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Human Tissue Authority

**Developing and implementing a
licensing framework to foster
research tissue banking – a risk
based approach to regulation**

Dr Sandy Mather
Director of Regulation

Aims

- HTA's structure and regulatory aim
- The legislative framework
- Licensing and inspection
- The role of the Designated Individual
- Risk based approach to regulation
- Results so far



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Structure and regulatory aim

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- Independent statutory regulator
- Human Tissue Authority – members
 - Lay chair
 - Professional representatives
- Human Tissue Authority – staff
 - 42
 - Four directorates – regulation, policy, communications and resources

The HTA's regulatory aim

To create an effective regulatory framework for the removal, retention, use and disposal of human tissue and organs in which the public and professionals have confidence.

A wider regulatory remit than storage for research

- Human application
- **Research**
- Post mortem services
- Anatomy
- Public display
- Organ transplantation

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

Working with researchers

- Brunswick sub-group – Research issues in Higher Education – Mar 2006
- British Association of Tissue Bankers Annual Conference – Apr 2006
- NHS R&D annual conference – May 2006
- Belfast research workshop – Jun 2006
- Medical Research Council workshop – Jul 2006
- NCRI Cancer Conference – Oct 2006
- British Association of Tissue Bankers Symposium – Nov 2006
- Bio industry European Conference – Dec 2006
- IDRN London – March 2007



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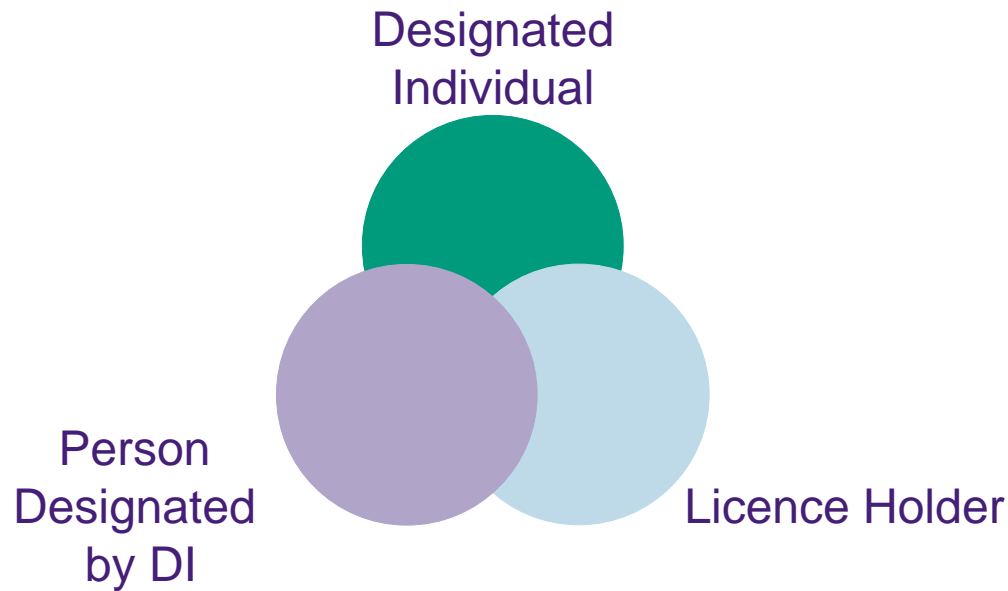
Legislative framework

Current legislative framework

- Human Tissue Act 2004
- Human Tissue (Scotland) Act 2006
- Commencement Orders
- 2006 Regulations (include exemptions to licensing)
- Draft Human Tissue (Quality and Safety for Human Application) Regulations 2007
 - Directive 2004/23/EC (EUTCD)
 - Directive 2006/17/EC (TD1)
 - Directive 2006/86/EC (TD2)

Licensing

HTA framework - based on governance of institution



Other people working on licensed premises and carrying out licensed activities do so **under the direction of**

the Designated Individual or a Person Designated by the DI

The role of the Designated Individual (DI)

- Designated Individual
 - Person under whose supervision the licensed activity is authorised to be carried on
 - Must consent to an application or make it himself
 - Statutory duties under Section 18 of the HT Act
- Statutory duties
 - that the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity
 - that suitable practices are used in the course of carrying on that activity and
 - that the conditions of the licence are complied with

Key duty of the DI to secure compliance with licence conditions (s18)

- Standard conditions
 - Sector specific and some generic
 - All licences in each sector (ie PM, anatomy, etc) have the same standard conditions
 - DI undertakes annual training (generic to all sectors)
 - DI ensures compliance with Directive 2004/23/EC (specific)
- Additional conditions
 - Specific to a licensed establishment
 - Imposed on the grant of a licence
 - Help to achieve compliance with HTA licensing requirements
 - Can also be used to restrict the manner in which a licensable activity can be performed

Licensing

- One activity per licence
- A licence must specify the premises where the activity is to be carried out
- A licence cannot authorise licensed activity on premises at different places
- One person (Designated Individual) supervises the activities under a licence

Section 16 – Licensable activities

16 (2) (a) the carrying out of an anatomical examination

(b) the making of a post mortem examination

(c) The removal from the body of a deceased person [otherwise than in the course of an activity mentioned in paragraph (a) or (b)] of relevant material of which the body consists or which it contains, for use for a ***scheduled purpose*** other than transplantation

Section 16 – Licensable activities

16 (2) (d) The storage of an anatomical specimen

(e) the storage [in any case not falling within paragraph (d)] of (i) the body of a deceased person, or (ii) relevant material which has come from a human body, for use for a ***scheduled purpose***

(f) the use, for the purpose of public display, of (i) the body of a deceased person, or (ii) relevant material which has come from the body of a deceased person

Research –

1 licence, 8 scheduled purposes

16 (2) (e) (ii) the storage of relevant material which has come from a human body for use for a scheduled purpose

Research

Scheduled purposes – part 1 general

- Establishing after a persons death the efficacy of any drug or other treatment administered to him
- Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person)
- Public display
- Research in connection with disorders, or the functioning, of the human body

Scheduled purposes – part 2 – deceased persons

- Clinical audit
- Education or training relating to human health
- Public health monitoring
- Quality assurance

Relevant material – Definition in the Act

- Material other than gametes which consists of or includes human cells
- Does not include
 - Embryos outside the human body or
 - Hair and nail from the body of a living person

Categories of tissues and cells and whether they are “relevant material”

- Specifically identified
 - Yes - stem cells, bone marrow, primary cell cultures
 - No - cell lines, extracted DNA or RNA
- Processed material
 - Yes – Plastinated tissue
 - No - if the process renders the material acellular eg plasma and serum
- Bodily waste products
 - Yes – even a single cell if it is stored for research

Licensing exemptions

- HT Act (2004) licensing exemptions
- HT Act 2004 (ethical approval, exceptions from licensing and supply of information about transplants) regulations 2006
- Material stored from the deceased
 - If the material or body is more than 100 years old at the time of commencement of the Act (Sept 2006)
 - If material is transferred to a tertiary centre for specialised analysis other than research
- Material stored from the living or deceased
 - Incidental to transportation (hours or days only)
 - Organ or part organ for transplantation
 - Material for transplant that is stored for less than 48 hours

Research

- Licensing exemptions for the **storage** of material from the **living** and **deceased** for the primary purpose of research are the same
- Tissue stored for the primary purpose of research
 - Distribution to other researchers (tissue bank) – licence
 - A specific research project with ethical approval – no licence
 - A possible project in the future – licence

Research

- Licensing requirements for the **removal** of material from the **living** and **deceased** for the primary purpose of research are different
- The HT Act requires a licence for the **removal** of material from the **deceased** for the primary purpose of research

Consent exemptions

- HT Act 2004 Section 1(7) and (9) and 2006 Exemption regulations
- Consent is not needed for research in connection with disorders or the functioning of the human body if
 - the material has come from the body of a living person and
 - the research is ethically approved by a REC recognised by UKECA and
 - it is to be or is carried out in circumstances such that the person carrying it out is not in possession and not likely to come into possession of information from which the person from whose body the material has come can be identified

Consent exemptions

- Existing holdings
 - A body of a deceased or relevant material from living or deceased held before the day the Act commenced (1 Sept 2006)
 - Pathological and former anatomical specimens can continue to be stored and used for E&T without consent under HT Act (but a licence is needed)
- This exemption does not apply to storage or use of dead bodies for anatomical examination
- Bodies or body parts donated under the Anatomy Act 1984
 - Deemed to be consent under the HT Act for the storage and use where an authority exists under the Anatomy Act 1984

Scheduled Purposes *exemptions to licensing if stored material is from the living

**exemptions if stored material is from the living or deceased and project is REC approved

- Part 1 - Scheduled purposes
 - Anatomical examination
 - *Determining the cause of death
 - *Establishing after a person's death the efficacy of any drug or treatment administered to him
 - *Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person)
 - *Public Display
 - **Research in connection with disorders, or the functioning, of the human body
 - Transplantation
- Part 2 - Scheduled purposes
 - *Clinical audit
 - *Education or training related to human health
 - *Performance assessment
 - *Public health monitoring
 - *Quality assurance

Risk based approach



Working with researchers

- HTA research working group to develop licensing standards
 - Membership - COREC, representatives from tissue banking community, research funders, professional organisations, other regulators etc
 - Two meetings – Jan and Feb 2006
- Other meetings
 - Cancer Research, Medical Research Council, Wellcome, Bio Industry Association, NPSA (COREC) etc
- Advice and guidance
 - Telephone, email, face to face
- DI training workshops
 - 7 multi disciplinary training events in 2006/07
 - Research only - 22 May 2007 in Birmingham
 - Research only - 10 July 2007 in London
 - di@hta.gov.uk

Licensing guidance

- [Expected standards \(Directions\)](#)
- [Guidance for completing licence applications](#)
- [Licensing and consent exemptions](#)
- [Definition of relevant material](#)
- [Non-consensual DNA analysis](#)

Codes of Practice

Model consent forms

Public display guidance

EU Tissues and Cells Directive

Regulatory alerts

[Home](#) > [Guidance](#) > [Licensing guidance](#)

Licensing guidance

This section provides links to the HTA expected standards (Directions) and to guidance for completing the compliance report licence applications.

Please click on the links below to find the guidance you are looking for:

- [Expected standards \(Directions\)](#)
- [Guidance for completing compliance report licence applications](#)
- [Licensing and consent exemptions from the Human Tissue Act](#)
- [Definition of relevant material under the Human Tissue Act](#)
- [Non-consensual DNA analysis](#)

See also

- [Apply online](#)
- [FAQs](#)
- [Codes of Practice](#)

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Schedule site visits based on risk

Schedule site visits based on risk

- Phase 1 inspection - desk based
 - All establishments
 - Evaluation of self assessed compliance report
 - Licence issued with licence specific conditions
- Phase 2 inspection - site visit
 - Risk based schedule
 - High risk and sample of low risk
- Assessing high risk
 - Additional conditions
 - Complexity of service
 - Legislative requirements
 - New and emerging information



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And the results so far.....

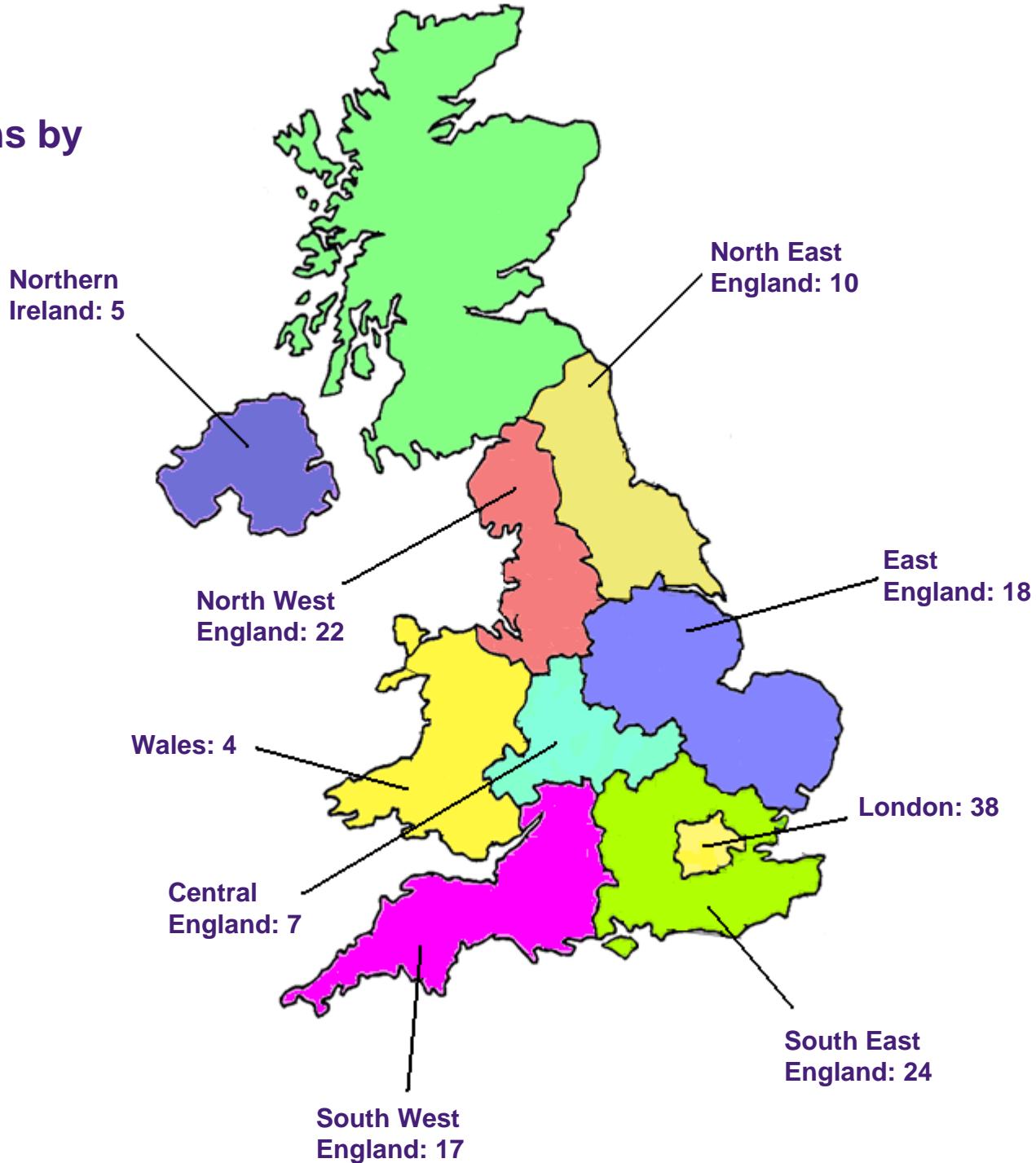
Regulatory activity – licensed establishments and satellites per sector

- Human Application 230 (230 licences)
 - Research 220 (220 licences)
 - Post Mortem 280 (potentially 840 licences)
 - Anatomy 40 (potentially 160 licences)
 - Public Display 10 (potentially 20 licences)
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- NB figures are rounded to the nearest whole number

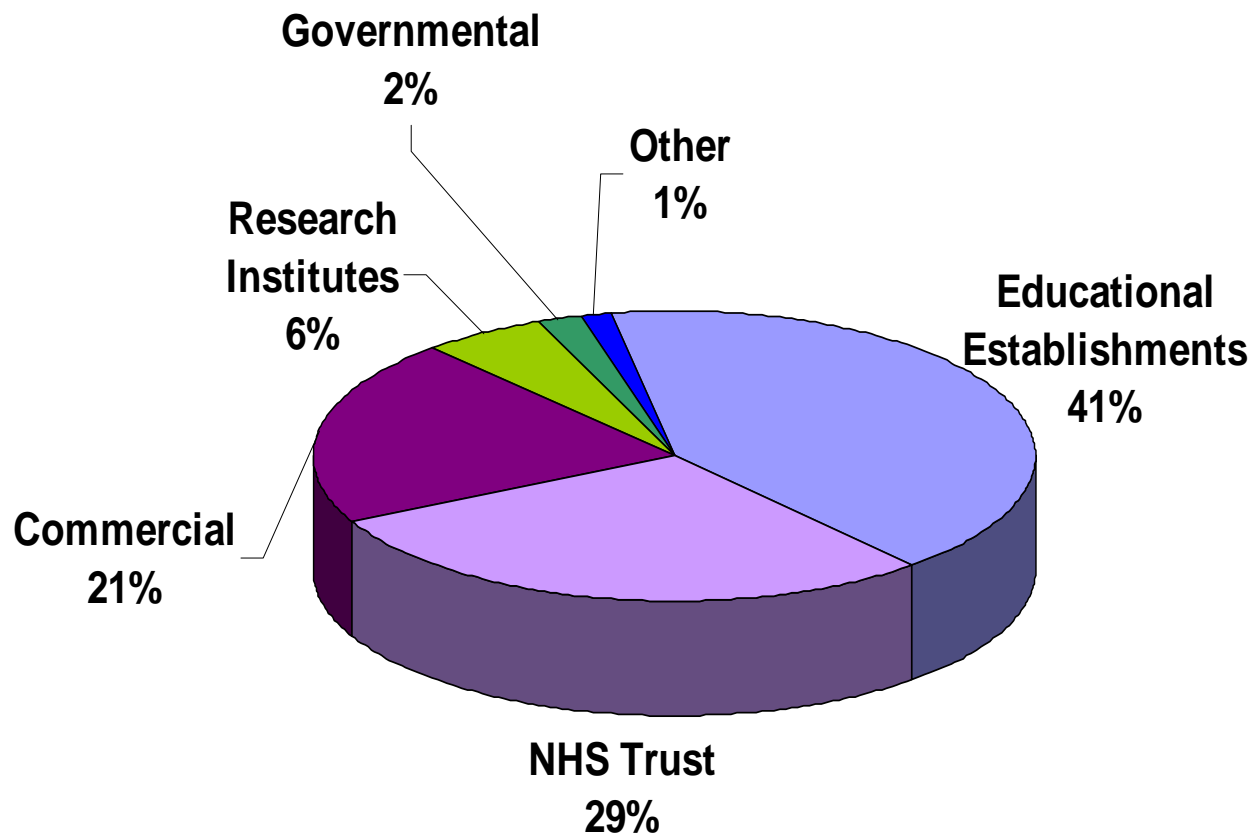
April 2006 – February 2007

- DI training workshops 600 people
- Phase one inspections 262 establishments
- Phase two inspections 9 establishments
- Regulatory Alert 1 issued
- Special Directions 1 issued

Number of applications by region



Applications by type of research establishment

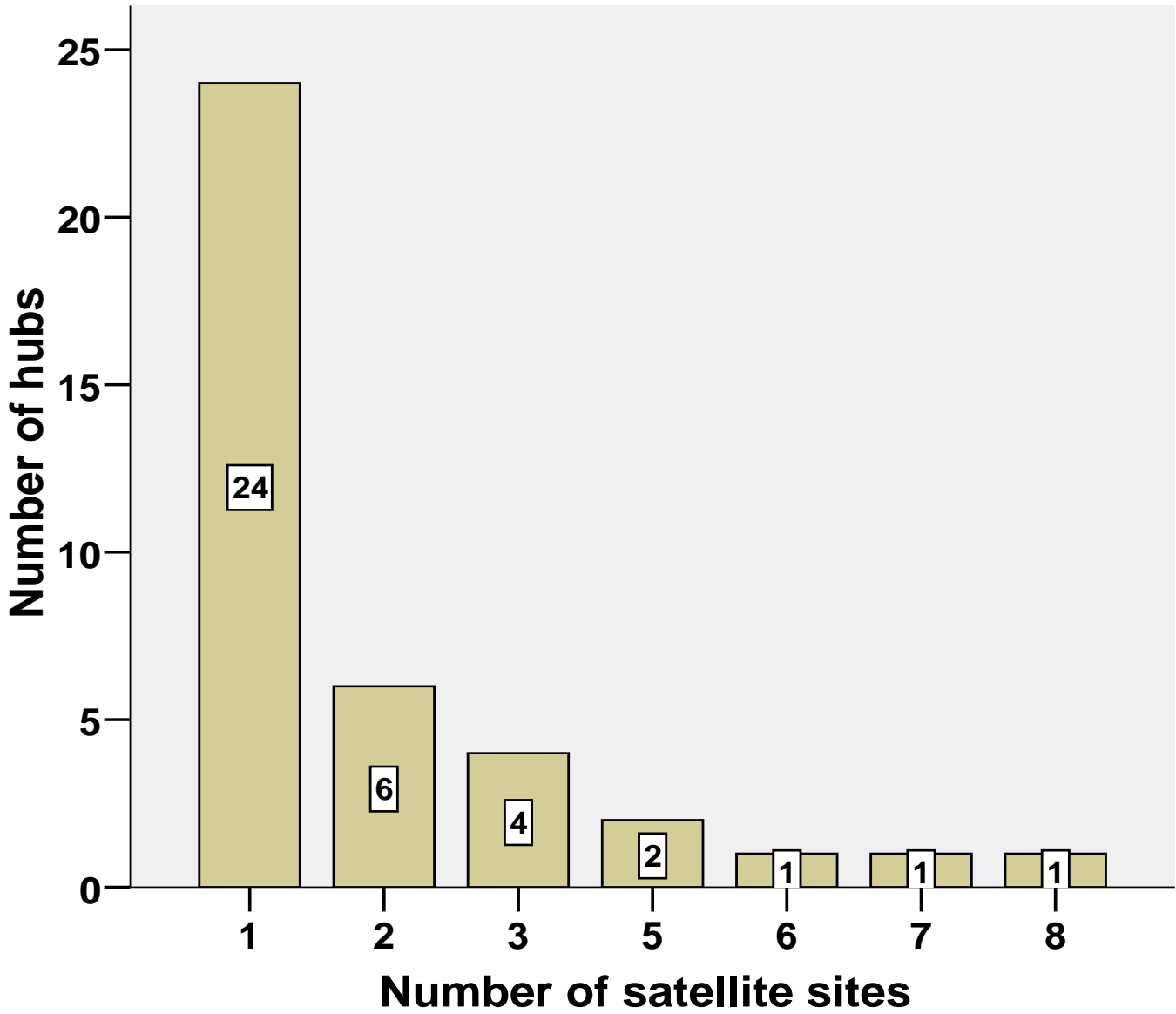


Licence applications from the research sector (n=145)

- Single establishments 106
- Hubs 39 (79 satellites)
- Total applications 145
- Total licensed premises 224
- Corporate Licence Holders 139

- Late applications 16

Distribution of number of satellites per hub



Research licence conditions so far

- Phase one inspection
 - 14 compliance reports
 - Half have additional conditions on their licence
- Additional conditions
 - Most relate to lack of compliance with standards for Governance and Quality Systems and some to the Consent standards

Research licence conditions so far

- Link to standards for Governance and Quality Systems
- Lack of audit systems for stored material
 - Lack of quality management system
 - Lack of documented processes for distributing human material to other establishments
 - Lack of coding and records system for traceability of tissue and cells

Research licence conditions so far

- Link to standards for Consent
 - Lack of service level agreements with 3rd parties who procure on the establishment's behalf
 - Lack of staff training in consent processes

Summary

- HTA's approach to regulation
- Flexibility, advice and guidance
- Risk based approach to regulation
- Working with professionals
- Role of the Designated Individual
- Licensing storage of material for research in England, Wales and Northern Ireland

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