

# ESBIO WP4 - Ethics and communication

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## *Description of work*

*Ethical rules and practise, social and legal aspects*

Overview of legal constraints

Overview of current practices in different countries

Overview of new insights and trends based on current research related to ethics in population studies

## *Deliverables*

D4.1 Publication on available practices described in the inventory and from focus interviews

D4.2 Workshop with major stakeholders identifying major items for guidelines for ethical issues

D4.3 Justified concept for dissemination and communication of results within participants of the pilot project



An overview on available practices regarding data protection and ethics committees have been developed in the form of information sheets on regulation regarding data protection and on regional ethics committees in most EU countries. These sheets are published at the ESBIO webpage.

Most ESBIO participating countries have provided information about country specific practice and regulations regarding HBM

Most countries comply with Good Clinical Practice Directive and Data Protection Directive by national legislation

Only Germany, Czech Republic and Belgium have specified how to handle biomonitoring information from surveys

Rules of biobanking have to be followed unless samples are collected and handled within a single institution

The level of anonymisation is different between countries in selection of and communication with study participants



The workshop and ESBIO meeting on ethics and communication was held in Copenhagen March 2007 with more than 50 attendants from industry, governments, science and European countries of Austria, Belgium, Croatia, Cyprus, Czech Republic, Denmark, Estonia, France, Germany, Italy, Luxembourg, Netherlands, Poland, Portugal, Romania, Slovakia, UK and USA.



## Publications suggested for Environmental Health – web based

Meeting in Copenhagen on ethical issues related to human biomonitoring – a highlight/ *Lisbeth E. Knudsen, Franco Merlo and Uffe Lind*

Research on ethics in ECNIS and NewGeneris: a bottom up Approach *Birgit Dumez and Ludwine Casteleyn, University of Leuven/*

Ethical issues in human biomonitoring - a view from science Studies \*/*Susanne Bauer Medical Museion,*

Issues of biobanking related to HBM / *Kirsi Vahakangas Lisbeth E.Knudsen, Franco Merlo,*  
Ethical issues experienced in HBM within Portuguese health surveillance and research projects\*/ *by Susana Segurado and Fatima Reis*

Activity of Biomedical Ethics Committees and Data Protection issues in Poland by\* *Danuta Ligocka, NIOM, Lodz, Poland*

Scientific integrity: a critical issue in environmental health research *DF Merlo, K Vahakangas, LE Knudsen.*

Knowledge for action: joint reflection on environment & health-data by *Hans Keune, Gudrun Koppen, Karen Van Campenhout*

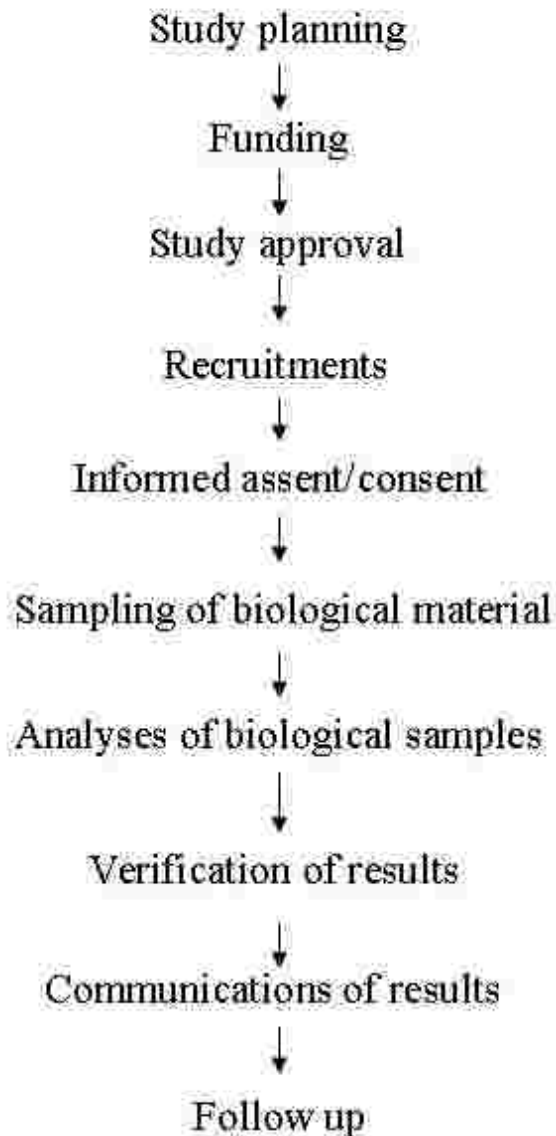
Communicating human biomonitoring results - interference with public health recommendations, by *Maryse Lehnert- Arendt*

Stakeholder interest in HBM *Ovnair Sepai, Clare Collier and Birgit van Tongelen*

WP3 contribution *Roel Smoelders et al*

The importance of communication in the succes of a large biomonitoring study Example of the French Dioxin and Incinerators Study *Nadine Frery et al*

# European Human Biomonitoring



Researchers, Statistician, Communities, Participants representatives

Regulators, Politicians, Industry

Research ethics committees (regional and/or institutional)

Study persons, Parents or other relatives, School teachers, Patients organisations, Nurses, Technicians, Paediatricians, Researchers

Researchers, Technicians, Statistician

Researchers, Paediatricians, Nurses, Technicians, Media

Regulators, Communities, Industry, Participants representatives

Researchers, Paediatricians, Nurses, Technicians, Media

# Recommendations

A protocol to be developed at an early stage describing rationale, justification of study, calculation of minimum number of study persons needed for sufficient power of study, recruitment of study persons

Informed consent, information material and protocols to ethics committees and other authorities before initiation of studies

Biobanking issues to be solved regarding informed consent

Incentives for participation, special concerns regarding children

Information about study results, including right not to know

Follow up procedures must be described in protocol

Harmonised approaches to steps of recruitment of study persons, format of information, consent, data protection, biobanking, dissemination and data/sample transfer between countries and institutions should be considered eg in future directives/guidelines for human environmental biomonitoring in Europe (and worldwide).



# Brussels stakeholder workshop December 2006

Transparency in the aims and realistic outputs from such studies were key requirements especially at the planning stage.

Despite differences in data protection and ethics approval legislation across the Member states, a level of harmonisation can be reached that allows a more coordinated approach to HBM in the EU

Stakeholders in human biomonitoring from industry, government, research and NGOs gave opinions on organisation of biomonitoring studies including children.

*Enrolment could either be through direct approaches to parents or advertisements.*

*Repeated measurements were fully acceptable by all and the majority accepted all samplings of blood, urine, scalp hair and questionnaire.*

*Study persons should be informed about study results or request results.*

*Data should be protected by coding and made available for governments and research after anonymisation.*

*Reimbursement of expenses related to participation should be organised while different views were expressed regarding incentives as gifts and payment.*



Justified concept for dissemination and communication of results within participants of the pilot project

- Transparency in all steps
- Stakeholder involvement in all steps
- Comply with ethics and data protection
  - Informed consent with sufficient participant understanding of current and future use of samples and data
  - Biobanking, including data and sample sharing
  - Incentives (refund, gifts)
  - Children (vulnerable, behavior, comparison)
- Governmental interests/roles
- EU requests and interests