

# Regulating human tissue: reflections on the Human Tissue Act 2004

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“Who Owns Your Body?” Conference on Property Rights in Human  
Bodies, Tissue and Data, and on Human Transplantation  
Centre for Medical Ethics and Law, University of Hong Kong

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# The PHG Foundation

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**MISSION - to make science work for health**

- We provide knowledge, evidence, tools and opportunities for policymakers to deliver rational and responsible changes in health policy and practice
- Member of Cambridge University Health Partners and Cambridge Institute of Public Health
- Active since 1997



# Overview

- Background and context to the Human Tissue Act
- Main provisions
  - Removal, storage and use of human material
  - DNA analysis
- Exceptions
- Points of friction

# Human Tissue Act 2004

Serves multiple policy objectives:

- Update regulatory framework by entrenching **consent** as a fundamental principle underpinning tissue storage and use
- Provide a statutory framework for the **use of DNA** and deterrent to non-consensual or deceitful use of personal genetic information for non medical purposes,
- Supported by civil and criminal **sanctions**
- Restoring **public confidence and trust**

# Triggers for government intervention: "The Alder Hey Scandal"



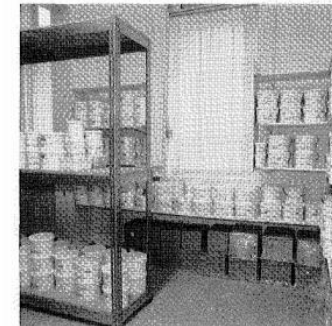
"During the period from September 1988 to 1994 a very substantial store of foetal and infant organs built up at the Alder Hey hospital. Investigations carried out after September 1999 found more than 2,000 pots containing organs from approximately 850 post mortem examinations in store at the hospital."

Andrew Collender QC – GMC Fitness to practice hearing

The basement cellars at Myrtle Street (where containers were stored)



Containers holding organs – now stored in accommodation at Alder Hey



The Royal Liverpool Children's Hospital Inquiry 2001

# Chief Medical Officer's Recommendations

Retention of organs is 'commonplace'

**Table 1: Total organs, body parts or fetuses dating from 1970 onwards held in pathology collections at the time of the census at the end of 1999**

Time originally removed at post-mortem	Number of organs stored at census point
1970 – 1989	15,700
1990 – 1998	20,600
1999	2,900
Medical School Data post-1970	15,200
<b>Total 1970 – 1999</b>	<b>54,300</b>

<http://doh.gov.uk/organcensus/census.pdf>

*Recommendation 6:* As soon as possible, there should be a more fundamental and broader revision of the law, encompassing the taking, storage and use of human tissue from the living and the dead and introducing an independent system of regulatory control. To be comprehensive this should encompass aspects of coroners' practice. It should shift the emphasis from 'retention' to 'donation' to signal a new relationship with the public and bereaved families.

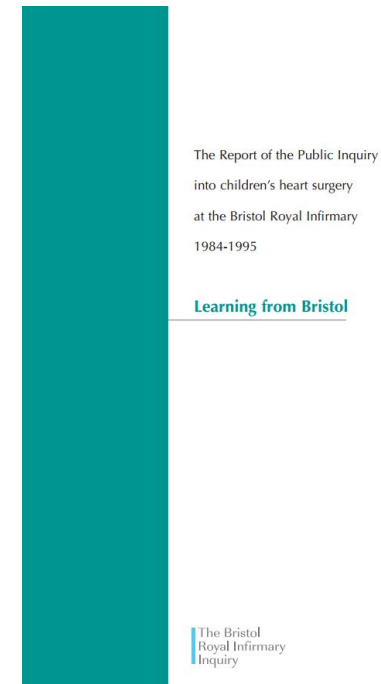


# Recommendations from Bristol Royal Infirmary Inquiry

**Consent to treatment** (In relation to post-mortems and the removal and retention of human material, we restate here those Recommendations from the Inquiry's Interim Report which related to consent:

*'Recommendation 26: Obtaining parents' consent should be seen as a **process**, and not just the signing of a form. As part of that process, parents should be allowed **proper time to reflect** and be informed that they may change their minds until such time as they sign a form indicating their consent.'*

*'Recommendation 27: As part of that process, parents should have access to: **advice and information which is comprehensible, accessible,** and in a form which allows it to be taken home if desired.'*)



The Bristol Royal  
Infirmary Inquiry 2001

# The need to reconcile divergent interests

“Research into cures for children’s cancers is being set back....”

“Donations of tissue to the national tumour bank for children’s cancer fell by 40% after the scandal”



The screenshot shows the top portion of a Guardian news article. The Guardian logo is in the top right corner. Below it is a navigation bar with links for 'home', 'UK', 'society', 'law', 'scotland', 'wales', 'northern ireland', 'education', 'med', and 'all'. The article is categorized under 'Society'. The main headline reads 'Alder Hey scandal has hampered child cancer research, says charity'. Below the headline are social media sharing icons for Facebook, Twitter, Email, and a more options menu. The author is identified as Sarah Boseley, health editor, and the article was published on Tuesday, 17 December 2002 at 08.32 GMT. The article text states that research into cures for children's cancers is being set back by parents' unwillingness to allow small tissue samples from tumours to be stored for future study and doctors' reluctance to ask them, according to a leading cancer charity. It further explains that the impact of the scandal at Alder Hey hospital in Liverpool, where dead children's organs were retained for research without discussion with parents, lingers on, leading to a 40% drop in tissue donations to the national tumour bank for children's cancer, according to Cancer Research UK, which launched a campaign to change attitudes.



# Human Tissue Act 2004, Section 1

Makes 'consent the fundamental principle'

The Act makes lawful certain activities:

- Storage and use of *relevant material* from the living
  - Removal, storage and use of relevant material from the deceased
- for scheduled purposes
  - with appropriate consent
  - Sets up systems of inspection and licensing for certain activities
  - *Relevant material* means material which consists of or includes human cells (excluding DNA, gametes, embryos outside the body, and hair and nail from the living)



## Human Tissue Act 2004

CHAPTER 30

CONTENTS

PART 1

REMOVAL, STORAGE AND USE OF HUMAN ORGANS AND OTHER TISSUE FOR SCHEDULED PURPOSES

1	Authorisation of activities for scheduled purposes
2	"Appropriate consent": children
3	"Appropriate consent": adults
4	Nominated representatives
5	Prohibition of activities without consent etc.
6	Activities involving material from adults who lack capacity to consent
7	Powers to dispense with need for consent
8	Restriction of activities in relation to donated material
9	Existing holdings
10	Existing anatomical specimens
11	Coroners
12	Interpretation of Part 1

# 'Appropriate consent'

- From a competent living adult – consent of that individual (s. 3)
- Living children lacking capacity or deceased children – parental responsibility (s. 2)
- Deceased person – a hierarchy
  - ∅ A decision made by the deceased before death (s. 3(6))
  - ∅ Nominated representative (s.4)
  - ∅ Parental responsibility if deceased was a child (s.2)
  - ∅ A 'qualifying relationship' (s. 27)
- Consent in writing required for public display or anatomical examination
- Interests of others (consent dispensed with)



# Qualifying relationships (qualifying consent) (s.27(4), s.54(9))

The consent of any **one** person from a ranked list suffices:

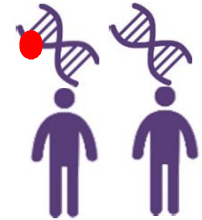
- Spouse or partner
- Parent or child
- Brother or sister
- Grandparent or grandchild
- Niece or nephew
- Stepfather or stepmother
- Half-brother or half-sister
- Friend of long standing



- ∅ Reflects biological and social relatedness
- ∅ Relationships listed together are accorded equal ranking(27(5))
- ∅ Consent of one of those ranked equally in the hierarchy is sufficient (27(7))
- ∅ A person may be omitted if impractical to seek consent from them (27(8))
- ∅ Right of veto irrespective of reasons and timing of refusal
- ∅ Uncle and aunt omitted

# Consent required whether material is from the living or the dead (Schedule 1 Part 1)

- obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person) (4)
- transplantation (7)
- research in connection with disorders or the functioning of the human body (6)
- anatomical examination (1), determining cause of death (2), establishing drug or treatment efficacy post-mortem (3)
- public display (5)



## Consent required when material is from the dead but not from the living (Schedule 1 Part 2)

Consent is not required where material from the living (i.e. from the body of a person who was alive at the point of separation) is used for:

- Clinical **audit** (8)
- **Education** or training relating to human health (9)
- Performance assessment (10)
- **Public health monitoring** (11)
- Quality assurance (12)



# Human Genetics Commission: Inside Information

## Balancing interests in the use of personal genetic data

### Factors distinguishing personal genetic information (1.18)

- Unique identifier
- Small amount (possibly without consent)
- Predictive power
- Susceptibility to rare disease but also potential for treatment
- Used for purposes beyond those for which originally collected
- Interests of others (family members, employers, insurers)

“We recommend that consideration be given to the creation of a criminal offence of the non-consensual or deceitful obtaining and/or analysis of personal genetic information for non-medical purposes” (3.60)



Human Genetics Commission 2002

# DNA analysis offence

A person commits an offence if –

- He has any *bodily material* intending –
- that any **human DNA** in the material be **analysed** without *qualifying consent*, and
- that the results of the analysis be **used** otherwise than for an excepted purpose (s. 45)

*Bodily material* (s.45(5) and Schedule 4):

- a) has come from a human body, and
- b) consists of or includes human cells

[Therefore excludes extracted DNA]

*Qualifying consent* (Schedule 4 Part 1 s.1-3):

Living adult > qualifying relationship (unranked)

Living competent child > parental responsibility > qualifying rel

Dead person > [parental responsibility] > qualifying  
rel(unranked)

# DNA and subcellular material

## Excepted purposes: Schedule 4/Section 45

- **Medical diagnosis or treatment** of the person whose body manufactured the DNA (s.5(1)(a))
- **State sanctioned uses:** (s.5(1))
  - Prevention or detection of crime or the conduct of a prosecution
  - Coroner/procurator fiscal
- **Health service** related uses of material from the living for clinical audit, education or training or public health monitoring (s.8)
- Deemed consent to gain scientific or medical **information** for the benefit of another
- REC approved **research** (anonymised material from the living) (s.6)
- **Existing holdings** (for 'Schedule 1' purposes)





# A Proportionate Approach to Tissue Use

## Some exceptions and exclusions

### NOT REGULATED

- Removal of material from living which continues to be governed by the common law (HTA EN[9])
- Medical diagnosis and treatment of the donor
- Excepted material
  - DNA and sub-cellular material
  - Gametes, hair and nail
  - Material created outside the body (e.g. cell lines, s.54(7))
  - Imported material
  - Material >100 years old

### MODIFIED RULES APPLY

- Research: REC approved research using anonymised material from the living (s.1(8-9))
- Untraced or unresponsive donors (s.7(1) and s.7(2))
- Certain state sanctioned uses:
  - Criminal justice
  - Coroner/procurator fiscal
- Existing holdings

# Application of skill: the intersection with the common law

Follows *Doodeward v. Spence* (1908) 6 CLR 406

*"[W]hen a person has by the lawful exercise of work or skill so dealt with a human body or part of human body in his lawful possession that it has acquired some attributes differentiating it from a mere corpse awaiting burial, he acquires a right to retain possession of it..."*

*Re Organ Retention Group Litigation*

[2004]EWHC644; [2005]QB506

Q: 1) whether the removal of organs at post-mortem was unlawful

2) whether application of work or skill had created property rights

*'part of a body may acquire the character of property' where that part 'has been the subject of skill such as dissection or preservation techniques' [148]*

*'Following the post-mortem, the hospital acquired proprietary and possessory rights to the organs'. [257]*

Gage J

# Statutory extension of the work and skill exception to material from the living

## Prohibition of commercial dealings in human material for transplantation

S. 32(8) controlled material is any material which-

- (a) consists of or includes human cells
- (b) is, or is intended to be removed, from a human body
- (c) is intended to be used for the purpose of transplantation..

S. 32(9) The following kinds of material are excepted-

- (a) gametes
- (b) embryos, and
- (c) material which is the subject of property because of an application of human skill.

## S. 54(7) General interpretation

For the purposes of this Act, material shall not be regarded as from a human body if it is created outside the human body.

# Human Tissue Authority Codes of Practice

Table setting out consent requirements under the HT Act for scheduled purposes.

Scheduled purpose	Consent required for human tissue from the living			Consent required for human tissue from the deceased		
	Removal	Storage	Use	Removal	Storage	Use
Anatomical examination	N/A	N/A	N/A	✓	✓	✓
Determining the cause of death**	N/A	N/A	N/A	✓	✓	✓
Establishing after a person's death the efficacy of any drug or other treatment administered to them	N/A	N/A	N/A	✓	✓	✓
Obtaining scientific or medical information about a living or deceased person which may be relevant to any person (including a future person)	X*	✓	✓	✓	✓	✓
Public display	X*	✓	✓	✓	✓	✓
Research in connection with disorders, or the functioning of the human body	X*	✓	✓	✓	✓	✓
Transplantation	X*	✓	✓	✓	✓	✓
Clinical audit	X*	X	X	✓	✓	✓
Education or training	X*	X	X	✓	✓	✓
Performance assessment	X*	X	X	✓	✓	✓
Public health monitoring	X*	X	X	✓	✓	✓
Quality assurance	X*	X	X	✓	✓	✓

- ✓ Consent is required under the HT Act
- X Consent is not required under the HT Act
- \* Consent is required under the common law on removal of tissue from the living
- \*\* Consent is not needed for investigating cause of death under coroner authority

<https://www.hta.gov.uk/sites/default/files/files/Code%20A.pdf>

# Recent developments in the common law

*Yearworth V North Bristol NHS Trust* [2009] EWCA Civ 37

'..although the subsection would fortify the view that the common law treats parts or products of a living human body as property if they have been subject to an application of human skill (which, presumably, has changed their attributes), *the effect of the subsection could not be to confine the common law's treatment of such parts or products as property if otherwise it would rest on a broader basis.*'

Lord Judge, Chief Justice of England and Wales at p. 38.

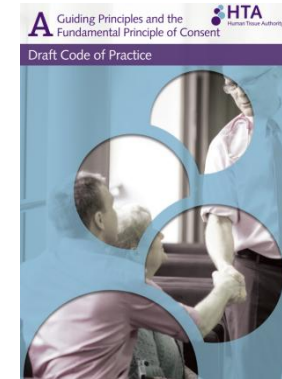
- Ø The importance of the distinction between 'preservation' and 'transformation'?
- Ø Intended 'future use'?



# Ambiguous status of extracted DNA Human Tissue Authority Codes of Practice

*7 codes – into force 3 April 2017* Consent Code:

“7. The Codes do not include information about the analysis of DNA. This is because the HTA has no regulatory or statutory powers in relation to the non-consensual analysis of DNA, for which the provisions are set out in Section 45 of part 3 and Schedule 4 of the HT Act. Separate guidance in the form of frequently asked questions is available on the HTA’s website”.



<https://www.hta.gov.uk/sites/default/files/files/Code%20A.pdf>

## What is the distinction between extracted DNA and tissue for these purposes?

“If human tissue is being held while it is processed with the intention to extract DNA or RNA, or other subcellular components that are not relevant material (i.e. rendering the tissue acellular), it is viewed as analogous to the incidental to transportation exception. A licence is not required, providing the processing takes a matter of hours or days and no longer than a week”.

<https://www.hta.gov.uk/policies/licensing-exemptions> accessed 31.3.17

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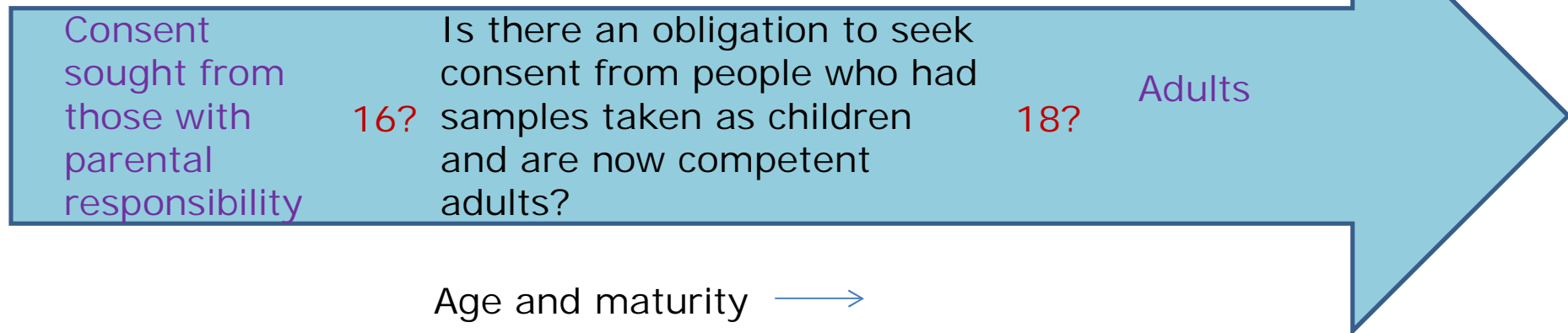
# Managing samples from children once they attain maturity

Children lacking competence to consent

Gillick Competent children



Adults who are competent to consent



Precedents exist e.g. Information Commissioners Office Guidance on the General Data Protection Regulation

“Parental consent will always expire when the child reaches the age at which they can consent for themselves. You need therefore to review and refresh children’s consent at appropriate milestones”

<https://ico.org.uk/media/about-the-ico/consultations/2013551/draft-gdpr-consent-guidance-for-consultation-201703.pdf>

# Implications for practice 10 years on - is wider reform required?

- Is there a regulatory gap around DNA and serum regulation?
  - The Human Tissue Authority has no statutory oversight, but Health Research Authority a governance function for research
- What are the public expectations around use of tissue and data? Do the public distinguish between these?
  - HTA/HRA joint project to explore in depth, public views on:
    - “When tissue becomes data
    - Broad consent for linking patient data with donated tissue
    - Electronic dynamic consent.. [allowing] ongoing dialogue between researchers and donor”
- How will challenges of re-consenting be managed?
- In an era of increased personalisation and automation are distinctions between tissue and data becoming increasingly irrelevant?
- Will new platforms enable or impede effective regulation?



Watson IoT with Blockchain



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