Herzlich Willkommen!

Workshop: Personal Data Issues in European/International Medical Research Projects, Berlin, 8.12.2006

Published Online Material on the Use of Personal Data in Medical Research.

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Disclaimer

This presentation is...

- ... Not the result of systematic observation,
- ... Based on an (almost random) exploration,
- ... Incomplete,
- ... Not representative,
- ... Entirely subjective

It is nevertheless intended (and hoped) to be of some help in the issues at hand.

Goals

The Problems:

- Legislation is national
- Personal data issues are a new area of legislation
- Legislation (except for EU-directives) generally isn´t translated

The Goal:

- Find sources (preferably in English) on
  - Legislation
  - Official authorities involved
  - Interpretations and guidelines
- Find potential cooperation partners

Needle in a haystack

For the keywords:

- Personal
- Data
- Medical
- Research

Google reports 45 million hits.

Adding

- Regulations

Reduces the count to 5 million

Adding

- Pseudonym

Still leaves 200 000

Glancing at the haystack

Even though some of the search terms are quite general, one easily finds many entries actually related to our topic. Personal data in medical research seems to be an issue that many have something to say about.

Specifically, one finds:

- Policy statements
- Text (mostly excerpts) of relevant laws and regulations
- Commentaries and opinions on laws and their interpretation
- Reports
- Book reviews
- ... (other things)
- The explicit statement not to have a position on this issue
  - www.amrc.org.uk

The needle is hot

Relevant contributions come from:

- Government and international bodies or agencies
- Universities and other research institutions
- Academic societies
- Publishers

Even though the search was only done in English, countries in Europe are well represented

General impression: Aside from business interests and government sources, there appears to be a widespread desire or perceived necessity to bring one‘s view „on record“.

Some interesting information found on web pages

What is anonymous ?

The EMEA proposes the following definitions:

Identified – these datasets contain personal identifiers from which individuals can be distinguished.

Coded – identifiable information is substituted by a code of randomly assigned numbers and/or letters. The data is anonymous to the research team and the key to the code is held securely by those responsible for the patients' care or a third party. In some cases, a second coding system can be added to further increase data security. Researchers would only be able to gain access to identifiable data via the custodian of the code(s). This could be subject to defined conditions.

Anonymised – all personal identifiers or codes are removed. This offers an additional level of security.

(cited by the Parliamentary Office of Science and Technology, UK)

Terminology remains a major problem

Example: Study on costs of consent processes

http://www.bmj.com/cgi/content/full/333/7561/255/DC1

- ‘Express Consent’ – where each potential participant is individually informed about the study, and their consent sought (and possibly formalised on paper)
- ‘Opt-out’ – where each potential participant is individually informed about the study, and included unless they object;
- ‘Social Contract’ – people are informed generally about research and information is freely available on specific projects and will be included unless they object (either generally to being a research subject or to being included in a specific study) – basically the costs of information provision are greatly reduced.
- **‘Anonymise’ – where data is de-identified, possibly leaving a pseudonym for linking and tracing if needed**, so that there is no legal requirement for consent. However, this is still a point of contention and no clear guidelines exist. We presume that this is a viable option without impacting the results of the study.

Guidelines

- National guidelines are available
- Example for the UK:

http://www.recordsmanagement.ed.ac.uk/InfoStaff/DPstaff/DP_Research/ResearchAndDPA.htm

- Details ?
- Usefulness ?
- Translations ?
- Multinational trials ?

Someone´s already done the work...

A fairly well structured and comprehensive collection of pertinent information and document references may be found at:

www.privireal.org

- Project started in 2001
- Funded by the European Commission
- Coordinated by faculty at the University of Sheffield
- Systematic comparison of EU Member States
- Information about non-EU countries
- Project results available as book (2004)

Interesting points

www.privireal.org

Cirticisms or problems related to 95/46/EC

- Definition of anonymisation conflicts with common use
- Anonymisation is processing protected by the directive
- Ambiguity: narrow or broad conception of privacy
- Personal data relating to dead people

Recommendation related to 2001/20/EC

- Ethics committees

Anonymised Data

Narrow conception

- Subject has no interest in anonymised data
- No need to inform subject about later processing
- Abstracted information is not personal data – no restrictions

Broad conception

- Subject can no longer exercise rights after anonymisation
- Must inform subject about planned processing
- Restrictions apply to processing of abstracted information

Well... Maybe not all of the work is done

www.privireal.org

Problems:

- Project focus is on analysis of legal issues in 95/46/EC
- Members involved in medical research ?
- Biomaterials ?
- Practical solutions ?
- Current project activities ?
- Will there be more ? When ?

Looking for reports ...

Example: Brief Report on the Data Protection Audit

Data Processing Infrastructure Concept of the Schering Corporation for the Secure Pseudonym Storage and Keeping of Blood and Tissue Samples intended for genetic analyses

http://www.datenschutzzentrum.de/audit/kurzgutachten/a0303/a0303_engl.htm

Example: Data Protection Commissioner Activity Report (Eire)

http://www.dataprotection.ie/documents/press/Annual2004Press.doc

↳**Biometric** central databases are not required in all circumstances.

↳**Medical research** is not impeded by adhering to data protection principles.

What was not found ?

- Guidelines for multinational (!) research projects
- Useful recommendations for implementations
  - Comprehensive guidelines
  - Recommendations for organisational structures
  - Information technology
  - Documentation (e.g., consent forms)

Conclusions

- The WWW is big, very big (trivial)
- Useful information about personal data issues is scarce
- Many contributions reflect the current state of debate
  - Uncertain terminology
  - Lack of consent in key issues between countries
  - Little awareness of this problem and the consequences
  - Very little practical help, especially for international activities
- The TMF should consider co-operation with PRIVIREAL

Vielen Dank für Ihrer Aufmerksamkeit!

Mehr Information:

http://www.tmf-ev.de/