



# **Ethics and data protection in human biomarker studies in environmental health**

**Collegium Ramazzini  
Carpi October 2010**

**Ludwine Casteleyn, Birgit Dumez,  
An Jamers, Karel Van Damme**

# Need for more harmonized approach

*Particularly with respect to some specific conditions in research using human biomarkers:*

- o **Secondary use** of personal data and biological material
- o (Secondary) use of personal data and biological materials in **transnational projects** (differences in regulations and research culture)

# Challenge

Facilitation of valuable and ethically correctly conducted research in the field of human biomonitoring studies.

Who decides upon what, for whom, why, how and on which grounds?

# ECNIS Volume: main questions

- Do ethical and data protection issues related to the use of HBM in environmental health studies substantially differ from studies in clinical settings, where full emphasis lies on decisional autonomy and protection of individuals?
- Is the current ethical and/or legal framework workable as the notion of public interest moves more to the forefront in case of public health concern? Does the current framework protect what it should protect? Should rethinking of the current ethical and legal framework be put on the agenda?
- Is the current composition and functioning of the ethical committees suitable for environmental health research? Who should be involved in the decision making processes and on what level?

- Autonomy
- Beneficence, non-maleficence
- Justice
  
- Respect for human dignity (equality of moral status of individuals!)
- Solidarity
- Social Justice
- Democratic participation
  
- Confidentiality, privacy, informed consent

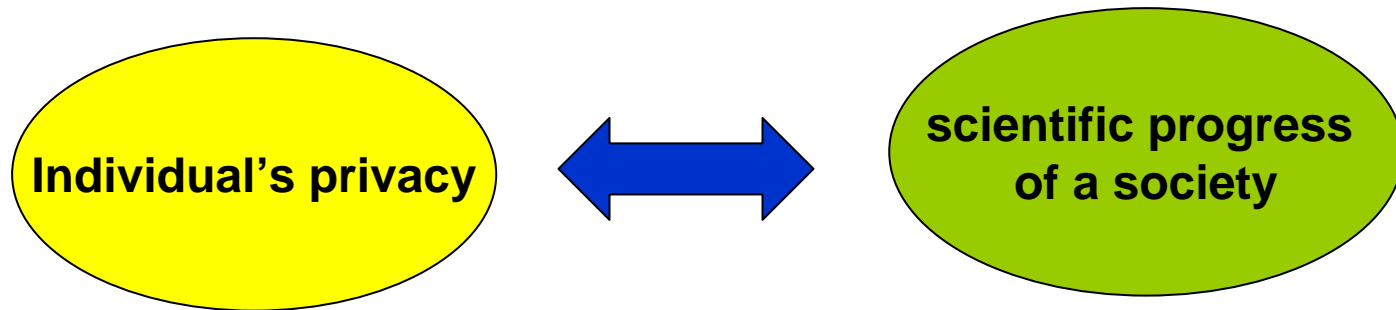
# Some of the items addressed

- the role and functioning of ethics committees;
- the tension and balance between the individual and societal interest;
- the possible consequences of the requirement of informed consent;
- the impact of the professionalism involved, of the experience and the formal role of the researcher on the nature of the practice and the perception by the study participants;
- the influence of scientific uncertainties on the decision making process.

# ECNIS Volume: Ethics and data protection in human biomarker studies

## MAJOR problems situated at different levels (2)

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- A stronger focus is needed on good communication practices at all stages of a research project. This is key for a respectful approach to study subjects and to create trust in science.

# DVD

## Dissemination and promotion of film on informed consent

### 1. Didactic purpose

- how to strive for an *authentic* informed consent?

### 2. Complexity of communication

- Explanation of complexity and uniqueness of interaction between different **personality types**

### 3. Bring daily life closer to scientific world

### 4. Distribution

- to all interested parties

# What is an authentic consent?

- **Authenticity**
  - **Free** in decision to participate
  - **Equal** in relationship with recruiter
  - Be **listened** to and receive answers
  - At personal level of **understanding**
  - Feel **comprehended**
- **Conflict**
  - Strive for informed consent
  - Samples are crucial for science

# Possible pitfalls during IC procedure

- **Status** of the person providing the information?
- Limited **accuracy** of information
- Correct **understanding** of the information?
- Ability to **decide**?
- Decisional **autonomy** vs **social** constraints
- Context of **power inequality**?
- Complex **interaction** of personalities!



# Interviews

## Physician

## Patient

Interview 1

Authoritarian

Very cooperative

Interview 2

Authoritarian

Suspicious, mistrusting,  
rebellious

Interview 3

Authoritarian

Aggressive, sadistic

Interview 4

Lack of empathy

Aggressive, sadistic


Interview 5

Responsible,  
educative, guiding

Very cooperative

Acted but realistic situations!

# DVD about informed consent

- Basis = respect
  - Respect for **dignity** and **integrity**
  - Respect as best guarantee for **trust** in science
- How to strive for an authentic consent?
  -  WILLINGNESS to reach authenticity  
and EMPATHY skills
  - **Different** people may communicate **different** information in a **different** way to obtain a same level of authenticity
  - Complex **UNIQUE** situation (vs. formalistic approach)
  - Not everyone might be **suited** to perform the interviews



# Thank you!

KUL team

Ludwine Casteleyn, Birgit Dumez, An Jamers  
Karel Van Damme