science and policy
for a healthy future

HBM4EU project

A01 Ethics

1.How to serve the participants

2.Contractual Demands

3.Conclusions and recommendations

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1st HBM4EU Training School 2018

A01-Ethics, Afternoon Session
Wednesday , June 20th, 13.00 -17.00

1. How to serve the participants

Summary

1. Learning Objectives

The Participant has an overview of ethics requirements for HBM4EU studies

The Participant can apply these principles and requirements to her/his own HBM4EU study

2. Strategy

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

1. Information

2. Consent – Specific, broad, dynamic

3. Feed-back and forward of results

1. Information: Bioethics – Principles

Beuchamp and Childress:

1. *Respect for autonomy*
2. *Beneficence*
3. *Non-maleficence*
4. *Justice*

http://www.ethics.org.au/on-ethics/blog/august-2017/thomas-beauchamp-james-childress-medical-ethics

EU Charter of Fundamental rights:

1. *Human Dignity, Art 1 and*
2. *Integrity, Art 3.*
3. *Protection of Personal Data, Art.8*
4. *Freedom of arts and sciences, Art. 13*
5. *Rights of the Child, Art 24*
6. *Health care Art 35*
7. *Environmental protection Art 37*

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012P/TXT

1. Information: Bioethics – Principles

EU Charter of Fundamental rights: Integrity of the Person Art 3.

Everyone has the right to respect for his or her physical and mental integrity.

*In the **fields of medicine and biology**, the following must be respected in particular:*

The free and informed consent of the person concerned, according to the procedures laid down by law;

The prohibition of eugenic practices, in particular those aiming at the selection of persons;

The prohibition on making the human body and its parts as such a source of financial gain;

The prohibition of the reproductive cloning of human beings.

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012P/TXT

2. Consent- specific, broad, dynamic

1. Consent: Specific - Based on the Information material and the consent form

2. Consent: Broad - Repositories and Biobanks

3. Consent: Dynamic - Ongoing contact with the research participants

1. Consent - specific: Information and invitation

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

HBM4EU Ethics Policy:

The merging of Bioethics and Dataethics principles

The principle of easily understandable language

(Bioethics Convention) and (GDPR) targeted to the age and maturity of the group of prospect participants.

Rights of the person seen as a research participant:

What is the project about?

What are the implications of participating?

Who is leading the project?

Who has financed the project?

Reflection time before agreeing to participation

Possibility of withdrawal from the project

Secondary research, Data sharing and data transfer

Dynamic consent vs broad consent

Definition of dynamic consent: ***Dynamic consent is placing the participants in the center. The consent is an ongoing process facilitated by social media or via other modern communication strategies to inform, involve, and obtain consent for every research projects based on biobank resources, thus giving the participants more control over "their" data and better access to information about projects***
The dynamic consent is most relevant in studies with results becoming available many years after sampling.

Broad consent: The research participant consents to a wide range of research projects within certain limits, including ones yet to be conceived. "Broad consent permits specific limitations on the future use of samples. For example, if there are specific types of research known to conflict with donors' fundamental values, such as studies on human cloning, these could be precluded by the initial consent."

Wendler, D. (2013). Broad versus Blanket Consent for Research with Human Biological Samples. *The Hastings Center Report*, *43*(5), 3–4. http://doi.org/10.1002/hast.200"

3. Feed-back and forward of results

1. *The informed consent form is the roadmap for information and feed-back to the research persons*
2. *What is the agreement between the researcher and the research participant about level of feed-back?*
3. *Trend: The research persons want to know the results -even if there are no immediate health related implications.*

Human bioMorello-Frosch, Rachel, Julia Varshavsky, Max Liboiron, Phil Brown, and Julia G. Brody, 'Communicating Results in Post-Belmont Era Biomonitoring Studies: Lessons from Genetics and Neuroimaging Research', *Environmental Research*, 0 (2015), 363–72 <https://doi.org/10.1016/j.envres.2014.10.001>
Rachel Morello-Frosch and others, 'Communicating Results in Post-Belmont Era Biomonitoring Studies: Lessons from Genetics and Neuroimaging Research', *Environmental Research*, 0 (2015), 363–72 <https://doi.org/10.1016/j.envres.2014.10.001>.

3. Feed-back

Special cases:

1. Children – Special communication: Age and maturity
2. Occupational Studies - Special Caveats about confidentiality towards employer, special caveats about notification of public health and environmental authorities
3. Incidental Findings –Special caveats about notification

1. Data Protection

2. Data and sample transfer

3. Sample Exchange

2. 1 Data protection Dataethics Principles

Handling of data derived from biological samples and questionnaires

Wet data: Biological samples

Dry data: Digital data derived from biological samples and other data

General Data protection regulation:

Definitions Article 4

Principles Article 5

Link to GDPR:
https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679&from=EN

Ethics and data protection

General Data Protection Regulation (GDPR)

The main objectives of GDPR

-Rules fit for the digital single market (harmonized and simplified)

-Putting individuals in control of their data (an updated set of rights and obligations)

-A modern data protection governance

-Harmonised in EU with one single set of DP one interlocutor and one interpretation

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: Lawfulness of processing

GDPR Article 6 Exerpt

1. Processing shall be lawful only if and to the extent that at least one of the following applies:

(a)the data subject has given consent to the processing of his or her personal data for one or more specific purposes;

(b)processing is necessary for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract;

(c)processing is necessary for compliance with a legal obligation to which the controller is subject;

(d)processing is necessary in order to protect the vital interests of the data subject or of another natural person;

(e)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 controller;

(f)processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child.

Data and Sample Transfer

Responsibility for data and data transfer:

Check National and Regional Ethics Approval Committees and National Data Protection Agencies:

Do you need approval before data transfer?

Compliance with GDPR:

Data Controller and Data Processors obligations:

Article 29: Processing under the authority of the controller

The processor and any person acting under the authority of the controller or of the processor, who has access to personal data, shall not process those data except on instructions from the controller, unless required to do so by Union or Member State law.

Article 30: Records of processing activities

Each controller and, where applicable, the controller's representative, shall maintain a record of processing activities under its responsibility.

Data protection

Evolution rather than revolution spelling out the right to be forgotten with emphasis on

Principles of processing

Fair and lawful processing

Purpose limitation

Data Minimisation

Rules for further processing

Data Retention

Data accuracy

Accountability

The controller being responsible and able to demonstrate compliance

Sample Exchange

Transfer of Samples:

The GDPR does (most likely) not include Biological Samples under its remit: Recital 35: "… ***information derived from the testing or examination of a body part or bodily substance, including from genetic data and biological samples; and any information on, for example, a disease, disability, disease risk, medical history, clinical treatment or the physiological or biomedical state of the data subject independent of its source, for example from a physician or other health professional, a hospital, a medical device or an in vitro diagnostic test."***

Transfer of Samples will thus be governed by National Law

Check National Ethics Approval systems and National Regulation.

-Transfer to E -country? Transfer to 3. country?

Check the original Informed consent forms to check whether research persons have Agreed to Sample Transfer

Set up Material Transfer Agreements.

Transfer of Data – A Danish Example HBM4EU and IpCheM

Request to the Danish Data Inspectorate on transfer of data to HBM4EU database and IpChem:

"Terms

The permission is given on the following terms that you are responsible for complying with:

1. Transmission may only be made for the purpose of the conduct of a survey for statistical or scientific purposes, cf. section 10 2nd

2. The information may only be disclosed in a form where they are not immediately personally identifiable to the recipient. That is, you must ensure that identification information prior to the transmission is encrypted or replaced by a code number or similar so that the recipient can not identify the registered persons.

The Data Inspectorate's permission is provided on the condition that you have not promised the data subjects that information about them will not be disclosed or otherwise used in other scientific or statistical contexts."

1. Conclusions

3. Recommendations

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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

Berit A. Faber, LLM works as a research assistant at Faculty of Health and Medical Sciences, Environmental Epidemiology Group, Copenhagen University, Denmark. Has worked in the Danish Ministry of Health, the Danish Council of Ethics and The Danish National Committee on Health Research Ethics. In HBM4EU she is working for Prof. Lisbeth E. Knudsen in WP1.

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