HBM4EU project

Information, Invitation and Informed Consent

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2ndHBM4EU Training School 2018

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

1. Overview

Objectives: To present the key principles and concepts forming the basis of information, invitation and informed consent

2. Strategy

Giving an overview of the bioethics and dataethics principles governing the design of information, invitation and informed consent in HBM4EU projects

1. Principles for Information, Invitation, and Informed Consent
2. Information and Invitation
3. Informed Consent
4. Special cases: Children, Occupational Studies, Genetic Studies
5. HBM4EU Ethics Policy: Ethics Policy Paper and WP 7 Recommendations

1. Principles for information, invitation and informed consent

The research participant: 2 areas of protection:

1. A human individual participating in biomedical research

2.A human individual participating in research involving health data/ biomonitoring data concerning the person

Bioethics:

World Medical Association (WMA): Helsinki declaration

Bioethics convention

Data ethics:

General Data Protection Regulation (GDPR)

2. Information and invitation

Requirements for information about the project - examples of important issues:

HBM4EU Ethics Policy: Openness, transparency, soundness, quality

Results to be available to HBM4EU

Templates available for information and for consent

Rights of the person seen as a data subject.

GDPR. Lawfulness of processing data: (consent and other lawful ways of processing)

Rights of the person seen as a data subject in relation to research

The GDPR creates an exemption to the principle of purpose limitation for research. Article 5(1)(b) states, "further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes." Article 89 sets out the safeguards that controllers must implement.

4 Dataethics and GDPR - Principles

GDPR Article 5: Principles

Data should be processed lawfully, fairly and in a transparent manner in relation to the data subject ('lawfulness, fairness and transparency');

GDPR Article 6: Lawful means of processing

1. *Consent – the data subject whom the personal data is about has consented to the processing -*
2. *Contractual – processing is necessary for the performance of a contract with the data subject or to take steps to enter into a contract*
3. *Legal obligation – processing is necessary for compliance with a legal obligation*
4. *Vital interests – processing is necessary to protect the vital interests of the data subject or another person*
5. Public tasks – *processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the business*
6. *Legitimate interests – processing is necessary for purposes of legitimate interests pursued by the business or a third party, except where such interests are overridden by the interests, rights or freedoms of the data subject.*

HBM4 EU Ethics Policy: Ethics and approval of study protocol What is required and how to arrange it

Lawfulness and HBM4EU

1. *Compliance with the requirements of HBM4EU Ethics Policy – which will take into account:*
2. *Compliance with EU- and other international ethics and legal framework:*
3. *Bioethics: WMA: Declaration of Helsinki,*
4. *Council of Europe: Bioethics Convention, EU: Charter of Fundamental rights Childrens' rights, Occupational Research participants' rights.*
5. *Dataethics: EU: General Data Protection Regulation*

The rights of the data subjects are mirrored in the obligations of the data controller

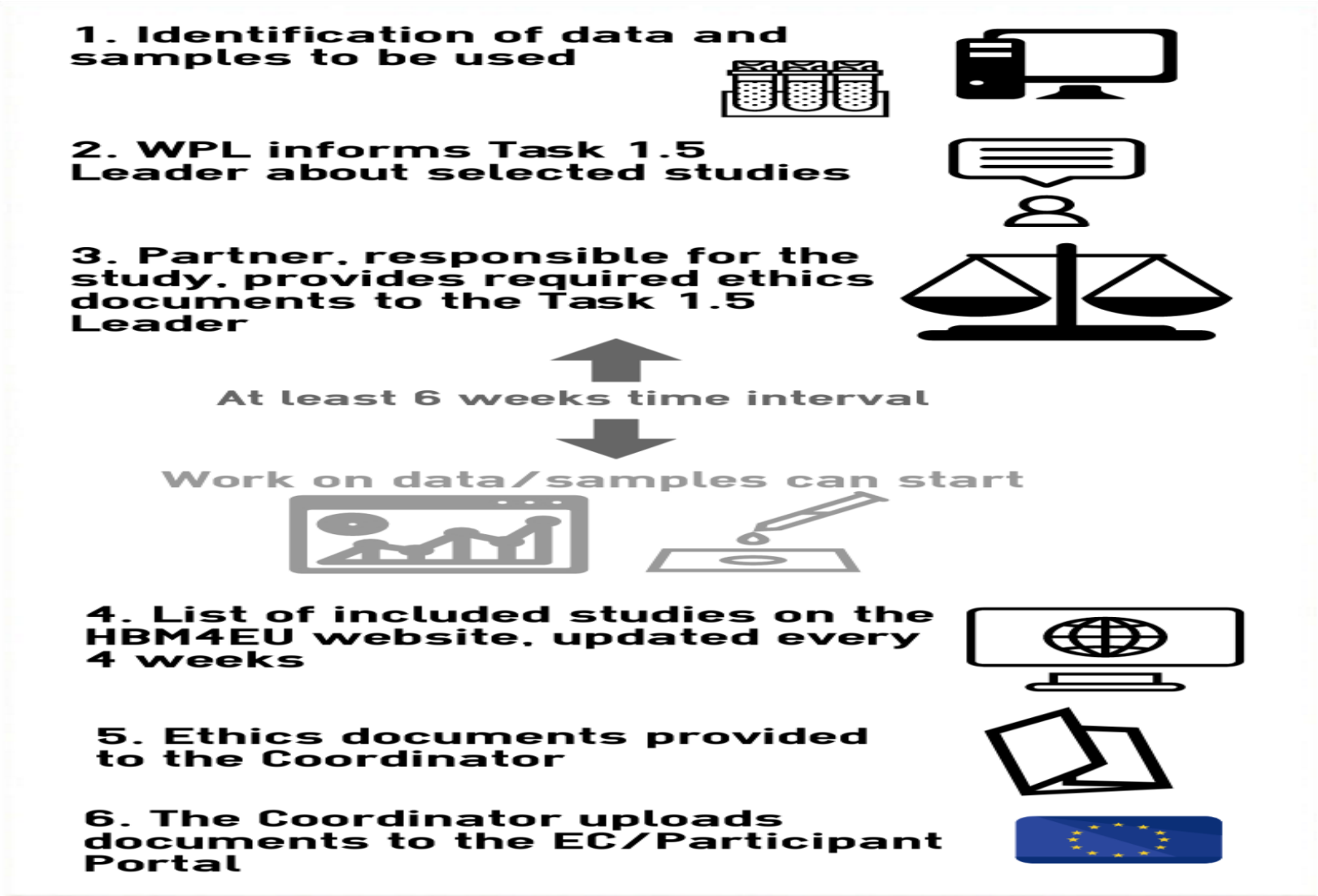
Information, Invitation, Informed Consent Form

Information material: Designed to meet target group's level of maturity and understanding - creating transparency about the project and the role and rights of the research participant (Principle: Autonomy, Self determination)

Invitation: Remember to include consideration time and info about rights of participants (Principle: Autonomy, Self determination)

Consent form: State all info from information material in short versions – Why? Because this is the contractual basis for the informed, signed consent.
NB! Separate consent forms for Parents and Children is recommended – in order to track each research subject- consider assent of older children (Principle: Autnomy, Traceability, Transparency)

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

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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

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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

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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

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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),

The Informed consent form

The nature of the informed consent form: A contract between the researcher (data controller) and the research participant delineating the ethics and legal framework for the relation between the two parties.

Differences in how the two parties are obligated by the contract

The researcher's obligations:

The research participant

The National ethics committee (the National Data Protection Agency)

HBM4EU

Other partners in research

The participants obligations:

They can quit the project whenever they want, but they cannot stop the use of already processed information

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

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 ?
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	Partner in HBM4EU	Partners ?
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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:	

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	

			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

HBM4 EU Ethics Policy Ethics and approval of study protocol: How to arrange it

1. *Check your National system for ethics approval of research projects*
2. *Check your National system – Does your National System require approval both for the bioethics-part of the research project and for the dataethics-part of the project?*
3. *Biological samples: Check if your National system requires special approval for collecting, storing, handling and sharing of biological samples and data derived from these.*

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