Data for Research
a comparative overview

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Contents

- The basis: EC Directive 46/95
- Did not harmonise:
  - definitions;
  - concrete applications
- A scheme with some distinctions
- Some examples

- How to proceed further ??

EC Directive, 1995

- Basis: freedom of services within in the EC, various data protection regimes would hamper this (not data protections as such)
- Long drafting process
- Has not been revised since
  - Contrary to much other EC legislation, like pharma
- Directive must be implemented in national legislation

Free flow of p.data within the EC …..

- Legislation of ‘controller’ applies
  - Controller vs. processor
- Other country cannot make objections if controller complies with national legislation (even in data are processed in that other country)

Principles of Directive

- Use for a specific purpose; other purposes compatible
- In principle consent
  - Legal obligation
  - Contract..
- Transparency
- Proportionality
- Sensitive data special protection

- Exemptions: a.o. research

Scheme of relevant issues

- Scope of application
- Type of exemptions for medical research
- Use of civil registration number (if any)
- Authorisations if any of National Data Protection Authority (DPA)

Personal data according to Directive

principles of protection must apply to any information concerning an identified or identifiable person; whereas, to determine whether a person is identifiable, account should be taken of all the means likely reasonably to be used either by the controller or by any other person to identify the said person;

p. data

- Indirectly identifiable
- Directly identifiable
  - Level of aggregation decides
- Coded data
  - One way or two way coding
  - Two way most important
  - Different category

Scheme types a data

Anonymous		*P. Data*	
Ordinary	**Coded**	**Indirectly identifiable**	**Directly (NAW)**
		Coded or non coded	

National differences

- What are p. data
  - Principles or contextual approach
- Exemptions on consent for research with p. medical data
  - Most countries do, but differs widely
- Use of genetic data as special category (in the law)

Exceptions on consent

- Dutch
  - anonymous data which are coded do not become p. data, makes TTP very interesting
  - If it infeasible (very difficult) to ask consent
  - Use indirectly identifiable data
  - Patient should not have objected in general
  - If it impossible to ask consent
  - Even directly identifiable data
  - Patient should not have objected

Exceptions on consent, 2

- Belgium:
  - Coded data are p. data
  - More or less the same but not system for opting out and the DPAuthority should give permission (in holland not, ethics committee)
- France :
  - Coded data are p. data
  - Much more difficult, but officially the CNIL can grant exceptions

Exceptions 3

- Austria:
  - Data may considered anonymous if researcher would have to use illegal means
  - Derogations from consent possible

- Denmark
  - Are p. data
  - Can always be used without consent if DPA has given permission:
    - Rendered semi anonymous: indirectly identifiable and coded

Scheme consent research with residual tissue

	specifie k	Mutliple choice	General	Opt-out	Exception.
Un.	X				X
RvE		X			
Fr.	X, prot.				
Swd/Nrw			X, ziekte		De facto
UK			X		X
Den				X	
Dutch Code				X	

Way forward

Pragmataic

- Use concept of controller
- PET's , like TTP constructions, contractual arrangements

More principled level…..

- Rethinking concept of consent