Ethics assessment in research & innovation: policy encounters

SATORI workshop

Brussels, 23 May 2017

The Role of the Council of Europe in Biomedical Research

Prof. Elmar Doppelfeld MD

Former Chair of the „Steering Committee on Bioethics (CDBI)“

Member of the German Delegation to the Committee on Bioethics
Council of Europe

Chairman of „European Network of Research Ethics Committees (EUREC)“

Council of Europe

- Established in 1949 - “Intergovernmental body”
- 47 Member States (Population: ~ 900 Mio)
- Observer States (Canada, Holy See, Japan, Mexiko, USA)
- „Human Rights, Democracy“
- Harmonization of European legislation
- Conventions and Additional Protocols: treaties!
  - Signature and ratification: decision of the Member States

Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950

Engagement in Bioethics

- Structure and Aim -

- 1985: “Ad hoc Committee of experts on Bioethics (CAHBI)”,set up under the direct authority of the Committee of Ministers
  - responsibility: intergovernmental activities of the Council of Europe in the field of bioethics
- 1992: CAHBI became the “Steering Committee on Bioethics (CDBI)”
- 2012: “Committee on Bioethics (DH-BIO)” takes over the responsibilities of the Steering Committee on Bioethics (CDBI)

- Protection of Human Rights and Fundamental Freedoms with regard to the Application of Biology and Medicine
- Scope e.g. Medical routine, transplantation of human organs and tissues, human genetics, biomedical research including biobanks

Accepted Ethical Principles

- Respect for persons
- Beneficence
- Justice

The Belmont Report, Washington D.C. 1978

- Respect for persons
- Beneficence
- Nonmaleficence
- Justice

Beauchamp, T. Childress, J.
Principles of Biomedical Ethics (1979), Oxford 2009

Data Protection and Ethics in R&I

- In order to facilitate scientific research, personal data can be processed for scientific research purposes, subject to appropriate conditions and safeguards.
- Restrictions on the exercise of some provisions may be provided for by law with respect to data processing for scientific or historical research purposes or statistical purposes when there is no recognisable risk of infringement of the rights and fundamental freedoms of data subjects.

Statement of Dr. Sophie Kwasny, Conseil de l'Europe, Committee of Convention 108

Ethical and socially aware Use of Data

- Balance of all interests concerned, "controllers and processors should adequately take into account the likely impact of the intended Big Data processing and its broader ethical and social implications"
- "Personal data processing should not be in conflict with the ethical values commonly accepted in the relevant community or communities». «the common guiding ethical values can be found in international charters of human rights and fundamental freedoms, such as the European Convention on Human Rights → compliance with ECHR, compliance with ethics.
- Ethics committee: controllers **could establish** an ad hoc ethics committee, or rely on existing ones, to identify the specific ethical values to be safeguarded in the use of data.

Preventive policies and risk-assessment

- Risk-assessment must take into account social and ethical impact of this use, ethics as focal point
- Principles of legitimacy of data processing and quality of data of Convention 108 must be taken into account for the assessment
- Assessment of the likely impact of the intended data processing on the rights and fundamental freedoms of data subjects, notably the respect for the right to non-discrimination taking into account social and ethic impacts.
- Assessment process should be carried out by persons with adequate professional qualifications and knowledge
- Principle of transparency: the results of the assessment process should be made publicly available, without prejudice to secrecy safeguarded by law. In this case, not publicly available but may be accessed by the supervisory authorities.

Guidelines on the protection of individuals with regard to the processing of personal data in a world of Big Data, adopted on 23 January 2017 by the Committee of Convention 108

Council of Europe

- Provisions for Biomedical Research -

Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo,4.IV.1997 (ETS No 164)

Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research, Strasbourg, 25.I.2005 (CETS No 195)

Recommendation CM/Rec(2016)6 of the Committee of Ministers to member states on research on biological materials of human origin, *Adopted by the Committee of Ministers on 11 May 2016*

- *The only legally binding international instruments covering all kind of biomedical research involving human beings, compulsory for all researchers*

- Guide for Research Ethics Committee Members

Freedom of Research

„Scientific research in the field of biology and medicine shall be carried out freely, subject to the provisions of this Convention and the other legal provisions ensuring the protection of the human being.“

Article 15, Convention on Human Rights and Biomedicine

Qualification and Quality

- Qualification of researcher
  - „duly qualified“
  - physician – specialized or not or to what extent specialized? reaction to contingencies or adverse events? duty of care?
  - other researchers: e.g. psychology, biochemistry, biophysics
- Quality of the research project
  - scientific quality
  - accordance with national or international law
  - ethical acceptability
- Assessment by independent bodies, e.g.
  - Research Ethics Committee, scientific bodies, authorities

Proportion of Risk and Benefit

- Minimising of risk and burden for research participants!
- No potential direct benefit (healthy volunteers)
  - ➢ only acceptable risk and acceptable burden for the participant
- Potential direct benefit, persons able or not able to consent
  - ➢ risk and burden must not be disproportionate to the potential direct benefit for the involved person
- ✧ Research without potential direct benefit on persons not able to consent
  - ➢ only minimal risk and minimal burden

Research on Persons able to consent

- Free informed consent
  - „free“: no undue influence, no vulnerability, no coercion, no disadvantages in case of refusal, withdrawal at any time
  - „informed“: all relevant information before starting a project including information on foreseen or foreseeable further use of the results, alternatives, protective legal or other provisions
  - consent to a specific project or to projects in the future

Research on Persons not able to consent

- All conditions for research must be fulfilled!
- In addition:
  - justification for research on this specific group, „no alternative of comparable effectiveness”
  - authorization by the legal representative according to national law; assent of the represented person
  - information and participation in the authorization procedure of the represented person to the extent of his or her understanding
  - normally only research for the potential direct benefit
  - exceptionally research without potential direct benefit: protective provisions prescribed by law, only minimal risk and minimal burden!

Specific Situations

- Research during pregnancy and breastfeeding
  - benefit for other women in relation to reproduction, for other embryos, foetuses or children
  - avoiding any adverse impact on the health of a breast fed child
- Research on persons deprived of liberty
  - permission by law
  - benefit to persons deprived of liberty

✧ Conditions for both situations

- justification for research on this specific group, „no alternative of comparable effectiveness“
- minimal risk and minimal burden

Emergency Situations

- Research on persons in emergency clinical situations
  - legal regulation
  - person concerned not able to consent
  - because of urgency of the situation authorization not possible
  - research of comparable effectiveness cannot be carried out on persons in non-emergency situations
  - approval of the project specifically for emergency research by the competent body after ethical assessment
  - potential benefit not disproportionate to risk
  - no potential direct benefit for the person concerned: minimal risk and minimal burden
  - ✧ information of the person concerned or of the legal representative as soon as possible for free informed consent/authorization

Examination and Approval

- Every research project shall be submitted for independent examination of its ethical acceptability to an ethics committee
- Research may only be undertaken if the research project has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of research, and multidisciplinary review of its ethical acceptability

✧ Ethical assessment before approval!

Collections - Biobanks

- Removal of human tissue and storage for future research use
  - ➢ “Broad” free informed consent / “broad” authorization by the legal representative
- Scientific use and storage of human tissue removed for other purposes
  - ➢ “Broad” free informed consent / “broad” authorization by the legal representative
- ✧ Confirmation of a previous authorization by the person concerned after gaining or regaining ability to consent!
- Decision of a donor on future contacts
- Assessment and approval of research projects by competent bodies