Det Sundhedsvidenskabelige Fakultet

# Ethical considerations,engagement, trust and transparancy in HBM

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## My background

Lisbeth E. Knudsen.,MSc, PhD professor in toxicology has worked with ethics and HBM since 1987 in designing, performing and reporting field studies. Appointed scientific member of the Regional ethics committee and chair of Committee. The chair of the institutional ethics committee. Partner in several EU programs/projects with human samples:NANOTEST, COPHES/ DEMOCOPHES, ESBIO, NEWGENERIS, CANCERRISK BIOMARKERS, BIOMODEM, HBM4EU

Ethics advisor in PARC and more

# ISSUES of HBM and Ethics

**Funding agencies**

Ethically spound studies with hypotheses and qualified independent personell securing trust and transparency

**Institutions performing the studies**

Independent, certified, trusted

**Participants**

RECRUITMENT on informed basis with written consent

Donating samples (Blood, urine, hair)

Providing personal information by questionnaires and interviews-demographic, lifestyle, health

Engagement, personal interest in individual participation and/or Altruism, confidentiality following the GDPR rules

# 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, President of the European Group on Ethics (EGE)

# 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.*

# How do you strengthen the ethical perspective?

Conditions:

- The initiative must include all partners and all individual researchers participating in research
- Ethical questions that arise must be addressed with transparency
- The initiative must reflect the genuine desire to foster best ethical practices (no window dressing)
- Recourse to independent expert advice in ethics maybe necessary
- Need for periodical review within the management structure of how ethical issues are dealt with

# Ethical issues

**Human embryos/foetus**

Stem cells, embryos, foetal cells

**Human participation: Study persons/tissues**

Who, where, how

Informed consent

data privacy,

bio banking

Secondary use

**Animal experiments**

3Rs Replacement, refinement, reduction

**Non EU-countries**

**Environmental protection and safety**

**AI**

## Ethics check list

### Informed Consent

Does the proposal involve children?

Does the proposal involve patients or persons not able to give consent?

Does the proposal involve adult healthy volunteers?

Does the proposal involve Human Genetic Material?

Does the proposal involve Human biological samples?

Does the proposal involve Human data collection?

### Research on Human embryos/foetus

Does the proposal involve Human Embryos?

Does the proposal involve Human Foetal Tissue/Cells?

Does the proposal involve Human Embryonic Stem Cells?

### Privacy

Does the proposal involve processing of genetic information or personal data (eg. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical convinction)?

Does the proposal involve tracking the location or observation of people?

An informed consent form is required in the following cases:

**When the research involves:**

Patients

Children

Incompetent/Incapacitated persons

Healthy volunteers

Immigrants

Others (i.e.prisoners)

**When the research uses/collects:**

Human Genetic Material

Biological samples

Personal data

A statement that the study involves research subjects and an **explanation of the purposes of the research.**

The **expected duration of the subject's participation.**

A **description of the procedures to be followed/ of the medicine that is going to be** tested, and an identification of any procedures which are experimental.

A statement that participation is **voluntary.**

Information about who is organising and funding the research.

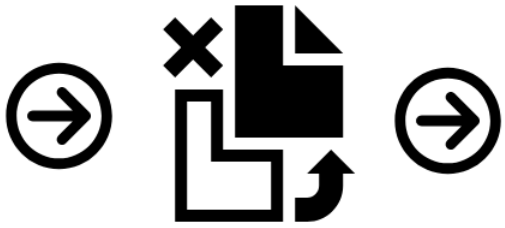
A description of any reasonably **foreseeable risk, discomfort or disadvantages.**

A description of any **benefits to the subject or to others which may reasonably be** expected from the research avoiding inappropriate expectations.

A disclosure of appropriate **alternative procedures for treatment/diagnosis if any,** that might be advantageous to the subject.

A statement describing the procedures adopted for ensuring **data protection/confidentiality/privacy including duration of storage of personal data.**
A description of how **incidental findings are handled.**
A description of any planned **genetic tests.**
For research involving more than minimal risk, an explanation as to whether there are any **treatments or compensation if injury occurs and, if so, what they consist of,** or where further information may be obtained. Insurance coverage should be mentioned.
A reference to **whom to contact for answers to pertinent questions about the** research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
A statement offering the subject the **opportunity to ask questions and to withdraw at any time from the research without consequences.**
An explanation of what will happen with the **data or samples at the end of the research period and if the data/ samples are retained or sent/sold to a third party for**
further research.
Information about what will happen to the **results of the research.**

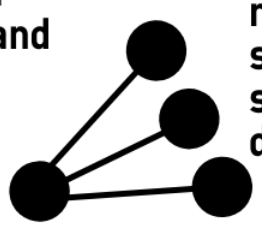
Original survey data with personal ID



Personal ID replaced with study ID

Key between personal ID and study ID

Coded data



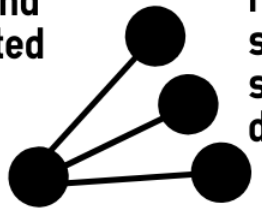
Sharing the data research groups in same institute, same country, different countries

Pseydonymized

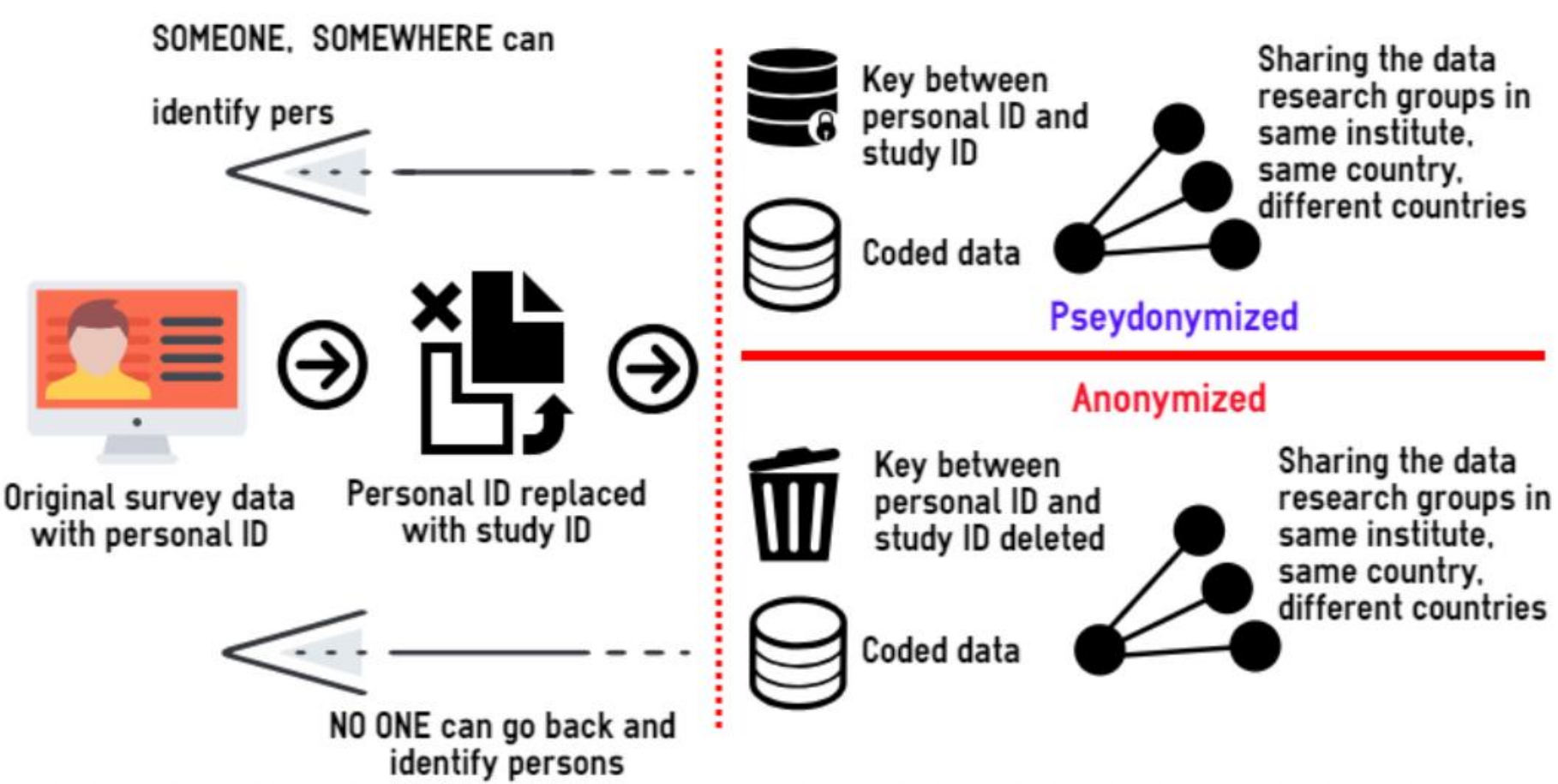
Anonymized

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

**Before submission of proposal**

- Identification by all partners of actual and potential ethical issues in the research program
- Preliminary reflection on how these will be addressed in the proposal
- Formulation of a policy outlining how ethical issues will be dealt with overall and within each individual workpackages

**During funding period**

- Implementation of the ethical policy
- Continual feedback from parties about ethical issues
- Periodic review of ethical strategy in view of feedback
- Formulation of updated ethical policy as need be

| | |
|---|---|
| Study planning | Researchers, Statistician, Communities, Participants representatives |
| Funding | Regulators, Politicians, Industry |
| Study approval | Research ethics committees (regional and/or institutional) |
| Recruitments | Study persons, Parents or other relatives, School teachers, Patients organisations, Nurses, Technicians, Paediatricians, Researchers |
| Informed assent/consent | |
| Sampling of biological material | Researchers, Technicians, Statistician |
| Analyses of biological samples | Researchers, Paediatricians, Nurses, Technicians, Media |
| Verification of results | Regulators, Communities, Industry, Participants representatives |
| Communications of results | Researchers, Paediatricians, Nurses, Technicians, Media |
| Follow up | |

# Before initiating a study

Ethics Review (study protocol approval-apply well in advance!)

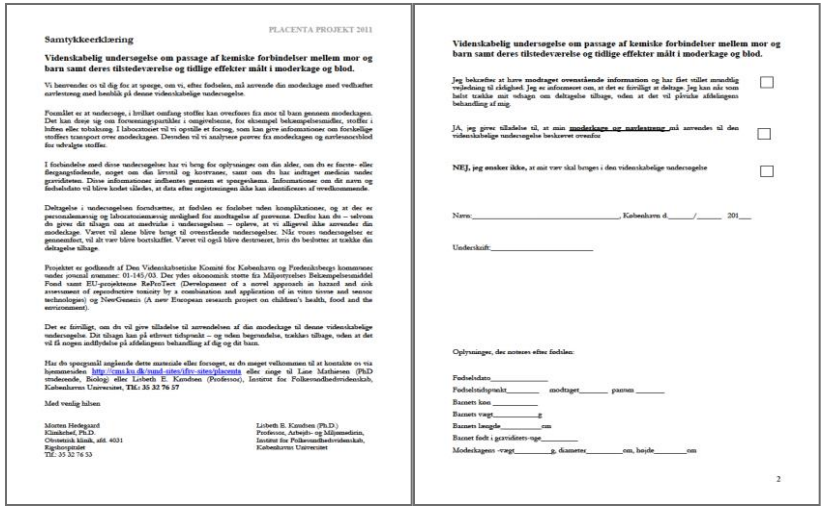
Reporting study to individual participants- publishing/releasing data

Respect the rights of study participants

Adverse discoveries/Incidental findings

**Confidentiality**

Informed written Consent



PLACENTA PROJEKT 2011

**Samtykkeerklæring**

**Videnskabelig undersøgelse om passage af kemiske forbindelser mellem mor og barn samt deres tilstedeværelse og tidlige effekter målt i moderkage og blod.**

Vi henvender os til dig for at spørge, om vi, efter fødslen, må anvende din moderkage med vedhæftet navlestreng samt hendes på denne videnskabelige undersøgelse.

Fosmiet er at undersøge, i hvilket omfang stoffer kan overføres fra mor til barn gennem moderkagen. Det kan dreje sig om forureningspartikler i omgivelserne, for eksempel bekæmpelsesmidler, stoffer i luften eller tobaksrøg. I laboratoriet vil vi opstille et forsøg, som kan give informationer om forskellige stoffers transport over moderkagen. Derudover vil vi undersøge passive fra moderkagen og navlestrengen for udvalgte stoffer.

I forbindelse med denne undersøgelse har vi brug for oplysninger om din alder, om du er første- eller flergangsfødende, noget om din livsstil og kostvanes, samt om du har indtaget medicin under graviditeten. Disse informationer indhentes gennem et spørgeskema. Informationer om dit navn og fødselsdato vil blive kodet således, at data efter registreringen ikke kan identificeres af uvedkommende.

Deltagelse i undersøgelsen forudsætter, at fødslen er forløbet uden komplikationer, og at der er personalemæssig og laboratoriemæssig mulighed for modtagelse af prøverne. Desuden kan du – uafvoen du giver dit tilsagn om at medvirke i undersøgelsen – opleve, at vi alligevel ikke anvender din moderkage. Værdet vil alene blive brugt til ovenstående undersøgelser. Når vores undersøgelser er gennemført, vil alt væv blive destrueret, hvis du bedstemt at trække din deltagelse tilbage.

Projektet er godkendt af Den Videnskabsetiske Komité for Københavns og Frederiksbergs kommuner under journal nummer: 01-145/03. Der ydes økonomisk støtte fra Miljøstyrelsen Bekæmpelsesmiddel Fond samt EU-projektene ReProTect (Development of a novel approach in hazard and risk assessment of reproductive toxicity by a combination and application of in vitro tiovse and omvse technologies) og NewGeneris (A new European research project on children's health, food and the environment).

Det er frivilligt, om du vil give tilladelse til anvendelsen af din moderkage til denne videnskabelige undersøgelse. Dit tilsagn kan på ethvert tidspunkt – og uden begrundelse, trække dit tilsagn, uden at det vil få nogen indflydelse på afdelingens behandling af dig og dit barn.

Har du spørgsmål angående dette materiale eller forsøget, er du meget velkommen til at kontakte os via hjemmesiden http://cmo.ku.dk/rund-sites/ifrv-sites/placenta eller ringe til Lone Mathiesen (PhD studerende, Biolog) eller Lisbeth E. Knudsen (Professor), Institut for Folkesundhedsvidenskab, Københavns Universitet, Tlf.: 35 32 76 57

Med venlig hilsen

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Jeg bekræfter at have modtaget ovenstående information og har fået stillet muntlig vejledning til rådighed. Jeg er informeret om, at det er frivilligt at deltage. Jeg kan når som helst trække mit tilsagn om deltagelse tilbage, uden at det vil påvirke afdelingens behandling af mig. ☐

JA, jeg giver tilladelse til, at min **moderkage og navlestreng** må anvendes til den videnskabelige undersøgelse beskrevet ovenfor. ☐

**NEJ, jeg ønsker ikke**, at mit væv skal bruges i den videnskabelige undersøgelse ☐

Navn:_____, Københavns d._____/_____ 201___

Underskrift:_____

Oplysninger, der noteres efter fødslen:

Fødselsdato:_____
Fødselstidspunkt:_____ modtaget_____ pasrun _____
Barnets køn:_____
Barnets vægt:_____g
Barnets længde_____cm
Barnet født i gravviditets-uge_____
Moderkagens -vægt_____g, diameter_____cm, højde_____cm

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