Exchange of Residual Tissue for Research

the Tubafrost Code of Conduct

Valencia November 12 2005

Med Law consult

Challenge….

- Many European research projects exchange data and residual tissue

- How
  - without undue hindrances…
  - Not stopped at the border
  - In an ethically balanced way

Why a challenge

- Research with residual tissue = research with data plus
- Plus:
  - Sensitiveness
  - Research can lead to patents
  - Special data (underscored)

- Data:
  - Accompany the tissue
  - Will be derived from the tissue
  - New data can be connected to this outcome

Different regimes

- Regulatory point of view:
  - Research with (patient) data
  - Research with residual tissue
- these regimes differ between European countries
- Also regimes on research with patient data
  - In spite of Directive 95/46 EC
- Hence the challenge for Tubafrost
  - How to exchange in spite of various regulations ?

What next…..

- Explain differences in regulatory regime for residual tissue
  - Always two steps, data and tissue
- Then various options for Tubafrost
- Coordinating principle
- Rest of Code of Conduct
  - Principles, little hard rules

‘Consent’ for residual tissue research, anonymous but coded

Netherlands	Opt out (proposed in self regulation
Denmark	Opt out
Germany	Opt out (proposed in Report of “Ethikrat”)
UK	No consent (HTAact), opt out HTAuthority
France	Consent (specific)
Sweden	Approval from national body, consent but can be waived
Netherlands	Opt out, proposed in self regulation
European Union	No regulation (not competent)

Consent systems/2

US, under 'common rule' (under FDA rules can be different)	No consent (is not considered human subject research at all)
UNESCO, Declaration on Human Genetic Data	Consent, but can be waived and (probably) not if one way coded
CoE, draft protocol to Biomedicine Convention	Consent, not even broad (NB, draft published in 2002 will not become law)
NB, privacy legislation complicates this. In some countries anonymous but coded means anonymous, in others it becomes identifiable.	

Options for Tubafrost

- The starting point:

Tissue which has become available in country 1 should also be used for research in country 2

- New rules, valid for all countries
  - What, cannot be “average” as that would be insufficient for country with stricter regime
  - Would lead to upward trend, in spite of democratic decisions in other countries

Options 2 and 3

- Take one the many international instruments
  - Are guidelines, principles
  - Are sometimes stricter than very recent national legislation
  - Democratic process lacking at the international level
- Forget any attempt to harmonise and set a rule of mutual acceptance

Coordinating Principle

- If tissue and data may legitimately be used for research in the country where is was taken out from the patient and subsequently stored, it may also be used for such research in a country where it is sent to, even if in that other country a stricter (consent) regime would apply.

- Institutions who sends residual tissue and data remains ‘controller’ in the sense of the Data protection directive..

Conditions of the Code of Conduct

- Lays down a bottom line: opt out…
- Only anonymised but coded data (and tissue) can be exchanged
- Strict privacy protection, visitor of search engine or receiving researcher will never be able to retrieve the identity of the patient.

- ‘good research practices’
- Issues of ‘ownership’ and patents

Good research practices

- Use a little tissue as possible with as little data as scientifically sound
- Adhere to the rules of the institution e.g. for ethical review of the project
- Transparency about research projects
- Try alliances with patient organisations
- Research is aimed at scientific publications, shared in the research community
- Ultimate aim improvement of health care

Code of Conduct originates in academic research

- ‘ownership’
  - European approach, tissue as such cannot give rise to financial gain
  - Not who ‘owns’ it but who may do what with it under what circumstances
  - Nuanced system
- Patents
  - Will be through aggregate of data
  - Possible but reinvested in research, this ultimately health care as we know it in Europe

Next…

- Coordinating principle of Code of Conduct not only for Tubafrost
- All similar research projects….

- Will pre-empt any need for ‘harmonisation’
  - If any does not harmonise
  - Is usually detrimental to academic research
  - Leads to ‘accidents’

- Spread the good news of the coordinating principle…