarighed, effektparametre, ændringer om de forsøgsansvarlige eller forsøgssteder samt indholdsmæssige ændringer i det skriftlige informationsmateriale til forsøgspersonerne.

Hvor nye oplysninger betyder, at forskeren overvejer at ændre proceduren eller stoppe forsøget, skal komiteen orienteres om det.

Afslutning:

Den forsøgsansvarlige og en evt. sponsor skal senest 90 dage efter afslutningen af projektet underrette komiteen herom, jf. komitelovens § 31, stk. 1.

Afbrydes projektet tidligere end planlagt, skal en begrundelse herfor sendes til komiteen senest 15 dage efter, at beslutningen er truffet, jf. komitelovens § 31, stk. 2.

Hvis projektet ikke påbegyndes, skal dette samt årsagen hertil meddeles komiteen.

Komiteen beder om kopi af den afsluttende forskningsrapport eller publikation, jf. komitelovens § 28, stk. 2.. Vi skal i den forbindelse gøre opmærksom på, at der er pligt til at offentliggøre både negative, positive og inkonklusive forsøgsresultater, jf. komitelovens § 20, stk. 1, nr. 8.

Pligten til at indberette afsluttende forsøg og rapport påhviler forsøgsansvarlig og en evt. sponsor i forening.

Tilsyn:

Komiteen fører tilsyn med, at projektet udføres i overensstemmelse med godkendelsen, jf. komitelovens § § 28 og 29

Følgende komitemedlemmer har indgået i bedømmelsen af projektet:

- Niels V. Olsen, Mogens Fenger, Erik R. Gregersen, Karsten Skawbo-Jensen, Inge-Merete Sams, Alice Rudkjær, Kasper Tingkær, Trine Stougaard Madsen og Walter Fischer

Med venlig hilsen

Niels Vidiendal Olsen
Formand for Komite E

Kopi til:
- Jeanette Nielsen

Region Hovedstaden

Center for Sundhed

De Videnskabsetiske Komiteer

Regionsgården
Kongens Vænge 2
3400 Hillerød

Opgang B+D
Telefon 3868 6395
Mail vek@regionh.dk

Protokol nr.: H-1-2014-004

Dato: 30. marts 2016

Professor Lisbeth Ehlert Knudsen
Københavns Universitet
Institut for Folkesundhedsvidenskab, Afd. Miljø og Sundhed
Øster Farimagsgade 5, 5B, 2. sal
1014 København K

Dispensation fra indhentning af samtykke i forbindelse med registerforskningsprojektet:
Befolkningens eksponering for pesticider, paracetamol og metabolitmønster ved måling i urin samt DNA-methylering ved måling i blod

Sekretariatet for De Videnskabsetiske Komiteer for Region Hovedstaden modtog den 17. marts 2016 tillægsprotokol, anm.nr. 52773.

Afgørelse:

Tillægsprotokollen er godkendt i henhold til lov nr. 593 af 14. juni 2011 om videnskabsetisk behandling af sundhedsvidenskabelige forskningsprojekter

Godkendelsen forlænges til 31. december 2016

Med venlig hilsen

Carina Hay
Sekretær

Kopi til:
- Jeanette Nielsen

Approvals

Data

DATATILSYNET

Professor, ph.d. Lisbeth E. Knudsen
Sektion for Miljø og Sundhed
Institut for Folkesundhedsvidenskab
Københavns Universitet
Øster Farimagsgade 5
1014 København K

Sendt til: liek@sund.ku.dk

8. oktober 2011

Datatilsynet
Borgergade 28, 5.
1300 København K

CVR-nr. 11-88-37-29

Telefon 3319 3200
Fax 3319 3218

E-post
dt@datatilsynet.dk
www.datatilsynet.dk

J.nr. 2011-41-6607

Sagsbehandler
Frederik Rechenback
Enelund
Direkte 3319 3245

Vedrørende anmeldelse af: "DEMOCOPHES (DEMOnstration of a study to COordinate and Perform Human biomonitoring on a European Scale)"

Ovennævnte projekt er den 19. august 2011 anmeldt til Datatilsynet efter persondatalovens[1] § 48, stk. 1. Der er samtidigt søgt om Datatilsynets tilladelse.

Det fremgår af anmeldelsen, at du er dataansvarlig for projektets oplysninger. Behandlingen af oplysningerne ønskes påbegyndt snarest og forventes at ophøre 31. december 2021.

Projektet vil omfatte en biobank (samling af biologisk materiale).

Oplysningerne vil blive behandlet på følgende adresse:
Sektion for Miljø og Sundhed, Institut for Folkesundhedsvidenskab, Københavns Universitet, Øster Farimagsgade 5, rum 5.2.12., 1014 København K

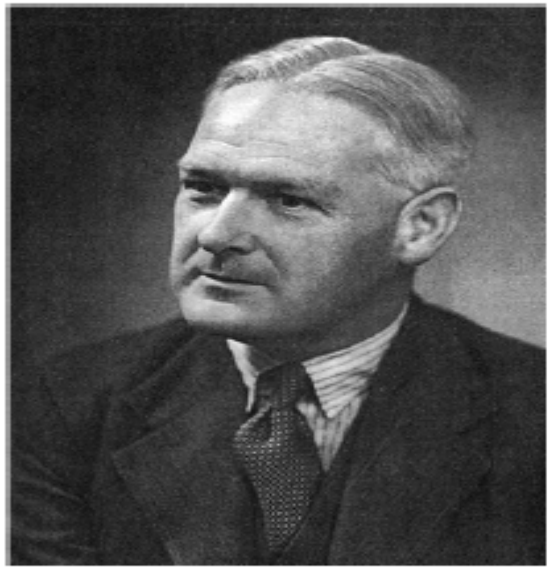
Oplysningerne vil endvidere blive behandlet ved de deltagende centre.

Der skal ske behandling af oplysninger ved følgende databehandlere:

1. Antonia M. Calafat, National Centre for Environmental Health, 4770 Buford Highway NE, Mailstop F53, Atlanta, GA 30341, USA.
2. Holger M. Koch, Research Institute of Occupational Medicine, Ruhr-University Bochum, Bürckle-de-la-Camp Platz 1, 44789 Bochum, Tyskland.
3. Adrian Covaci, Toxicological centre, Department of Pharmaceutical Sciences, University of Antwerp, Universiteitsplain 1, 2610 Antwerp, Belgien.

[1] Lov nr. 429 af 31. maj 2000 om behandling af personoplysninger med senere ændringer.

Association criteria of Bradford Hill



1. Strength
2. Consistency
3. Specificity
4. Temporal relationship
5. Dose-response relationship
6. Biological plausibility
7. Coherence
8. Reversibility/Experiment
9. Analogy

UNIVERSITY OF COPENHAGEN

Contacts

Lisbeth E. Knudsen, Professor
University of Copenhagen
Faculty of Health and Medical Sciences, Dept of Public Health, Environmental Epidemiology Group
liek@sund.ku.dk
https://cms.ku.dk/sund-sites/ifsv-sites/ifsv-inst/

Speaker's information

Lisbeth E. Knudsen.,MSc, PhD professor in animal free toxicology has worked with ethics and HBM since 1987 in designing, performing and reporting field studies. Appointed scientific member of the Regional ethics committee. The chair of the institutional ethics committee. Leader of Task 1.5 in HBM4EU: Ethics and data protection and partner in the Task 2.5 Training. National Hub contact point of Denmark

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 733032.