HBM4EU project

science and policy
for a healthy future

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Ethics and approval of study protocol

Session 6, Nov 20th: 2nd HBM4EU Training School 2018

Session 6:
Orientation on the design HBM4EU studies Tuesday 20th November 9:30-10.00

1. Overview: Bioethics and Data Ethics
2. The International Ethics- and Legal Landscape
3. Bioethics
4. Dataethics
5. HBM4EU Ethics Policy – Approval of Study Protocol

1. Overview

Objectives: To present the key principles and concepts forming the basis of bioethics and data ethics in relation to approval of study protocols

2. Strategy

Giving an overview of the ethics- and legal "landscape" for approval of study protocols – clarifying the principle of lawfulness in bioethics and dataethics

What is ethics?

An academic discipline. Ethics is the critical study of the norms that guide our actions.

Practical skills. Ethics is the practical art of knowing how to apply moral principles in concrete situations

Value systems. Ethics deals with the core values that guide a person or an organisation on the way to its shared vision

- *Ethics is the result of our pursuit to systematically reflect on, analyse, and question the norms and values that guide human action.*

- Göran Hermerén, former President of the European Group on Ethics (EGE)

‘Classical ethics’

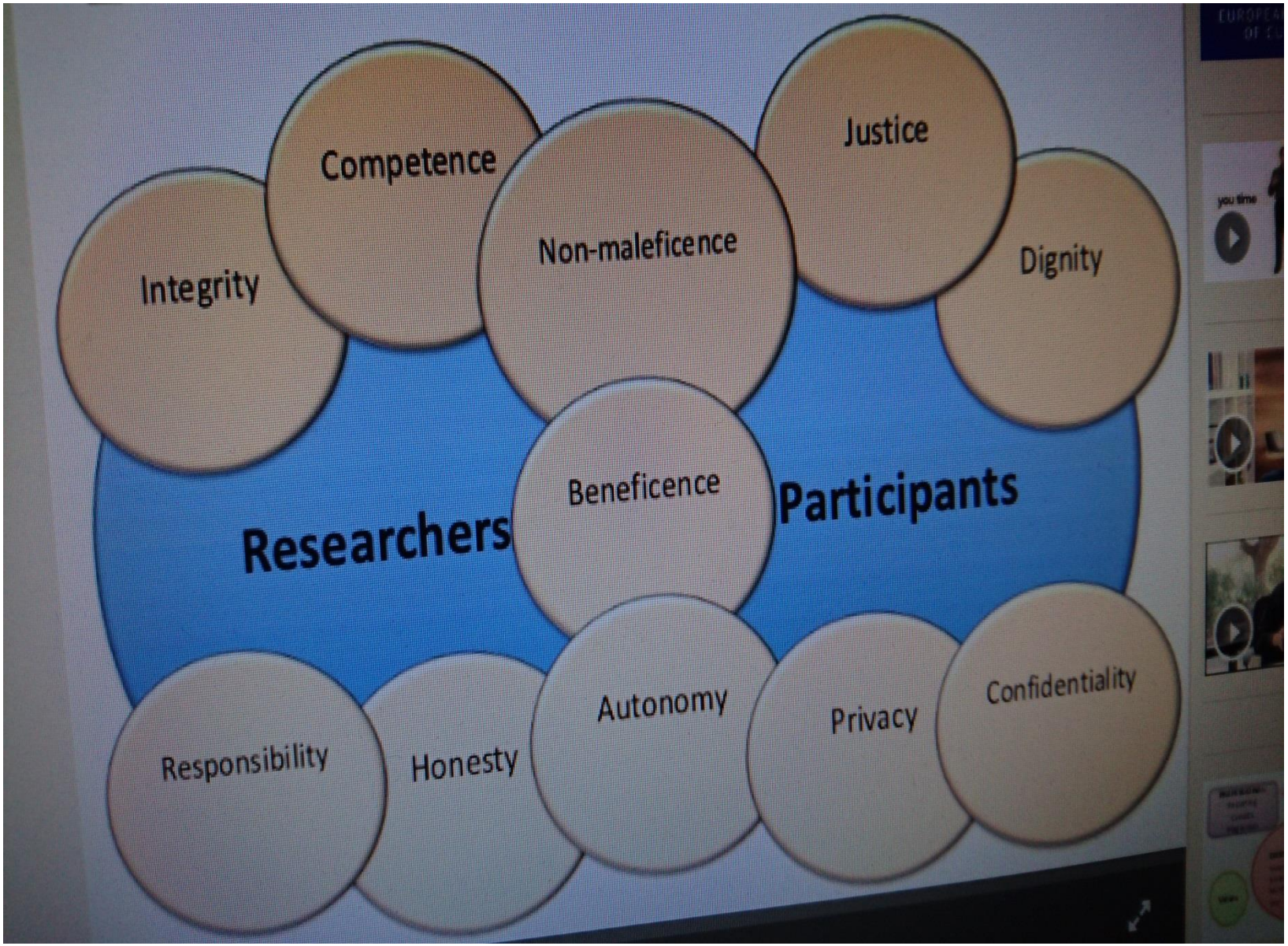
- **Autonomy** – The right for an individual to make his or her own choice.
- **Beneficence** – The principle of acting with the best interest of the other in mind.
- **Non-maleficence** – The principle that “above all, do no harm,” as stated in the Hippocratic Oath.
- **Justice** – A concept that emphasizes fairness and equality among individuals.

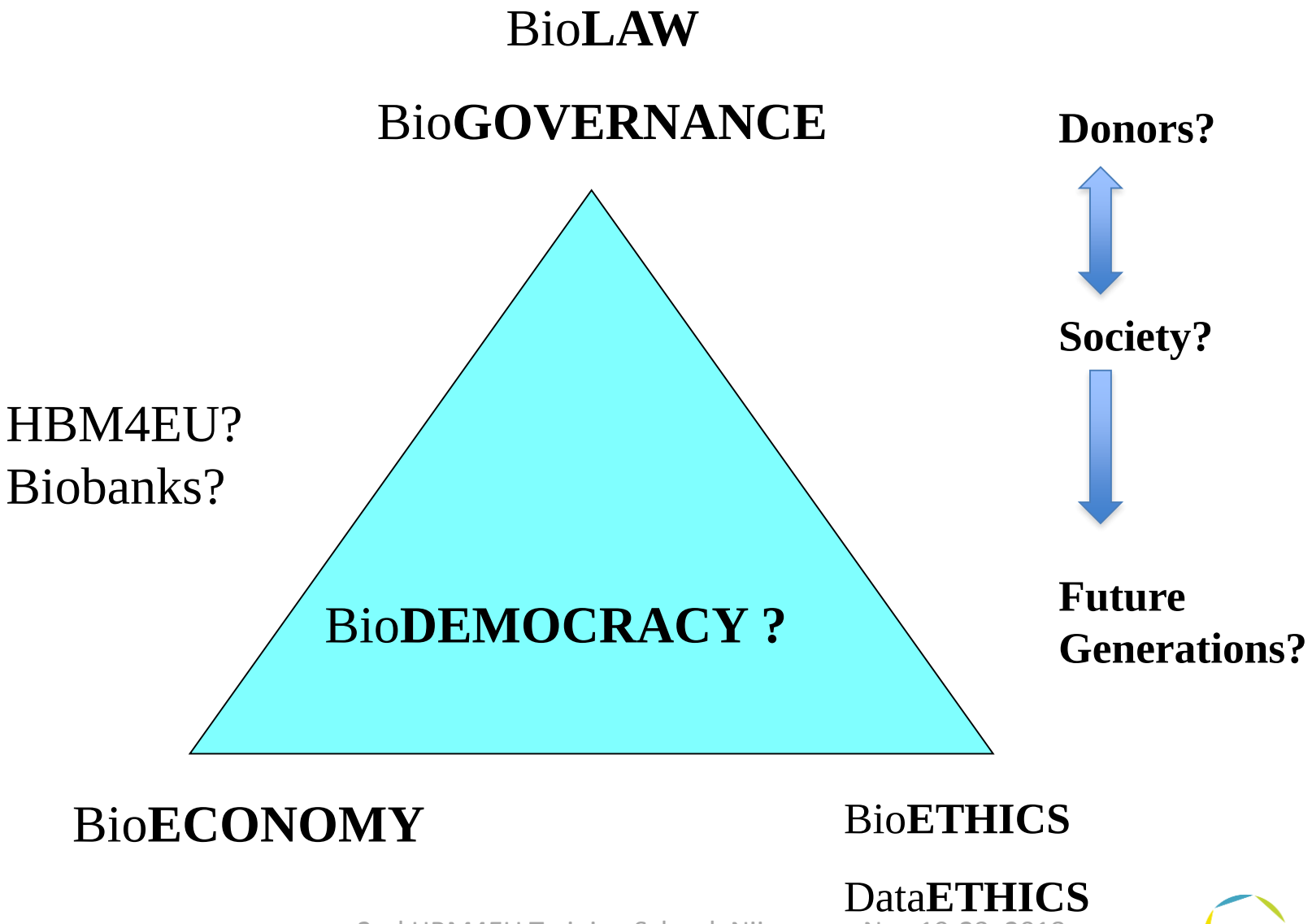
Tom L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics*, 7th ed (New York: Oxford University Press, 2013

Principles of European research ethics

- •The principle of respect for human dignity
- •The principle of utility
- •The principle of precaution
- •The principle of justice

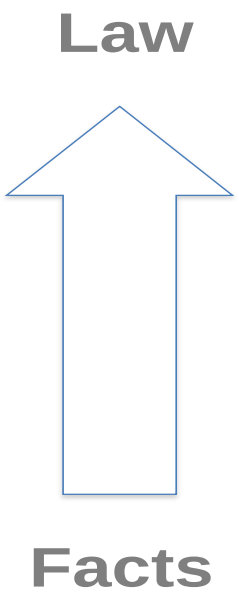
- A moral principle is a general guide of action that provides a standard of relevance or ”reasonableness”
- A moral principle is applied *prima facie, i. e. it must be observed unless it comes in conflict with any other, equally pertinent, consideration.*


Competence
Justice
Integrity
Non-maleficence
Dignity
Researchers
Beneficence
Participants
Responsibility
Honesty
Autonomy
Privacy
Confidentiality


BioLAW
BioGOVERNANCE
Donors?
Society?
Future Generations?
HBM4EU?
Biobanks?
BioDEMOCRACY ?
BioECONOMY
BioETHICS
DataETHICS

2. How to establish what the law is in areas of new emerging technologies?

Biotech
New elements in creating legal decisions



Jurisprudence – Legisprudence – Professional Guidelines and SOPs

"You never can tell with bees"

Winnie The Poo

How can you tell with lawyers?

What are the principles and definitions forming the basis for the legal regulation of human biomonitoring and the use of health data in research?

The principle of lawfulness:

You have to have a legal basis before setting up research and/or using health data.

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. *Data ethics: EU: General Data Protection Regulation*

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.*

2. 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

Incidental findings policy

Secondary research, Data sharing and data transfer

Information and invitation

Rights of the Person seen as a data subject

GDPR: states the definitions, principles, and the means of lawful processing

Article 4: Definitions

Article 5: Principles

Article 6: Means of lawful processing

Bioethics

Anonymised

Anonymised data are de-identified data impossible to trace back to the person, from where the data originate. In the framework of the HBM4EU anonymised data means, that persons cannot be identified by the researchers providing the data in the different countries. As long as the key to reidentification exists somewhere, the data is not anonymised, but pseudonymized.

The GDPR mentions that the regulation does not concern the processing of such anonymous information, including for statistical and research purposes:

"The principles of data protection should therefore not apply to anonymous information, namely information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable. This Regulation does not therefore concern the processing of such anonymous information, including for statistical or research purposes."

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

Bioethics

Pseudoananymised

The GDPR introduces the concept of pseudonymisation as a tool for enhancing security by design. The GDPR defines pseudonymisation as:

"The processing of personal data in such a way that the data can no longer be attributed to a specific data subject without the use of additional information." To pseudonymise a data set, the "additional information" must be "kept separately and subject to technical and organizational measures to ensure non-attribution to an identified or identifiable person." Pseudonymisation is thus seen by the GDPR as a privacy-enhancing technique where directly identified data is held separately and securely from processed data in order to secure non-attribution. The GDPR sets new standards for Data protection by design and accountability. Organisations are required to adopt significant new technical and organisational measures to demonstrate their GDPR compliance.

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

Bioethics

Pseudoananymised

Recital no. 26 states the following on pseudonymisation:

". The principles of data protection should apply to any information concerning an identified or identifiable natural person. Personal data which have undergone pseudonymisation, which could be attributed to a natural person by the use of additional information should be considered to be information on an identifiable natural person. To determine whether a natural person is identifiable, account should be taken of all the means reasonably likely to be used, such as singling out, either by the controller or by another person to identify the natural person directly or indirectly. To ascertain whether means are reasonably likely to be used to identify the natural person, account should be taken of all objective factors, such as the costs of and the amount of time required for identification, taking into consideration the available technology at the time of the processing and technological developments."

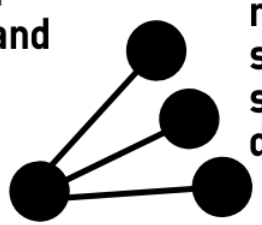
Link to GDPR:
https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679&from=EN

Original survey data with personal ID

Personal ID replaced with study ID

Key between personal ID and study ID

Coded data



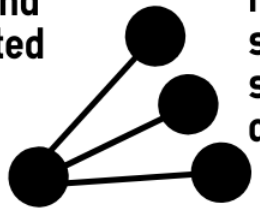
Sharing the data research groups in same institute, same country, different countries

Pseydonymized

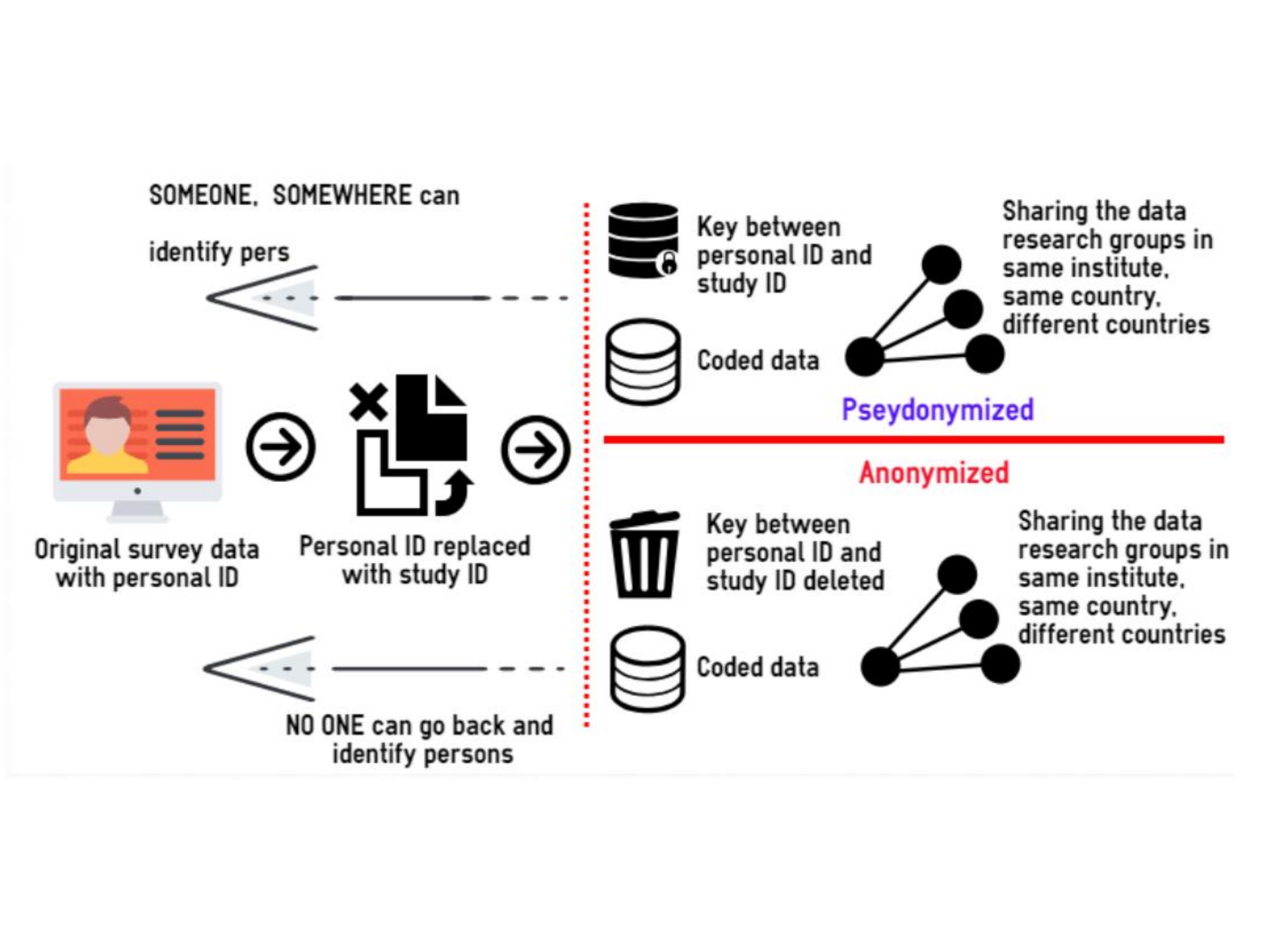
Anonymized

Key between personal ID and study ID deleted

Coded data



Sharing the data research groups in same institute, same country, different countries


SOMEONE, SOMEWHERE can
identify pers
Original survey data with personal ID
Personal ID replaced with study ID
NO ONE can go back and identify persons
Key between personal ID and study ID
Coded data
Sharing the data research groups in same institute, same country, different countries
Pseydonymized
Anonymized
Key between personal ID and study ID deleted
Coded data
Sharing the data research groups in same institute, same country, different countries

4.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

4. Dataethics - Datalaw 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.

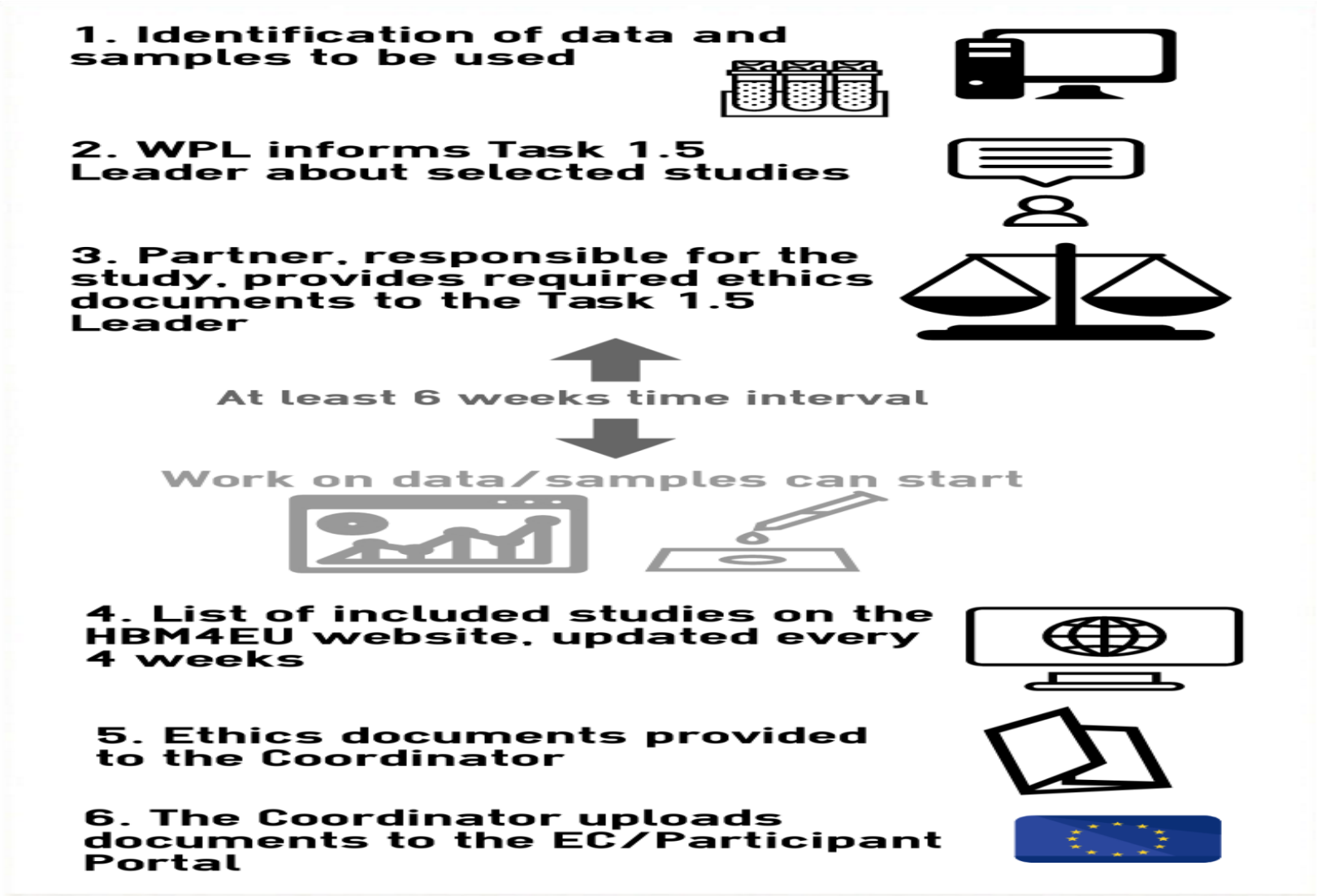
Information, Invitation, Informed Consent Form

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

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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

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