



HTA

Human Tissue Authority

Human tissue legislation and the research sector

15 September 2010

**Baroness Diana Warwick,
Chair**

HTA and the legislation

- Human Tissue Act 2004
 - ‘relevant material’ for research
 - separate legislation in Scotland
- ‘Quality and Safety Regulations’
 - ‘Competent Authority’ under the EU Tissue and Cells Directive
 - Tissue used as part of treatment (bone marrow, cord blood, chondrocytes)
 - Tissue that may be used in future treatment (e.g. stem cells)

HTA's regulation of research

- We license establishments...
 -not researchers, projects or clinical trials
 - 144 main sites, 92 satellites
- Under the HT Act: we license tissue storage if the research does not have ethics approval from a recognised REC
- Under the Q&S Regulations: we license establishments using tissues or cells for human application as part of a clinical trial

HTA's risk-based approach

- Strong emphasis on providing advice and guidance
- Risk-based inspections
- Take regulatory action only where needed
- Raise awareness of regulation to improve confidence

HTA's small but significant role

- We believe good regulation supports good science
- Our regulation ensures tissue is of high quality and is taken with consent
- We work with researchers and other organisations to streamline regulation: collaboration is the key

HTA: effective and efficient

- Praised by Hampton Implementation Review team
 - provision of advice and guidance
 - reduced burden of inspection and data collection
- Opinion Leader research
 - most participants said we perform well - legislation and regulation has increased public confidence and improved standards for storage

Supporting R&D and 'UK plc'

- Importance of strategic support for R&D at Board level for
- Equipping R&D Officers to feel confident
- Working together to formulate joint guidance and streamline regulation

HTA and others: working together to support research and potential treatments

- 12 establishments fall under remits of HTA and MHRA
 - HTA regulate donation, procurement and testing before tissue / cells become IMPs or MPs and become remit of MHRA
 - programme of joint inspections started
- joint position statements with MHRA, HFEA and NRES
- MoUs being developed

Working to support research and potential treatments with stem cells

- Contributed to UK Stem Cell Toolkit
- Working collaboratively with UK National Stem Cell Network, GTAC, Stem Cell Communications Coalition....

HTA's challenges: perceptions

- Opinion Leader evaluated perceptions about impact of the HT Act and HTA regulation
- Legislative, regulatory and governance framework viewed as one broad area
- Highlighted importance of organisations working to streamline and reduce unnecessary barriers

HTA's challenges: sector-specific issues

- No typical researcher or organisation
- 'Bottlenecks' and potential barriers
 - reluctance by NHS Trust Boards to support research
 - do the research-active Trusts support generic consent?
 - consent for research and diagnosis not taken at same time – missed opportunity?
- Medical science is fast-moving: responsive to developments
- HTA's remit over bench research does not extend to Scotland

Challenges of the ALB Review

- Recognition of our achievements
- HTA's work will continue as our functions transfer
- We're committed to business as usual : efficient and effective
- Working closely with DH to advise on how proposals could be implemented



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www.hta.gov.uk

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