

WMA Declaration on Ethical Considerations regarding health databases and biobanks

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Background

- The current version (2002), which was little known only, needs to be updated.
- A draft of the modified version was published for public consultation 18/3/2015.
- More than 80 comments were received.
- All commentators were invited to participate in the meeting in Copenhagen.
- About 40 people from all continents attended the meeting.

Critical Issues of the current Draft

- All health databases and biobanks are addressed.
- One size fits all, e.g. data base for a thesis.
- Differentiates between ,fully anonymised‘ and ,pseudonymised‘ databases, and refers to ,not fully anonymised‘ ones only.
- The issue of incidental findings not properly addressed.
- Although ,broad consent‘ is considered acceptable the respective paragraph (18.) is confusingly formulated.
- A waiver of prior Informed Consent may be accepted by the EC, even without a legal basis.
- Adequate transparency is not asked for.

Points of intensive discussion

- Requirement of accreditation of RECs.
- Level of detail, i.e. short or long declaration.
- Is anonymisation still feasible? If not – consequences?
- Addressee: physicians and/or researchers only?
- Role of research in society.

Additional Observations re Denmark

- There were many speakers (ethicists, philosophers, medical researchers) from Denmark. Although in Dk almost all databases can be linked by the SSN, it seems to be accepted by the population.
- Research per se is considered by law as beneficial for society in Dk.
- As methodologically flawed/biased science is considered unethical, data privacy has to accept the primacy of the pursuit of excellent data quality.
- RECs should not adversely interfere with the progress of medical science, e.g. bioinformatics.

Outlook

- It is a major challenge to write a declaration which can be accepted by representatives from 5 continents.
- As **the** major problem are the ,administrative‘ data bases considered, medical research plays a minor role only.
- There will be a similar meeting in SE Asia early next year.
- The final text will be submitted to the GA of the WMA at the earliest in autumn 2016.