
# Independent Cancer Patients' Voice Autumn workshop

7 September 2012

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# Human Tissue Authority – about us

- 47 staff
- We license four sectors under the Human Tissue Act (2004) in England Wales and Northern Ireland
  - **Post mortem**
  - **Research**
  - Public Display
  - Anatomy

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# Human Tissue Authority – about us

- We license two other sectors across the UK:
  - Tissue and cells for patient treatment (human application)
  - Organs for transplant

- We also regulate across the UK:
  - all organ donations from living people
  - bone marrow and stem cell donations from children and incapacitated adults

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# Human Tissue Act 2004

- About the Act
  - Consent is central principal of the Act
  - HTA established by the Act to be the guardians of consent
  - Looking to the decision of the individual in life and / or the wishes of their family and friends after death

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# HTA 'right touch' regulation

- Starting point = advice and guidance.
- Keeping the burden low – information requests, licensing standards required, inspections
  - Piloting themed inspections
- Proportionate and sufficient – based on *risk* (compliance and activity-based) and *impact* (immediate and indirect) – clear and objective decision-making processes.

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# Human tissue and its use in research

- Research is essential for continuing improvement in the quality of healthcare in the UK
- The public supports research and donates large sums of money to medical research charities
- The use of human tissue in research is essential for the understanding of disease mechanisms, and the prevention, diagnosis and treatment of disease
- HTA recognises the importance of research and the need to allow this work to continue and flourish in the future

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# Our role in research

The HTA:

- licenses storage of tissue for research, and its removal from the deceased
- licences establishments, not research projects
- does ***not*** license the use of tissue for research, and does not approve clinical trials
- supports generic yet informed consent for future research, particularly for samples surplus to diagnostic requirements.

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# Licensing and consent exemptions for research

You do not need:

- an HTA licence when a research project has ethics committee approval
- consent for research if *all* these three criteria are met (although it is good practice):
  - the tissue comes from living people (e.g. biopsy)
  - the samples are coded (anonymised)
  - project has ethics committee approval

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# Licensing

- Storage of tissue (relevant material) for scheduled purposes, including research
- Often as part of another licence

- Compliance standards
  - Consent
  - Governance & quality
  - Premises, facilities and equipment
  - Disposal

- Includes Research Tissue Banks (RTBs)

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# Licensing exemptions in more detail

- Stored in order to process to become acellular e.g. plasma, serum
- REC-approved specific project
- Incidental to transportation
- Person died over 100 years ago

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# Consent under the HT Act – when is it required?

- Consent under the HT Act relates to ‘scheduled purposes’ for which relevant material might be removed, stored or used. Broadly, consent is required to:
  - store and use dead bodies
  - remove, store and use relevant material from a dead body
  - store and use relevant material from the living

- Anyone removing, storing or using material in circumstances for which the HT Act requires consent must be satisfied that consent is in place.

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# Consent: appropriate and valid

- Given by the right person
  - donor or person in qualifying relationship

- Consent must be valid for the purpose and at the time material is used
  - HTA encourages generic consent
  - taken by trained personnel
  - explain types of research tissue may be used for
  - whether it will be used by a commercial organisation
  - whether it will be used alongside animal tissue
  - how it might be disposed of

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# Consent exemptions

- Existing holdings: material stored before 1 September 2006
  - From the living or the deceased
- Not required for tissue from living, anonymised, ethically approved research
  - By recognised research ethics committee
  - Good practice to obtain consent

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# Post-mortem examination – code of practice 3

- Consent is *not* required for a post mortem authorised by the coroner

- It *is* required for the retention of any material for a scheduled purpose *(including research)* when the coroner's authority ceases

- Consent *is* required for hospital post mortems

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# Code 3 – practical application

- Hospital post mortems
  - Information leaflet and model consent forms available on website - can be adapted for local use
  - Consent to the post mortem and removal and storage of tissue and organs (including blocks and slides) can be recorded on one form, although they are separate decisions
  - **Consent for the use of tissue for research may also be sought at the same time, but we suggest this is recorded as a separate decision**
  - The person obtaining consent must be trained in the Human Tissue Act and our Codes of practice

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# Code 3 – practical application

- Coroners' post mortems (>95 per cent)
  - Do not require consent but important that information is shared with the family
  - When and where the post mortem examination will take place and their right to attend or be represented
  - The storage and use of any tissue removed once the coroner's authority has ceased *must* have consent

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# Publication of post mortem information for the public

- Provides information on what public expectations should be for the retention of PM tissue
    - particularly after hospital / consented and coroners post mortems
- Content was commented on by
    - Public / patient groups and
    - the HTA Histopathology Working Group
- Published on HTA website

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# Publication of ICPV information for the public

- Your views on HTA leaflet
- HTA can help develop and promote yours

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# Supporting research through collaboration

- ‘Right touch’ regulation, increasing efficiency and reducing burden, through collaboration:
  - National Research Ethics Service – part of the Health Research Authority
  - Medicines and Healthcare products Regulatory Agency
  - Human Fertilisation and Embryology Authority
  - Others: MRC, NIHR, UKCRC, Welcome Trust, Cancer Research UK

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# Partnership work with NRES / HRA

- We worked with NRES to ensure that:
  - more than 200 HTA-licensed tissue banks benefit from a streamlined process where Research Ethics Committees give generic approval for tissue collection, storage and release, so researchers do ***not*** need a HTA licence or ethics committee approval.
  - through jointly produced guidance, workshops and sharing information, our advice and guidance is coherent, consistent and valued by researchers.

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# Feedback from stakeholders

## Ipsos MORI evaluation

- Research sector highest level of confidence in the HTA of all licensed sectors (at 90% in 2010)
- Public confidence in human tissue regulation increased from 52 to 57% (2007– 2010)
- Knowledge of regulation means public more confident to donate

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# Feedback from stakeholders

## HTA feedback

- More work to do with public groups
- 98% establishments say HTA inspection has improved way they work
- Post mortem sector confidence is high and has increased since 2010
- Appreciation of HTA's work to support communications between Coroners, pathologists police and families

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# Feedback from stakeholders

- “Whilst being appropriate...the **relationship between the College and the HTA is extremely positive**, and I am delighted to report has improved considerably over the last year. **The HTA continues to reduce the burden of regulation whilst being proportionate and risk-based in its approach.** The HTA’s Histopathology Working Group has made much progress in addressing the concerns of the sector, whilst balancing them with those of the public and the requirements of the Human Tissue Act. The College will be responding shortly to the consultation on the future development of the HTA’s several functions.” ***Dr Archie Prentice, new President of the Royal College of Pathologists (2012)***

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# Feedback – what do you think?

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# Arm's-Length Bodies Review consultation

7 September 2012

Shaun Griffin

# ALB Review consultation

- Runs from 28 June to 28 September 2012
- Presents three options for the HTA's functions:
  - transfer them in their entirety to the Care Quality Commission (Government preference)
  - separate functions and move into several different organisations
  - keep HTA as separate entity and make further efficiencies.
- Any transfer is not likely to take place before 2015.

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# ALB Review consultation

The key priority for the HTA is to ensure that human tissue and organs continue to be used safely and ethically, and with proper consent, during and after any transfer of HTA functions. This will ensure continued public and professional confidence.

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# ALB Review consultation – Option One

- Transfer all HTA and Human Fertilisation and Embryology Authority (HFEA) functions to the Care Quality Commission (CQC), with the exception of HFEA functions relating to research that will transfer to the Health Research Authority (HRA); and abolish the HFEA and HTA.
- This is the Government's preferred option.

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# ALB Review consultation – Option Two

- Proposes separating the HTA's functions.
- The HTA opposes this option as it is likely to result in more complex, bureaucratic and costly regulation, without delivering any benefit to the public.

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# ALB Review consultation – Option Three

- HTA (and HFEA) retain their functions but deliver further efficiencies.
- This is the HTA's preferred option because it will:
  - minimise the risks associated with the use of human tissue
  - protect public confidence.

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# ALB Review consultation – HTA position

- We argue our functions should remain together for benefit of professionals and the public. Government agrees. If transferred we will seek assurances that:
  - our functions can be carried out effectively and efficiently
  - the transfer will provide genuine benefits in terms of cost savings and accountability
  - expertise will be preserved

- Public Authority meeting 10 July.

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# ALB Review consultation – HTA position

- The HTA believes that option three...is, *subject to clarification of the further efficiencies* expected, by far the best option for the regulated sectors and the public as a whole. It is our view that this option would continue the effective and efficient regulation of human tissue and organs by the HTA, minimise the risks associated with the use of human tissue, and protect public confidence.
- The HTA is of the view that the specialist knowledge and experience we have developed further supports option three.

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# Value for money

- The HTA has made efficiencies of 27% in last two years
- The HTA reduced licence fees by 30% in the research sector in 2011/12 and, as a result of improved efficiencies, they reduced by a further 14% in 2012/13 (to £3,600 per establishment). The marginal cost of regulating research among other activities is relatively low.

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# ALB Review consultation – views from stakeholders

- Overwhelmingly in favour of keeping HTA as separate entity and make further efficiencies.

- What do you think?

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# And finally...

- Please respond to consultation

- Feedback and questions?

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