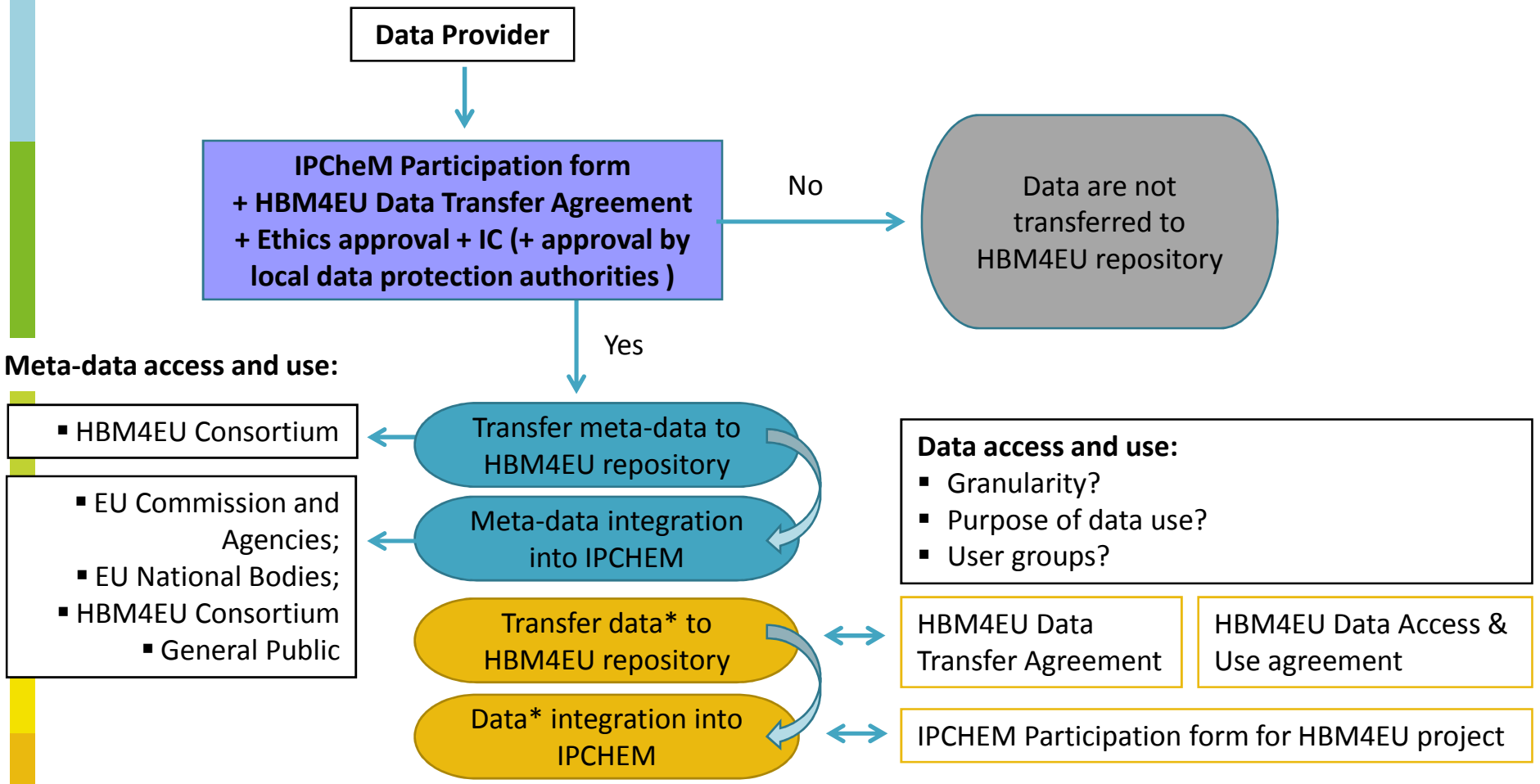
science and policy
for a healthy future

HBM4EU project

HBM4EU templates

A01 Session 3 Templates

Overview of Procedures



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

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

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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

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Purpose of the form and signatures	P. 1

Version Number of the HBM4EU Data Transfer Form: 2

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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

Data Transfer

Form to be used

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)

	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

Metafiche

DK DEMOCOPHES

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

☑ ical 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

Metafiche

DK DEMOCOPHES

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

Metafiche

DK DEMOCOPHES

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:

Metafiche

DK DEMOCOPHES

☑ 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

Metafiche

DK DEMOCOPHES

☑ 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)						

Template

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

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).
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			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	To be used by WP	WP?	Other WP / tasks:
	To be used in Task	Task?	
	The work will start	Calender	
Information on planned material use	To be used by WP	WP?	
	To be used in Task	Task 1.4	
	The work will start	Calender	

Template

			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

Informed consent

DK DEMOCOPHES

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: _____

DEMOCOPHES Samtykkeerklæringer, version 3, 12.07.2011 Side 3 af 4

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 Komitéer
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 Fangel 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/klm

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 3866 6395
Direkte 38666327
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
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 –
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

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 komiteen, jf. komitelovens § 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 3866 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.

Material transfer

Draft

HBM4EU science and policy for a healthy future	Form: **Material Transfer Record Form**	
	Valid since: **Mai 2018**	Version: **V 0.1**

Material Transfer Record Form **Page 1 of 2**

Provider

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

Recipient

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

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

Description of the MATERIAL(S): *Briefly describe the MATERIAL(S) being transferred (quanitity, type of materials) under the HBM4EU MTA. Detailed information including the unique identifyer (Barcode) of each sample will be provided by the Provider with each shipment in the data transfer template form. Add additional pages if required.*

Description of the agreed use of the MATERIAL(S) including the termination of this agreement: *Add additional pages if required.*

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

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

Samples will be:

- ☐ Completely consumed during analysis.
- ☐ Destroyed after analysis. Estimate date for destruction of samples (year, month):
- ☐ Returned after analysis. Estimate date for return of samples (year, month):

Other:

Page 2 of 2

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

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

HBM4EU science and policy for a healthy future	Form: **Material Transfer Record Form**	
	Valid since: **Mai 2018**	Version: **V 0.1**

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

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

[*Optional clause*] Any dispute or controversy arising in connection with the transfer of MATERIAL(S) documented herewith which is not resolved by the designated officers of this PROVIDER and RECIPIENT in accordance with the HBM4EU MTA shall be finally settled in accordance with the following terms:

Describe the controlling law and any dispute mechanism (in the event that this is left blank the controlling law will be the jurisdiction in which the HBM4EU member institution is located. Add additional pages if required):

The PROVIDER and RECIPIENT, by their duly authorized representatives, hereby accept all terms and conditions expressly stated in the HBM4EU MTA including its further applicable documents.

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

Duplicate originals of this form shall be fully completed and executed and exchanged, with copies sent (electronically via facsimile transmission, pdf attachment to e-mail, or the like) within three days to the Ethics Board (Lisbeth E. Knudsen, University of Copenhagen, Faculty Of Health Sciences, Department of Public Health, Øster Farimagsgade 5A, room 5.2.12, DK-1353 Copenhagen, Denmark, Phone: +45 35327653, E-Mail: liek@sund.ku.dk) or to such other e-mail address as may be provided by the management board of HBM4EU in the future.

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

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

UNIVERSITY OF COPENHAGEN

Contacts

Lisbeth E. Knudsen, Professor
University of Copenhagen
Faculty of Health and Medical Sciences,
Dept of Public Health, Environmental Epidemiology Group
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Speaker's information

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