

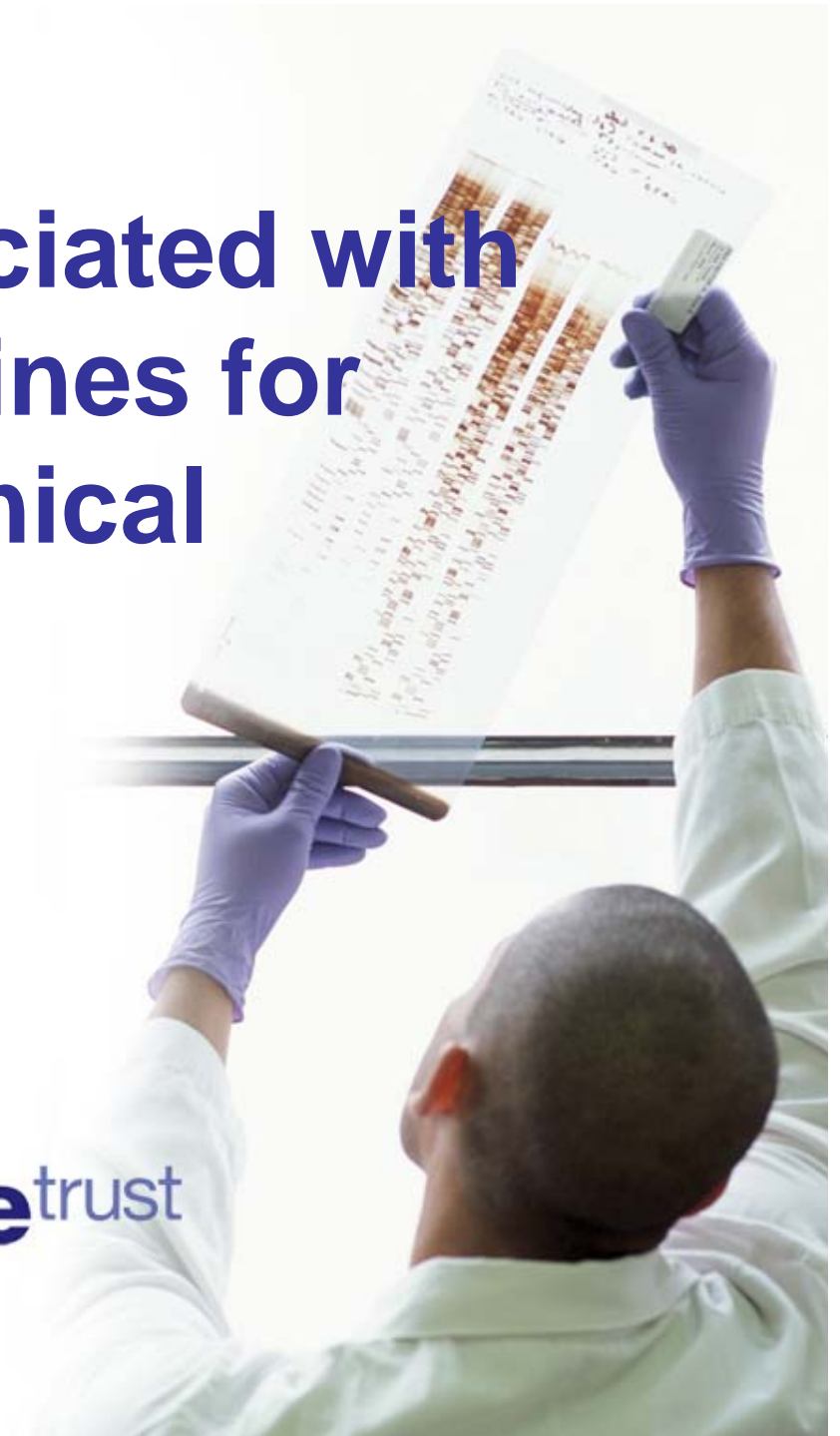
# Legal Issues Associated with Developing Guidelines for Publications in Clinical Proteomics

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# Purpose of this talk

- To outline some of the legal requirements
- To suggest if, and how, these could be incorporated into guidelines



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# Consent

- Data Protection Directive 95/46/EC
  - ‘explicit’ consent for the processing of identifiable, sensitive information
  - differences between members states as to what is ‘identifiable’
  - application to tissue?
- Convention on Human Rights and Biomedicine 1997
  - informed consent for research



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# Consent for Tissue Use

- Article 21 – General rule
  - Research on biological materials should only be undertaken if it is within the scope of the consent given by the person concerned.
- The person concerned may place restrictions on the use of his or her biological materials.
  - Council of Europe Committee of Ministers Recommendation Rec(2006)4



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# Consent for Tissue Use

- Article 22 – Identifiable biological materials
  - Does allow use if cannot contact individual and
    - a. the research addresses an important scientific interest;
    - b. the aims of the research could not reasonably be achieved using biological materials for which consent can be obtained; and
    - c. there is no evidence that the person concerned has expressly opposed such research use.



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# Research Ethics Approval

- Convention on Human Rights and Biomedicine 1997
  - requirement that there should be research ethics approval
  - standard practice
- Variations in approval within, and between jurisdictions
- Clinical Trial Directive



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# Confidentiality

- Obligations on clinicians to protect patient confidentiality
- Can also be used for trade secrets
  - Injunction if publish results of a study without consent



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# Intellectual Property

- Copyright
  - Protects the expression of the idea
- Patents
  - Protection of an invention that is novel, and involves inventive step
- Database Directive
  - Protection of a database but not material within it
- Biotech Directive
  - Preamble individual must have given consent if material is subject to a patent



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# What is required in Law?

- Consent
- Licenses for export and import
- Research Ethics Approval
- Publication does not breach copyright and other IP protections
  - journal could be subject to an injunction



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# Should these be required for publishing?

- Consent
- Licenses for export and import
- Research Ethics Approval
- Publication does not breach copyright and other IP protections



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# Other considerations?

- Acknowledgement of the source of the sample?
  - Donor
  - Biobank
- Funders?
- Order of authorship?



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