



# **Impact of legislation and Human Tissue Authority regulation on research**

September 2009

## **Introduction from the HTA**

At the end of 2008, the Human Tissue Authority (HTA) commissioned Opinion Leader to conduct an evaluation of perceptions on how human tissue legislation and its required regulation by the HTA has affected researchers working with human tissue. This introduction summarises the results from the evaluation and our plans for taking the findings forward. Opinion Leader's full report follows this introduction.

### **Why we carried out the evaluation**

The HTA licenses organisations that store human tissue for research under the Human Tissue Act 2004 (HT Act). The HT Act has inevitably had an impact on the way that research using human tissue is carried out. This project aimed to review perceptions about what this impact has been and to check that tissue-based research has not been inappropriately held up.

Before undertaking the project we had heard anecdotal positive and negative feedback from people in the research sector about how human tissue legislation and HTA regulation was affecting their work. Concerns about the potential impact of the legislation were also raised during the passage of the Human Tissue Bill. We hoped that the project would clarify this issue by providing us with robust evidence about the impact of the legislation and HTA regulation on research.

We worked with an external consultancy on this project to ensure that the results were independent. We selected Opinion Leader because they had an understanding of our regulation of the research sector having worked with us on our codes of practice consultation. Opinion Leader had also undertaken other evaluation projects in this area.

We held a development meeting with representatives from the research community at the beginning of the project, so that we could receive early input from the sector into how the evaluation was designed. Opinion Leader also carried out a literature review of work that had already taken place in this area, so as not to duplicate effort.

Although the HTA only licenses a small proportion of the research that is carried out using human tissue, we wanted to involve as many people from the research sector as possible so that we could assess whether there was any difference in views across the sector, and between establishments that were licensed and those that were not. We also aimed to identify any differences in

views between researchers working in the research, post mortem and human application sectors.

### **What the results tell us**

Opinion Leader carried out the evaluation between January and April 2009. 295 people took part via telephone and online interviews. The results are provided in Opinion Leader's report.

The main findings were:

#### ***Awareness of the HTA's role***

There was high awareness of the broad roles of the HTA, for example issuing licences and producing codes of practice. Most participants reported that the HTA performs well on delivering against these roles.

#### ***Views of the HTA's performance***

When asked to consider the various organisations governing research in isolation, perceptions of the HTA's performance were relatively positive and were better than those of other organisations in the research sector.

#### ***Views of the impact of legislation and HTA regulation***

Participants found it difficult to distinguish between human tissue legislation and HTA regulation, and between the range of research activities beyond the HTA's remit, including ethics committee approval, funding and NHS Research and Development approval. For this reason, views of the impact of human tissue legislation and HTA regulation are closely correlated with general views about governance in the research sector. The results of the evaluation therefore provide less information about the direct impact of human tissue legislation and HTA regulation than we had hoped, and need to be read in this context. Nevertheless, the results provide valuable insight into the views of the research community on the wider legislative, regulatory and governance framework in which they work.

#### ***Differences in views across the research sector***

There were key differences in views across the research sector. Designated Individuals and others who were more aware of the HTA's role and remit were less likely to say human tissue legislation and HTA regulation has had a negative impact. Those who were more positive about wider legislation and regulation were also more positive about human tissue legislation and HTA

regulation. People working in the NHS and pathologists were more likely to say human tissue legislation and HTA regulation has had a negative impact, and were less likely to be positive throughout the survey.

## **How we are working with the research sector to improve regulation**

The results from the evaluation demonstrate the importance of working with the research sector and other governance bodies to improve regulation. The work that we are already doing to take forward the issues raised by the evaluation is set out below.

### ***Working with other organisations in the research sector***

- We work closely with other organisations and regulators to streamline systems and processes. Examples of this include a [Memorandum of Understanding with the National Research Ethics Service \(NRES\)](#), the development of a [stem cell regulatory route map](#) with other UK regulators, and the publication of [joint policy statements on Advanced Therapy Medicinal Products and embryonic stem cells](#).
- We have published a [joint position statement with NRES to clarify the licensing requirements for diagnostic archives](#).

### ***Providing clear advice and guidance***

- We have developed a [new code of practice on research](#) which came into force in September 2009. The research sector contributed to the development of the code via a consultation and workshops.
- We launched our [new website](#) in June 2009 with a more user-friendly structure and an improved search facility. Feedback from the research sector was incorporated into development of the new site via responses to an online survey and user testing.
- We will publish our 2009 [summary compliance reports](#) in October 2009, to share lessons learned and help improve standards.
- We provide advice and guidance to the research sector on an ongoing basis when responding to enquiries and on inspections. The cost of this advice and guidance is included in the licence fee.

### ***Providing value for money***

- We have listened to the views of the licensed sectors in relation to licence fees. We held workshops in June 2009 to discuss how we might set fee levels in the future. As a result, we have decided to consider how we might develop a fee structure based – at least partially – on charging

for the specific activity or service provided from 2011/12. We will run a full consultation on this at the appropriate time.

### ***Ensuring researchers have access to high quality samples***

- We support consolidation of tissue stocks to give researchers wider access to high quality samples. Our advice and guidance provides researchers with clear information about how best to consolidate stocks and we encourage researchers to get in touch with us if they have any questions. Valuable tissue should not be disposed of provided that it is being held in accordance with HTA standards. In 2009 we will target professional publications with further advice and guidance on this area.

### ***Reducing the burden on the research sector***

- We have moved from fixed-term licences to a continuous open-ended licensing system following feedback from the licensed sectors.
- We take a risk-based approach to licensing and inspections. We have found the research sector has good compliance with our standards and we focus on acting in a proportionate way to ensure that research establishments continue to meet our standards.
- We always try to bring licensed establishments that are not up to standard back into compliance through advice and guidance before we resort to regulatory action.
- Every storage licence we issue across all sectors allows tissue to be used for research. In addition, tissue banks can receive Research Ethics Committee approval and be licensed by the HTA so that researchers do not need to reapply for individual projects.

### ***Following Better Regulation principles***

- The Better Regulation Executive published its report of the Hampton Implementation Review of the HTA in July 2009. The review, carried out in November 2008, praised the HTA for using the principles of Better Regulation to ensure we are risk-based, proportionate and transparent. The review team rated the HTA highly on provision of advice and guidance and minimisation of inspections and data collection burdens.
- The review also found that the HTA:
  - has done a lot to keep the costs of regulation to a minimum
  - inspectors are helpful and pragmatic
  - staff are described as supportive, friendly and approachable

## Conclusion

This project aimed to evaluate perceptions of the impact of human tissue legislation and HTA regulation on research.

The results have shown that people working in the research sector view the wider legislative, regulatory and governance framework as one broad area, and find it difficult to provide specific views about how human tissue legislation and HTA regulation has affected them. For this reason, the results of the survey are less informative about the direct impact of our work than we had hoped.

However, the results demonstrate the importance of organisations governing the research sector working closely together to streamline activities and reduce the burden on the sector. The HTA will continue to work within its statutory remit to help achieve this goal.

OnCore published a report in September 2009 titled 'The effect of regulation and governance on research led by pathologists or involving pathology in the UK'. The report recommended that guidance for the research sector should be "consolidated into an accessible, authoritative and consistent multi-regulator endorsed resource". The HTA fully supports this recommendation.

The results from our report support the steps that the HTA is already taking with the sector to continually improve our regulation. We hope that these steps will help us to achieve our strategic aim to create a regulatory system for the removal, use and disposal of human tissue and organs that is clear, consistent and proportionate and in which professionals, patients, families and members of the public have confidence.

A handwritten signature in black ink, appearing to read 'S. Griffin', with a long horizontal line extending to the right.

Dr Shaun Griffin  
Director of Communications, HTA



## Human Tissue Authority

Impact of legislation and Human Tissue Authority regulation on research



### **Freedom of Information Act 2000**

This document contains commercially sensitive and confidential information. The contents of this document should not be copied, reproduced or disclosed to any third party without prior written permission from a Director at Opinion Leader Research.

# Content

- 1. Executive summary ..... 3
- 2. Introduction ..... 6
- 3. Objectives ..... 7
- 4. Approach..... 8
- 5. Awareness and performance of the HTA ..... 15
- 6. Views of the HTA in the wider research context ..... 20
- 7. General views of legislation, regulation and governance in the research sector ..... 22
- 8. HTA licensing ..... 26
- 9. HTA regulation and clarity of requirements against the wider legislation, governance and regulation framework..... 29
- 10. Views of human tissue legislation..... 31
- 11. Overall impact of human tissue legislation and HTA regulation on research..... 34
- 12. Perceived and actual impacts on research..... 38

# 1. Executive summary

## Background, objectives and approach

The Human Tissue Authority (HTA) is a regulatory body that licenses establishments that store and use tissue for purposes such as research, post mortem examination and patient treatment.

The HTA commissioned Opinion Leader to conduct an evaluation of the extent to which the introduction of the Human Tissue Act and its required regulation by the HTA has affected researchers working with human tissue. The purpose was to inform performance against one of its key strategic aims: not to hold up tissue-based research. A survey on the impact of human tissue legislation on the research community was a business objective in the 2008/9 financial year. Opinion Leader conducted the evaluation between January and April 2009. The project overlapped with an HTA consultation on licence fees.

Opinion Leader undertook a four-stage research programme which consisted of:

- A five day literature review of various reports and articles from across the research sector and the media
- A development meeting with stakeholders from across the research sector to identify hypotheses and inform the subsequent research design
- A quantitative questionnaire, conducted by telephone and online, with 295 members of the research community
- A series of ten in-depth interviews with a range of people from the research community to provide added detail to the evidence elicited.

The research was designed to understand how legislation and the required regulation by the HTA may have affected different groups within the research sector with varying relationships with the HTA – including Licence Holders, Designated Individuals (DIs) and bench/clinical researchers (these roles are explained in more detail in section 4). Where possible it looked to identify differences between those licensed by HTA and those not licensed; and between sectors with different links to research.

## Main Findings

There is high awareness of the broad roles of the HTA, such as *issuing licences for storing human tissue for scheduled purposes including research*<sup>1</sup> (97% aware) and *producing codes of practice* (93%

---

<sup>1</sup> Within this executive summary wording in *italics* denote actual wording used in the quantitative questionnaire

aware). Most participants report that the HTA performs well on delivering against these roles (giving an average score of 3.9 out of 5.0 for providing licences / 3.8 out of 5.0 for producing codes).

When asked to consider the various bodies in the research sector in isolation, perceptions of the HTA's performance, as a regulatory body, are relatively positive. Participants rated their *overall impression of applying for an HTA licence* as 3.1 out of 5.0 compared to 2.7 out of 5.0 for *applying for NHS R&D approval or applying for funding*. Those applying for a HTA licence rated the performance of the HTA positively on *being responsive* (3.6 out of 5.0), *being efficient* (3.5 out of 5.0) and *providing information* (3.7 out of 5.0). These scores are better those of other organisations in the research sector.

Despite this high level of awareness of key parts of the HTA's role and remit, half of the participants do not make a distinction between human tissue legislation and the HTA. They also find it difficult to isolate human tissue legislation and HTA regulation against the backdrop of a broad range of activities beyond the remit of the HTA, including ethics committee approval, funding and NHS Research and Development approval. **For this reason, views of the impact of human tissue legislation and HTA regulation are closely correlated with general views about the wider legislation, regulation and governance in the research sector. Findings from this survey should therefore be read in this context.**

As a group, respondents report that wider legislation, regulation and governance is necessary to *ensure that human tissue is used appropriately* (75% agree); and to *ensure that human tissue is used with informed consent* (75% agree). A fifth agreed that legislation, regulation and governance *did not hold up research unnecessarily* (20%). Less than a fifth agreed that *requirements are easy to comply with* and that wider legislation, regulation and governance *is streamlined* (17% and 16% respectively). One in ten agreed that requirements are uncomplicated and easy to understand (9%).

When asked to comment specifically on human tissue legislation and its required implementation by the HTA regulation, the majority of participants report that *human tissue legislation and subsequent regulation by the HTA had a negative impact on the research sector* (59% said together they had slightly or very negative impact).

**There are some key differences of opinion across sub groups.** Most notably, DIs and others who are more aware of the HTA's role and remit, and those who are broadly in favour of regulation, are less likely to say human tissue legislation and subsequent regulation by the HTA has had a negative impact. Those who are more positive about wider legislation and regulation are also more positive about human tissue legislation and regulation by the HTA. However, those in the NHS and pathologists<sup>2</sup> are more

---

<sup>2</sup> Overlapping criteria - pathologists also typically work in the NHS, although not all of those responding from the NHS are pathologists

likely to say human tissue legislation and subsequent regulation by the HTA has had a negative impact. These groups were more likely to be negative throughout the survey.

We used two methods to obtain participants' views on the impact of human tissue legislation and subsequent HTA regulation on research: an open question format – to capture top of mind views; followed by a prompted question – to test hypotheses emerging in a previous literature review and development meeting with stakeholders (described in more detail in section 4). When asked an open question on why they say human tissue legislation and subsequent regulation had a negative impact, a quarter mentioned bureaucracy / paperwork (26%), a fifth that it has made it more difficult to do research (21%) and 15% that it is time consuming. When asked an open question on why they say it has had a positive impact participants report that human tissue legislation and subsequent HTA regulation has raised standards (16%) and helped to clarify processes and systems already in place (9%).

Within the prompted question we asked participants the extent to which they agreed or disagreed with a number of statements about the potential impacts of human tissue legislation and regulation by the HTA. Half of the participants agree that it has *led to researchers changing their research plans* (50%). The majority also agree that it has made it *more difficult to get hold of samples* (68%); and that *potentially valuable samples have been disposed of* (61%).

Participants also say that human tissue legislation and regulation by the HTA has *raised standards of research processes and storage* (65%), *ensured that informed consent is given by donors* (70%), and led to *clearer guidance on what can and cannot be done legally* (57%).

## 2. Introduction

The Human Tissue Authority (HTA) licenses a significant number of research establishments (236 between September 2006 and 31 March 2008), regulating these through a combination of desk based and site visit inspections. The evidence from these inspections<sup>3</sup> is that the research sector as a whole demonstrates good compliance with HTA standards, with adequate consent provisions and some exemplary storage systems.

Previous engagement with those working with human tissue for research purposes, through formal consultation and workshops on the draft Codes of Practice, showed that many appreciated the HTA's positive approach and clear desire to operate as a 'modern, light touch, regulator'. There was anecdotal evidence however of concern about the impact of legislation on the research sector, both in general and on particular aspects, such as stem cell research. Some thought the effect of the required regulation by the HTA combined with other legislation placed disproportionate burdens on the sector. Others told of researchers consequently seeking 'loopholes' and/or being deterred from undertaking potentially important activities.

The HTA commissioned Opinion Leader to conduct independent research to provide feedback on the impact of human tissue legislation and regulation on the research sector. This will inform its performance against one of its key strategic aims - to not hold up tissue-based research – and one of its business objectives – to complete a survey on the impact of human tissue legislation on the research community.

In parallel to this project the HTA held a consultation on its new licence fee structure, which ran from 8 December 2008 to 5 March 2009.

---

<sup>3</sup> HTA *Summary of Inspections 2006-08: Research Opinion Leader*

### 3. Objectives

There were a number of research objectives for the project. These are highlighted below.

NB objectives **emboldened** were seen as the priority objectives. The work is intended to provide quantitative evidence on which to build future strategy and communications.

#### Understanding the research sector

- To map the research community and stakeholders
  - where possible to segment and prioritise them
- To understand needs and expectations of the research sector with regards to regulation
- To explore communication preferences and existing links to, from, between and within the research community

#### Exploring research community understanding of the role and remit of the HTA and legislation

- To identify the levels of awareness and understanding of the HTA and legislation – exposing any information or comprehension gaps
- To explore views of the research sector on the link between HTA licensing and other governance arrangements e.g. NHS R&D, research ethics committee approval, research funding bodies.

#### Identifying the impact of legislation on research

- To assess the extent to which the introduction of human tissue legislation and the required regulation by the HTA has affected researchers working with human tissue
  - **How easy / difficult is it to meet HTA standards**
  - **How is consent working in practice**
  - **How the HTA has benefited or hindered research**
- To map the transition from non-regulated activities to regulated activities
- To identify best practice examples
- To identify potential routes for improving regulation – particularly in the field of stem cell research
- Across all objectives understand how regulation may have affected different groups:
  - Research funders, Designated Individuals (DIs), Licence Holders, heads of department, bench scientists, public and private sector or research activities (e.g. clinical, import / export, post-mortem and living tissue, stem cells, tissue banks, small research establishments, different tissue types)
  - Where possible to contrast the views of those licensed versus those who are not licensed

# 4. Approach

## Summary

The project encompassed four iterative stages as outlined in the diagram below:



## Literature Review

The first stage of the project was to uncover what has already been said about human tissue legislation and regulation by the HTA. This was intended to provide a basis for discussion in the development meeting and to inform the quantitative sample and questionnaire.

The rapid review drew from sixteen sources including primary research and journalistic comment. The full report and bibliography can be found in the appendix.

In summary the literature report highlighted that:

- There is confusion within the research community regarding the specific role and function of each of the bodies in charge of regulation and governance

- There is perceived to be a lack of consistency between bodies in terms of what they consider to be mandatory, what best practice is, as well as how they define key terms (e.g. research)
- There is a mixed reaction to human tissue legislation and the required HTA regulation, with some positive impacts, e.g. driving up standards, and some negative impacts, e.g. expensive and time consuming.
- There seems to be some confusion over where researchers go for advice on interpreting human tissue legislation and the required HTA regulation, particularly for specific disciplines (such as stem cell research) or for complex issues spanning multiple regulators.

However, the rapid review did not uncover a large number of academic, robust sources relating specifically to the area of legislation and HTA regulation in research using human tissue. The majority of comments written about this field is journalistic work that appears to have been taken a specific stance. This supports the HTA's desire to undertake primary research to verify some of the anecdotal evidence that has emerged.

## Development workshop

A development workshop convened in January 2009 aimed to inform key stakeholders of the evaluation and gain their input into the process. The following organisations were represented:

National Research Ethics Service (NRES)	Wellcome Trust
NHS Research and Development (NHS R&D)	Department of Health (DH)
Cancer Research UK (CRUK)	Wellcome Trust Sanger Institute
Human Tissue Authority	

In addition, Professor Sir James Underwood, HTA Member and former President of the Royal College of Pathologists, attended the meeting.

The output from the development meeting mirrored the results from the rapid review to a certain extent. Stakeholders believed that there were misconceptions about how bodies work together, that there were competing standards, requirements and criteria to adhere to. They believed that these discrepancies could lead to some researchers believing they must adhere to all of the guidance (as opposed to just that which is mandatory).

Stakeholders put forward a number of ideas to be considered in the approach. For example, they stressed the importance of separating out where possible, issues around human tissue legislation and HTA regulation. They advised it would be interesting to know where researchers go for advice. This feedback was used to inform the development of the questionnaire and sample frame.

## Quantitative approach and sample

The main stage of the research programme consisted of a quantitative survey with 295 participants.

### *Approach*

The survey was conducted via two methods: telephone and online. These were used in conjunction in order to provide adequate reach and depth of coverage and ensure that a wide range of participants could take part. No fixed quotas were set as the full population of the research community is unknown (the sample is discussed below in full).

The two surveys carried the same questions in the same order.

### *Telephone approach*

An opt in mechanism was set up to build a sample list. This was built via an email request to DIs and Licence Holders, on the HTA contacts database followed by telephone calls to identify bench and clinical researchers. In addition a further email request was administered by stakeholder organisations to help target non-licensed researchers – NRES, CRUK and MRC.

120 interviews were conducted over the telephone.

### *Online approach*

The online survey was scripted and distributed via the HTA contacts database, posted on the HTA website and distributed by NRES, CRUK and MRC. The link was further distributed by the Royal College of Pathologists and other participants.

### *Sample*

Due to the nature of the sampling and recruitment for the quantitative questionnaire we cannot say that the participants in the survey are a representative sample of the research community, indeed it is not known what a representative sample would be.

However, it was important to get a good spread of participants and sufficient numbers in particular subgroups to enable analysis across sub groups.

The people consulted during the project had varying relationships with the HTA. They also vary in how direct their link is to research activities, e.g. their primary role may be working in post mortem services or in patient treatment, or they may be directly involved in research.

Those consulted fell into one of the categories described below:

- DIs who are central to the HTA licensing framework, as they are responsible for ensuring compliance with human tissue legislation and the conditions of the HTA licence. DIs are also responsible for ensuring that suitable people and practices are involved in the licensed activities. DIs generally have regular and direct contact with the HTA, e.g. during inspections, when attending DI training or HTA events, when making enquiries, or when receiving the HTA e-newsletter.
- Licence Holders are named on the HTA licence and are responsible for payment of the licence fee. Licence Holders are usually a corporate body, e.g. an NHS Trust, rather than an individual. Where this is the case, the HTA asks for the contact name of an individual who will act as a representative for the corporate body. This person will normally be more senior than the DI, e.g. a Medical Director or Director of Clinical Governance. For these reasons, Licence Holders generally have less direct contact with the HTA.
- Bench / clinical researchers in two categories: 1. Working at licensed establishments – who are involved in carrying out the operational activities taking place under the licence. Bench / clinical researchers will usually have little direct contact with the HTA, however DIs are expected to pass on relevant information about the HTA to those staff working under the licence. 2. Bench / clinical researchers may also be working at establishments that do not require an HTA licence, e.g. because the project that they are working on has approval from a recognised research ethics committee.
- Other participants include pathologists and clinicians

A good response rate was achieved from the breadth of the sector, as detailed below:

Table 1: Quantitative sample breakdown<sup>4</sup>

Category	Number of participants	Proportion of sample
<b>Primary Organisation</b>		
Public Sector – NHS organisation	121	43%
Public Sector – Higher Education Institute	109	36%
Private	40	14%
Public Other	13	5%
Charity	9	3%
Other	1	
<b>Job role</b>		
Pathologist	82	28%
Head of department	74	25%
Clinical academic	52	18%
Research governance	37	13%
Bench scientist	34	12%
Clinician	22	8%

Chief Executive	13	4%
<b>Areas of research</b>		
Non-communicable diseases inc Cancer	170	60%
Clinical trials	131	46%
Bank that provides tissue for research	107	38%
Genetic disorders	68	24%
Genetic treatments and technologies	50	18%
Communicable diseases	44	15%
<b>Types of tissue</b>		
Tissue from the living	260	91%
Tissue from the deceased	145	51%
Tissue from children	79	28%
Stem cells	64	22%
Fetal tissue	33	12%
None of the above	8	3%
<b>Licensed</b>		
Yes	239	86%
No	20	7%
<b>Type of HTA licence research activity takes place under</b>		
Research	156	64%
Post mortem examination	46	19%
Human application	25	10%
<b>Licence job roles</b>		
DI	83	35%
Bench researcher	57	24%
Person Designated	29	12%
Licence Holder	24	10%

### *Analysis*

As described above, two methods were used for gaining feedback from the research community on the impact of human tissue legislation and its required regulation by the HTA on research. In summary these were:

- A telephone survey – to which participants opted-in
- An online survey which was linked to on the HTA website and subsequently distributed by HTA, CRUK, MRC, NRES. It was then spread by word of mouth/email

The two surveys used the same question wording and order. The two surveys provided divergent responses with the online survey showing more negative scores overall. The online survey also had a different profile of respondent – in particular, those responding online had a lower awareness of HTA and a greater number of pathologists responded online.

Analysis shows that the differences in results between the data sets are due to the profile of the respondents, rather than the data collection method per se. Those with lower awareness of HTA and pathologists are more likely to give more negative responses to questions via both methods. Given this, the two data sets have been merged.

Merging the data provides the following additional benefits

- One clear, coherent picture
- Greater number of responses, thus making it possible to conduct subgroup analysis on a variety of factors.

We present overall scores but highlight where there are significant differences so that the results can be read in this context. Statistically significant differences have been highlighted in the report where they exist.<sup>5</sup>

Note: A large proportion of online respondents only completed the first few questions of the survey, we have included any answers completed, but have removed the subsequent ‘uncompleted answers’ from the percentages totals for the later questions, to avoid confusion. This explains differing base sizes on some questions, however these are clearly marked.

### Qualitative approach and sample

More detail was added to the quantitative findings with an additional qualitative stage. We conducted 10 telephone interviews selected from respondents opting in on during the telephone survey. These qualitative interviews were chosen to add more depth and evidence to information provided in the open ended questions in the survey. The sample breaks down is as follows

Table 2: qualitative sample

Type of researcher
Pathologist who uses existing holdings of tissue
Paediatric pathologist
Researcher conducting multi centre or large scale research
Researcher on small projects
Researcher who has stopped using human tissue / reduced use

<sup>5</sup> Statistical significance relates to a difference between subgroups which is unlikely to have occurred by chance. It does not mean that the difference is necessarily large. For some sub groups the sample size is very low, therefore differences should be taken as indicative only.

Researcher in the field of tissue for human application
Researcher undertaking clinical trials
Stem cell researcher
Public sector researcher
Private sector researcher

We aimed to get a spread of different levels of seniority (i.e. Licence Holders, DIs and bench researchers). We also wanted a mix of respondents who were positive, neutral and negative about the impact of legislation and the required regulation by the HTA, and a mix of respondents from establishments both licensed and not licensed. Results of the qualitative interviews can be found in the appendix.

Discussions were semi-structured, to allow the respondent to lead the discussion and present any concrete evidence they had on the impact of legislation and/or regulation. See appendix for prompt sheet.

### About this report

This report provides the results from the survey. It does not attempt to draw any conclusions or recommendations from these results, as the HTA will be considering the impact of the results on its work in consultation with relevant stakeholders. The qualitative case studies are provided in the appendix.

## 5. Awareness and performance of the HTA

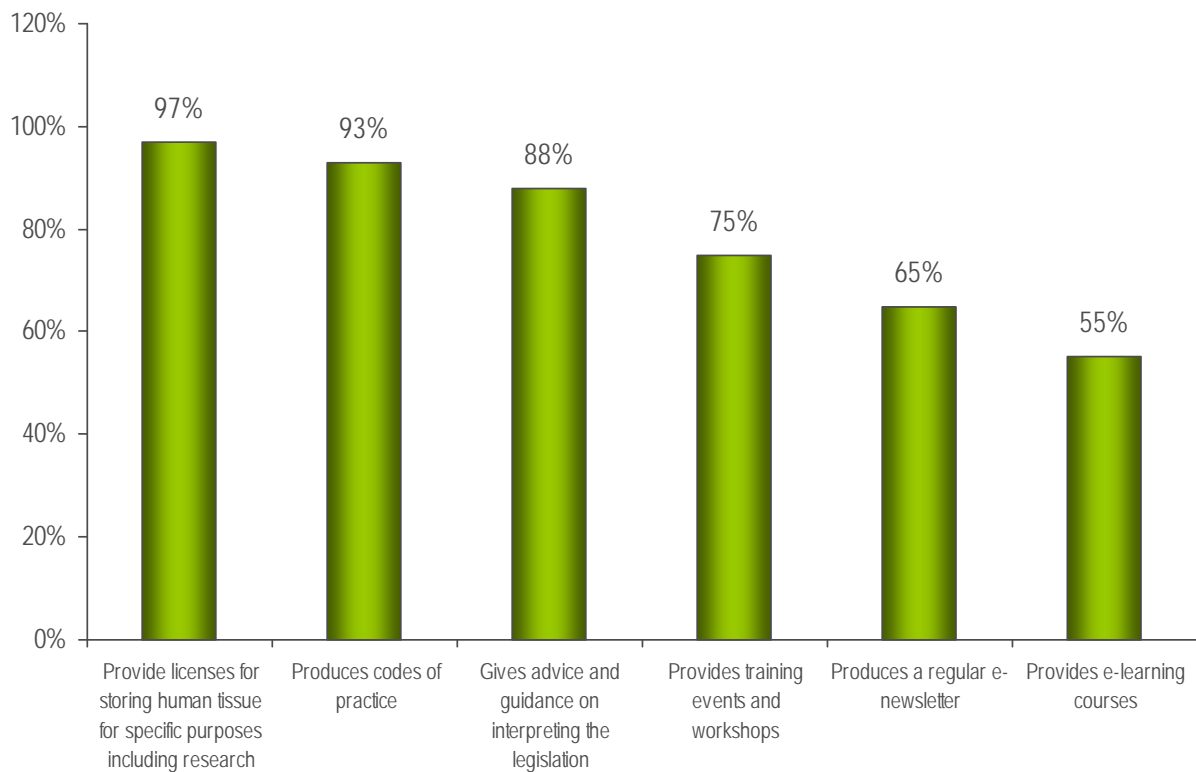
### Summary:

- There is high awareness of the HTA's broad roles such as issuing licences and producing codes of practice (97% and 93% aware respectively).
- Most participants report that the HTA performs well at delivering these roles (rating 3.9 out of 5.0 for issuing licences / 3.8 out of 5.0 for producing codes).
- There was lower awareness of the HTA's e-learning courses and e-newsletter. However, those aware, (base 148 out of 213), report the HTA performs well at these activities (4.1 out of 5.0).

### *Awareness of HTA role and remit*

There is a high level of awareness of certain elements of the HTA's role and remit. The vast majority of participants are aware that the HTA **issues licences for storing human tissue for specific purposes including research (97%), produces codes of practice (93%) and gives advice and guidance on interpreting the legislation (88%).**

Chart 1: Awareness of HTA's role and remit



Q16. Please state if you are aware of this element of the HTA's role and remit...

BASE: 213 respondents

In comparison, certain other aspects of the HTA's role and remit have lower levels of awareness: just over half of participants are aware that the HTA provides e-learning courses (55%), while around two thirds (65%) are aware of the HTA producing a regular e-newsletter.

Levels of awareness differ depending on the participant's role. The subgroup differences are highlighted in table 3 below:

- DIs who have more direct contact with HTA, have a very high awareness of all aspects of the HTA's role and remit, including producing regular e-newsletters (87% aware) and e-learning courses (78% aware).
- Bench researchers have lower awareness of these two aspects, with 40% aware of the e-newsletter and 37% aware of e-learning courses

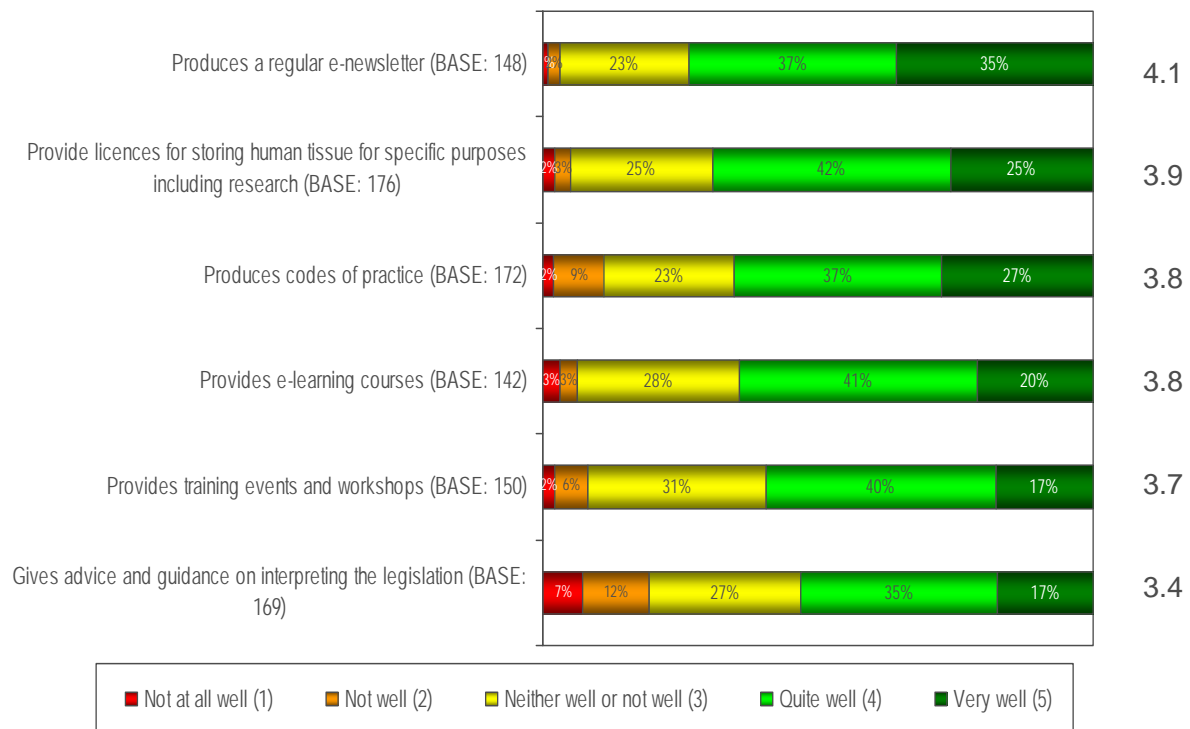
Table 3

More likely to be aware of HTA's role and remit	Less likely to be aware of HTA's role and remit
<b>Participant's roles</b>	
DIs (more likely to be aware of all aspects – at least 78% awareness for all aspects)	Bench researchers (more aware of core aspects – issuing licences and codes of practice – low awareness of e-learning courses at 37% and newsletter at 40%)

### HTA performance

Those who were aware of the different elements of the HTA's role and remit were then asked to rate the HTA's performance in each of these (where 5 = very well and 1 = not at all well). Mean scores are all over 3.0 out of 5.0 indicating a positive performance across the board.

Chart 2: HTA performance



Q16. How well do you believe the HTA performs on.....  
(BASE: all aware of element at Q16a)

While awareness of the HTA **producing a regular e-newsletter** was relatively low, it has the highest performance rating (4.1).

One of the core elements of the HTA's role and remit, **producing codes of practice** is seen as performing relatively well (total mean 3.8). However, there are some subgroup differences (table 4):

- DIs are more likely to be very positive about the HTA's performance on producing codes of practice (4.2)
- NHS institutes are less positive about the HTA's performance on codes of practice (3.4).
- Pathologists are less positive (mean of 3.3)

Table 4

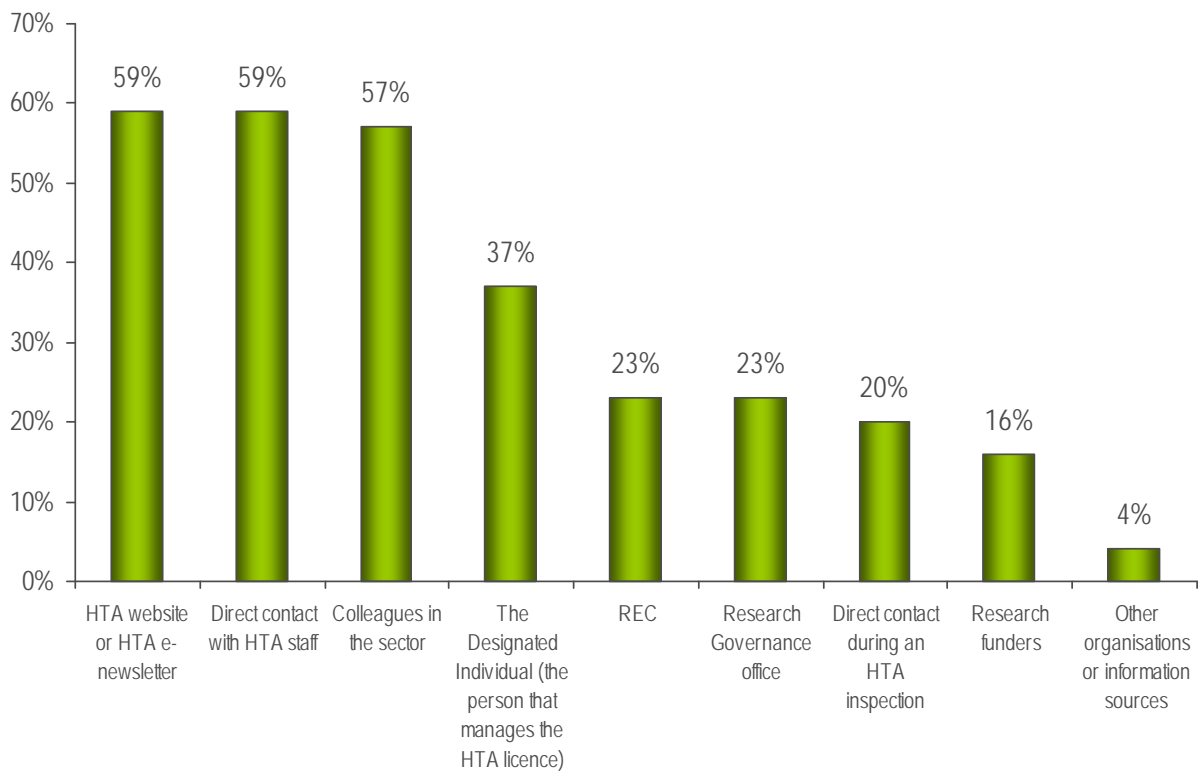
More positive about HTA's performance on producing codes of practice	Less positive about HTA's performance on producing codes of practice
<b>Organisation type</b>	
	NHS organisations (3.4)
<b>All job roles</b>	
	Pathologists (3.3)
<b>HTA licence roles</b>	
DIs (4.2)	

Participants suggest that the HTA performs relatively less well on **giving advice and guidance on interpreting the legislation** as this is the aspect with the lowest mean score (3.4). While overall respondents are still positive, almost one in five (17%) think the HTA is not doing well in this area.

*Sources of information*

Participants were asked what they base their assessment of the HTA's role and remit on. The most common basis of opinion is from the **HTA website or HTA e-newsletter** (59%) and from **direct contact with HTA staff** (59%). However over half of participants also base some of their assessment on **colleagues in the sector** (57%).

**Chart 3: Sources of information**



*Q17. What have you based your assessment on?*

*BASE: 246 Respondents*

There are significant differences in responses between different job roles (table 5):

- Pathologists, clinicians and clinical academics are most likely to base their assessments on colleagues in research sector (pathologists (58%), clinicians (63%) compared to the total (57%).
- DIs are more likely to base their assessments on direct contact with the HTA (88% compared to total (59%)) and the HTA website or e-newsletter (77% compared to total (59%)).
- Bench researchers base their assessments on colleagues in the sector (53% compared to total (57%)) and the DI from their organisation (45%).

**Table 5 (Low Bases)**

More likely to base assessments on direct contact with HTA / website or e-newsletter (total 59% and 59% respectively)	More likely to base assessments on their colleagues in the sector (total 57%) or DI in the organisation (total 37%)
<b>All job roles</b>	
	Pathologists (58%)
	Clinicians (63%)
<b>HTA licence roles</b>	
DIs (88% direct contact with HTA / website or e-newsletter (77%))	Bench researchers (the DI in the organisation (54%))

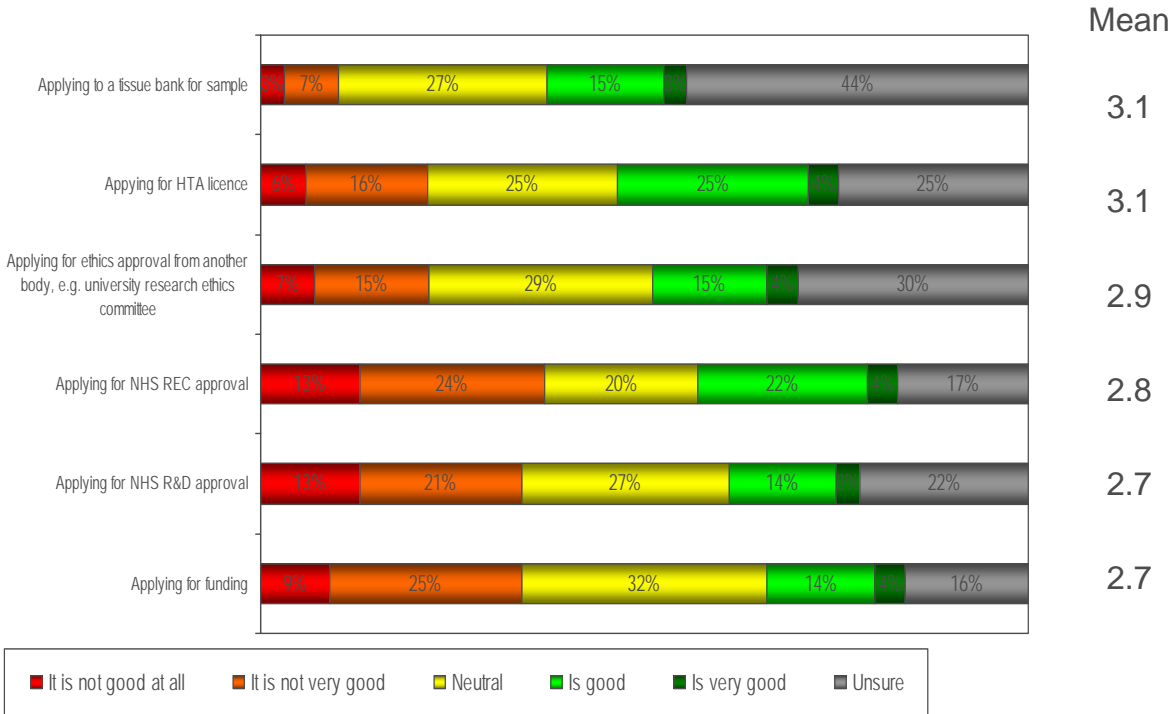
## 6. Views of the HTA in the wider research context

**Summary:**

- Perceptions of the HTA’s performance, as a regulatory body, are relatively positive. Participants rate their overall impression of applying for an HTA licence as 3.1 out of 5.0 compared to 2.7 out of 5.0 for applying for NHS R&D approval or applying for funding.
- Those applying for an HTA licence rate the performance of the organisation relatively positively: on being responsive (3.6 out of 5), being efficient (3.5 out of 5) and providing information (3.7 out of 5). These scores are higher those of other organisations in the research sector.

Participants rate their overall impressions of the process of applying for an HTA licence as fair (3.1 out of 5.0, where 1 is not at all good and 5 is very good) (Chart 4). More respondents report that the process of applying for an HTA licence was positive than report it was negative (29% compared with 22%). The only other process to obtain a similar mean score was applying to a tissue bank for samples with a mean of 3.1<sup>6</sup>. Applying for NHS R&D approval and applying for funding have the lowest mean scores of 2.7.

**Chart 4: Overall impressions of regulation and governance processes involved in research.**



Q13. Please tell me your overall impression of the following...  
 Base: 259 Respondents

<sup>6</sup> Mean scores are calculated without the don't knows and unswers. This is a more accurate measure when there are a large number of don't know/unsure responses

Certain subgroups differences emerge:

- Private organisation are more likely to be positive about applying for an HTA licence (3.6) while NHS organisations are more likely to be negative (2.8)
- Pathologists are more negative (2.4), while DIs are more positive (3.4)
- Those who work in the field of stem cells are more positive than the mean (3.4)

Table 6

More likely to be positive about applying for an HTA licence	More likely to be negative about applying for an HTA licence
<b>Organisation type</b>	
Private (3.6)	NHS organisations (2.8)
<b>All job roles</b>	
	Pathologists (2.4)
<b>HTA licence roles</b>	
DIs (3.4)	
<b>Area of human tissue research</b>	
Stem cells (3.4)	

Participants rated the various organisations on their performance. The process of applying for an HTA licence received the best scores on providing information (3.7 out of 5.0), being responsive (3.6) and being efficient (3.5).

Table 7: Evaluating regulation and governance processes involved in research

	Applying for an HTA licence	Applying to a tissue bank for samples	Applying for NHS REC approval	Applying for funding	Applying for ethics approval from another body, e.g. university research ethics committee	Applying for NHS R&D approval
Providing information	3.7	3.5	3.4	3.4	3.3	3.1
Being responsive	3.6	3.5	3.3	3.2	3.3	3.1
Being efficient	3.5	3.4	3.2	3.2	3.2	2.8

## 7. General views of legislation, regulation and governance in the research sector

The literature review, development meeting and our pilot of the research questionnaire highlighted that many participants found it very difficult to distinguish between human tissue legislation and HTA regulation against the backdrop of a broad range of activities beyond the remit of the HTA, including ethics committee approval, funding and NHS Research and Development approval. **For this reason, views of the impact of human tissue legislation and HTA regulation are closely correlated with general views about the wider legislation, regulation and governance in the research sector. Findings from this survey should therefore be read in this context.**

### Summary:

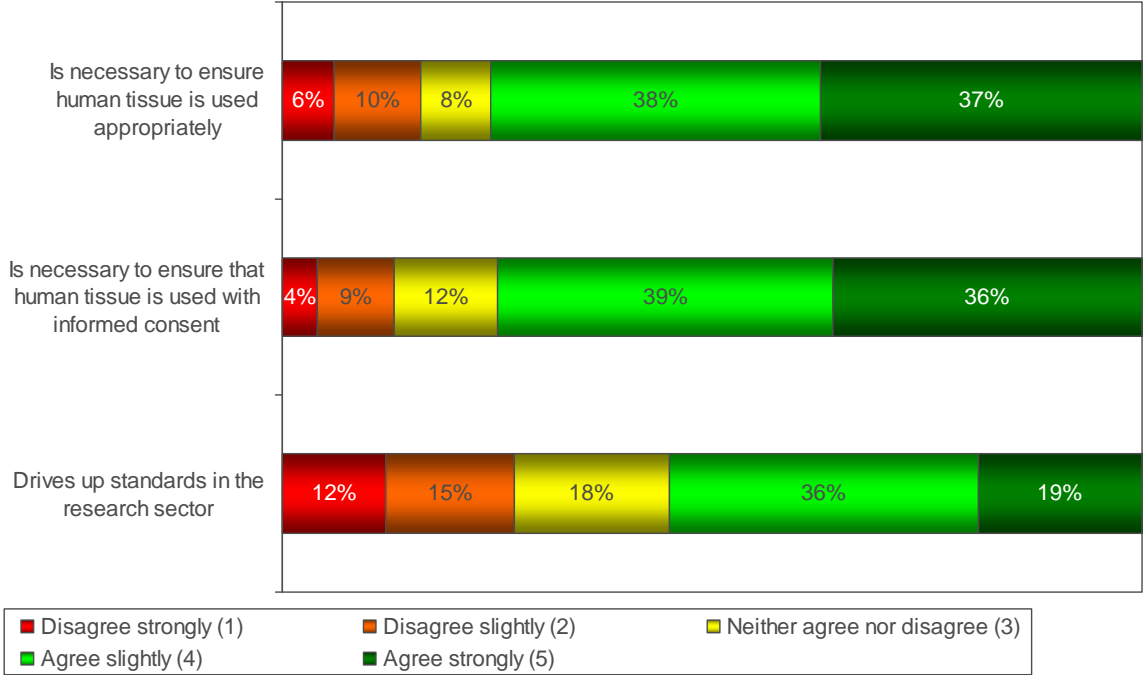
- Participants agreed that for the research sector, legislation, regulation and governance was **necessary to ensure human tissue is used appropriately** (75%)
- They also agreed that legislation, regulation and governance was **necessary to ensure that human tissue is used with informed consent** (75%).
- A smaller proportion agreed that for legislation, regulation and governance in the research sector:
  - requirements are uncomplicated and easy to understand (9%)
  - **did not hold up research unnecessarily** (20%)
  - **requirements are easy to comply with** (17%)
  - **is streamlined** (16%)

Participants were first asked to express their views on wider legislation and regulation in the research sector. This was introduced with the following preamble

*I am now going to read out some general statements about legislation, regulation and governance which could be associated with the research sector. By legislation we mean laws and acts associated with conducting research. By regulation and governance we mean the act of controlling behaviour in accordance with the legislation or administration of processes*

Three quarters of participants in the quantitative survey agreed that in general, legislation, regulation and governance in the research sector is **necessary to ensure human tissue is used appropriately** (75%, mean 3.9 out of 5) (Chart 5). Three quarters of participants also agreed that legislation, regulation and governance in general is **necessary to ensure that human tissue is used with informed consent** (75%, mean 3.9). Just over a half of participants agreed that legislation, regulation and governance in general **drives up standards in the research sector** (55%).

Chart 5: Legislation, regulation and governance in the research sector

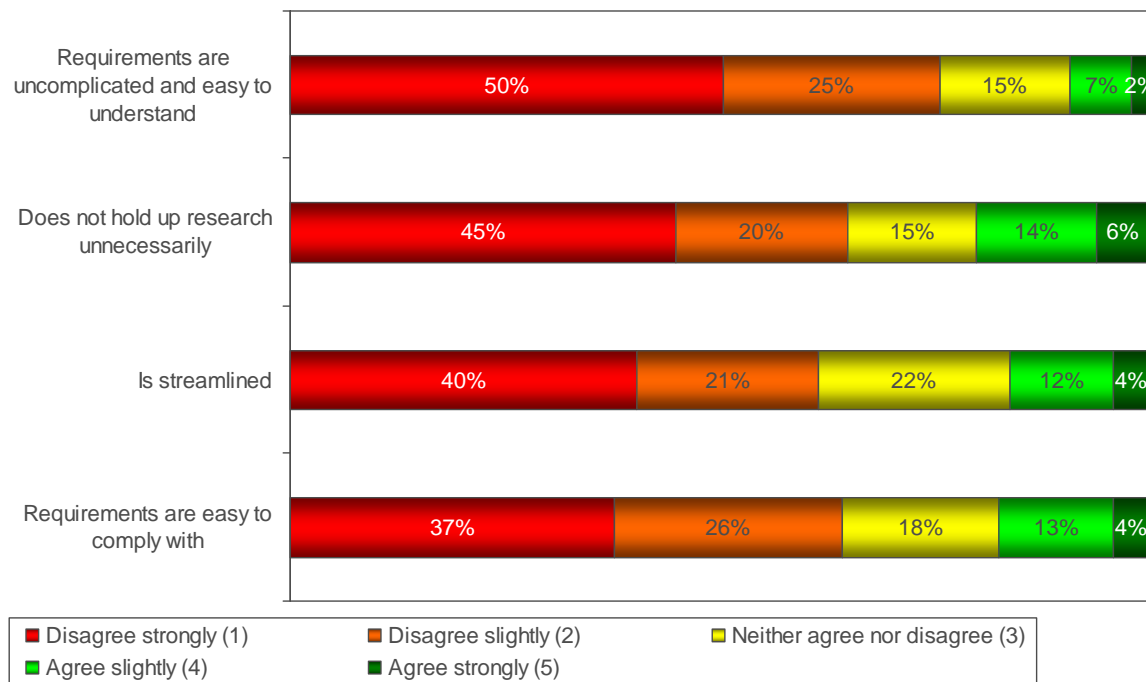


Q11. Legislation, Regulation and governance in the research sector...

Base: 267 respondents

A fifth agreed that legislation, regulation and governance **did not hold up research unnecessarily** (20%). Less than a fifth agreed that **requirements are easy to comply with** and that legislation, regulation and governance in general **is streamlined** (17% and 16% respectively). Almost one in ten agreed that **requirements are uncomplicated and easy to understand** (9%).

Chart 6: Legislation, regulation and governance in the research sector



Q11. Legislation, Regulation and governance in the research sector...  
Base: 267 respondents

Sub group analysis reveals a number of differences amongst organisation types, job roles, licence roles and main activities (table 8). DIs and those in research governance are more likely to agree with positive statements about the wider legislation, regulation and governance. Pathologists and clinical academics tend to be less likely to agree with positive statements about wider legislation, regulation and governance.

Sub group differences are highlighted in the table below (table 8).

Table 8

More likely to agree with positive statements and disagree with negative statements	More likely to disagree with positive statements and agree with negative statements
<b>Organisation type</b>	
Private (e.g. drives up standards in the research sector – 3.6 / is necessary to ensure human tissue is used appropriately - 4.2)	NHS organisations (is streamlined – 1.8 / requirements are uncomplicated and easy to understand - 1.5)
<b>All job roles</b>	
Research governance (is necessary to ensure human tissue is used appropriately – 4.1 / drives up standards in the research sector – 3.9)	Pathologists (does not hold up research unnecessarily – 1.6)

	Clinical academics (Does not hold up research unnecessarily – 1.3)
<b>HTA licence roles</b>	
DIs (Is necessary to ensure that human tissue is used with informed consent – 4.1)	
<b>Area of human tissue research</b>	
Communicable diseases (is necessary to ensure human tissue is used appropriately – 4.2)	
<b>Main activity</b>	
	Post mortem (Does not hold up research unnecessarily – 1.8)

NB Mean scores = Drives up standards in the research sector (3.4) Is necessary to ensure human tissue is used appropriately (3.9), Does not hold up research unnecessarily (2.2), Is necessary to ensure that human tissue is used with informed consent (3.9), Is streamlined (2.2), Requirements are uncomplicated and easy to understand (1.9), Requirements are easy to comply with (2.2).

In addition to the common sub group differences, higher education institutes were less likely to agree than the total that legislation, regulation and governance in the research sector is easy to comply with (2.0) and uncomplicated and easy to understand (1.7)

## 8. HTA licensing

### Summary:

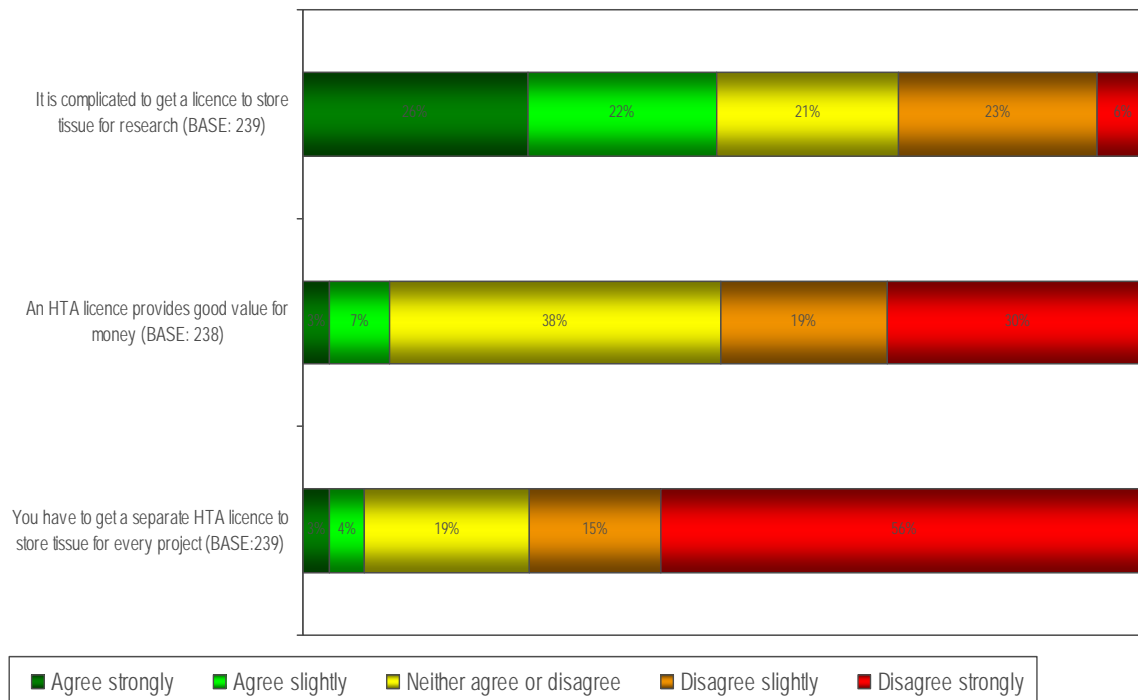
- One in ten agree (10%) agree that an **HTA licence provides value for money**. Half disagree (49%).
- Half agree it is complicated to get a licence to store tissue for research (48%)
- However, participants are less likely to agree that you have to get a separate HTA licence to store tissue for every project (7% agree)

Participants were asked a number of questions around HTA regulation, and specifically about getting a licence.

One in ten agree that **an HTA licence provides good value for money** (10%). A large proportion of participants disagree (49%), with around a third strongly disagreeing. (Note: this survey was conducted at the same time as a separate consultation on HTA licence fees.) Just under half of participants also agree with the statement that **it is complicated to get a licence to store tissue for research** (48%), with just over a quarter disagreeing (29%).

Seven percent agree that **you have to get a separate HTA licence to store tissue for every project**. 71% disagree. This indicates that the majority are aware that a generic (rather than project-specific) HTA licence for storage of material for research is required.

Chart 7: HTA licence processes



Q22. To what extent do you agree or disagree with the following statements concerning human tissue legislation, and regulation by the HTA, including the process of getting a licence?  
 BASE: All respondents

There are some differences of opinion regarding the statement **it is complicated to get a licence for research**. These are in line with other subgroup differences that occur throughout the survey

- Private organisations are more likely to disagree (3.5 compared to mean of 2.6 where 1 is agree strongly and 5 is disagree strongly)
- Pathologists and bench researchers working at licensed establishments are more likely to agree (2.2 and 2.1 respectively)

Table 9

More likely to agree that it is complicated to get a licence	More likely to disagree that it is complicated to get a licence
<b>Organisation type</b>	
	Private (3.5)
<b>All job roles</b>	
Pathologists (2.2)	
Bench researchers (2.1)	

Heads of department are the only subgroup more likely to disagree strongly that a HTA licence provides good value for money compared to the other groups (2.0).

Table 10

More likely to agree that it provides good value for money	More likely to disagree that it provides good value for money
All job roles	
	Heads of department (2.0)

There are no sub group difference on the statement that you have to get a separate HTA licence to store tissue for each new project.

# 9. HTA regulation and clarity of requirements against the wider legislation, governance and regulation framework

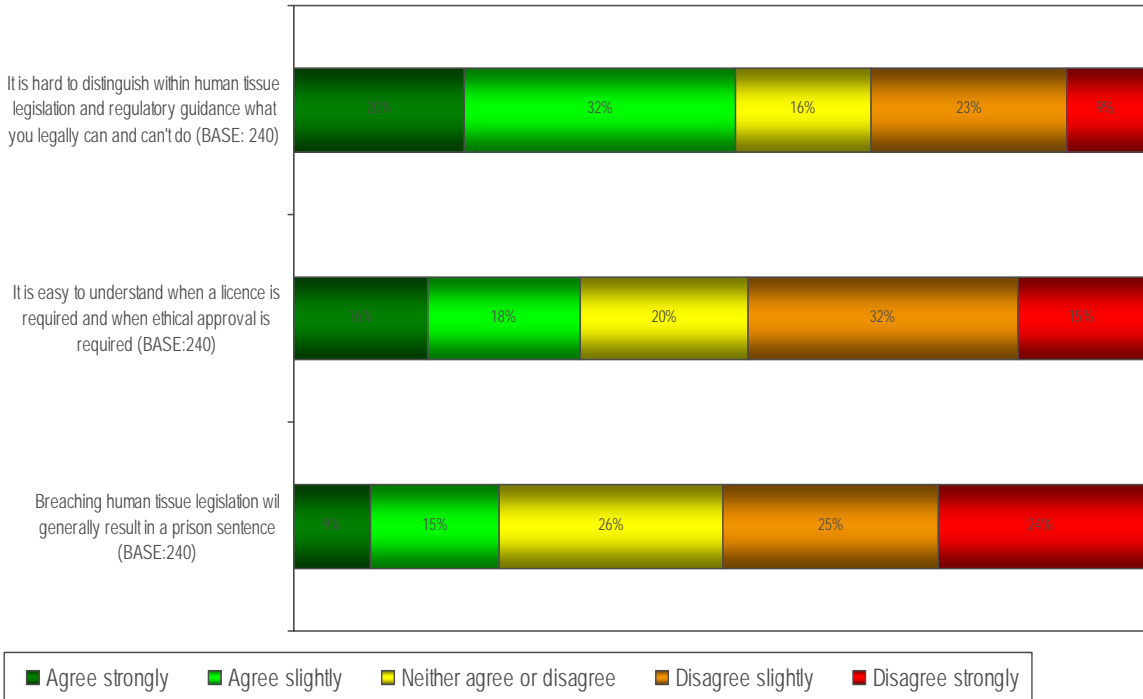
**Summary:**

- Half of the participants do not make a distinction between human tissue legislation and the HTA (50%)
- The majority of participants agree that it is hard to distinguish within human tissue legislation and regulatory guidance what legally you can and cannot do (52%).
- A third agree that it is easy to understand when a licence is required and when ethical approval is required (33%), half disagree (48%).

Despite the high level of awareness of parts of the HTA 's role and remit, as mentioned in section 5, half of respondents (50%) do not make a distinction between human tissue legislation and the HTA. However, other responses of those who do perceive a difference are not significantly different to those who do not perceive a difference.

This split is reflected evenly across the majority of subgroups

**Chart 8: HTA regulation and clarity in the wider legislation, governance and regulatory framework**



Q22. To what extent do you agree or disagree with the following statements concerning human tissue legislation, and regulation by the HTA, including the process of getting a licence?

BASE: All respondents

Over half agree that **it is hard to distinguish within human tissue legislation and regulatory guidance what you legally can and can't do** (52%), with a fifth agreeing strongly (20%). A third (32%) disagree overall.

A third agree that **it is easy to understand when a licence is required and when ethical approval is required** (33%); just under half disagree (47%) and a third agree overall.

For both these statements certain sub groups are more likely to agree or disagree with these statements compared to the mean:

- DIs are more likely to agree with the statement that it is easy to understand when a licence is required and when ethical approval is required (3.2 compared to an overall mean of 2.9, where 1 is disagree strongly and 5 is agree strongly)
- NHS organisations are more likely to agree with the statement it is hard to distinguish within human tissue legislation and regulatory guidance what you legally can and can't do (2.4 compared to a mean of 2.7 where 1 is agree strongly and 5 is disagree strongly).

Table 11  
(Overall mean of 2.9)

More likely to agree with the statement that it is hard to distinguish when a licence is required and when ethical approval is needed	More likely to disagree with the statement that it is hard to distinguish when a licence is required and when ethical approval is needed
<b>HTA licence roles</b>	
DIs (3.2)	

(Overall mean of 2.7)

More likely to be positive about statements overall	More likely to be negative with statements overall
<b>Organisation type</b>	
NHS organisations (2.4)	

A quarter agree overall that **breaching human tissue legislation will generally result in a prison sentence** (24%); just under half of participants disagree (48%).

## 10. Views of human tissue legislation

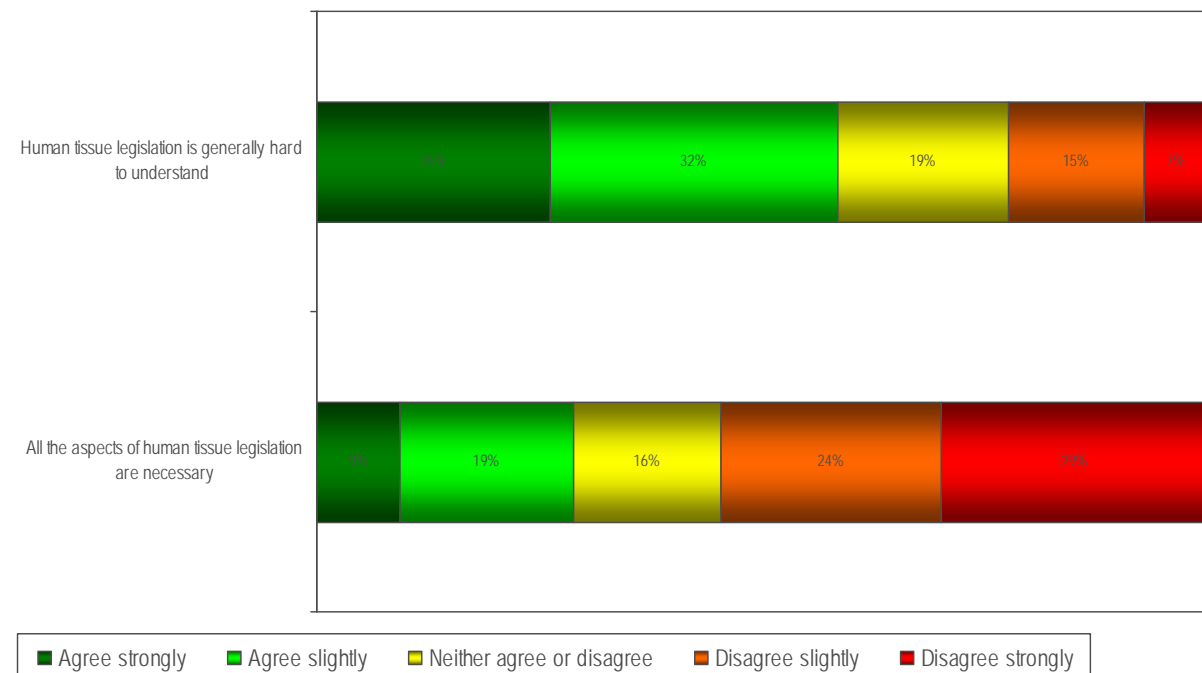
### Summary:

- The majority of participants agree that human tissue legislation was generally hard to understand
- Participants were also more likely to disagree that all aspects of the human tissue legislation are necessary

Over half of participants agree that **human tissue legislation is generally hard to understand** (57% agree) and one in four agrees strongly that it is hard to understand (26%). However one in five disagree that it is hard to understand (22%).

The mean is 2.5 (based on 1 agree strongly and 5 disagree strongly) showing that the scale of feeling is somewhere between agree slightly and neutral.

Chart 9: Experience of human tissue legislation



Q22. To what extent do you agree or disagree with the following statements concerning human tissue legislation, and regulation by the HTA, including the process of getting a licence?  
BASE: 242

Some sub groups are more likely to agree or disagree with this statement compared to the mean. Overall none of the sub groups think that human tissue legislation is easy to understand but some groups are less negative or more neutral about this statement.

- Those who work for NHS organisations and those who work in the post mortem sector are more likely to agree with this statement compared to the mean (2.2 and 2).

- Those who work in the area of communicable diseases are more positive than the mean (2.9).
- Pathologists are more likely to agree than the mean (2) while those who fall into the 'other' category are more likely to disagree compared to the mean (2.9).

Table 12

Mean = 2.5

More likely to agree compared to the mean	More likely to disagree compared to the mean
<b>Organisation type</b>	
NHS organisations (2.2)	
<b>Main activity</b>	
Post mortem (2)	
<b>All job roles</b>	
Pathologist (2)	Other (2.9)
<b>Area of human tissue research</b>	
Communicable diseases (2.9)	

Awareness of the HTA's role and remit has an effect on how likely respondents are to disagree. Those who are only slightly aware are more likely to agree (2.1). How positive people are about the HTA also reflects on if respondents find human tissue legislation hard to understand; those who are very positive about the HTA's performance are more likely to disagree compared to the mean (3). Those who are positive about HTA regulation are more likely to be positive about legislation too<sup>7</sup> (3.4) compared to 1.8 for those who are negative about HTA regulation.

One in ten (9%) strongly agree **all aspects of human tissue legislation are necessary** (54%). Just over half disagree with over a quarter strongly disagreeing (29%) (mean score 2.5).

- Public institutions, both higher education institutes and NHS organisations, are more likely to disagree that all aspects of human tissue legislation are necessary (2.2). While private organisations are more likely to agree compared to the mean (3.3).
- Those who work in communicable diseases are more likely to agree compared to the mean (3.0).
- For different job roles within these institutions, bench scientists are more likely to agree than the mean (3.0 and 3.2 respectively), while pathologists and clinical academics are more likely to disagree (1.8 and 1.9 respectively).

---

<sup>7</sup> A composite cross break was created, in which the scores respondents gave across each aspect of regulation were grouped into those broadly in favour (over 22 points), broadly neutral (15 to 21 points) and broadly against (under 15).

Table 13  
 Mean = 2.5

More likely to agree compared to the mean	More likely to disagree compared to the mean
<b>Organisation type</b>	
Private organisations (3.3)	Public institutions (2.2)
	NHS organisations (2.2)
<b>All job roles</b>	
Bench scientists (3.0)	Pathologist (1.8)
	Clinical academics (1.9)
<b>Area of human tissue research</b>	
Communicable diseases (3.0)	

In a similar pattern to the previous statement, those who are less aware of the HTA's role and remit are more likely to disagree compared to the mean (2.3) and those who rate the HTA's performance highly are more likely to agree (3.1).

## 11. Overall impact of human tissue legislation and HTA regulation on research

### Summary:

- A quarter of participants report that human tissue legislation and HTA regulation has had a positive impact on the research sector (26%). Three fifths report that it has had a negative impact (59%)
  - Those who are more aware of the HTA role and remit and those who are broadly in favour of HTA regulation are more likely to say it has had a positive impact.
  - Those in the NHS and pathologists<sup>8</sup> are more likely to say it has had a negative impact.
- Research demonstrates that perceptions of the impact of human tissue legislation and HTA regulation is likely to be influenced by a host of other factors including:
  - General views and perceptions of legislation and governance in the research sector
  - Awareness of the HTA's role and remit
  - Perceptions of the HTA's performance
  - Views on processes associated with applying for a licence

### *About this question*

*Participants were asked the overarching question 'considering everything you have heard about human tissue legislation would you say that its introduction and subsequent regulation has had a positive or negative impact on the research sector? Legislation and regulation have been combined for this question because many respondents in the piloting of the questionnaire were unable to distinguish between the two and felt they were too closely linked.'*

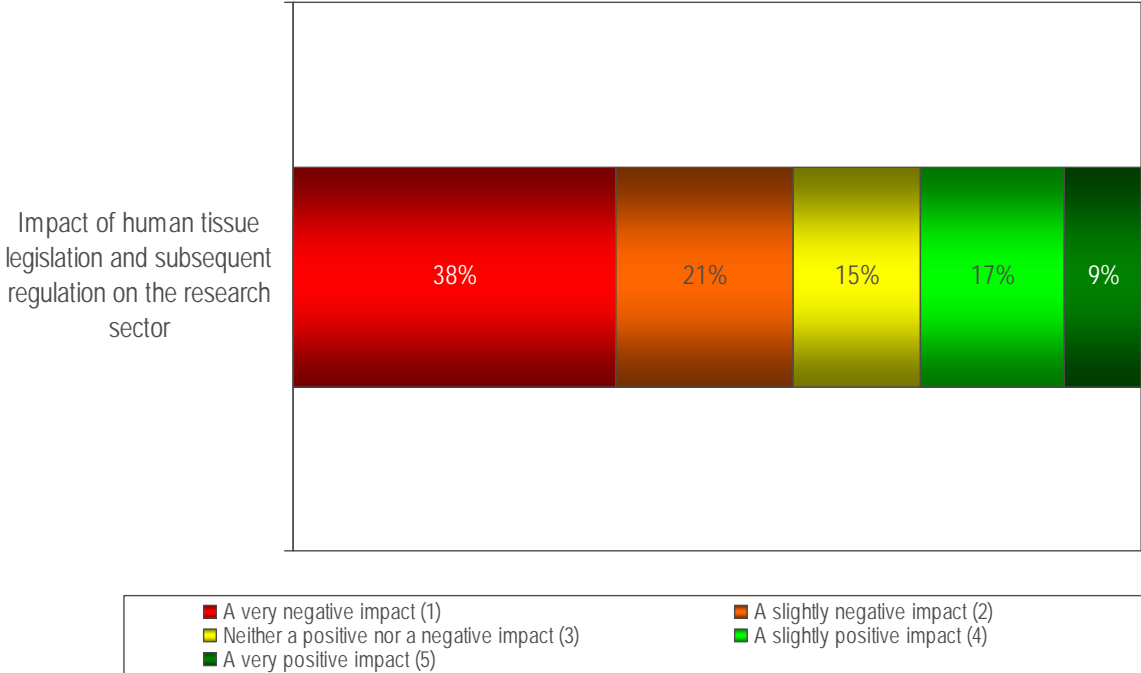
### *Overall impact*

The majority of participants report that human tissue legislation and HTA regulation has had a negative impact on the research sector. The strength of feeling about the impact leans towards the strongly negative with over a third of participants reporting it had had a very negative impact (38%). Only one in 10 (9%) believe that it had had a very positive impact. One in six of the participants report that it had neither a positive or a negative impact (15%).

---

<sup>8</sup> Overlapping quotas pathologists also typically work in the NHS, although not all of those responding from the NHS are pathologists

Chart 10: Impact of human tissue legislation and HTA regulation on the research sector



Q19. Considering everything you have heard about human tissue legislation would you say that its introduction and subsequent regulation has had a positive or negative impact on the research sector overall.  
 Base: 242 (all participants)

The mean overall was 2.4 showing that respondents report that the impact had been more negative than positive. This can be broken down by different sub-groups to show which organisations and individuals are more or less positive.

No sub-groups report human tissue legislation and HTA regulation had had a positive impact overall, but some groups were slightly less negative than the mean and some were a lot more negative than the mean. A similar pattern in sub group responses is reflected through out the survey.

*Organisational differences*

- Private organisations, while still slightly negative, are more positive than the mean (2.9)
- For HTA licenced organisations whose main activity is research are more positive than mean (2.7)
- Participants who work for NHS organisations are more likely to be negative (mean of 1.9), with over half saying human tissue legislation and HTA regulation had a very negative impact (54%)
- Those whose main activity is post mortem are overall more negative than the mean (1.7)

### Job role differences

There are some difference in opinion by job roles throughout the survey, that are highlighted in this question<sup>9</sup>

Pathologists are the most negative group throughout the survey; with 3 in 4 (75%) saying that the introduction of human tissue legislation and HTA regulation has had a very negative impact.

Differences in terms of job roles under HTA licences are also highlighted. DIs are significantly more likely to be positive than the mean (2.8), Licence Holders tend to be the most positive<sup>10</sup> (3.5), while bench researchers<sup>11</sup> are the most negative of this group (2.1).

For the different areas of human tissue research and different types of tissue used there are very little differences by sub group. However those who work in communicable diseases are more positive than the mean (3).

Table 14  
Mean = 2.4

More likely to be more positive than the mean	More likely to be more negative than the mean
<b>Organisation type</b>	
Private (2.9)	NHS organisations (1.9)
<b>Main activity</b>	
Research (2.7)	Post mortem (1.7)
<b>All job roles</b>	
Research governance (3.1)	Pathologist (1.4)
Bench scientist (3.0)	Clinical academic (1.8)
<b>HTA licence roles</b>	
DIs (2.8)	Bench Researchers (2.1) <sup>12</sup>
Licence Holders (3.5) <sup>13</sup>	
<b>Area of human tissue research</b>	
Communicable diseases (3)	

<sup>9</sup> Some small bases sizes

<sup>10</sup> Small base size so not statistically significant

<sup>11</sup> Small base size so not statistically significant

<sup>12</sup> Small base size so not statistically significant

<sup>13</sup> Small base size so not statistically significant

### *Closeness to HTA*

Closeness to the HTA has an impact on how participants feel about the impact of human tissue legislation and subsequent HTA regulation. It also has an impact throughout the survey on how positive participants feel about both HTA regulation and legislation. Those who have less awareness of the HTA role and remit<sup>14</sup> are more negative compared to the mean (1.8), while those who have a greater awareness are more positive than the mean (2.7)<sup>15</sup>. Equally those who rate the HTA as having a very good performance<sup>16</sup> are more likely to think that overall human tissue legislation and HTA regulation has had a positive impact, compared to the total mean (3.2).

---

<sup>14</sup> Those who were only aware of 4 or less of the HTA's roles and responsibilities

<sup>15</sup> Those who were aware of 5 or 6 of the HTA's roles and responsibilities

<sup>16</sup> The cross break on HTA's performance was taken by adding up the scores respondents gave HTA's performance at Q16b, the majority of respondents were positive so the scale is weighted towards the positive. Very Positive performance (over 22 points), positive performance (16 to 21) and neutral performance (15 or less).

## 12. Perceived and actual impacts on research

### Summary:

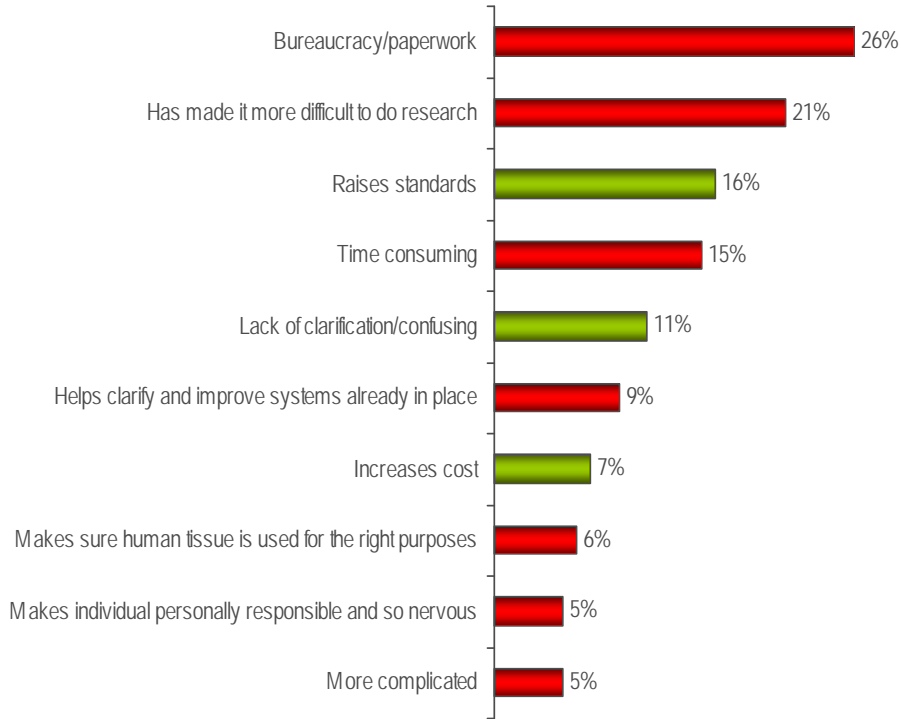
- The majority agree that human tissue legislation and required HTA regulation has ensured that informed consent is given by donors (70% agree), it has led to improved standards for storage of tissue for research (65% agree), and it has led to clearer guidance on what you can and cannot do legally (57% agree)
- However, the majority also agree that human tissue legislation and required HTA regulation has made it more difficult to get hold of samples (68% agree) and has led to disposal of potentially valuable samples (61% agree).
- Half of participants agree that human tissue legislation and required HTA regulation has led to researchers changing their research plans
  - Those with a closer relationship with HTA and who are more aware of their full remit are more positive about the impact of legislation and regulation.

Participants were asked to explain why they had reported that human tissue legislation and HTA regulation had been positive or negative. This question was unprompted, so therefore raised top of mind responses. A quarter of respondents mention the bureaucracy/paperwork (26%) with around one in six also spontaneously mentioning that it has been time consuming (15%). Around a fifth report that human tissue legislation and HTA regulation has made it more difficult to do research using human tissue (21%).

Some respondents report positive impacts such as raising standards (16%), clarifying and improving systems (9%) and ensuring that human tissue is used correctly (6%).

A small number also mentioned that it could be confusing (11%) and that it was more complicated than what had existed before (5%).

Chart 11: Perceived impacts of human tissue legislation and required regulation by the HTA (spontaneous comments – red bars reflect responses given by those who report a very negative impact, green bars reflect responses given by those who report a less negative impact)



Q20: Please explain in detail your answer to the previous question (Q19)  
 Base: 295

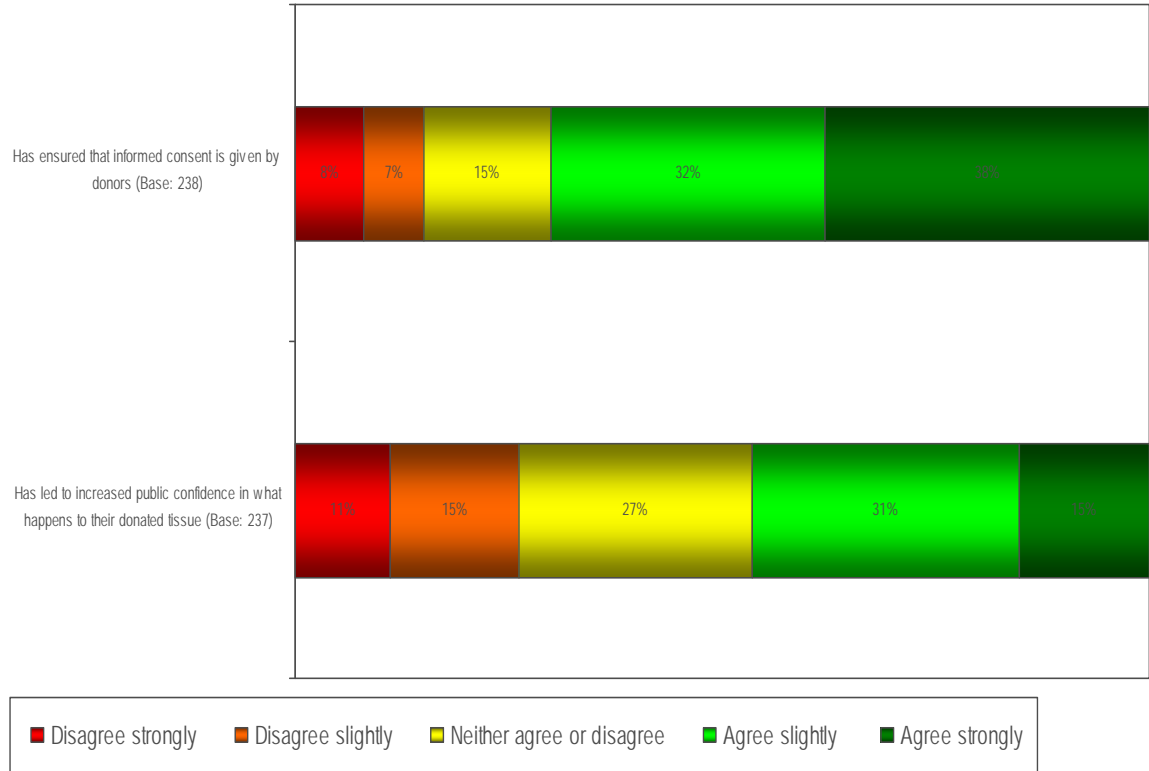
Participants were then asked to what extent they agreed or disagreed with a variety of statements about what the perceived impact of human tissue legislation and HTA regulation has been.

*Consent and the public*

Over two thirds of respondents (70%) agree that human tissue legislation and HTA regulation **has ensured that informed consent is given by donors**, with over third agreeing strongly (38%). Less than one in six disagree overall (14%), with less than one in ten disagreeing strongly (8%).

More participants agree than disagree that human tissue legislation and HTA regulation **has led to increased public confidence in what happens to their donated tissue**, with just under half (46%) agreeing overall; one in six strongly agree (15%). Over a quarter of respondents would neither agree nor disagree (27%).

Chart 12: Consent and the public



Q23. These are some statements which others have made about human tissue legislation and associated regulation by the HTA. To what extent do you agree or disagree with the following statements in your personal experience.  
 BASE: All respondents

There are very few sub group differences for these statements.

There are no significant differences by sub groups regarding agreement that human tissue legislation and HTA regulation has ensured that informed consent is given by donors.

In contrast to other findings NHS organisations and pathologists are likely to be more neutral than negative that human tissue legislation and HTA regulation has led to increased public confidence in what happens (3.0 and 3.3 respectively)

Table 15  
Mean = 2.8

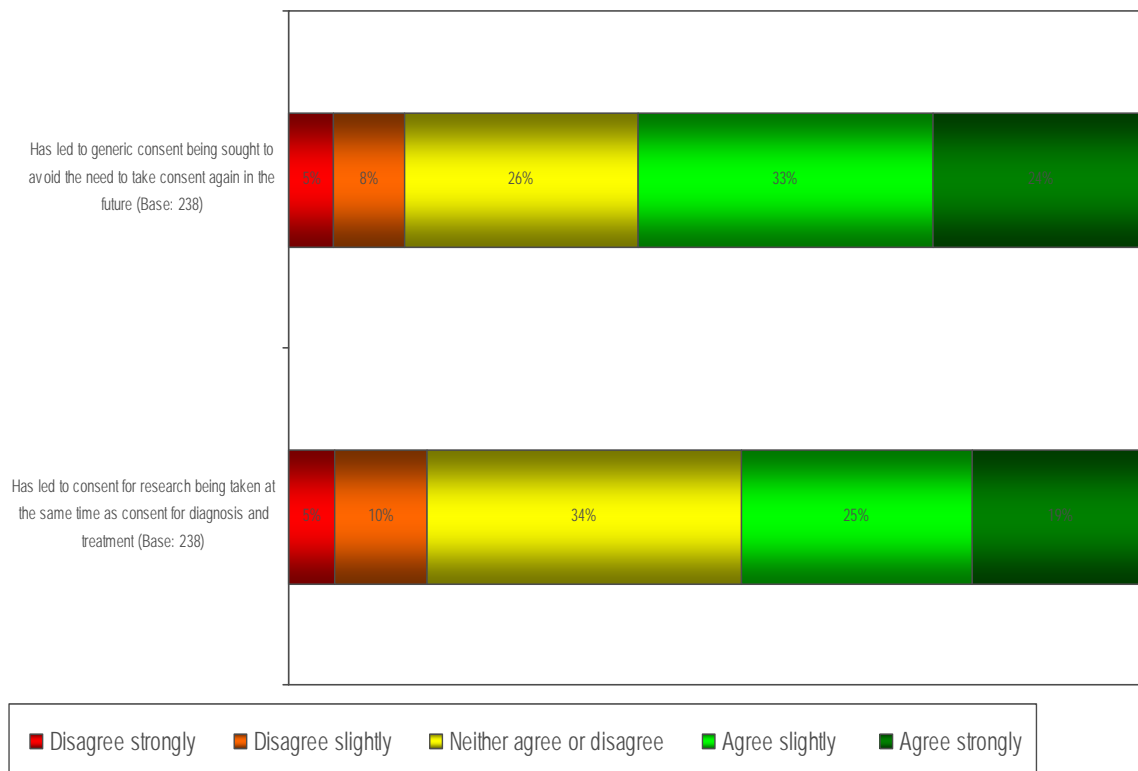
More likely to be more neutral
Organisation type
NHS organisations (3)
All job roles
Pathologist (3.3)

### Consent processes

Over half of respondents agree (57%) that generic consent is sought, with around a quarter strongly agreeing. Just over a quarter (26%) neither agree nor disagree that generic consent is sought.

Slightly less agree that consent for research is taken at the same time as consent for diagnosis and treatment, with just under half agreeing (44%). Around a third neither agree nor disagree with this statement (34%).

Chart 13: Generic consent and consent processes



Q23. These are some statements which others have made about human tissue legislation and associated regulation by the HTA. To what extent do you agree or disagree with the following statements in your personal experience.  
BASE: All respondents

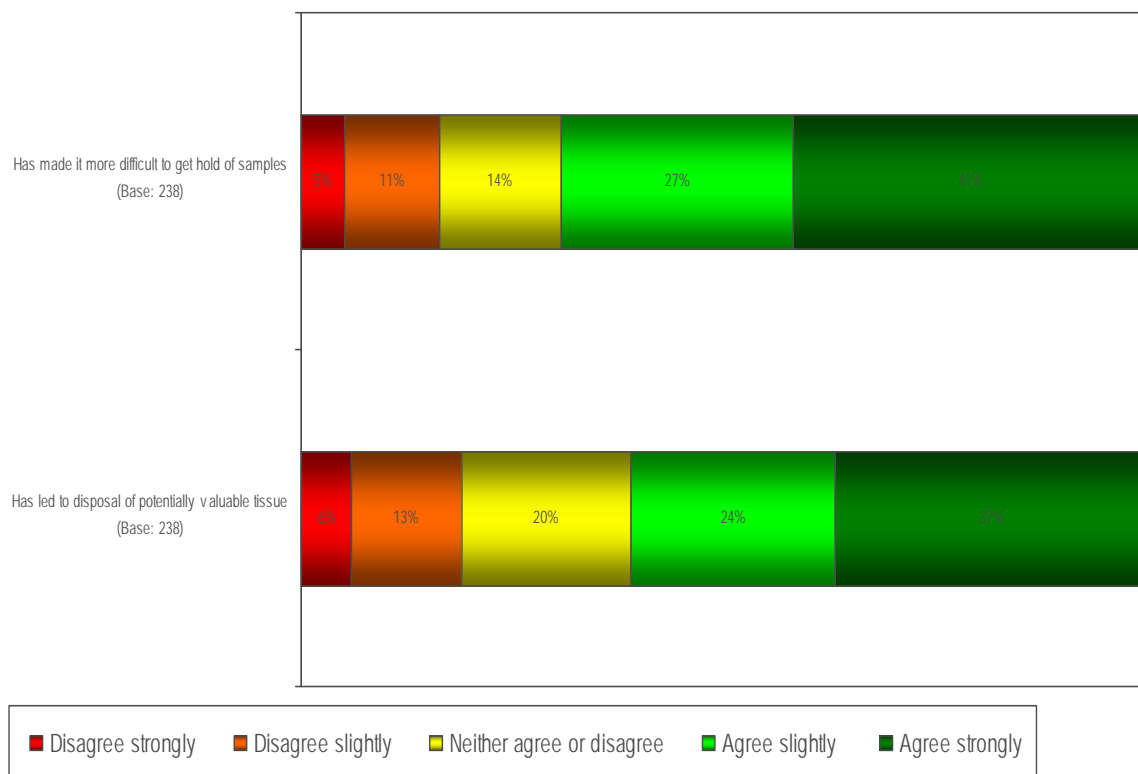
There are very few sub group differences with these statements:

- Private organisations less likely to agree overall that generic consent is taken (39% compared to 57% overall).
- NHS organisations are more likely to agree overall that consent for research is taken at the same time as consent for diagnosis and treatment (53% compared to 44% overall).

### Availability of tissue

The next two statements reflect on what the impacts have been on the availability of tissue.

Chart 14: Availability of tissue



Q23. These are some statements which others have made about human tissue legislation and associated regulation by the HTA. To what extent do you agree or disagree with the following statements in your personal experience.  
 BASE: All respondents

The majority of respondents agree overall that human tissue legislation and HTA regulation **has made it more difficult to get hold of samples** (68%) and that it **has led to the disposal of potentially valuable tissue** (61%), with over a third strongly agreeing for both statements (41% and 37% respectively). Disagreement with these statements overall is quite low, with around one in six (16%) disagreeing that it has made it more difficult to get samples and slightly more disagreeing that it has led to the disposal of potentially valuable tissues (19%).

The means for both these statements fall around 2.0, on a scale where 1 is agree strongly and 5 is disagree strongly. This shows respondents believe that the introduction of human tissue legislation and the required HTA regulation has made it more difficult to get hold of samples and that it has led to the disposal of potentially valuable tissue.

Similar sub groups differences emerge

- NHS organisations, and higher education institutions are more likely to agree that human tissue legislation and HTA regulation has made it more difficult to get hold of samples and that it has led to the disposal of potentially valuable tissue.
- Private organisations are more likely to disagree with both statements
- Those institutes with an HTA post mortem licence are more likely to agree compared to the mean for both statements
- Those in the research sector (compared to the post mortem sector) are less likely to agree than the mean that it has made it more difficult to get hold of samples (2.3)
- DIs are less likely to agree compared to the mean (2.6).

Table 16  
 Mean = 2.1 (Has made it more difficult to get hold of samples)

More likely to agree than the mean	More likely to disagree than the mean
<b>Organisation type</b>	
NHS organisations (1.7)	Private (2.5)
<b>All job roles</b>	
Pathologists (1.5)	Other (2.6)
<b>Main activity</b>	
Post mortem (1.7)	Research (2.3)

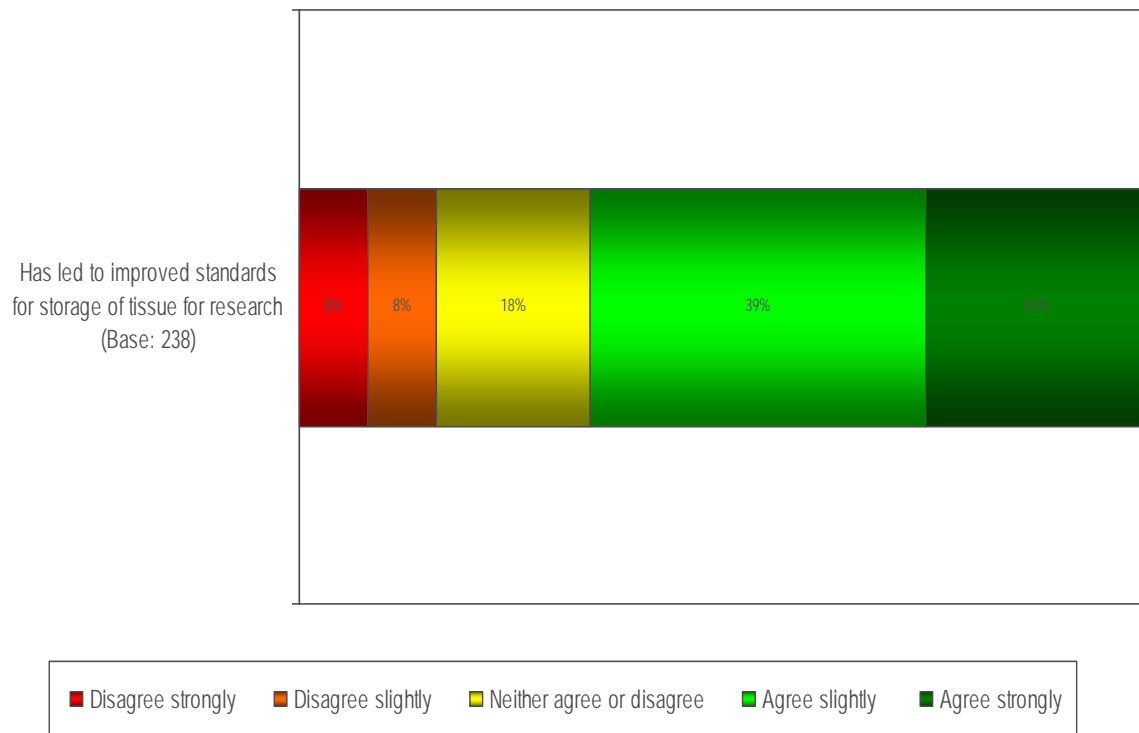
Mean = 2.3 (Has led to the disposal of potentially valuable tissue)

More likely to agree than the mean	More likely to disagree than the mean
<b>Organisation type</b>	
NHS organisations (2)	Private (2.9)
Higher education (2)	
<b>All job roles</b>	
Pathologists (1.7)	Other (2.6)
<b>HTA licence roles</b>	
DIs (2.6)	
<b>Main activity</b>	
Post mortem (1.8)	

### Standards of storage

While the majority of respondents report that following human tissue legislation and the required HTA regulation it has become more difficult to get hold of tissue, the majority also agree overall that it **has led to improved standards for storage of tissue for research** (65%), with a quarter strongly agreeing (26%). One in six (16%) disagree overall.

Chart 15: Standards of storage



Q23. These are some statements which others have made about human tissue legislation and associated regulation by the HTA. To what extent do you agree or disagree with the following statements in your personal experience.  
 BASE: All respondents

The mean is 2.3 showing that respondents agree slightly that human tissue legislation and HTA regulation has led to improved standards of tissue storage. There are a number of sub group differences

- NHS organisations were more likely to agree that accessing tissue has become more difficult, and equally are less likely to agree that it had led to improved standard of storage (2.6).

Table 17

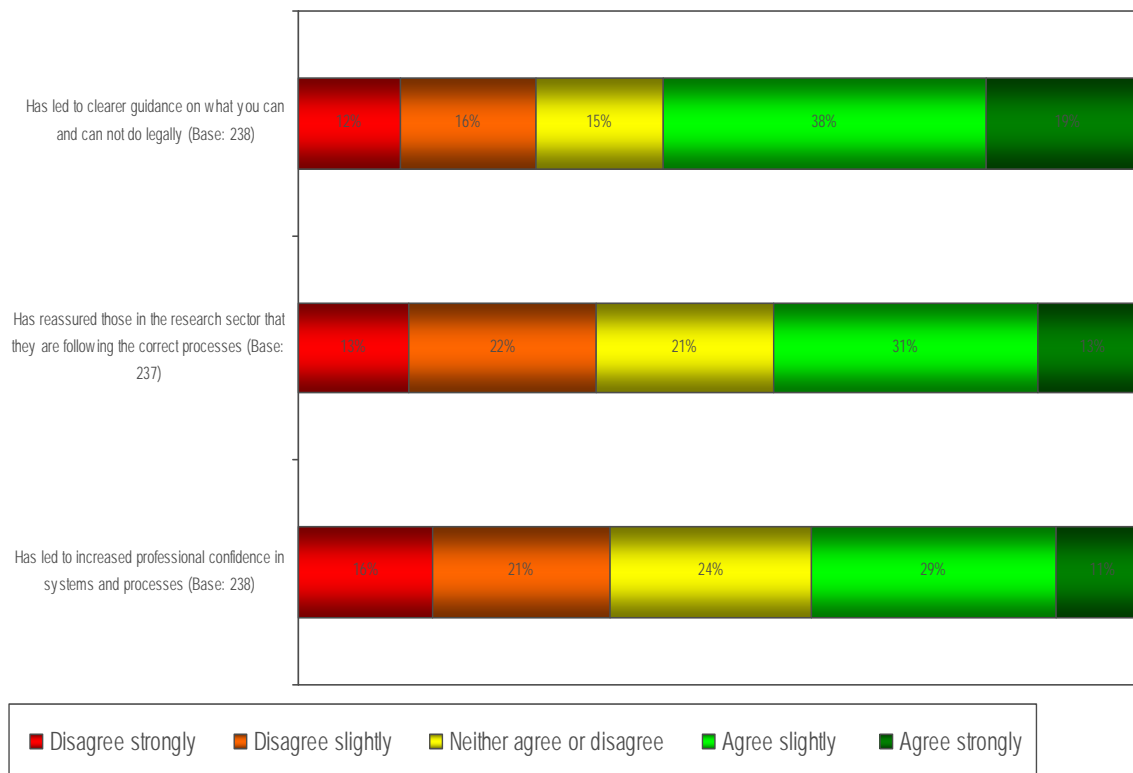
Mean = 2.3

More likely to agree than the mean	More likely to disagree than the mean
<b>Organisation type</b>	
	NHS organisations (2.6)
<b>HTA licence roles</b>	
DIs (1.9)	

## Guidance and processes

The following statements examine how human tissue legislation and HTA regulation has impacted on researchers in terms of guidance, reassurance and confidence in system and processes.

Chart 16: Guidance and processes



Q23. These are some statements which others have made about human tissue legislation and associated regulation by the HTA. To what extent do you agree or disagree with the following statements in your personal experience.  
BASE: All respondents

The majority of respondents agree overall that **human legislation and HTA regulation has led to clearer guidance on what you can and can not do legally** (57%), with just over a quarter disagreeing overall (28%).

The statements around how human tissue legislation and HTA regulation **has reassured those in the research sector that they are following correct processes** and if legislation and regulation **has led to increased professional confidence in systems and processes** are more split between overall agree and disagree. For the statement about reassurance 44% agree compared to 35% disagreeing. While for the statement about professional confidence in systems and processes 39% agree compared to 37% disagreeing. There is a higher percentage of neither agree nor disagree for both statements.

Certain sub groups are more likely to agree or disagree with these statements:

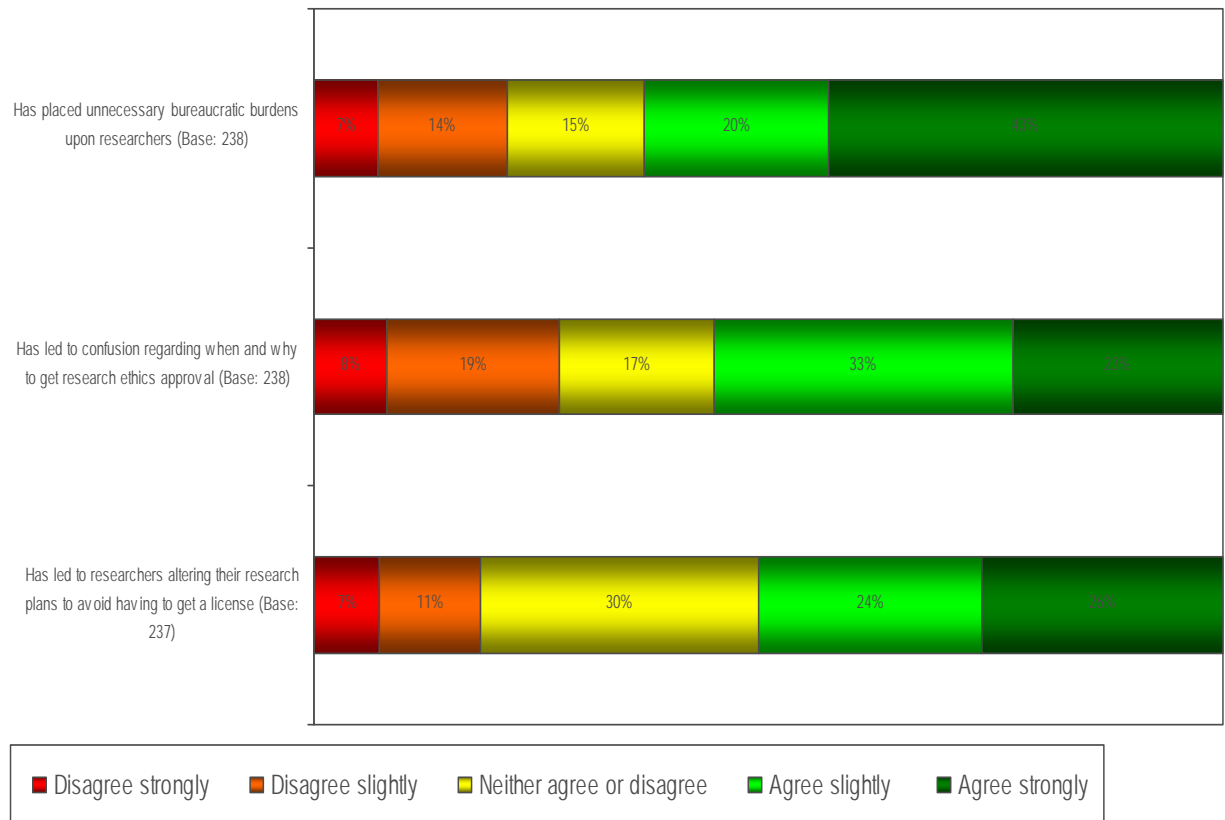
Table 18

Mean score across 3 statements (2.9)

More likely to agree compared to the mean across all statements	More likely to disagree compared to the mean across all statements
<b>Organisation type</b>	
Private (2.3)	NHS organisations (3.2)
	Higher education organisations (3)
<b>All job roles</b>	
Other (2.4)	Pathologists (3.4)
<b>HTA licence roles</b>	
DIs (2.5)	
<b>Area of human tissue research</b>	
Communicable diseases <sup>17</sup> (2.5)	

*Processes*

Chart 17: Processes



Q23. These are some statements which others have made about human tissue legislation and associated regulation by the HTA. To what extent do you agree or disagree with the following statements in your personal experience.  
 BASE: All respondents

<sup>17</sup> Only for the guidance and confidence questions

There is very strong agreement about human tissue legislation and HTA regulation **placing unnecessary bureaucratic burdens on researchers**, with over two fifths strongly agreeing (43%) and just under two thirds agreeing overall (63%). Just over one fifth disagree overall (21%).

The strength of feeling is slightly less for the statements around **confusion over when to apply for research ethics approval** and **researchers altering their research plans to avoid having to get a licence**, but a majority still agree overall for both statements. Around a quarter disagree overall that there is confusion over when and why to get research ethics approval (27%) with around a fifth disagreeing that researchers have altered their research plans (18%). Around a third (30%) neither agree or disagree that human tissue legislation and HTA regulation has led researchers altering their research plans.

There are certain sub groups which are more likely to agree or disagree with these statements:

Table 19

More likely to agree compared to the mean across all statements	More likely to disagree compared to the mean across all statements
<b>Organisation type</b>	
Private (3)	NHS organisations (2.1)
<b>All job roles</b>	
	Pathologists (1.8)
<b>Area of human tissue research</b>	
Communicable diseases (2.6)	

The statement around unnecessary bureaucratic burden has several more sub group differences in job roles compared to the other statements in this section:

- Those in research governance, and DIs are more likely to disagree compared to the mean,
- Clinical academics and pathologists are more likely to agree

For the statement about researchers choosing to alter plans to avoid having to get a licence, those in the post mortem sector are more likely to agree.

## Appendix – Qualitative findings

The qualitative sample was decided based on key issues arising in the quantitative survey that the HTA wanted to investigate further. There was a mix of job role, sector and licensed / not licensed personnel. The full sample is outlined in section 4.

### *Case studies*

#### **Tissue bank manager - Not licensed (because based in Scotland)**

- Manager for a bio-repository
- She is unhappy about the gap in regulation for managing tissue in Scotland and believes that it will eventually result in Scotland falling behind other countries as their research practices due to the lack of consistency in the way that human tissue is managed.
- She is very positive about HTA's regulation of human tissue, particularly the codes of practice.
  - Have helped clarify lots of issues
  - Have helped bio-repositories in England secure funding.
  - Boosted the quality of tissues and the standards of storage (including the necessity to store things)
  - Provided a network of resources
  - Helped clarify what can and can't be done
- The only negative as far as she is concerned for the people who are licensed is the cost
- She is concerned that Scotland will fall behind England in terms of standards of research and standards of regulation, because they lack a specific research code.

#### **Tissue procurement manager - Not licensed**

- Perception that legislation was all over the place, and a framework was sorely needed both for work with human tissue also for the preservation of tissue to ensure quality samples.
- However, she has found that the cost of an HTA licence has made it increasingly hard for small companies and small projects that she works with, as it is a lot more expensive to carry out research.
- For these small companies the cost of a license is very large and can only be paid in one payment. This in turn drives small companies into trying to find ways to avoid the requirement to be licensed, stop using human tissue in research or going abroad.
  - This is because it takes too long to get samples in the UK due to so many processes

#### **Freedom of Information Act 2000**

This document contains commercially sensitive and confidential information. The contents of this document should not be copied, reproduced or disclosed to any third party without prior written permission from a Director at Opinion Leader Research.

involved now the HTA regulation has come into force, and samples from the US come in a couple of weeks.

- Even with shipping costs, it is cheaper to get from the US.
- Feels that this is a shame and it should not be like that, there are the resources in the UK, but too many hurdles hamper this.
- Need to consider making them more palatable payments, perhaps over a year or according to the size of company. "Why should huge research companies with hundreds of employees pay the same as somewhere that only has about 12 employees?"

#### **Licence Holder – Higher education institute working in stem cells**

- Believes the perimeters of regulation are not clearly laid out in the field of stem cells
  - Too many overlapping and in some cases contradictory regulatory bodies working in this area (HTA, HFEA, EMA and MHRC) "It's a minefield understanding it all"
  - Knowledge gap amongst regulators and governance bodies as it is a field of technology that is growing very quickly.
  - Surprised that there has not been more leadership in this area given it is a flagship area of research for the UK
  - Inconsistencies in guidance which makes it hard for him to comply.
- He does perceive that the HTA has shown greater leadership than other governance bodies
- He perceives the HTA to be unresponsive to email/telephone queries and doesn't have a named contact to go to and frequently doesn't receive a call back to answerphone messages
- Perception that things have got better as principles have become more embedded and regulators have established their roles.
- Perception that current legislation and regulation would put off other teams of researchers in universities moving into the field of stem cells, particularly those from smaller organisations. "If I knew then what I know now, I would not have done it."
  - The cost is also thought to be prohibitive for small teams. It is disproportionate and a significant part of their funding
- This, in his appraisal, would ultimately impact on competitiveness in the sector

#### **Consultant Histopathologist from a public higher education institute**

##### **DI for a research licence**

- Feels that legislation was very much in response to issues in the press following Alder Hey which has resulted in 'over regulation' and makes research 'more bureaucratic'.
- However, the law did need changing anyway as at the time everyone was operating under the 1961 Human Tissue Act which was very out of date at the time.
- Perception that access to samples is getting worse and will continue to do so given pre-2006

samples will be in short supply and issues around consent make new samples harder to come by.

- Groups most affected are those who are less well funded and find it harder to stick to the rules, and may stop doing research, whereas big companies have more resources both staff and money and it is easier for them.
- Believes that small exploratory work will suffer given the need for informed consent. Translational research is also suffering
- For information he goes directly to the HTA, either by the website or email as he is the DI. Information given and courses which he has been to have been very useful, although does take a long time to reply, but feels this is understandable as they don't have the man power to cope with the demand.

#### **Person Designated Large University**

- She is currently trying to set up a tissue bank within the university and is speaking to their local NHS Trust partner to arrange consent for collecting tissue for research.
- For rectal cancer samples she has been trying to find an appropriate place in the pathway where potential donors can be given information to allow them to make informed decisions about deciding to donate tissue.
- The clinicians she has been working with have told her that the only time consent can be obtained is during the diagnostic meeting.
- While donors will be given information about what they are agreeing to and are therefore giving 'informed consent', the timing means that the donor will be concentrating on other parts of information
- Before the Human Tissue Act was introduced different researchers within the university all had their own collections of tissue. These collections were not always kept in adequate storage facilities.
- After the Act was introduced samples of tissue became centralised so they could be stored correctly under license. Some of the old tissue samples were found to have been poorly stored and had to be disposed of, however new tissue collected now is correctly stored and therefore of a much higher quality

#### **Histopathologist, DI in post mortem sector**

- He can understand that the legislation needed improving, to be clearer and needed to be made more fit for purpose, and as a result of problems in the media. However does not feel the current Act is particularly any clearer, and further improvements in clarity is needed but he understands it is an evolving progress.
- Waste material from the living is an issue, in the past the codes of practice stated that if it is anonymised that consent was not needed from the patient. But the emphasis is now on good

practice and gaining consent, although a minor change but means a lot more time in clinics and paperwork and this affects research. This then also raises the issue of what is informed consent, is it enough to say 'research' or does the patient need to know more.

- He feels the legislation has an ethical background of trying to keep the members of the public happy, which means organisations have to track every single sample, which he feels has turned into a 'bureaucratic nightmare'.
- He looks after a number of MSc students and junior doctors running small (1-2 month) research projects as part of their studies/training. He is now trying to encourage them to run 'audit' projects rather than 'research' projects because of the bureaucracy entailed which is prohibitive for these small projects.

### **Head of pathology at public higher education institute**

#### **DI for research licence**

- He feels the legislation and HTA regulation was necessary, and inevitable. And although a huge amount of effort has gone into making it fit for purpose, there are still problems. It is presenting challenges to researchers on the ground.
- Regulation was also very rushed due to pressures, and this means problems have arisen.
- It means in his institution it has consumed too much time of both support staff and research staff, which in turn has impacted on the amount of research being done and the amount of projects.
- The regulation is demoralising, it has increased anxiety over getting things wrong. Takes up time in their thoughts, which means people are less likely to do research on human tissue
- He feels the biggest effect has been on people who wouldn't be using human tissue as the dominant aspect of their research. These people would stop doing small exploratory, pilot studies as a lot of work is required (consent principles, licence applications etc) to allow them to conduct a small amount of research. For example
  - Research active clinicians who in times gone by as part of the projects would have had pathology parts requiring research, however now the bar is too high and they won't do these projects.
  - Translational research involving only small amounts of human tissue
- He has found the HTA has been very helpful with providing information, and very useful in the information they give. However they need to make it less confusing for those who want to use one category of research, i.e. blood for DNA studies, at the moment they have to read all the guidance and have more than one set of regulations. E.g. A one page flow chart which shows the decision tree which leads you to what you need to do.

#### **Academic researcher at a university and DI for a research licence for a private organisation**

- He has seen an impact on the cord blood research industry as they now have to operate to the required standards, as well as procurement and traceability has been greatly improved.
- HTA regulation has ensured quality of samples and of the standard of laboratories, and further benefits the general public who might not even realise it but they will now receive a much better service.
- He feels regulation was something that was needed and required for a while, and great relief to have a proper coordinated and sensible regulation. It covers all aspects including the European tissue directive, and this has meant the HTA have done well at regulating the industry in the UK. It makes sure that everyone is operating to the correct standards, it hasn't had any major impact on the research for his organisation, only more paperwork but this is worth doing and straightforward.
- He has used the HTA website, which is very useful and if not he then uses contacts from the HTA who are very helpful and give good information. Thinks that they are meeting their remit, and are good at keeping DIs updated.

#### **Head of safety and security for a public organisation**

##### **Licence Holder for research licence**

- He has found the costs of the licence far too high, the annual fee is much higher than any other regulatory body.
- The amount of work they do is not proportionate to the amount of the licence as most of their work with human tissue does not need a licence, and only have a small amount of tissue on site which doesn't come under consent.
- Inspections are essential for the HTA's credibility and is a real bug bear for him after he had an inspection when the HTA first started. Part of his job as health and safety is to ensure these are done, and in the HTA inspection they tried to enforce health and safety requirements, and they didn't have enough experience or knowledge, and weren't in line with the brief which they have.
- Believes that the HTA should work with health and safety people, or get a professional in, not try to do something which is not in their experience.

## **Bench scientist undertaking clinical trials**

### **Research licence**

- She works in an organisation which has a coordinator who is in charge of the regulation and information and makes sure the database is kept up to date, which means there is not too much extra work for those doing the research.
- The issue is that not everyone will have this system and not adhere to the regulation. She has heard about some people, especially those only doing small projects, who have stopped using tissue, as it is easier and less paperwork, but this could have a terrible affect on the research community.
- She doesn't have much experience of the HTA in terms of support, as have a person in the organisation who is responsible for regulation and always go to them for support or information, and so has no need to use the HTA for this.
- It is a lot more paperwork, but means that everything is more traceable and ensures better storage both in her organisation and for other organisations who may want to use these samples. There are issues, but it is a good thing overall.