Regulations on residual tissue for research in Europe

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Summary

- Difference in ‘parlance’ US- Europe
- Tissue and data
- Three “regulatory” systems
  - EU/EC
  - Council of Europe
  - Countries

- No sweeping statements but two:
  - national differences
  - Exchange on the basis of mutual recognition

Difference in parlance

- Observational research vs. interventional research
- In US: both are human subjects research
- In Europe: usually not
  - Interventional = research involving human subjects
  - Observational:
    - Research with data follows data protection legislation
    - Residual tissue separate regimes and follows data protection legislation

Tissue and data

- Tissue = data + plus
- Data:
  - Accompany the tissue
  - May be linked to results on research on tissue
- Plus =
  - sensitiveness of tissue
  - Data can be derived from tissue

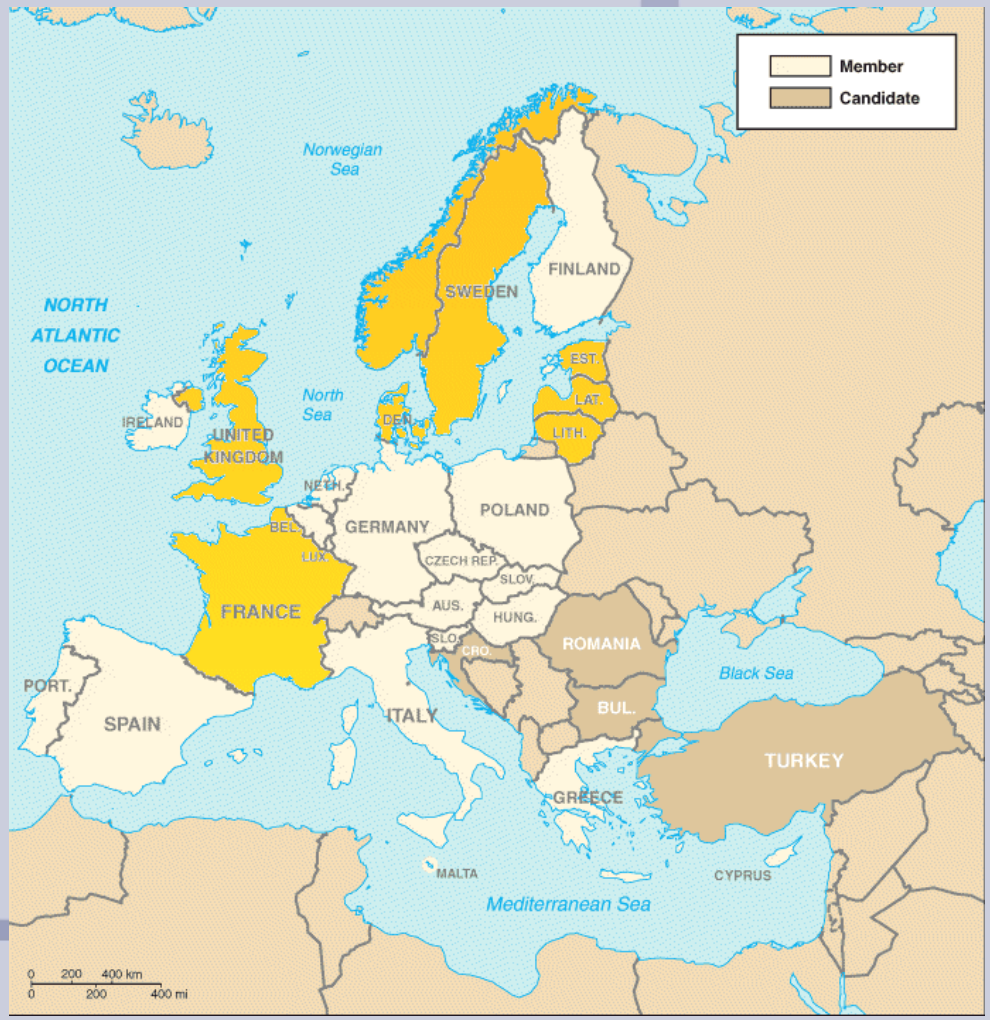
- **If you cannot use the data, you cannot use the tissue: type of data you are allowed to use determines type of tissue**

Types of tissue

1. Fully anonymous
2. Anonymous on the level of the researcher but coded
    1. One way >from identifiable data to a codenumber
    2. Two way > also the other way around
3. Directly identifiable

- Note: 2.2 is sometimes called indirectly identifiable. This has also another meaning: aggregation level such that researcher could in theory retrieve identity of the donor

Countries in Europe which regulated residual tissue tissue



Complicated regulatory picture

- Countries have autonomy unless….
- International Treaty
  - Nothing ‘federal’ on the European level, not even that of the EU/EC.
  - ‘legislation’ of EU/EC is Treaty based
  - Difference between EU and EC

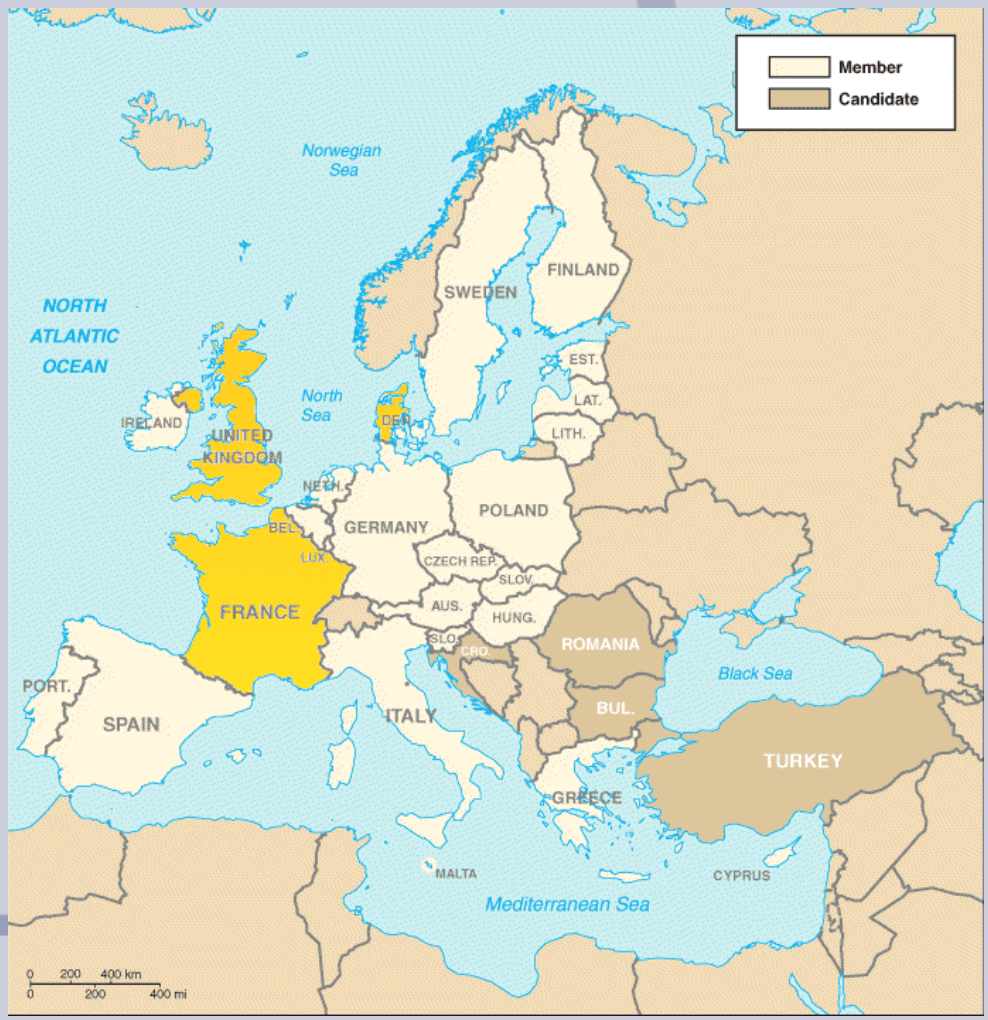
European Community

- For regulation EC is most important
  - Separate legal order, overriding national law, can regulate,
  - Only for:
    - common market
    - Health protection in certain specific areas
  - If so, decision making complex procedure, in general majority rule
  - EC not competent to regulate research as such
  - Did “harmonise” data protection as an aspect of free rendering of services. Still huge differences between countries with respect to medical data for research

Council of Europe

- Cooperation most of all in the field of human rights
- Treaties which therefore need ratification
  - European Convention of Human Rights
    - European Court of Human Rights
  - European Convention on Human Rights and Biomedicine
- Recommendations
  - Draft Recommendation on research on biological materials of human origin
  - Stricter than some recent national legislation

Countries which I shall discuss



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General preliminary remarks

- Incomplete picture as…
- Rules on residual tissue and data protection form part of larger scheme of regulations
- Are embedded in cultural traditions, in traditions of administrative and constitutional law
- ‘responsiveness’ of government agencies

- In the health care system all:
  - In all publicly available health care
  - Social system, based on solidarity
  - Some: availability of compulsory cancer registries

Issues

- Consent system
- is ‘banking’ as such regulated ?
- Are coded anonymous data considered personal data?
- If so, does the patient need to consent for their use in research ?
- Can the civic registration number be used for linking patient data ?
- Are authorisations needed ?

Denmark

- **Opt out** for coded or directly identifiable tissue
- No consent at all for fully anonymous
- Banking as such is not regulated
- Coded anonymous data are considered personal data
- But can be used without consent with approval of D. DPA, is granted when privacy enhancing technologies are implemented.
- Civic registration no. can be used !!!
- Yes, but only mentioned approval for data use >quick, light procedure.

GBR

- No consent – broad consent coded anonymous
- Banking will be regulated by the Human Tissue Authority (www.hta.gov.uk)
- Coded anonymous data are not considered personal data
- However, there is considerable confusion on consent and waiver of consent for use of data in research. See report Ac. Med. Sciences (http://www.acmedsci.ac.uk/images/project/Personal.pdf)
- No civic registration no., (sci-fi) NHS electronic record
- 'just' the approval of an ethics committee

France

- In general: to use tissue for research patient has not opted out
- some regulations on banking
- Coded anonymous are considered p. data
- Patient should have consented to specific project, can be waived (exceptionally)
- Coded anonymous research projects, specific informed consent is needed
- No civic reg. no. can be used
- Many: not , cumbersome
- Regulations in Code de la Sante Publique and Data Protection Act

Conclusions

- Divergent solutions
- Harmonisation ?
  - Will not work, see data protection Directive
  - Has a tendency to raise standards, see CoE Recommendation
  - International instruments: danger of ‘rhetoric’ instead of balance with practical feasibility
- For Europe: mutual recognition, if tissue from country A may legitimately be used for research in A, country B should accept that use in B as well

Conclusions 2

- Mutual recognition, provided that
  - Some form of consent has been achieved, opt out basis
  - A remains ‘controller’ of data in the sense the data protection Directive and by analogy also of the residual tissue
- Will that work outside Europe ?
  - Complexities of transferring data outside E.

To be continued……

- Mini-symposium on 29 June Utrecht in the context of the bi-annual epidemiological congress Euroepi 2006